UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 25, 2024

Aileron Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-38130	13-4196017
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

738 Main Street #398 Waltham, MA	02451
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 995-0900

(Former Name or Former Address, if Changed Since Last Report)

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

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	ALRN	The Nasdaq Capital Market

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

Emerging growth company ☐

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

Item 8.01 Other Events.

This Current Report on Form 8-K updates information regarding Aileron Therapeutics, Inc., or the "Company", "we" or "us". Unless otherwise defined herein, capitalized terms used in this Current Report on Form 8-K have the same meaning as set forth in the preliminary proxy statement filed with the Securities and Exchange Commission on January 19, 2024.

Forward-Looking Statements

This Current Report on Form 8-K, or the Current Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Current Report, 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;
- 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;
- the outcome of any legal proceedings that may be instituted against us following the Lung Acquisition;
- 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 holders of our Series X Non-Voting Convertible Preferred Stock, or the Series X Preferred Stock, requiring us to settle any conversion demand in cash in the event we are unable to obtain stockholder approval for the conversion of our Series X Preferred Stock;
- 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 Current Report, 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.

LUNG MATERIAL AGREEMENTS

On October 31, 2023, we acquired Lung Therapeutics, Inc., or Lung, pursuant to an Agreement and Plan of Merger, the Lung Acquisition Agreement, by and among the Company, AT Merger Sub I, Inc., a Delaware corporation and the Company's wholly owned subsidiary, or the First Merger Sub, AT Merger Sub II, LLC, a Delaware limited liability company and the Company's wholly owned subsidiary, or the 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 our 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, or the Lung Acquisition. Lung previously entered into the following agreements, which are also described in this Item 8.01 under the heading *Description of Business* below and which were assumed by the Company under the Lung Acquisition Agreement:

- Exclusive License Agreement, dated as of November 12, 2020, by and between Lung and Taiho Pharmaceutical Co. Ltd., or the Taiho Agreement;
- 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, or the UTHSCT Agreement;
- 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, or the UT Austin 6607 Agreement;

- 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, or the MUSC Agreement; and
- License Agreement, effective as of March 8, 2018, by and between Lung Therapeutics, Inc. and Vivarta Therapeutics, L.L.C., or the Vivarta Agreement.

The descriptions of the Taiho Agreement, UTHSCT Agreement, UT Austin 6607 Agreement, MUSC Agreement, and Vivarta Agreement, or collectively, the Agreements, provided in this Item 8.01 are only a brief summary of the respective material terms of the Agreements and do not purport to be a complete description of the rights and obligations of the respective parties thereto. The respective summary descriptions are qualified in their entirety by reference to the full text of the respective Agreements, which are attached hereto as Exhibit 10.1, 10.2, 10.3, 10.4, and 10.5, and incorporated by reference into this Item 8.01.

RISK FACTOR SUMMARY

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 Current Report. 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 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.

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 are unable to hold a meeting to obtain stockholder approval for the conversion of our Series X Preferred Stock, we may be in breach of the terms of the Financing[1]. If we are unable to obtain stockholder approval for the conversion of our Series X Preferred Stock, the holders of our Series X Preferred Stock may require us to settle any conversion demand made thereafter in cash by delivering to the holder an amount of cash equal to the then-current fair value of the underlying common stock. If we are in breach of the terms of the Financing or the holders of our Series X Preferred Stock require us to settle any conversion demand, our business may be materially harmed.
- 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 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.

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[1] 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, or the 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.

RISK FACTORS

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 November 30, 2023, we had approximately $19.9 million in cash and cash equivalents. Based on our current operating plan, we believe that existing cash, cash equivalents, and short-term investments, 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 quarters ended September 30, 2023 and 2022, we reported an operating loss of $2.0 million and $6.5 million, respectively. As of September 30, 2023, we had an accumulated deficit of $281.2 million. Our financial information presented in the foregoing two sentences is for periods that occurred prior to the closing of the Lung Acquisition. 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.

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Based on our current operating plan, we believe that existing cash, cash equivalents, and short-term investments, will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. To date, we have not generated product revenues from our activities and have incurred substantial operating losses. 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. 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. 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. 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.

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 fully and carefully evaluate all data. 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 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 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

delay significantly 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 1 January 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 U. K. 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 abbreviated new drug applications, or 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 LTI-01 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, we 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, or Vivarta, 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 are unable to hold a meeting to obtain stockholder approval for the conversion of our Series X Preferred Stock, we may be in breach of the terms of the Financing. If we are unable to obtain stockholder approval for the conversion of our Series X Preferred Stock, the holders of our Series X Preferred Stock may require us to settle any conversion demand made thereafter in cash by delivering to the holder an amount of cash equal to the then-current fair value of the underlying common stock. If we are in breach of the terms of the Financing or the holders of our Series X Preferred Stock require us to settle any conversion demand, our business may be materially harmed.

Under the terms of the Lung Acquisition Agreement, we agreed to call and hold a meeting of our stockholders to obtain the requisite approval for the conversion of all outstanding shares of Series X Preferred Stock issued in the Lung Acquisition and the Financing into shares of our common stock, as required by the Nasdaq listing rules. Under the terms of the Financing, we are required to hold the meeting within 120 days after the closing date of the Lung Acquisition. If we are unable to hold the meeting within such time period, we could be in breach of the terms of the Financing. Additionally, if our stockholders do not approve the conversion of our Series X Preferred Stock within six months of the Lung Acquisition, then the holders of our Series X Preferred Stock may be entitled to require us to settle their shares of Series X Preferred Stock for cash at a price per share equal to the then-current fair value of the underlying common stock, as described in the Certificate of Designation. If we are forced to settle a significant amount of Series X Preferred Stock, it could materially affect our results of operations, including raising a substantial doubt about our ability to continue as a going concern.

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 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 states that we have 45 calendar days, or until February 20, 2024, to submit a plan to regain compliance with the Annual Meeting Listing Rule. We are filing this proxy statement for the 2023 annual meeting with the SEC, and we intend to submit a plan (which will reflect calling and holding the 2023 annual meeting) to regain compliance with the Annual Meeting Listing Rule within the required time frame. While the plan is pending shares of our common stock will continue to trade on the Nasdaq Capital Market.

If Nasdaq accepts our plan, Nasdaq may grant us an extension of up to 180 calendar days from our fiscal year end, or until June 28, 2024, to regain compliance. The Notice further states that in determining whether to accept our plan, Nasdaq will consider such things as the likelihood that the annual meeting can be held within the 180-day period, our past compliance history, the reasons for the delayed meeting, other corporate events that may occur during the review period, our overall financial condition and our public disclosures. If Nasdaq does not accept our plan, we will have the opportunity to appeal the decision in front of a Nasdaq Hearing Panel.

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 regain compliance with the Annual Meeting Rule or continue to maintain compliance with the other 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, are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 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.

Our management is required to devote substantial time to new compliance initiatives. Any failure to maintain effective internal control over our financial reporting could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

As a public company, we incur, and particularly after we are no longer a "smaller reporting company" we will incur, significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We have had to hire additional accounting, finance, and other personnel in connection with our becoming a public company, and our efforts to comply with the requirements of being a public company, and our management and other personnel devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

In addition, Section 404 of the Sarbanes-Oxley Act of 2002 requires us, on an annual basis, to review and evaluate our internal controls. To maintain compliance with Section 404, we are required to document and evaluate our internal control over financial reporting, which is both costly and challenging. We will need to continue to dedicate internal resources, continue to engage outside consultants, and follow a detailed work plan to continue to assess and document the adequacy of internal control over financial reporting, continue to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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, 2022, we had federal net operating loss carryforwards of $239.6 million, of which $129.6 million will, if not utilized, begin to expire in 2029. As of December 31, 2022, we had state net operating carryforwards of $231.6 million, which will, if not utilized, begin to expire in 2030. Our federal and state research and development tax credit carryforwards of $2.7 million and $1.9 million, respectively, will, if not utilized, begin to expire in 2025 and 2026, respectively. We also have federal orphan drug tax credit carryforwards of $2.4 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.

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.

We have not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. We may have experienced such ownership changes in the past and may experience such ownership changes in the future as a result of any strategic transaction. If we have experienced, or do experience, a change of control, as defined by Section 382, at any time since inception, our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

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 November 30, 2023, we had 4,885,512 shares of common stock outstanding and 24,610 shares of our Series X Preferred stock outstanding.

Concurrently and in connection with the execution of the Lung Acquisition Agreement, our directors and officers of 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 the Registration Rights Agreement with the Investors. Pursuant to the Registration Rights Agreement, we have agreed to prepare and file a resale registration statement with the SEC by the Filing Date. We will use our commercially reasonable best effort to cause the registration statement to be declared effective by the SEC within 30 calendar days of the Filing Date (or within 60 calendar days in the event the SEC reviews and has comments to the registration statement). Once this registration statement is declared effective, the shares subject to the registration statement will no longer constitute restricted securities and may be sold freely in the public markets, subject to 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 November 30, 2023, entities and individuals affiliated with Bios Partners (collectively, the “Bios Entities”) beneficially owned 4.08% of our outstanding common stock. This ownership percentage does not, due to certain restrictions on conversion and exercisability, take into account the issuance of any 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 November 30, 2023, own 42.65 % of our outstanding common stock.

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.

DESCRIPTION OF BUSINESS

Overview

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.

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. The increase in sRAGE provides further evidence of increased AEC2 survival, 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 10 centers in the U.S., UK, Belgium, Germany and Australia. Patients in the trial will either receive 5 mg (two 2.5 mg capsules) 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 second 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. Based upon safety and signs of preliminary efficacy from our completed Phase 2a and Phase 1b clinical trials in patients and the potential to be the first and only approved drug for LPE, third party market research with physician interviews performed by MME, a wholly-owned subsidiary of Indegene, Inc, suggest 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

Lastly, 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.

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, 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 The University of Texas at Austin, or 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.

As of December 22, 2023, we own or have licensed 30 issued patents and 30 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. Thirty issued patents worldwide and nine pending patent applications are owned by the UT System, which have granted us exclusive license rights to the technology. We own ten pending patent applications worldwide together with the UT System, which have granted us exclusive license rights to the technology. Our policy is to file patent applications to protect technology, inventions and improvements to inventions that are commercially important to the development of our business. We seek U.S. and foreign patent protection for a variety of technologies, including 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

We own two pending PCT applications, seven pending U.S. patent applications including one pending U.S. provisional applications, and 15 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, 24 patents granted outside of the U.S., two pending U.S. application, and seven 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

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.

Facilities

We lease 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 expires on March 31, 2024. We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

Employees and Human Capital Resources

As of November 30, 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 738 Main Street #398, Waltham, MA 02451, and our telephone number is (617) 995-0900.

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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1*#	Exclusive License Agreement, dated as of November 12, 2020, by and between Lung Therapeutics, Inc. and Taiho Pharmaceutical Co. Ltd.
10.2*	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.
10.3*	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.
10.4*	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.
10.5*	License Agreement, effective as of March 8, 2018, by and between Lung Therapeutics, Inc. and Vivarta Therapeutics, L.L.C.
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document).

* 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 Securities and Exchange Commission upon request.

\# Certain schedules and exhibits have been omitted from this filing pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished to the Securities and Exchange Commission upon request.

SIGNATURES

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

AILERON THERAPEUTICS, INC.

Date: January 25, 2024

By: /s/ Manuel C. Alves-Aivado, M.D., Ph.D
Manuel C. Alves-Aivado, M.D., Ph.D.
Chief Executive Officer

Exhibit 10.1

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

EXCLUSIVE LICENSE AGREEMENT

between

TAIHO PHARMACEUTICAL CO., LTD.

and

LUNG THERAPEUTICS, INC.
a Texas corporation

Dated as of November 12, 2020

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EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT (the **"Agreement"**) is entered into as of November 12, 2020 (the **"Effective Date"**) by and among **LUNG THERAPEUTICS, INC.**, a Texas corporation, having an address of 2600 Via Fortuna, Suite 360, Austin, Texas 78746, USA (**"Lung Tx**") and **TAIHO PHARMACEUTICAL CO., LTD.**, a company incorporated under the laws of Japan, having an address of 1-27 Kandanishiki-cho, Chiyoda-ku, Tokyo, Japan 101-8444 (**"Taiho"**). Lung Tx and Taiho may be referred to herein individually as a "**Party**" or collectively, as the "**Parties**."

RECITALS

Whereas, Lung Tx is a pharmaceutical company that has proprietary rights related to a chemical entity and pharmaceutical product formulation known as LTI-01 (defined as the "Product", as more fully described below);

WHEREAS, Taiho is engaged in the research, development and commercialization of pharmaceutical products and has particular expertise in the development and commercialization of pharmaceutical products in the Licensed Territory (as defined below); and

WHEREAS, Taiho and Lung Tx desire to enter into a collaborative relationship for the clinical development and commercialization of the Product by Taiho, subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 "Affiliate" means, with respect to a particular Party, a person, corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this **Section 1.1**, "control" (including, with correlative meaning, the terms "controlled by" or "under the common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such entity, whether by the ownership of fifty percent (50%) or more of the voting stock of such entity, or by contract or otherwise. Notwithstanding the foregoing, the Affiliates of Taiho shall exclude any person, corporation, or other entity that is controlled by Otsuka Holdings (other than Taiho and any person, corporation, partnership, or other entity that is controlled by Taiho).

1.2 "**Approved Reimbursement Price**" means the price for each Product Unit of the Product that is established by Regulatory Authorities in the Licensed Territory in connection with Pricing Approval.

1.3 "**Business Day**" means a day that is not a Saturday, Sunday or a day on which banking institutions in Austin, Texas or in Japan are authorized by Law to remain closed.

1.4 "Calendar Quarter" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30 and December 31.

1.5 "**[**]**" means [**].

1.6 "Claim" has the meaning provided in **Section 12.3**.

1.7 "Clinical Supply Price" means **[**]**.

1.8 "Commercialize" or **"Commercialization"** means all activities undertaken before and after obtaining Regulatory Approval relating specifically to the pre-launch, launch, promotion, marketing, offer for sale, sale, distribution and otherwise commercialization of a pharmaceutical product, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and product support; and (b) any Phase IV Clinical Trial or other post- Regulatory Approval clinical trial undertaken by Taiho; and (c) all customer support and product distribution, invoicing and sales activities.

1.9 "Confidential Information" means, with respect to a Party, all confidential Information of such Party that is disclosed to the other Party under this Agreement, which may include specifications, know-how, trade secrets, technical information, drawings, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications, whether disclosed in oral, written, graphic, or electronic form. All information disclosed by either Party pursuant to the Mutual Confidential Disclosure Agreement between the Parties dated [**] shall be deemed such Party's Confidential Information disclosed hereunder.

1.10 "Control" means, with respect to any Information, Patent or other intellectual property right, possession by a Party of the ability (whether by ownership, license or otherwise) to grant access, a license or a sublicense to such Information or intellectual property right without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.11 "**Cover**," "**Covered**" or "**Covering**" means, with reference to a Patent, that the making, having made, using, selling, offering for sale or importing of a composition of matter or practice of a method would infringe a Valid Claim of such Patent in the country in which such activity occurs.

1.12 "Denied Parties Lists" has the meaning provided in Section 15.10(a)(ii).

1.13 "Develop" or **"Development"** means all non-clinical, clinical research and drug development activities with respect to the Product, including preparing and conducting testing, toxicology release and stability testing, human clinical studies and regulatory affairs, and regulatory activities pertaining to designing and carrying out clinical studies and obtaining the Regulatory Approval. Development shall include the Global Clinical Trials as provided in **Section 1.22**.

1.14 "Development Plan" means the plan for conducting Development of the Product to be Commercialized by Taiho in the Licensed Territory.

1.15 "Diligent Efforts" means, with respect to a Party's obligation under this Agreement to Develop or Commercialize a Product, the level of efforts required to carry out such obligation in a sustained manner consistent with the efforts a similarly situated pharmaceutical company devotes to a product of similar market potential, based on conditions then prevailing. Diligent Efforts requires, with respect to such an obligation, that the Party: (a) promptly assign responsibility for such obligation to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (b) set and consistently seek to achieve specific, meaningful and measurable objectives for carrying out such obligation; and (c) consistently make and implement decisions and allocate resources designed to advance progress with respect to such objectives, in each case taking into account issues of safety and efficacy, product profile, the proprietary position, the then-current competitive environment for such product and the likely timing of such products entry into the market, the regulatory environment and the status of such product, and other relevant scientific, technical and commercial factors.

1.16 "Dollar" means a U.S. dollar, and "$" shall be interpreted accordingly.

1.17 "EMA" means the European Medicines Agency, or any successor agency thereto performing similar functions.

1.18 "**Extension Term**" has the meaning provided in **Section 13.2**.

1.19 "FDA" means the United States Food and Drug Administration, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and devices in the United States of America.

1.20 "**Field**" means the treatment, prevention, prognosis or diagnosis of any and all diseases and conditions in humans.

1.21 "First Commercial Sale" means, with respect to the Product, the first sale on a commercial basis for end use or consumption of such Product in a country after the governing health regulatory authority of such country has granted Regulatory Approval; provided, that, for clarity First Commercial Sale does not include the sale of a Product for compassionate use. Sale to an Affiliate shall not constitute a First Commercial Sale unless the Affiliate is the end user of the Product.

1.22 "Global Clinical Trial" means all clinical trials of the Product to be Commercialized by Lung Tx outside the Licensed Territory, including, but not limited to, the clinical trial of the Product currently being conducted by Lung Tx with the title "LTI-01-2001", as further described in the clinical trial registry found at www.ClinicalTrials.gov, including any subsequent modifications made by Lung Tx after the Effective Date.

1.23 "**Global Development Plan**" means the plan for conducting Global Clinical Trial of the Product to be Commercialized by Lung Tx outside the Licensed Territory.

1.24 "Governmental Authority" means any multi-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.25 "IND" means an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any equivalent agency or government authority outside of the United States (including the MHLW and any supra-national agency such as in the European Union) necessary to commence human clinical trials in such jurisdiction.

1.26 "**Indemnified Party**" has the meaning provided in **Section 12.3**.

1.27 "**Indemnifying Party**" has the meaning provided in **Section 12.3**.

1.28 "Information" means all tangible and intangible (a) techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material.

1.29 "Joint Inventions" has the meaning provided in **Section 9.1**.

1.30 "Joint Patents" has the meaning provided in Section 9.3(c).

1.31 "Joint Development Committee" means the committee formed pursuant to **Section 2.1**.

1.32 "Laws" means all relevant laws, statutes, rules, regulations, guidelines, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.33 "Licensed Territory" means Japan, including its territories and possessions.

1.34 "**Losses**" has the meaning provided in **Section 12.1**.

1.35 "**Lung Tx Indemnitee**" has the meaning provided in **Section 12.2**.

1.36 "Lung Tx Inventions" has the meaning provided in **Section 9.1**.

1.37 "Lung Tx Know-How" means Information Controlled by Lung Tx on the Effective Date or during the Term that is necessary or useful for the Development, manufacture and Commercialization of the Product in the Licensed Territory.

1.38 "Lung Tx Patents" means all Patents Controlled by Lung Tx on the Effective Date and during the Term that Cover the Development, manufacture or Commercialization of the Products in the Licensed Territory including any Patents filed on Lung Tx Inventions, including without limitation, the Patents set forth on ***Exhibit B***.

1.39 "Lung Tx House Marks" means the Lung Tx name and logo as set forth in ***Exhibit A***.

1.40 "Lung Tx Technology" means the Lung Tx Patents and Lung Tx Know-How.

1.41 "Lung Tx Trademark" means (a) the product-specific trademarks owned or Controlled by Lung Tx and designated by Lung Tx for use with the Product, as reflected on ***Exhibit C***; and (b) any other product-specific trademarks that Lung Tx and Taiho mutually agree upon for use with the Product in the Licensed Territory during the Term.

1.42 "Marketing Authorization Application" or **"MAA"** means an application for Regulatory Approval (but excluding Pricing Approval).

1.43 "MHLW" means the Ministry of Health, Labor and Welfare or any successor thereto, which govern the scientific review of human pharmaceutical products in Japan.

1.44 "Minimum Royalty and Transfer Price" has the meaning provided in **Section 7.3(b)**.

1.45 "Net Sales" means **[**]**.

1.46 "**[**]**" means **[**]**.

1.47 "**[**]**" means **[**]**.

1.48 "**Otsuka Holdings**" means Otsuka Holdings Co. Ltd., having offices at 2-9 Kanda- Tsukasamachi, Chiyoda-ku, Tokyo 101-0048 Japan.

1.49 "Patents" means (a) pending patent applications, including provisional patents, issued patents, utility models and designs, and (b) extensions, reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, requests for continued examination, continuations-in-part, or divisions of or to any patents, patent applications, utility models or designs.

1.50 "Pharmacovigilance Agreement" has the meaning provided in Section 4.5(b).

1.51 "**Phase III Clinical Trial**" means a clinical trial in humans that is intended to (a) establish that a Product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with such Product in the dosage range to be prescribed, and (c) support Regulatory Approval for such Product, and designed to satisfy the requirements of 21 C.F.R. § 312.21(c) or corresponding provision outside the United States.

1.52 "Phase IV Clinical Trial" means a clinical trial of a Product conducted after Regulatory Approval of such Product has been obtained from an appropriate Regulatory Authority, which trial is (a) conducted voluntarily by a Party to enhance marketing or scientific knowledge of the Product, (b) conducted pursuant to a request or requirement of a Regulatory Authority, or (c) conducted for expansion of the Product labeling and dose optimization.

1.53 "**PMDA**" means the Pharmaceutical and Medical Devices Agency (formerly known as IYAKUHIN IRYOKIKI SOGO KIKO) in Japan or any successor thereto.

1.54 "Pricing Approval" means such approval, agreement, determination or governmental decision establishing prices for the Product Unit that can be charged to consumers and will be reimbursed by Governmental Authorities in the Licensed Territory.

1.55 "Product" means Lung Tx's proprietary pharmaceutical product known generically as LTI-01 (a recombinant single chain urokinase plasminogen activator) which is currently being developed by Lung Tx in the United States as of the Effective Date that meets the Specification, including all forms, presentations, doses and formulations.

1.56 "Product Labeling" means (a) the full prescribing information for the Product approved by the applicable Regulatory Authority, and (b) all labels and other written, printed or graphic information included in or placed upon any container, wrapper or package insert used with or for the Product.

1.57 "**Product Unit**" means one day's dosage of the Product, which may be contained in one or more vials.

1.58 "Promotional Materials" means all sales representative training materials and all written, printed, graphic, electronic, audio or video presentations of information, including, without limitation, journal advertisements, sales visual aids, formulary binders, reprints, direct mail, direct-to-consumer advertising, internet postings, broadcast advertisements and sales reminder aides (for example, note pads, pens and other such items) intended for use or used by Taiho, its Affiliates or sublicensees in connection with any promotion of a Product in the Licensed Territory, but excluding Product Labeling.

1.59 "Quality Agreement" means the Quality Agreement between the Parties as set forth in **Section 6.9**.

1.60 "Regulatory Approval" means any approvals (including without limitation supplements, amendments, and Pricing Approvals), licenses, registrations or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, necessary for the manufacture, distribution, use or sale of a pharmaceutical product.

1.61 "Regulatory Authority" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including without limitation, (a) in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over the Product, (b) in Japan, the MHLW and PMDA and (c) in Europe, the EMEA.

1.62 "Regulatory Data Exclusivity" means any exclusive marketing rights, data exclusivity rights or other benefits conferred by any Governmental Authority with respect to the Product other than a patent right in the Licensed Territory, including, where applicable, pediatric exclusivity and/or orphan drug exclusivity and/or any other regulatory data protection or exclusivity.

1.63 "Regulatory Documents" means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Develop, manufacture, or Commercialize the Product in a particular country, territory or possession. Regulatory Documents include, without limitation, INDs, MAAs, and applications for Pricing Approvals.

1.64 "**Required Studies**" means has the meaning provided in **Section 3.1**.

1.65 "Royalty and Transfer Price" has the meaning provided in Section 7.3(b).

1.66 "**Safety Reasons**" has the meaning provided in **Section 13.4(a)**.

1.67 "Specification" shall mean tests and standards applicable to the Product described in ***Exhibit D*** which is attached hereto and made a part hereof and other items which shall hereinafter be designated and/or modified between the Parties pursuant to the terms of **Section 3.3(e)**.

1.68 "**[**]**" means **[**]**.

1.69 "Supply Agreement" means the Supply Agreement between the Parties as set forth in **Section 6.9**.

1.70 "**Taiho Indemnitee**" has the meaning provided in **Section 12.1**.

1.71 "Taiho Inventions" has the meaning provided in **Section 9.1**.

1.72 "Taiho Know-How" means all Information Controlled by Taiho or its Affiliates that arises from Taiho's activities under this Agreement during the Term and is necessary or useful for the Development, manufacture or Commercialization of the Product. For clarity, Taiho KnowHow excludes the Taiho Patents.

1.73 "Taiho Patents" means all Patents, if any, that is Controlled by Taiho or any of its Affiliates during the Term, claims a Taiho Invention and is necessary or useful for the Development, manufacture or Commercialization of the Product.

1.74 "Taiho Technology" means the Taiho Patents and Taiho Know-How.

1.75 "Term" has the meaning provided in **Section 13.1**.

1.76 "Third Party" means any entity other than Lung Tx or Taiho or an Affiliate of Lung Tx or Taiho.

1.77 "**Third Party CMOs**" has the meaning provided in **Section 6.4**.

1.78 "**Third Party CROs**" has the meaning provided in **Section 6.4**.

1.79 "Valid Claim" means (a) an unexpired claim of an issued Patent that has not been disclaimed, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken, or (b) a claim of a pending Patent application.

1.80 "Yen" means a Japanese yen, and "¥" shall be interpreted accordingly.

ARTICLE 2

GOVERNANCE

2.1 Joint Development Committee. Promptly after the Effective Date, the Parties will form a Joint Development Committee that shall monitor and coordinate communication regarding the Parties' performance under this Agreement to Develop and obtain Regulatory Approval for the Product within and outside the Licensed Territory. Lung Tx and Taiho shall each designate [**] representatives to serve on the Joint Development Committee. Taiho shall designate one of its representatives on the Joint Development Committee to serve as the chairperson of the Joint Development Committee. The Joint Development Committee shall meet at least [**] times per year during the Term or at such greater frequency as the Joint Development Committee agrees. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties, and the Parties shall agree upon the date and time of meetings. The Joint Development Committee chairperson shall be responsible for preparing and issuing minutes of each such meeting within [**] days thereafter. A reasonable number of additional representatives of a Party may attend meetings of the Joint Development Committee in a non-voting capacity.

2.2 Joint Development Committee Functions and Powers. The role of the Joint Development Committee shall be as follows:

(a) to review the overall strategy for seeking Regulatory Approval of the Product in the Licensed Territory, including, but not limited to, the strategy for orphan drug designation;

(b) to facilitate the exchange of information between the Parties with respect to the activities hereunder for the Licensed Territory and to establish procedures for the efficient sharing of information and materials necessary for Taiho's Development of the Product hereunder, consistent with this Agreement;

(c) to review, approve, and, if necessary, amend the Development Plan or the Global Development Plan (provided that, for the avoidance of doubt, this only applies to Development in the Licensed Territory);

(d) to review the Global Development Plan (provided that, for the avoidance of doubt, the Joint Development Committee shall not have the power to approve or modify the Global Development Plan for the Development outside the Licensed Territory);

(e) to provide a forum to evaluate strategies for obtaining, maintaining and enforcing patent and trademark protection for the Product in the Licensed Territory; and to perform such other functions as appropriate to further the purposes of this Agreement, as determined by the Parties.

The Joint Development Committee shall have only the powers assigned expressly to it in this **ARTICLE 2** and elsewhere in this Agreement, and the Joint Development Committee shall not have any power to amend, modify or waive compliance with this Agreement.

2.3 Joint Development Committee Decision-Making. Decisions of the Joint Development Committee shall be made by unanimous vote, with each member having one (1) vote. No vote of the Joint Development Committee may be taken unless at least [**] representatives of each Party on the Joint Development Committee vote. If the Joint Development Committee is unable to reach a unanimous vote on any matter, then the matter shall be referred to the CEO of Lung Tx or its respective designee and the President of Taiho or its respective designee for further discussion and resolution. These individuals shall as soon as practicable attempt in good faith to resolve the matter and thereby make the decision on behalf of the Joint Development Committee. These individuals may obtain the advice of other employees or consultants as they deem necessary or advisable in order to make the decision. If the CEO of Lung Tx or its respective designee and the President of Taiho or its respective designee are unable to reach agreement on any matter, (a) the CEO of Lung Tx shall have the final decision making authority with respect to any matter pertaining to the Development of the Product in the Licensed Territory prior to Regulatory Approval to the extent there is a portion of the Global Clinical Trial that covers the Licensed Territory with the objective of supporting the filing of the MAAs by Taiho in the Licensed Territory and such decision would have any material effect on the Global Development Plan outside of the Licensed Territory, and (b) the President of Taiho shall have the final decision making authority with respect to (i) any matter pertaining to the Development of the Product in the Licensed Territory, except for any matter set forth in this **Section 2.3(a)** above, but including, but not limited to, any local bridging studies of the Product in the Licensed Territory, and (ii) any matter pertaining to the Commercialization of the Product in the Licensed Territory.

ARTICLE 3

PRODUCT DEVELOPMENT

3.1 Overview. Taiho shall have the sole right and shall use Diligent Efforts to Develop the Product in the Field in the Licensed Territory as provided in this **ARTICLE 3** and in accordance with the Development Plan, which shall set forth all Development activities to be performed by Taiho under this Agreement, including without limitation such activities as may be required by the Regulatory Authorities in the Licensed Territory for Regulatory Approval of the Product for use in the Field in the Licensed Territory, and any additional activities necessary for any Product to meet the requirements of the Japanese pharmaceutical affairs law or any other listings that are necessary or helpful for obtaining Pricing Approval for such Product in the Licensed Territory (such additional activities, **"Required Studies"**). As between the Parties, Taiho shall bear all of the costs and expenses incurred in connection with any of the activities performed by Taiho pursuant to the Development Plan.

3.2 Development Plan. Taiho shall prepare a brief summary of the Development Plan within [**] following the Effective Date, and deliver such summary to Lung Tx. Thereafter, Taiho shall prepare an initial Development Plan within [**] following the consultation for the Product between Taiho and the PMDA to be conducted after the receipt of minutes by Taiho of the post Phase II meeting for the Product between Lung Tx and the FDA, and deliver such initial

Development Plan to Lung Tx. With the agreement of Lung Tx, such Development Plan will be incorporated herein by reference. From time to time, Taiho may submit to the Joint Development Committee for discussion any proposed modifications to the Development Plan, and the Joint Development Committee shall discuss such proposed modifications at its next meeting, and any such modification may be approved by the Joint Development Committee as provided in **Section 2.3**. The Development Plan shall, at all times, contain the following information for the Product in the Licensed Territory:

(a) scope and timelines for Taiho's performance of all studies (including any Required Studies) designed to support Regulatory Approval of the Product in the Licensed Territory, including without limitation, clinical trials, additional tests (including any and all carcinogenicity and toxicology studies), product stability studies, and filing submission dates;

(b) estimated dates of meetings with Regulatory Authorities in the Licensed Territory for such Product;

(c) Taiho's forecasts of its needs for clinical supply of the Products, its related substances (e.g., standard, impurities and degradation products) and the Product; and

(d) target dates for achieving milestones in Developing such Product.

3.3 Principles of Product Development. Taiho's Development of the Product in the Licensed Territory shall be conducted in a manner consistent with the following principles:

(a) using Diligent Efforts to seek a Regulatory Approval that includes a label for such Product as broad as reasonably possible;

(b) using Diligent Efforts to seek a product profile for such Product with maximum scope of recommended usage and minimum scope of restrictions on use, in each case to the extent reasonably possible;

(c) using Diligent Efforts to seek the highest possible price in connection with the Pricing Approval;

(d) using Diligent Efforts to obtain Regulatory Approval for such Product consistent with (a), (b) and (c) in a timely manner; and

(e) using Diligent Efforts not to adversely impact Lung Tx's own Development or Commercialization efforts for the Product outside the Licensed Territory, including without limitation, and where reasonably practicable, using and filing Regulatory Documents in the Licensed Territory that are equivalent to all MAAs and related filings for the Product that are provided by Lung Tx pursuant to **Section 4.2.** Notwithstanding the forgoing, Lung Tx acknowledges that Taiho's filings and specifications for the Product in the Licensed Territory may be modified from those for the relevant of the Product outside the Licensed Territory, in order to meet the requirements of the Regulatory Authority in the Licensed Territory, as mutually agreed by the Parties with both Parties acting in good faith and with neither Party unreasonably withholding its consent.

3.4 Taiho's Performance. Taiho shall use Diligent Efforts to Develop the Product in the Licensed Territory, consistent with the then-agreed Development Plan, and in accordance with this Agreement, including without limitation by using Diligent Efforts to perform its obligations under the Development Plan and in accordance with the regulations promulgated by the MHLW for the Development and Commercialization of pharmaceutical products in the Licensed Territory. Taiho shall provide financial and other support for the Development of the Product as necessary to carry out the Development Plan and to achieve the objectives of this Agreement; *provided, however*, that pursuant to the Supply Agreement, Lung Tx shall supply such Product quantities as are required for Taiho's Development of the Product in the Licensed Territory at the Clinical Supply Price consistent with the quantities forecasted in the Development Plan in connection with the initial Regulatory Approval of the Product in the Licensed Territory. With respect to any clinical trials other than those described in the previous sentence, Lung Tx and Taiho will share the costs of finished Product with respect to the Development for the purpose of filing the Regulatory Documents for the Regulatory Approval of the Product to obtain additional indication other than the first indication approved by such initial Regulatory Approval to the extent that Lung Tx and Taiho have agreed to the joint conduct of such trial as part of the Development Plan; *provided, however*, that the burden ratio of such costs for the finished Product shall be determined by negotiation between the Parties. Taiho shall conduct its activities under the Development Plan in good scientific manner and in compliance in all material respects with all applicable Laws. Taiho may not conduct any material Development activities with respect to any Product that are not set forth in the Development Plan or that are inconsistent with this Agreement without Lung Tx's prior written consent, which shall not be unreasonably withheld or delayed.

3.5 Records, Reports and Information. Taiho shall maintain complete, current and accurate records of all work conducted by it under the Development Plan and all data and other Information resulting from such work. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes and which shall include, without limitation, investigator's brochures, protocol of plan, sites and investigators, endpoints measured and results and all raw data from which results were derived. Lung Tx shall have the right to review such records maintained by Taiho at reasonable times, upon prior written request. Taiho shall provide [**] summary in English to the Joint Development Committee on its Development and regulatory activities with regard to the Product in the Licensed Territory, including without limitation any significant formal or informal meetings between Taiho and the Regulatory Authority in the Licensed Territory. Upon the request of Lung Tx, Taiho shall provide to Lung Tx copies in the original language of all records produced during the applicable time period covering the summary together with a brief summary of such records in English, if such records were originally created in a language other than English), including, without limitation, investigator's brochures, clinical protocols and amendments thereto, identification of clinical sites and investigators, endpoints measured and clinical and non-clinical study results and all raw data from which results were derived. Notwithstanding the foregoing, if an English translation of any such records does not exist, upon Lung Tx's written request, Taiho will, at Lung Tx's expense, provide Lung Tx with an English translation of such records.

ARTICLE 4

REGULATORY

4.1 Exchange of Data.

(a) Lung Tx Data.

(i) Within [**] after the Effective Date, **[**]**.

(ii) [**]. Notwithstanding anything to the contrary in this **ARTICLE 4**, any and all costs and expenses of such studies shall be borne by Lung Tx.

(iii) Within **[**]** after [**], which shall be provided promptly as set forth in **Section 4.5**.

(b) Data Generated by or on Behalf of Taiho. Taiho shall, in a timely manner, [**], which shall be provided promptly as set forth in **Section 4.5**. Notwithstanding the foregoing, if an English translation of any such Taiho Know-How does not exist, upon Lung Tx's written request, Taiho will, at Lung Tx's expense, provide Lung Tx with an English translation of such Taiho Know-How. **[**]**.

(c) Use of Data. All pre-clinical, nonclinical, analytical, manufacturing, and clinical data and associated reports and other regulatory materials disclosed by one Party to the other under this Agreement shall be deemed Confidential Information of **[**]**, subject to **ARTICLE 11** and all other applicable terms and conditions set forth herein. The receiving Party shall have the right to share any and all data, reports and other regulatory materials received from the disclosing Party with the receiving Party's Affiliates and Third Party (sub)licensees in its respective territory, subject to **ARTICLE 11** and all other applicable terms and conditions set forth herein.

4.2 Regulatory Filings and Approvals.

(a) In General. The Parties intend that the Development Plan will set forth the agreed regulatory strategy for seeking Regulatory Approval in the Licensed Territory. **[**]**.

(b) Rights of Reference to Regulatory Documents. Each Party hereby grants to the other Party a right of reference to all Regulatory Documents filed by such Party in its respective territory for the Product as follows: The right of reference granted to Lung Tx herein shall be solely for the purpose of **[**]**. The right of reference granted to Taiho herein shall be solely for the purpose of [**].

(c) Taiho Rights and Obligations.

(i) Taiho shall have the sole right and responsibility for **[**]**. As part of the foregoing, Taiho shall be responsible for [**].

(ii) Taiho shall use Diligent Efforts in compliance with applicable Laws and other regulatory obligations related to **[**]**.

(iii) All Regulatory Documents and Regulatory Approvals filed with Regulatory Authorities in the Licensed Territory shall be held in [**] name and shall be owned solely by [**], subject to [**] rights under this Agreement.

(iv) Taiho shall use Diligent Efforts to **[**]**.

(d) Consultation, Reporting and Review.

(i) Taiho shall, at its reasonable discretion, consult with Lung Tx regarding, and shall **[**]**.

(ii) Taiho shall provide Lung Tx with **[**]**.

(e) Global Clinical Trial. Lung Tx shall use Diligent Efforts to conduct a Global Clinical Trial following the Effective Date with the objective of [**].

4.3 Regulatory Costs. Taiho shall be responsible for all costs and expenses of preparing, maintaining, formatting, and filing Regulatory Documents for the Product in the Licensed Territory and for all other costs and expenses in connection with seeking and maintaining Regulatory Approval for the Product in the Licensed Territory.

4.4 No Harmful Actions.

(a) Taiho shall not take any action with respect to the Product in the Licensed Territory that could reasonably be expected to have a material adverse impact upon the **[**]**. Promptly following delivery of such notice, the Parties shall meet to discuss whether any such action reasonably would be expected to have such an impact, and potential alternative courses of action that Taiho could take to avoid such an impact. If the Parties cannot reach agreement as to such matters, then, at any time such disagreement exists, either Party may refer such matters for resolution pursuant to **Section 14.1**.

(b) Lung Tx shall not take any action with respect to the Product outside of the Licensed Territory that could reasonably be expected to have a material adverse impact upon the **[**]**. Promptly following delivery of such notice, the Parties shall meet to discuss whether any such action reasonably would be expected to have such an impact, and potential alternative courses of action that Lung Tx could take to avoid such an impact. If the Parties cannot reach agreement as to such matters, then, at any time such disagreement exists, either Party may refer such matters for resolution pursuant to **Section 14.1**.

4.5 Adverse Event Reporting and Safety Data Exchange.

(a) Each Party shall be responsible for all pharmacovigilance activities associated with the Product in its respective territory, including **[**]**.

(b) Following the Effective Date, with the precise timing to be mutually agreed upon by the Parties, but in any event prior to initiation of the first clinical trial of the Product within the Licensed Territory, the Parties shall enter into a pharmacovigilance agreement ("**Pharmacovigilance Agreement**") **[**]**.

(c) Without limiting **Sections 4.5(a)** and **(b)** above, within a reasonable period of time following the Effective Date (with the precise timing to be mutually agreed upon by the Parties, but in any event prior to initiation of the **[**]**. For the avoidance of doubt, the obligations to provide safety data under the Pharmacovigilance Agreement will be independent of any obligations to provide safety data pursuant to any other provisions contained in this Agreement.

4.6 Regulatory Inspection or Audit. If a Regulatory Authority in the Licensed Territory desires to conduct an inspection or audit with regard to the Product of Taiho's facility or a facility under contract with Taiho in or for the Licensed Territory, Taiho shall permit and cooperate with such inspection or audit, and shall cause the contract facility to permit and cooperate with such Regulatory Authority during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority and Taiho shall promptly provide to Lung Tx a brief summary of such observations in English, or shall, upon Lung Tx's written request and at Lung Tx's expense, provide Lung Tx with an English translation of such observations, Taiho shall prepare the response to any such observations, and shall provide to Lung Tx an English summary of such response or shall, upon Lung Tx's written request and at Lung Tx's expenses, provide an English translation of such responses. Taiho agrees to conform its activities under this Agreement to any commitments made in such a response, except to the extent it believes in good faith that such commitments violate applicable Laws. If a Regulatory Authority in the Licensed Territory desires to conduct an inspection or audit with regard to the Product of Lung Tx's facility or a facility under contract with Lung Tx for the Licensed Territory, Lung Tx shall permit and cooperate with such inspection or audit, and shall cause the contract facility to permit and cooperate with such Regulatory Authority and Taiho during such inspection or audit. Following receipt of the inspection or audit observations of such Regulatory Authority, Lung Tx shall prepare the response to any such observations, and shall provide a copy of such response to Taiho.

ARTICLE 5

COMMERCIALIZATION

5.1 Commercialization in the Licensed Territory. Taiho shall have the sole right and responsibility for Commercializing the Product in the Licensed Territory, as provided in this **ARTICLE 5**. Taiho shall bear all of the costs and expenses incurred in connection with all such Commercialization. Upon reasonable request of Lung Tx, Taiho shall provide Lung Tx an opportunity to review and comment on all significant marketing decisions for the Product in the Licensed Territory, including without limitation marketing strategy and launch decisions, and Taiho shall consider any comments thereon provided by Lung Tx in good faith, to the extent reasonable and practicable.

5.2 Pricing Approvals in the Licensed Territory. Taiho shall be responsible, at its own expense, for seeking Pricing Approval in the Licensed Territory. Taiho shall seek the highest possible price in connection with such Pricing Approval in the Licensed Territory. Taiho shall keep Lung Tx informed on an ongoing basis of Taiho's strategy for seeking, and the results it obtains in seeking, Pricing Approval in the Licensed Territory, including, without limitation, the results of any discussion or other communication with relevant Governmental Authorities regarding Pricing Approval, via regular reports to the Joint Development Committee no less frequently than such committee is required to meet pursuant to **Section 2.1**. In the event Taiho notifies Lung Tx in writing that the continued commercialization of the Product would not be commercially reasonable due to the unexpected circumstances including but not limited to the unexpected low Approved Reimbursement Price, the Parties agree to negotiate in good faith towards reaching mutually acceptable solution for such circumstances.

5.3 Pricing of the Product in the Licensed Territory. Taiho shall have the sole right to determine Product pricing in the Licensed Territory consistent with Pricing Approval and its other obligations herein. Subject to such obligations, Lung Tx shall not have any right to direct, control, or approve Taiho's pricing of the Product for the Licensed Territory. The provision to Lung Tx of any pricing data is for informational purposes only.

5.4 Taiho Performance. Taiho shall use Diligent Efforts to Commercialize the Product in the Licensed Territory following Regulatory Approval of the Product in the Licensed Territory in accordance with this Agreement. In addition, and subject to timely supply of the Product by Lung Tx pursuant to the Supply Agreement, Taiho shall achieve First Commercial Sale of the Product in the Licensed Territory promptly after, but in no event more than [**] after, the date on which Pricing Approval is granted for such Product in the Licensed Territory. Taiho shall provide Lung Tx (x) a sales report [**] on the quantity of the Product sold by Taiho in the Licensed Territory no later than [**] after the end of the preceding [**], and (y) a written report [**] during the Term summarizing Taiho's significant Commercialization activities with respect to the Product in the Licensed Territory pursuant to this Agreement, covering subject matter at a level of detail reasonably sufficient to enable Lung Tx to determine Taiho's compliance with its diligence obligation pursuant to this **Section 5.4**.

5.5 Compliance. Taiho shall comply in all material respects with all Laws in Developing and Commercializing the Product in the Licensed Territory under this Agreement.

5.6 Product Trademark; Lung Tx House Marks.

(a) Lung Tx Trademark. Taiho, its Affiliates and sublicensees will sell the Product in the Licensed Territory exclusively under the Lung Tx Trademark in accordance with the terms and conditions set forth in this Agreement, unless the Parties expressly agree otherwise in writing. If Lung Tx Trademarks listed in ***Exhibit C*** cannot be used (or if it is not advisable to use them) for legal, regulatory or other material reasons outside the Parties' reasonable control, in the Licensed Territory, Taiho may select an alternative Product Trademark reasonably acceptable to Lung Tx for use in the Licensed Territory. Lung Tx shall file, register and maintain a registration for the Lung Tx Trademark in the Licensed Territory at Lung Tx's cost and expense. Lung Tx shall retain ownership of the Lung Tx Trademark, subject to the license granted to Taiho pursuant to **Section 6.1** and **6.3**.

(b) Lung Tx House Marks. To the extent allowable by applicable Laws, Product packaging, Promotional Materials and Product Labeling for use in the Licensed Territory shall carry the Lung Tx House Marks, subject to Taiho's reasonable internal approval of the size, position, and location thereof. From time to time during the Term, Lung Tx shall have the right to obtain from Taiho samples of the Product sold by Taiho or its Affiliates or sublicensees in the Licensed Territory. Lung Tx shall use such Product samples solely to inspect the quality of such Products and use of the Lung Tx House Mark.

ARTICLE 6

LICENSES AND COVENANTS

6.1 Lung Tx Technology. Subject to the terms and conditions of this Agreement, Lung Tx hereby grants Taiho an exclusive (even as to Lung Tx), royalty-bearing license under the Lung Tx Technology to Develop (to the extent permitted in this Agreement), use, sell, offer for sale, import, package, have packaged, and Commercialize the Product in the Field in the Licensed Territory. The license granted in this **Section 6.1** may not be sublicensed by Taiho to its Affiliates or any Third Party without the prior written consent of Lung Tx, which may be withheld in Lung Tx's sole and absolute discretion.

6.2 Activities Outside the Respective Territory.

(a) To the extent permitted under applicable Laws, Taiho agrees that neither it, nor any of its Affiliates, will sell or provide the Product to any Third Party, if Taiho or its relevant Affiliate knows, or has reason to know, that Products sold or provided to such Third Party may be sold or transferred, directly or indirectly, for use outside the Licensed Territory.

(b) To the extent permitted under applicable Laws, Lung Tx agrees that neither it, any of its Affiliates nor licensees, will sell or provide the Product to any Third Party, if Lung Tx, its relevant Affiliate or licensees knows, or has reason to know, that Products sold or provided to such Third Party may be sold or transferred, directly or indirectly, for use in the Licensed Territory.

6.3 Trademarks.

(a) License. Lung Tx hereby grants to Taiho an exclusive (even as to Lung Tx), royalty-free license to use and display the Lung Tx Trademarks and the Lung Tx House Marks solely on the Product packaging, the Promotional Materials and the Product Labeling in connection with the Commercialization of the Product in the Field within the Licensed Territory, as provided under and in accordance with this Agreement. The foregoing license may be sublicensed by Taiho to Affiliates and to Third Pary sublicensees under the license granted in **Section 6.1** that are approved by Lung Tx in accordance with **Section 6.1**.

(b) Standards of Use. Taiho shall prepare any Product packaging, the Promotional Materials and the Product Labeling containing the Lung Tx Trademarks or the Lung Tx House Marks in accordance with reasonable policies provided by Lung Tx from time-to-time, and provide Lung Tx with copies of such Product packaging, the Promotional Materials and the Product Labeling. Taiho acknowledges Lung Tx's sole ownership of the Lung Tx Trademarks and the Lung Tx House Marks and agrees not to take any action inconsistent with such ownership. Taiho shall not use the Lung Tx Trademarks or the Lung Tx House Marks in a way that would adversely affect their value. Taiho covenants that it shall not use any trademark confusingly similar to any Lung Tx Trademarks or Lung Tx House Marks in connection with the Product sold by Taiho, its Affiliates and permitted sublicensees in the Licensed Territory. Taiho shall comply with reasonable policies provided by Lung Tx from time to time to maintain the goodwill and value of the Lung Tx Trademarks and the Lung Tx House Marks.

6.4 Subcontractors. Taiho may, at its discretion, subcontract certain obligations under this Agreement to Third Party contract manufacturing organizations ("**Third Party CMOs**") and Third Party contract research organization ("**Third Party CROs**") and other service providers engaged by Taiho, provided that if Taiho subcontracts to any Third Party CROs monitoring services for the clinical trials of the Product in the Licensed Territory, then Taiho shall notify Lung Tx of such Third Party CROs. Taiho shall be responsible and liable for each of its subcontractor's performance and compliance with all obligations of Taiho under this Agreement. Any purported subcontracting in violation of this **Section 6.4** shall be null and void.

6.5 Taiho Technology. Subject to the terms and conditions of this Agreement, during the Term, Taiho hereby grants to Lung Tx a non-exclusive, fully-paid, royalty-free license under the Taiho Technology to Develop, use, sell, offer for sale, and import the Product outside the Licensed Territory, and to make and have made the Product anywhere in the world for such Development or sale (subject to the exclusive rights granted to Taiho under this Agreement with respect to the Product in the Field in the Licensed Territory). Such license shall be sublicenseable by Lung Tx to any Affiliate of Lung Tx. Such license shall also be sublicenseable to any Third Party, with written notification to Taiho promptly following the grant of such sublicense.

6.6 No Implied Licenses. No right or license under any Patents or Information is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in the terms of this Agreement.

6.7 Taiho Covenant. In consideration of the licenses granted by Lung Tx under this Agreement, Taiho shall not, directly or indirectly, during the Term, **[**]**.

6.8 Lung Tx Covenant. During the Term, Lung Tx and its Affiliates shall not, and shall not **[**]**.

6.9 Product Supply. The Parties agree that Lung Tx shall be Taiho's exclusive manufacture and supply source for the Product to Taiho as required for Taiho's use in clinical Development and for Commercialization in the Licensed Territory under the terms of a supply agreement, which provides for the Parties' respective duties and obligations with respect to the manufacture and supply of the Product, to be negotiated and concluded by the Parties ("**Supply Agreement**"). The Parties shall use reasonable and diligent efforts to negotiate the terms of the Supply Agreement in good faith; provided, however, that the Supply Agreement shall contain the terms that are specifically required under this Agreement. The Parties shall, at an appropriate time before commencement of deliveries of the Product to Taiho, conclude and sign a separate agreement in a reasonable and customary format suitable for recording the agreed-upon specifications, procedures for change control and measures to assure compliance with Good Manufacturing Practices regarding production, storage, transportation and release of the Product ("**Quality Agreement**"). Taiho will be solely responsible, at its own expense, for the Product packaging and labeling for use or sale in the Licensed Territory in compliance with all applicable Laws and the requirements of any Regulatory Authority in the Licensed Territory. Lung Tx shall be responsible and liable for the performance and compliance of Third Party CMOs engaged by Lung Tx in connection with the manufacture of the Product (including the supply of any active ingredients therein) with all obligations of Lung Tx under this Agreement.

6.10 Audit. Taiho shall be entitled, during normal working hours and upon reasonable prior notice to Lung Tx, to inspect facilities utilized for the manufacture of the Product (including any active ingredients therein) and operation, books and records of Lung Tx and any Third Party CMOs engaged by Lung Tx in connection with the manufacture of the Product (including the supply of any active ingredients therein); provided that any audit or inspection of any Third Party CMOs engaged by Lung Tx shall be subject to reasonable limitations and requirements of such Third Party CMOs and any limitations and requirements included in the contract between Lung Tx and such Third Party CMO (including, without limitation, any limitation on the number of times such audit rights and inspections may be conducted during any period of time). The particulars of inspection set forth in this **Section 6.10** shall be set forth in the Supply Agreement and Quality Agreement.

ARTICLE 7

FEES AND PAYMENTS

7.1 License Fee. Taiho shall pay to Lung Tx a license fee equal to five million U.S. dollars ($5,000,000) due and payable within [**] after the receipt of an invoice by Lung Tx, as reimbursement for a portion of the Development expenditures of the Product incurred by Lung Tx before and after the Effective Date. Such license fee shall be paid in Dollars by wire transfer of immediately available funds into account designated by Lung Tx, and shall be non- refundable and non-creditable against any other payments due under this Agreement.

7.2 Milestone Payment. Taiho shall make milestone payments to Lung Tx based on the first achievement of each milestone event in the Licensed Territory for the Product as set forth in this **Section 7.2**. Taiho shall provide written notice to Lung Tx within [**] after the first achievement of the corresponding milestone event and shall pay to Lung Tx the amount set forth below within [**] after the receipt of an invoice by Lung Tx. Such payment shall be made by wire transfer of immediately available funds into account designated by Lung Tx. Such payment shall be paid in Dollars and shall be non-refundable and non-creditable against any other payments due under this Agreement. The Parties acknowledge that payment under this **Section 7.2** is reimbursement for a portion of the Development expenditures of the Product incurred by Lung Tx before and after the Effective Date. For the avoidance of doubt, the milestone payment by Taiho to Lung Tx under this **Section 7.2** shall be payable only once, and in no event shall the aggregate amount to be paid by Taiho under this **Section 7.2** exceed ten million U.S dollars ($10,000,000).

Milestone Event	Milestone Payment
[**]	$10,000,000

7.3 Product Royalty and Transfer Price.

(a) Transfer Price. The price to be paid by Taiho for the Product supplied by Lung Tx to Taiho pursuant to the Supply Agreement for commercial sale shall be [**] Yen (¥[**]) per Product Unit ("**Transfer Price**"). Within [**] of delivery to Taiho of each shipment of the Product and receipt of an invoice, Taiho shall pay to Lung Tx the Transfer Price of the Product.

(b) Product Royalty and Transfer Price. Subject to the terms and conditions of this Agreement, in consideration of the supply of the Product by Lung Tx pursuant to the Supply Agreement for commercial sale in the Licensed Territory and the other rights granted by Lung Tx to Taiho under this Agreement, Taiho shall pay to Lung Tx, as a combined royalty and Transfer Price for the Products sold by Lung Tx to Taiho pursuant to the Supply Agreement, [**] percent ([**]%) of total Net Sales in any Calendar Quarter during the Term ("**Royalty and Transfer Price**"); provided, however, that in no event shall the Royalty and Transfer Price be less than an amount equal to [**] ("**Minimum Royalty and Transfer Price**"). The Royalty (as defined below) shall be calculated and paid in accordance with the procedures described in **Section 7.3(c)**.

(c) Calculation of Royalties. Commencing with the Calendar Quarter in which the First Commercial Sale of the Product occurs and for each Calendar Quarter thereafter until the expiration of this Agreement, the Royalty and Transfer Price to be paid by Taiho as royalty for each applicable Calendar Quarter ("**Royalty**") shall be an amount equal to: [**].

(d) Royalty Report and Payment Terms. No later than [**] following the end of each Calendar Quarter during each year, Taiho shall provide Lung Tx with a report (each, a "**Royalty Report**") setting forth (i) the amount of Net Sales in Japanese Yen in the prior Calendar Quarter, (ii) the quantity of the Product (by Product Unit) sold in the Licensed Territory during such Calendar Quarter, and (iii) its calculation of the Royalty and Transfer Price based on such Net Sales in accordance with **Section 7.3(c)**, as well as the resulting Transfer Price and Royalty based on such Net Sales in accordance with **Section 7.3(c)**. Taiho shall pay the Royalty calculated in accordance with **Section 7.3(c)** above in Yen no later than [**] following Taiho's receipt of an invoice from Lung Tx, which shall be issued following Lung Tx's receipt of the applicable Royalty Report. For the avoidance of doubt, Lung Tx shall not be required to reimburse any amounts to Taiho under this **Section 7.3(d)**.

7.4 Acknowledgment of Lung Tx Contribution. The Parties hereby acknowledge that the value contributed by Lung Tx to the Product Developed and Commercialized by or on behalf of Taiho and its Affiliates is the access to the Lung Tx Technology and that the payments for the milestone and Royalty and Transfer Price described above in this **ARTICLE 7** will be payable by Taiho regardless of whether or not a Product is Covered by a Lung Tx Patent.

ARTICLE 8

PAYMENT; RECORDS; AUDITS

8.1 Exchange Rate; Manner and Place of Payment. All payments under **Section 7.1** and **Section 7.2** shall be payable in Dollars. All payments under this Agreement other than payments under **Section 7.1** and **Section 7.2** shall be payable in Yen. All payments owed under this Agreement shall be made by wire transfer in immediately available funds to a bank and account designated in writing by Lung Tx, unless otherwise specified in writing by Lung Tx.

8.2 Taxes.

(a) Cooperation and Coordination. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and legal, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use all commercially reasonable efforts to cooperate and coordinate with each other to achieve such objective.

(b) Payment of Tax. Subject to this **Section 8.2(b)**, Lung Tx shall pay any and all taxes levied on payments it receives pursuant to **ARTICLE 7.** If applicable Law requires that taxes be deducted and withheld from a payment made pursuant to **ARTICLE 7**, Taiho shall: (i) pay the required taxes to the proper taxing authority; and (ii) send evidence of the obligation together with proof of payment to Lung Tx within [**] following that payment; provided, that Taiho shall gross up the amount of the payment such that Lung Tx receives the amount hereunder that it would have received but for the deduction. Lung Tx acknowledges and agrees that Taiho shall be entitled to any refund related to such amounts withheld.

(c) Tax Residence Certificate. Lung Tx shall provide Taiho appropriate certification from relevant revenue authorities of jurisdiction where Lung Tx is a tax resident, if Lung Tx wishes to claim the benefits of an income tax treaty to which that jurisdiction is a party. Upon the receipt thereof, any deduction and withholding of taxes shall be made at the appropriate treaty tax rate.

(d) Assessment. Lung Tx may, at its own expense, protest any assessment, proposed assessment, or other claim by any Governmental Authority for any additional amount of taxes, interest or penalties or seek a refund of such amounts paid if permitted to do so by applicable Law. The Parties shall cooperate with each other in any protest by providing records and such additional information as may reasonably be necessary for Lung Tx to pursue such protest.

8.3 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of [**] percent ([**]%) per month; *provided, however*, that in no event shall such rate exceed the maximum legal annual interest rate.

8.4 Audits. During the Term and for a period of [**] thereafter, Taiho shall keep (and shall cause its Affiliates and permitted sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of the Products in sufficient detail to permit Lung Tx to confirm the accuracy of Royalty and Transfer Price due hereunder. Lung Tx shall have the right to cause an independent, certified public accountant reasonably acceptable to Taiho to audit such records to confirm Net Sales, Royalty and Transfer Price and other payments for a period covering not more than the preceding [**], *provided however* such audits shall take place [**] for a certain audited period and shall not take place more often than [**], *provided* that Lung Tx may conduct an additional audit if it has notice facts or circumstances that justify an additional audit. Such audits may be exercised during normal business hours upon reasonable prior written notice to Taiho. Prompt adjustments shall be made by the Parties to reflect the results of such audit confirmed by the Parties. Lung Tx shall bear the full cost of such audit unless such audit discloses an underpayment by Taiho of more than [**] percent ([**]%) of the amount of Royalty and Transfer Price or other payments due under this Agreement, in which case, Taiho shall bear the full cost of such audit and shall promptly remit to Lung Tx the amount of any underpayment.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Inventions. Lung Tx shall own any inventions made solely by its employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein (collectively, **"Lung Tx Inventions"**). Taiho shall own any inventions made solely by its employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein (collectively, "**Taiho Inventions**"). Any inventions made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, together with all intellectual property rights therein (collectively, "**Joint Inventions**"), shall be owned jointly by the Parties in accordance with joint ownership interests of co-inventors under U.S. patent laws, with each joint Party having the unrestricted right to license and grant rights to sublicense each such Joint Invention worldwide. Inventorship shall be determined in accordance with U.S. Patent laws. Taiho Inventions and Taiho's interest in all Joint Inventions shall be included in the Taiho Technology. Lung Tx Inventions and Lung Tx's interest in all Joint Inventions shall be included in the Lung Tx Technology. Taiho Know-How shall be the sole and exclusive property of Taiho.

9.2 Disclosure of Inventions. Each Party shall promptly disclose to the other any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing inventions that may be either Taiho Inventions, Lung Tx Inventions or Joint Inventions, and all Information relating to such inventions.

9.3 Patent Prosecution and Maintenance.

(a) Lung Tx Patents. Except as otherwise provided in this **Section 9.3(a)**, Lung Tx shall have the sole right and authority to prosecute and maintain the Lung Tx Patents other than Joint Patents on a worldwide basis. Lung Tx agrees to keep Taiho generally informed of the course of patent prosecution or other proceedings with respect to the Lung Tx Patents. Upon request of Taiho, Lung Tx shall provide Taiho reasonable opportunity to review and comment on such prosecution efforts regarding such Lung Tx Patents in the Licensed Territory. Upon request of Taiho, Lung Tx shall provide Taiho with a copy of material communications from any patent authority in the Licensed Territory regarding such Lung Tx Patents, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. If Lung Tx determines in its sole discretion to abandon or not maintain any Patent within the Lung Tx Patents in the Licensed Territory, then Lung Tx shall provide Taiho with [**] prior written notice of such determination (or such other period of time reasonably necessary to allow Taiho to assume such responsibilities) and shall provide Taiho with the opportunity to prosecute and maintain such Patent in the Licensed Territory on behalf of Lung Tx, at Taiho's sole expense. If Taiho desires Lung Tx to file, in the Licensed Territory, a patent application that claims priority from a Patent within the Lung Tx Patents other than a Joint Patent, Taiho shall provide written notice to Lung Tx requesting that Lung Tx file such patent application in such jurisdiction. If Taiho provides such written notice to Lung Tx, Lung Tx shall either (i) file and prosecute such patent application and maintain any Patent issuing thereon in such jurisdiction at Taiho's expense, or (ii) notify Taiho that Lung Tx does not desire to file such patent application and provide Taiho with the opportunity to file and prosecute such patent application and maintain any patent issuing thereon on behalf of Lung Tx at Taiho's sole expense, with the proviso that no patent claims or prosecution communications shall be filed without the prior written consent of Lung Tx, which shall not be unreasonably withheld or delayed.

(b) Taiho Patents. Except as otherwise provided in this **Section 9.3(b)**, Taiho shall have the sole right and authority to prosecute and maintain the Taiho Patents other than Joint Patents on a worldwide basis. Taiho shall provide Lung Tx reasonable opportunity to review and comment on such prosecution efforts regarding such Taiho Patents. Taiho shall provide Lung Tx with a copy of material communications from any patent authority regarding such Taiho Patents, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. If Taiho determines in its sole discretion to abandon or not maintain any Patent within the Taiho Patents other than a Joint Patent anywhere in the world, then Taiho shall provide Lung Tx with [**]' prior written notice of such determination (or such other period of time reasonably necessary to allow Lung Tx to assume such responsibilities) and shall provide Lung Tx with the opportunity to prosecute and maintain such Patent in the applicable jurisdiction on behalf of Taiho at Lung Tx's sole expense. If Lung Tx desires Taiho to file, in a particular jurisdiction outside the Licensed Territory, an application for a Patent that claims priority from a Patent within the Taiho Patents, Lung Tx shall provide written notice to Taiho requesting that Taiho file such patent application in such jurisdiction. If Lung Tx provides such written notice to Taiho, Taiho shall either (i) file and prosecute such patent application and maintain any Patent issuing thereon in such jurisdiction at Lung Tx's expense, or (ii) notify Lung Tx that Taiho does not desire to file such patent application and provide Lung Tx with the opportunity to file and prosecute such patent application and maintain any patent issuing thereon on behalf of Taiho, at Lung Tx's sole expense, with the proviso that no patent claims or prosecution communications shall be filed without the prior written consent of Taiho, which shall not be unreasonably withheld or delayed.

(c) Joint Patents. With respect to any potentially patentable Joint Invention, the Parties shall meet and agree upon which Party shall prosecute and maintain patent applications covering such Joint Invention (any such patent application and any patents issuing therefrom a **"Joint Patent"**) in particular countries and jurisdictions throughout the world. It is the intention of the Parties that, unless otherwise agreed, Lung Tx would prosecute and maintain the Joint Patents on a worldwide basis, subject to the Parties coordinating their efforts as appropriate to make such prosecution activities as efficient, convenient and harmonious as possible. Lung Tx shall bear its own costs and expenses incurred with respect to the prosecution of patent application in the Joint Patents outside the Licensed Territory and Taiho shall bear any out-of-pocket expenses incurred by Lung Tx with respect to the prosecution of patent application in the Joint Patent within the Licensed Territory, except as otherwise provided below. Lung Tx shall provide Taiho reasonable opportunity to review and comment on such prosecution efforts regarding the applicable Joint Patents in the Licensed Territory, and Taiho shall provide Lung Tx reasonable assistance in such efforts. Lung Tx shall provide the other Party with a copy of all material communications from any patent authority in the Licensed Territory regarding the Joint Patent being prosecuted by Lung Tx, and shall provide drafts of any material filings or responses to be made to such patent authorities a reasonable amount of time in advance of submitting such filings or responses. In particular, Taiho agrees to provide Lung Tx with all information necessary or desirable to enable Lung Tx to comply with the duty of candor/duty of disclosure requirements of

any patent authority. Except to the extent a particular Party is restricted by the licenses granted to the other Party and/or the other covenants contained in the Agreement, each Party shall be entitled to practice, and grant to Third Parties and its Affiliates the right to practice, the Joint Patents and all Joint Inventions without restriction or an obligation to account to the other Party, and the other Party shall consent, without additional consideration, to any and all such licenses. Either Party may determine that it is no longer interested in supporting the continued prosecution or maintenance of a particular Joint Patent in a country or jurisdiction, in which case: (i) such Party shall, if requested in writing by the other Party, assign its ownership interest in such Joint Patent in such country or jurisdiction to the other Party for no additional consideration, and (ii) if such assignment is so effected, any such Joint Patent would thereafter be deemed a Lung Tx Patent in the case of assignment to Lung Tx, or a Taiho Patent in the case of assignment to Taiho.

(d) Cooperation of the Parties. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent prosecution efforts provided above in this **Section 9.3**, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

9.4 Infringement by Third Parties. Lung Tx and Taiho shall promptly notify the other in writing of any alleged or threatened infringement of any Lung Tx Technology, Lung Tx Trademarks, Taiho Technology or Joint Patent of which they become aware. Both Parties shall use their commercially reasonable efforts in cooperating with each other to terminate such infringement without litigation.

(a) Lung Tx Technology and Lung Tx Trademarks. Lung Tx shall have the first right to bring and control any action or proceeding with respect to infringement of any Lung Tx Technology or Lung Tx Trademarks at its own expense and by counsel of its own choice. With respect to infringement of any Lung Tx Technology or Lung Tx Trademarks that is likely to have a material adverse effect on the Development or Commercialization of the Product in the Licensed Territory, Taiho shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and if Lung Tx fails to bring an action or proceeding within (a) [**] following the notice of alleged infringement or (b) [**] before the time limit, if any, set forth in the appropriate Laws for the filing of such actions, whichever comes first, Taiho shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Lung Tx shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(b) Taiho Technology. Taiho shall have the first right to bring and control any action or proceeding with respect to infringement of any Taiho Technology at its own expense and by counsel of its own choice. With respect to infringement of any Taiho Technology that is likely to have a material adverse effect on the Development or Commercialization of the Product outside the Licensed Territory, Lung Tx shall have the right, at its own expense, to be represented in any such action by counsel of its own choice, and if Taiho fails to bring an action or proceeding within (a) [**] following the notice of alleged infringement or (b) [**] before the time limit, if any, set forth in the appropriate Laws for the filing of such actions, whichever comes first, Lung Tx shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Taiho shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(c) Joint Patents. Lung Tx shall have the first right to bring and control any action or proceeding with respect to infringement of any Joint Patent at its own expense and by counsel of its own choice, and Taiho shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. If Lung Tx fails to bring an action or proceeding within the Licensed Territory within (a) [**] following the notice of alleged infringement or (b) [**] before the time limit, if any, set forth in the appropriate Laws for the filing of such actions, whichever comes first, Taiho shall have the right to bring and control any such action at its own expense and by counsel of its own choice, and Lung Tx shall have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(d) Procedure. If a Party brings an infringement action in accordance with this **Section 9.4**, the other Party shall cooperate fully, including, if required to bring such action, the furnishing of a power of attorney or being named as a Party. Within the Licensed Territory, neither Party shall have the right to settle any intellectual property infringement litigation under this **Section 9.4** relating to the manufacture, use or sale of the Product without the prior written consent of such other Party. Outside of the Licensed Territory, Taiho shall not have the right to settle any intellectual property infringement litigation under this **Section 9.4** relating to the manufacture, use or sale of the Product without the prior written consent of Lung Tx. Except as otherwise agreed to by the Parties as part of a cost-sharing arrangement, any recovery realized as a result of such litigation, after reimbursement of any litigation expenses of Lung Tx and Taiho, shall be shared equally between Lung Tx and Taiho.

9.5 Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Lung Tx shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights arising from or occurring as a result of Lung Tx Technology, Lung Tx Trademarks or Lung Tx's activities (including, but not limited to, manufacturing of the Product supplied to Taiho) at its own expense and by counsel of its own choice and shall indemnify and hold Taiho harmless from and against any and all liability arising from such claim, and Taiho shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Taiho shall have the sole right to control any defense of any such claim involving alleged infringement of Third Party rights arising from or occurring as a result of Taiho Technology or Taiho's activities at its own expense and by counsel of its own choice, and Lung Tx shall have the right, at its own expense, to be represented in any such action by counsel of its own choice. Neither Party shall have the right to settle any intellectual property right infringement litigation under this **Section 9.5** in a manner that diminishes the rights or interests of the other Party without the written consent of such other Party (which shall not be unreasonably withheld).

ARTICLE 10

REPRESENTATIONS AND WARRANTIES

10.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows:

(a) Corporate Existence and Power. It is a company or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including, without limitation, the right to grant the licenses granted by it hereunder.

(b) Authority and Binding Agreement. As of the Effective Date, (i) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms.

(c) No Conflict. As of the Effective Date, it is not a party to, and during the Term it shall not enter into, any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement.

(d) No Debarment**.** In the course of the Development of the Product, neither Party nor any of its Affiliates or their permitted contractors shall use, during the Term, any employee or consultant who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

(e) Compliance with the Law. Each Party covenants to the other that it shall comply in all material aspects with all Laws applicable to its performance under this Agreement.

10.2 Lung Tx Representations and Warranties. Lung Tx hereby represents, warrants, and covenants (as applicable) to Taiho as follows:

(a) Ownership of Lung Tx Technology. It owns or has the right to use the Lung Tx Technology and has the right to grant the license to the Product as set out in **Section 6.1** of this Agreement.

(b) No Conflicting Licenses. Lung Tx has not granted, and during the Term will not grant, any right to a Third Party under the Lung Tx Technology in the Licensed Territory that would conflict with any of the rights granted to Taiho under this Agreement.

(c) No Liens on Lung Tx Technology. As of the Effective Date, the Lung Tx Technology is free and clear of all liens, claims, security interests or other encumbrances of any kind in the Licensed Territory and Lung Tx shall not permit the Lung Tx Technology to become encumbered by any liens, claims, security interests or other encumbrances of any kind.

(d) Non-Infringement of Lung Tx Patents by Third Parties. As of the Effective Date, to the best knowledge of Lung Tx, there are no activities by Third Parties that would constitute infringement of any claims of the Lung Tx Patents (and in the case of pending Patent applications, the claims of such applications as if any such pending claims were issued).

(e) No Infringement. As of the Effective Date: (i) to the best knowledge of Lung Tx, the Development, manufacture, use, or sale or other Commercialization of the Product does not infringe any claim of an issued Patent or published claim of a Patent application (as if any such published claim were issued) owned by a Third Party; (ii) ***Exhibit B*** lists all patents and patent applications with respect to which Lung Tx or its Affiliates currently have any rights, or with respect to which they have at any time in the past had rights, and in each case that are necessary or useful to make, have, made, develop, use, import, sell and otherwise exploit the Product in the Licensed Territory.

(f) Non-Claims of Third Party Rights. As of the Effective Date, it has not been notified by a Third Party that the use of the Lung Tx Technology and the Development manufacture, use, or sale or other Commercialization of a Product infringes or misappropriates the proprietary rights of such Third Party.

(g) Non-Invalidity and Non-Unenforceability. As of the Effective Date, (i) all issued Lung Tx Patents are valid and enforceable; (ii) none of the Lung Tx Patents are subject to any pending or, to the best knowledge of Lung Tx, threatened re-examination, opposition, interference or litigation proceedings; and (iii) to the best knowledge of Lung Tx, there are no acts or omissions of Lung Tx that would (A) constitute inequitable conduct, fraud or misrepresentation with respect to any Patent application included within Lung Tx Patents, or (B) render any Patent within the Lung Tx Patents invalid or unenforceable in whole or in part.

(h) Non-Action or Claim. As of the Effective Date, there are no actual or pending, and to the best knowledge of Lung Tx no alleged or threatened, adverse actions, suits, claims, interferences or formal governmental investigations, or settlements or judgments, involving the Product, and/or the Lung Tx Trademarks by or against Lung Tx or any of its Affiliates in or before any Governmental Authority. In particular, there is no pending or, to the best knowledge of Lung Tx, threatened product liability action involving the use or administration of the Product.

(i) No Payments. As of the Effective Date, there are no royalties, fees, honoraria or other payments payable by Lung Tx to any Third Party by reason of the ownership, Development, use, license, sale or disposition of the Lung Tx Technology or the Product in the Licensed Territory.

(j) Title to Lung Tx Trademarks. All Lung Tx Trademarks existing as of the Effective Date are listed on ***Exhibit C***. Lung Tx owns the entire right, title and interest in, or otherwise has the right to grant the licenses and rights granted to Taiho herein, under the Lung Tx Trademarks. With respect to the Lung Tx Trademarks listed on ***Exhibit C***, ***Exhibit C*** contains a true, accurate and complete summary of the countries throughout the world in which each such Lung Tx Trademarks has been registered as of the Effective Date. Lung Tx has not assigned and shall not assign and has not granted licenses and shall not grant licenses to the Lung Tx Trademarks listed on ***Exhibit C*** in the Licensed Territory, and has not, and will not, grant any rights that conflict with licenses and rights granted to Taiho over the Lung Tx Trademarks herein or that would otherwise prevent Taiho from exercising its rights or performing its obligations hereunder over the Lung Tx Trademarks in the Licensed Territory.

(k) No Liens on Lung Tx Trademarks. As of the Effective Date, all Lung Tx Trademarks in the Licensed Territory are free and clear of all liens, claims, security interests or other encumbrances of any kind and Lung Tx shall not permit the Lung Tx Trademarks to become encumbered by any liens, claims, security interests or other encumbrances of any kind.

(l) Non-Infringement of Lung Tx Trademarks. The Lung Tx Trademarks do not violate, and when used by Taiho and its Affiliates in connection with the marketing, use, sale and offering for sale of the Products, shall not violate, the trademark, tradename or comparable rights of any Third Party in the Licensed Territory.

(m) No Material Misrepresentation. As of the Effective Date, Lung Tx has not, nor, to the best knowledge of Lung Tx, has any Third Party acting under authority of Lung Tx made an untrue statement of a material fact to any Regulatory Authority with respect to the Product, or intentionally failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Product. Lung Tx has, and, to the best knowledge of Lung Tx, such Third Parties have, complied and shall comply in all material respects with all regulatory requirements with respect to the Product. All Information within the Lung Tx Know-How has been generated in compliance with applicable Laws in all material respects, including, if applicable, ICH guidelines.

(n) Full Disclosure. As of the Effective Date, Lung Tx has not intentionally, knowingly or, due to its gross negligence, failed to furnish Taiho with or intentionally, knowingly or, due to its gross negligence, concealed from Taiho any material data and other Information under Lung Tx Control regarding the efficacy, side effects, injury, toxicity or sensitivity, reaction, incidents or severity thereof associated with the non-clinical use, clinical use, studies, investigations, or tests of the Products based thereon, which in each case would reasonably be expected to have a material adverse effect on the ability to Develop or Commercialize the Products in the Licensed Territory as contemplated in this Agreement.

10.3 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE TECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY UNDER THIS AGREEMENT ARE PROVIDED "AS-IS" AND EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

10.4 Limitation of Liability. EXCEPT FOR PAYMENTS UNDER **ARTICLE 7** OR LIABILITY FOR BREACH OF **ARTICLE 11**, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *PROVIDED, HOWEVER*, THAT THIS **SECTION 10.4** SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER **ARTICLE 12**.

ARTICLE 11

CONFIDENTIALITY

11.1 Confidential Information. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that, during the Term and for [**] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as expressly provided for in this Agreement any Confidential Information. Each Party may use such Confidential Information only to the extent required to accomplish the purposes of this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that its employees, agents, consultants and other representatives do not disclose or make any unauthorized use of the Confidential Information. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the Confidential Information.

11.2 Exceptions. Confidential Information shall not include any information which the receiving Party can prove by competent written evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party, generally known or available; (b) is known by the receiving Party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the receiving Party by a Third Party, as a matter of right and without restriction on disclosure; (d) is independently discovered or developed by the receiving Party without the use of or reference to the Confidential Information belonging to the disclosing Party; or (e) is the subject of a written permission to disclose provided by the disclosing Party.

11.3 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting Patents as permitted by this Agreement;

(b) regulatory filings for the Product such Party has a license or right to Develop hereunder;

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with applicable Laws, including regulations promulgated by security exchanges (specifically recommendations and requests from the Tokyo Stock Exchange (TSE)), applicable court orders or governmental regulations;

(e) exercising its or its Affiliates' rights under this Agreement, including in the case of Taiho, for the purpose of Developing the Product, seeking, obtaining and maintaining Regulatory Approvals in the Licensed Territory (including complying with the requirement of Governmental Authorities with respect to filing for, obtaining and maintaining Regulatory Approval of the Product in the Licensed Territory) and packaging or Commercializing the Product in the Licensed Territory; and

(f) disclosure to its or its Affiliates' employees, agents, consultants, contractors, (sub)licensees or others on a need-to-know basis, provided that in each case the recipient of such Confidential Information are bound by written obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this **ARTICLE 11** prior to any such disclosure.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to **Section 11.3(c)** or **(d)**, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such information at least as diligent as such Party would use to protect its own confidential information, but in no event less than reasonable efforts. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder. The Parties will consult with each other on the provisions of this Agreement to be redacted in any filings made by the Parties with the Securities and Exchange Commission or as otherwise required by law.

11.4 Publications. Each Party to this Agreement recognizes that the publication of papers regarding results of and other information regarding the Development of the Product, including oral presentations and abstracts, may be beneficial to both Parties provided such publications are subject to reasonable controls to protect Confidential Information. Accordingly, a Party shall have the right to review and comment on any material proposed for disclosure or publication by the other Party, such as by oral presentation, manuscript or abstract, which includes Confidential Information of the other Party. Before any such material is submitted for publication, the Party proposing publication shall deliver a complete copy of the material to the other Party prior to submitting the material to a publisher or initiating any other disclosure. Such other Party shall review any such material and give its comments to the Party proposing publication within [**] of the delivery of such material to such other Party. The publishing Party shall comply with the other Party's request to delete references to the other Party's Confidential Information in any such material and agrees to delay any submission for publication or other public disclosure for a period of up to an additional [**] for the purpose of preparing and filing appropriate patent applications, which period could be extended to an additional [**] period.

11.5 Publicity. It is understood that the Parties intend to issue a joint press release announcing the execution of this Agreement and agree that each Party may desire or be required to issue subsequent press releases relating to the Agreement or activities thereunder. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such press releases prior to the issuance thereof, provided that a Party may not unreasonably withhold consent to such releases, and that either Party may issue such press releases as it determines, based on advice of counsel, such press releases are reasonably necessary to comply with laws or regulations or for appropriate market disclosure. In addition, following the initial joint press release announcing this Agreement, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

11.6 Additional Matters. To the extent that any publication is permitted in **Section 11.4** or any press release is permitted in **Section 11.5,** Taiho shall have the right to permit Otsuka Holdings (or its successor) to publicly disclose the information contained in such publications or press release, at any time (including simultaneously with the release of such publications or press release statement by the Parties) and in any form, without the prior written consent of Lung Tx.

ARTICLE 12

INDEMNIFICATION

12.1 Indemnification by Lung Tx. Lung Tx hereby agrees to save, defend and hold harmless Taiho and its Affiliates and their respective directors, officers, employees and agents (each, a **"Taiho Indemnitee"**) from and against any and all claims, suits, actions, demands, liabilities, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, **"Losses"**), to which any Taiho Indemnitee may become subject as a result of any claim, demand, suit, action or other proceeding by any Third Party, to the extent such Losses arise directly or indirectly out of: (a) the Development, Commercialization, manufacturing, use, handling, storage, sale or other disposition of the Product by Lung Tx, its Affiliates or sublicensees (other than Taiho, its Affiliates and permitted sublicensees) outside the Licensed Territory, except for the Losses arising directly or indirectly out of activities by Taiho provided in **Section 12.2(a)** or the breach by Taiho provided in **Section 12.2(b)** below; (b) the breach by Lung Tx of any warranty, representation or covenant made by Lung Tx in this Agreement; or (c) the willful misconduct or negligent acts of Lung Tx, its Affiliates, or the officers, directors, employees, or agents of Lung Tx or its Affiliates; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Taiho Indemnitee or the breach by Taiho of any warranty, representation or covenant made by Taiho in this Agreement.

12.2 Indemnification by Taiho. Taiho hereby agrees to save, defend and hold harmless Lung Tx and its Affiliates and their respective directors, officers, employees and agents (each, a **"Lung Tx Indemnitee"**) from and against any and all Losses to which any Lung Tx Indemnitee may become subject as a result of any claim, demand, suit, action or other proceeding by any Third Party, to the extent such Losses arise directly or indirectly out of: (a) the Development, Commercialization, packaging, labeling, use, handling, storage, sale or other disposition of the Product by Taiho, its Affiliates and permitted sublicensees in the Licensed Territory, except for the Losses arising directly or indirectly out of activities by Lung Tx provided in **Section 12.1(a)** or the breach by Lung Tx provided in **Section 12.1(b)** above; (b) the breach by Taiho of any warranty, representation or covenant made by Taiho in this Agreement; or (c) the willful misconduct or negligent acts of Taiho, its Affiliates, or the officers, directors, employees, or agents of Taiho or its Affiliates; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Lung Tx Indemnitee or the breach by Lung Tx of any warranty, representation or covenant made by Lung Tx in this Agreement.

12.3 Conditions to Indemnification. The Party claiming indemnity under this **ARTICLE 12** (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of any claim, demand, suit, action or other proceeding by any Third Party in relation to which it wishes to claim indemnification hereunder (a "**Claim**"), provided that the failure to promptly provide such notice will not relieve the Indemnifying Party of any of its indemnification obligations hereunder, except to the extent that the Indemnifying Party's defense of the relevant Claim is prejudiced by such failure. The Indemnifying Party may upon such notice assume the defense of the Claim, and the Indemnified Party will provide the Indemnifying Party, upon the Indemnifying Party's request, with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and

monitor such defense with counsel of its own choosing at its sole expense. The Indemnifying Party may settle any Claim without the prior consent of the Indemnified Party unless such settlement would impose any monetary obligation on the Indemnified Party or require the Indemnified Party to submit to an injunction or otherwise materially limit the other Party's rights to conduct its business as then conducted or limit the Indemnified Party's rights under this Agreement, in which case the Indemnified Party must give its prior written consent, not to be unreasonably withheld. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party will not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (i) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (ii) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this **ARTICLE 12**.

12.4 Insurance. Each Party, at its own expense, shall maintain general commercial liability insurance, clinical trial insurance and product liability insurance (or self-insure) in an amount consistent with industry standards during the Term. It is understood that such insurance shall not be construed to create a limit of either Party's liability or indemnification obligations under this **ARTICLE 12**, or that the maintenance of such insurance shall not be construed to relieve either Party of its other obligations under this Agreement. Each Party shall provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to the other Party upon request.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. The term of this Agreement (the "**Term**") shall commence on the Effective Date and continue until the later of (a) ten (10) years after the date of First Commercial Sale in the Licensed Territory, (b) the expiration of the last Valid Claim of any Lung Tx Patents, if any, that Covers the Product in the Licensed Territory, and (c) the expiration of the Regulatory Data Exclusivity in the Licensed Territory, unless earlier terminated pursuant to **Section 13.4**.

13.2 Extension Term. No later than twelve (12) months before the expiration of the initial Term of this Agreement in accordance with the provisions of **Section 13.1**, Taiho may notify Lung Tx of its interest in continuing to Commercialize the Product in the Licensed Territory, in which case, the Parties shall meet within [**] of such notification to determine (i) the revised rate of "Royalty and Transfer Price" (i.e. [**] percent ([**]%) as of the Effective Date) and the revised price of "Minimum Royalty and Transfer Price" (i.e. [**] Yen (¥[**]) as of the Effective Date) set forth in **Section 7.3(b)** during the Extension Term (as defined below), and (ii) period of the Extension Term, provided that at Taiho's request, this Agreement shall be extended in accordance to its then current terms and conditions for the period necessary for the Parties to determine the revised rate of "Royalty and Transfer Price" and the revised price of "Minimum Royalty and Transfer Price" during the Extension Term. Within [**] of the determination of the terms and conditions of this Agreement during the Extension Term, Taiho may notify Lung Tx that it elects

to continue to Commercialize the Product in the Licensed Territory in accordance with the terms and conditions determined by the Parties and, upon such notice, the Term of this Agreement shall be deemed extended, for a period agreed by the Parties (the "**Extension Term**"), and during the Extension Term, the revised rate of "Royalty and Transfer Price" and the revised price of "Minimum Royalty and Transfer Price" agreed by the Parties pursuant to this **Section 13.2** shall be applied.

13.3 Fully Paid Up License. Upon expiration of the Term or Extension Term in accordance with **Section 13.1** and **Section 13.2** above and provided that Taiho has made payments for all amounts due hereunder prior to the expiration, the rights and licenses granted to Taiho hereunder by Lung Tx shall become fully paid up.

13.4 Early Termination.

(a) Termination by Taiho for Safety Reasons. Taiho shall have the right to terminate this Agreement, for any Safety Reasons upon at least three (3) months' prior written notice to Lung Tx or within a shorter period if required under applicable Laws. "**Safety Reasons**" shall mean that, based upon all relevant scientific data, there are safety and public health issues relating to the Product such that the medical benefit/risk ratio of such Product is sufficiently unfavorable as to materially compromise the welfare of patients so that the use in patients is no longer justifiable and that such issues are unlikely to be reversed within a reasonable period of time with a commercially reasonable level of investment.

(b) Termination by Taiho for Regulatory Reasons. Taiho shall have the right to terminate this Agreement upon three (3) months prior written notice, if the first Marketing Authorization Applications of the Product is not approved by the Regulatory Authority in the Licensed Territory by the third anniversary of filing for such first Marketing Authorization Applications.

(c) If Taiho terminates this Agreement pursuant to this **Section 13.4(a)** or **(b)**, then:

(i) Taiho shall not, during such three (3) month notice period, take any action that could adversely affect or impair the further Development and Commercialization of the Product in the Licensed Territory; and

(ii) the Joint Development Committee shall coordinate the wind-down of Taiho's efforts under this Agreement.

(d) Termination for Breach. In the event that either Party is in breach of any of its material obligations or any material breach of any representation or warranty under this Agreement, the other Party may give to such Party written notice identifying such breach. If such Party fails to cure such breach within [**] from the date of such notice (or within [**]' notice in the event such breach is solely based upon Taiho's failure to pay any amounts due Lung Tx hereunder) the other Party shall have the right to terminate this Agreement upon written notice to such Party.

(e) Termination for Bankruptcy. Either Party shall have the right to terminate this Agreement immediately upon written notice to the other party in the event that the other party (i) is adjudged bankrupt (not to include reorganizations); (ii) petitions for or acquiesces in the appointment of a receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets, (iii) shall generally not, or shall admit in writing its inability to, pay its debts as they become due, or (iv) commences proceedings (not dismissed within [**]) voluntarily or involuntarily, under any bankruptcy or similar law, or winding up for the purposes or reconstruction or amalgamation and such events materially and adversely affects such party's ability to perform its obligations hereunder, provided that applicable bankruptcy laws shall apply.

13.5 Effect of Termination.

(a) Upon Termination or expiration of the Agreement for any reason, the following shall apply:

(i) Termination or expiration of this Agreement for any reason shall not release a Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereto to the extent it is expressly stated to survive such termination.

(ii) Within [**] following the termination or expiration of the Agreement for any reason, Taiho shall provide Lung Tx with a Royalty Report for the period up to the date of the termination or expiration which is then not yet reported, if any, and Taiho shall pay to Lung Tx all amounts that have accrued under this Agreement, including unpaid license fees and accrued, but unpaid milestone payments under **Section 7.2** and Royalty under **Section 7.3**.

(iii) Subject to Taiho's obligations under **Section 13.5(a)(iv)**, each Party shall promptly destroy or return to the other Party all of such other Party's Confidential Information that was provided by or on behalf of such other Party hereunder that is in the possession or control of such Party (or any of its Affiliates). Notwithstanding the foregoing, a Party shall have the right to retain one copy of the Confidential Information of the other Party for legal and archival purposes, and the foregoing obligation of return or destruction shall not apply to Confidential Information or copies thereof maintained in routine, secure computer back-up files unless and until such information is accessed.

(iv) Notwithstanding anything herein to the contrary, within [**] following the termination or expiration of the Agreement for any reason, Taiho shall transfer, assign and deliver to Lung Tx all pre-clinical, non-clinical, analytical and clinical data, relating to the Product generated under **Section 4.1(b)** that are Controlled by Taiho.

(v) All licenses under **ARTICLE 6** shall terminate and Taiho shall cease, and shall cause its Affiliates and Third Party contractors and permitted sublicensees (if any) to cease, all Development and Commercialization of the Product; provided, that, for the avoidance of doubt, if applicable, the license under **Section 13.5(b)(ii)** shall survive.

(b) Upon termination by Lung Tx of the Agreement under **Section 13.4(d)** or **Section 13.4(e)**, or upon termination by Taiho under **Section 13.4(a) or Section 13.4(b)**, the following shall apply:

(i) Regulatory Materials. To the extent permitted by applicable Law, Taiho shall transfer and assign to Lung Tx all Regulatory Documents and Regulatory Approvals for the Product in the Licensed Territory that are Controlled by Taiho.

(ii) Taiho License. Upon written request of Lung Tx, Taiho grants to Lung Tx, effective only in such event, a perpetual, irrevocable, non-exclusive, worldwide, fully-paid, royalty-free license, with the right to grant multiple tiers of sublicenses, under the Taiho Technology solely to develop, make, have made, use, sell, offer for sale, and import the Products.

(iii) Transition Assistance. During a reasonable period not to exceed [**] following the effective date of termination, Taiho shall use commercially reasonable efforts to provide such assistance, [**], as may be reasonably necessary to transfer and/or transition to Lung Tx all then-existing commercial arrangements, that is, or are, necessary or useful for Lung Tx to commence or continue Developing or Commercializing the Product in the Licensed Territory, to the extent Taiho is then performing or having performed such activities.

(iv) Clinical Trial Funding. Except in case of termination by Taiho under **Section 13.4(a) and Section 13.4(b),** if Taiho has agreed to conduct or fund a clinical trial for the Product under the Development Plan prior to the effective date of termination, including its agreement to fund a Licensed Territory-specific arm of a Global Clinical Trial or to conduct a Phase IV Clinical Trial or other clinical trial designed to acquire data for the Licensed Territory, then Taiho's obligations to fund such clinical trial(s) shall survive the termination of this Agreement, provided that such trials will thereafter be conducted by or under the direction of Lung Tx. Lung Tx will invoice Taiho for its share of the costs of such clinical trials on a Calendar Quarterly basis after termination of this Agreement, which invoices shall be due and payable within [**] of the invoice date.

(v) Remaining Inventories. Lung Tx shall have the right to purchase from Taiho all of the inventory of the Product held by Taiho as of the effective date of termination of this Agreement at a price equal to Taiho's actual cost to acquire such inventory. Lung Tx shall notify Taiho within [**] before the date of termination of the Agreement whether Lung Tx elects to exercise such right. If Lung Tx does not exercise such right, then Taiho shall have the right to sell in the Licensed Territory any such remaining inventory over a period of no greater than [**] after the effective date of termination of this Agreement in the Licensed Territory.

13.6 Taiho's rights. Taiho may elect in lieu of terminating this Agreement under **Section 13.4(d)** or **Section 13.4(e)** to declare that the licenses granted pursuant to this Agreement shall include a license to make or have made the Product (which Lung Tx hereby grants in these cases) in the Licensed Territory. Lung Tx will continue to permit Taiho to place orders for the Product through any of Lung Tx's existing supply agreements with Third Party manufacturers as necessary to satisfy any manufacturing or supply obligations of Lung Tx under the Supply Agreement, subject to the terms and conditions of Lung Tx's agreements with such Third Parties, until Taiho has been able to find an alternative supplier and Lung Tx has disclosed the necessary Lung Tx Technology pursuant to the terms of a technology transfer agreement to be negotiated by the Parties.

13.7 Exercise of Right to Terminate. The use by either Party hereto of a termination right provided for under this Agreement shall not give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto.

13.8 Other Remedies. Termination or expiration of this Agreement for any reason shall not release any Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder or that may arise out of or in connection with such termination or expiration.

13.9 Surviving Obligations. The following provisions shall survive any expiration or termination of this Agreement for the period of time specified: **Sections 4.5** and **4.6**, **Section 7.3** (with respect to any Product sold prior to termination or expiration), **Sections 9.1, 9.3, 9.4(c)** and **9.4(d)** (with respect to Joint Patents only), **9.5, 10.3** and **10.4** and **ARTICLES 8, 11, 12, 13, 14** and **15**.

ARTICLE 14

DISPUTE RESOLUTION

14.1 Arbitration. Any dispute, controversy or claim with respect to the breach, interpretation or enforcement of this Agreement, including disputes relating to termination of this Agreement (each, a "**Dispute**"), shall be settled by binding arbitration in the manner described in this **ARTICLE 14**. The arbitration shall be conducted in accordance with the Rules of Arbitration of the International Chamber of Commerce (**"ICC"**) then in force. Notwithstanding those rules, the following provisions shall apply to the arbitration hereunder:

(a) Negotiation. A Party shall send written notice to the other Party of any Dispute ("**Dispute Notice**"). The Parties shall first attempt in good faith to resolve any Dispute set forth in the Dispute Notice by negotiation and consultation between themselves, including not fewer than [**] negotiation sessions attended by the CEO for Lung Tx and by the President for Taiho. In the event that such Dispute is not resolved on an informal basis within [**] after one party delivers the Dispute Notice to the other Party, whether the negotiation sessions take place or not, either party may initiate arbitration under **Sections 14.1(b)** and **(c)**.

(b) Arbitrators. The arbitration shall be conducted by a single ICC arbitrator mutually agreed upon by the Parties; provided that if the Parties are unable to agree upon a single arbitrator, the arbitration shall be conducted by a panel of three (3) arbitrators, with one (1) ICC arbitrator chosen by Lung Tx, one (1) ICC arbitrator chosen by Taiho, and one (1) ICC arbitrator appointed by the other two (2) ICC arbitrators. In any event, the arbitrator or arbitrators selected in accordance with this **Section 14.1(b)** are referred to herein as the "Panel" and shall be comprised of arbitrators who are familiar with worldwide development and commercialization in the pharmaceutical industry, unless otherwise agreed.

(c) Proceedings. Except as otherwise provided herein, the Parties and the arbitrators shall use their best efforts to complete the arbitration within [**] after the appointment of the Panel under **Section 14.1(b)** above, unless a Party can demonstrate to the Panel that the complexity of the issues or other reasons warrant the extension of one or more of the time tables. In such case, the Panel may extend such time table as reasonably required. The Panel shall, in rendering its decision, apply the substantive law of the State of New York, without regard to its conflicts of laws provisions, except that the interpretation of and enforcement of this **ARTICLE 14** shall be governed by the U.S. Federal Arbitration Act. The proceeding shall take place in New York, New York, U.S.A. The decision and/or award rendered by the arbitrator(s) shall be written, final, binding and non-appealable, and judgment on such decision and/or award may be entered in any court of competent jurisdiction. The fees of the Panel shall be paid by the losing Party which Party shall be designated by the Panel. If the Panel is unable to designate a losing Party, it shall so state and the fees shall be split equally between the Parties. Each Party shall bear the costs of its own attorneys' and experts' fees; provided that the Panel may in its discretion award the prevailing Party all or part of the costs and expenses incurred by the prevailing Party in connection with the arbitration proceeding.

14.2 Interim Relief. Notwithstanding anything in this **ARTICLE 14** to the contrary, Lung Tx and Taiho shall each have the right to apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction, or other similar interim or conservatory relief, as necessary, pending resolution under the above described arbitration procedures. Nothing in the preceding sentence shall be interpreted as limiting the powers of the arbitrators with respect to any dispute subject to arbitration under this Agreement. The Panel may award injunctive relief.

ARTICLE 15

GENERAL PROVISIONS

15.1 Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, U.S.A., excluding its conflicts of laws principles.

15.2 Entire Agreement; Modification. This Agreement is a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. This Agreement supersedes all prior and contemporaneous agreements and communications, whether oral, written or otherwise, concerning any and all matters contained herein. No rights or licenses with respect to any intellectual property of either Party are granted or deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

15.3 Relationship Between the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

15.4 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

15.5 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); *provided, however*, that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent:

(a) in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale of assets or otherwise, provided that in the event of a transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by operation of law (*e.g.*, in the context of a reverse triangular merger)), (i) intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) shall not be included in the technology licensed hereunder and (ii) any transferee or successor entity resulting from such transaction shall be liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations; or

(b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement shall be void.

15.6 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

15.7 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such adjudication shall not affect or impair, in whole or in part, the validity, enforceability or legality of any remaining portions of this Agreement. All remaining portions shall remain in full force and effect as if the original Agreement had been executed without the invalidated, unenforceable or illegal part.

15.8 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by any method of mail (postage prepaid) requiring return receipt, or by overnight courier, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, three days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries

If to Taiho, notices must be addressed to:

Taiho Pharmaceutical Co., Ltd.
1-27 Kandanishiki-cho, Chiyoda-ku
Tokyo 101-8444, Japan
Attention: Director, Business Development
Telephone: [**]
Facsimile: [**]

If to Lung Tx, notices must be addressed to:

Lung Therapeutics, Inc.
2600 Via Fortuna, Suite 360
Austin, Texas 78746
Attention: Chief Executive Officer
Email: [**] (Email notification shall not constitute formal notice)

with a copy to (which shall not constitute notice):

Ballard Spahr LLP
5480 Valmont Road, Suite 200
Boulder, Colorado 80301
Attention: Steven N. Dupont
E-mail: DupontS@ballardspahr.com

15.9 Force Majeure. Except for the obligation to make payment when due, each Party shall be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, pandemics (including the current Covid-19 pandemic) or any other event similar to those enumerated above. Such excuse from liability shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [**] after its occurrence. All delivery dates under this Agreement that have been affected by force majeure shall be tolled for the duration of such force majeure. In no event shall any Party be required to prevent or settle any labor disturbance or dispute.

15.10 Compliance and Ethical Business.

(a) Compliance.

(i) In performing their obligations under this Agreement, the Parties shall comply with applicable Laws and regulations and will take no action which may be reasonably expected to materially jeopardize the goodwill or reputation of the other Party.

(ii) Each Party represents and warrants to the other Party that it is not, nor are any of its legal representatives, as applicable, listed on the U.S. Treasury Department's List of Specially Designated Nationals and Blocked Persons (http://https://www.treasury.gov/ofac/downloads/sdnlist.pdf), the U.S. Commerce Department's Denied Persons List (http://www.bis.doc.gov/dpl/thedeniallist.asp) and Entity List (http://www.bis.doc.gov/entities/default.htm), or the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions (https://eeas.europa.eu/headquarters/headquarters- homepage/8442/consolidated-list-sanctions_en), or on any comparable denied parties list issued by the U.S., EU or another jurisdiction which is applicable to the products or technical data supplied under this Agreement (all of the foregoing collectively referred to as "Denied Parties Lists"). Each Party further represents and warrants to the other Party that it is not directly owned by fifty percent (50%) or more by a person or entity listed on any of the Denied Parties Lists. Each Party further represents and warrants to the other Party that it shall notify such other Party in writing promptly if it or any of its legal representatives become listed on any of the Denied Parties Lists or if it becomes owned by fifty percent (50%) or more by a person or entity listed on any of the Denied Parties List.

(b) Ethical Business.

(i) In performing their obligations hereunder, the Parties acknowledge that the corporate policy of each Party and their Affiliates require that such Party's business be conducted within the letter and spirit of the law. By signing this Agreement, the Parties agree to conduct the business contemplated herein in a manner which is consistent with all applicable Laws and good business ethics. Specifically, the Parties warrant and agree that, in connection with this Agreement and each Party's business relating thereto, they, their directors, their employees and their officers shall not offer, make or promise any payment, either directly or indirectly, of money or other assets (hereinafter collectively referred to as "**Payment**" for the purposes of this **Section 15.10(b)**), to any government, political party or international organization official, candidate or persons acting on behalf of any of the foregoing or directly associated with them including their staff, business partners, close associates and family (hereinafter collectively referred to as "**Officials**" for the purposes of this **Section 15.10(b)**) where such Payment would constitute a violation of any applicable Laws. In addition, the Parties shall make no Payment, either directly or indirectly, to Officials if such Payment is for the purpose of improperly influencing decisions or actions with respect to the subject matter of this Agreement or the business activities of each Party or their Affiliates.

(ii) Each Party acknowledges and agrees that in the event that such Party engages an Affiliate, (sub)licensee, subcontractor or agent in the performance of its obligations under this Agreement, that such Party will conduct due diligence on such Affiliate, (sub)licensee, subcontractor or agent to ensure such Affiliate's, (sub)licensee's, subcontractor's or agent's suitability to comply with the requirements set forth in this **Section 15.10(b)**, and will maintain records of such due diligence and any identified risks and mitigation records, consistent with such Party's customary procedures.

(iii) Each Party represents, warrants and covenants that all books, records, invoices, and other documents relating to payments and expenses under this Agreement are and shall be accurate and reflect in reasonable detail the character and amount of transactions and expenditures.

(iv) Each Party further represents, warrants and agrees that no "off the books" or other similar funds will be maintained or used in connection with this Agreement.

(v) Each Party agrees to ensure that all of such Party's employees, agents and subcontractors involved in performing the obligations under this Agreement are made aware of the prohibited nature of activities expressly prohibited under this **Section 15.10(b)**, including by participation, as appropriate, of such employees, agents and subcontractors in mandatory training to be conducted by such Party regarding such requirements prior to performing any obligations under this Agreement. Each Party further agrees to certify its continuing compliance with the requirements under this **Section 15.10(b)** on a periodic basis during the Term of this Agreement upon the other Party's request, such request to be made no more frequently than once in any calendar year.

(vi) Each Party shall have the right, upon reasonable notice and at a time mutually agreed by the Parties, to audit the books and records of the other Party to ensure compliance with this **Section 15.10(b)** during the Term of this Agreement and for a period of [**] thereafter, and the other Party shall provide its full cooperation and assistance in any such review conducted by such Party.

(vii) Each Party's violation of, or any breach of a representation or warranty set forth in this **Section 15.10(b)** shall be a material breach of this Agreement, and in such event the other Party may terminate this Agreement pursuant to **Section 13.4**.

15.11 Interpretation.

(a) Captions & Headings. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.

(b) Singular & Plural. All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.

(c) Articles, Sections & Subsections. Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.

(d) Days. All references to days in this Agreement shall mean calendar days, unless otherwise specified.

(e) Ambiguities. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

(f) English Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

15.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original document, and all of which, together with this writing, shall be deemed one instrument.

<< Signature Page Follows >>

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the date first above written.

LUNG THERAPEUTICS, INC.

By: /s/ Brian Windsor
Name: Brian Windsor
Title: CEO

TAIHO PHARMACEUTICAL CO., LTD.

By: /s/ Masayuki Kobayashi
Name: Masayuki Kobayashi
Title: President and Representative Director

Exhibit List

Exhibit A — **Lung Tx House Marks**

Exhibit B — **Lung Tx Patents**

Exhibit C — **Lung Tx Trademarks**

Exhibit D — **Product Specifications**

Exhibit E — **[**]**

Exhibit 10.2

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDED AND RESTATED

PATENT & TECHNOLOGY LICENSE AGREEMENT

This Amended and Restated Patent and Technology License Agreement ("Agreement"), effective as of December 19, 2013, is between the Board of Regents of The University of Texas System, an agency of the State of Texas whose address is 201 West 7th St. Austin, TX 78701 ("Board"), on behalf of The University of Texas Health Science Center at Tyler ("UTHSCT") (with Board on behalf of UTHSCT as "Licensor"), and Lung Therapeutics, Inc., a Texas Corporation, with its principal place of business at P.O. Box 150183, Austin, Texas 78715 ("Licensee") (collectively, "Parties", or singly, "Party").

Licensor and Licensee previously entered into this Patent & Technology License Agreement effective June 19, 2013, which agreement is amended and restated in its entirety by this Agreement.

No binding agreement between the Parties will exist until the Agreement has been signed by both Parties. Unsigned drafts of the Agreement shall not be considered offers.

Background

Licensor owns or controls Licensed Subject Matter (defined below). Licensee desires to secure the right and license to use, develop, manufacture, market, and commercialize the Licensed Subject Matter. Licensor has determined that such use, development, and commercialization of the Licensed Subject Matter is in the public's best interest and is consistent with Licensor's educational and research missions and goals. Licensor desires to have the Licensed Subject Matter developed and used for the benefit of Licensee, the inventors, Licensor, and the public.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereby agree as follows:

1. Definitions

"Affiliate" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.

"Contract Quarter" means the three-month periods ending on March 31, June 30, September 30 and December 31, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"Contract Year" means the 12-month periods ending on December 31, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"Effective Date" with respect to the first item on Exhibit A means June 19, 2013, and with respect to the amendments in this Agreement and the remaining items on Exhibit A, "Effective Date" means the date set forth in the first paragraph of this Agreement.

"FDA" means United States Food and Drug Administration.

"Field" means all fields.

"Fully Diluted Basis" means the calculation of percentage ownership that includes all shares of Licensee's common stock outstanding at the time in question, assuming conversion of all outstanding convertible securities then convertible into shares of Licensee's common stock. In the event that any of Licensee's non-convertible preferred stock are outstanding at the time in question, then each share of such preferred stock shall be treated as though it was ten shares of Licensee's common stock based upon the dividend rights of such preferred stock.

"Government" means any agency, department or other unit of the United States of America or the State of Texas.

"Gross Consideration" means all cash and non-cash consideration (e.g., securities).

"Inventors" (or singly, **"Inventor")** means an individual listed in Exhibit A as an inventor.

"Licensed Process" means a method or process whose practice or use is covered by a Valid Claim or uses Technology Rights.

"Licensed Product" means any product or component (i) whose manufacture, use, sale, offer for sale or import is covered by any Valid Claim or incorporates any Technology Rights, or (ii) which is made using a Licensed Process or another Licensed Product.

"Licensed Service" means performance of a service for any consideration using a Licensed Product, or the practice of a Licensed Process. For clarity, research and development of Licensed Products by Licensee, its Subsidiaries, or a Sublicensee does not constitute a Licensed Service.

"Licensed Subject Matter" means Patent Rights and/or Technology Rights.

"Net Product Sales" means [**].

"Net Service Sales" means [**].

"Non-Royalty Sublicensing Consideration" means [**].

"Patent Rights" means Licensor's rights in: (a) the patents and patent applications listed in Exhibit A to the Agreement; (b) all non-provisional patent applications that claim priority to any of the provisional applications listed in Exhibit A to the extent the claims of such non-provisional applications are entitled to claim priority to such provisional applications; (c) all divisionals, continuations and continuations-in-part of the non-provisional patent applications identified in (a) and (b) above to the extent that claims of such continuations-in-part are entitled to claim priority to at least one of the patent applications identified in (a) or (b) above; (d) all reissues, reexaminations, extensions, and foreign counterparts of any of the patents or patent applications identified in (a), (b) or (c) above; and (e) any patents that issue with respect to any of the patent applications listed in (a), (b), (c) or (d) above. From time to time during the term of the Agreement, upon written agreement by both Parties, Licensee and Licensor shall update the list of all patent applications and patents within the Patent Rights.

"Prosecution Counsel" means the law firm or attorney who is handling the prosecution of the Patent Rights. Prosecution Counsel as of the Effective Date is identified in Exhibit A to the Agreement.

"Regulatory Approval" means the approval needed by the Regulatory Authority for a particular national jurisdiction to market, Sell and use a Licensed Product or Licensed Service in that national jurisdiction.

"Quarterly Payment Deadline" means the day that is [**] after the last day of any particular Contract Quarter.

"Regulatory Authority" means the governmental authority responsible for granting any necessary licenses or approvals for the marketing, Sale and use of a Licensed Product or Licensed Service in a particular national jurisdiction, including without limitation FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare).

"Sale of Licensee" means a transaction or series of related transactions whereby: (i) Licensee is not the surviving entity in any merger, consolidation or other reorganization (or survives only as a subsidiary of an entity other than an entity wholly-owned by Licensee immediately prior to such merger, consolidation or other reorganization); (ii) Licensee is the surviving entity in any merger, consolidation or other transaction or series of related transactions in which the owners of the Licensee's common stock on a Fully Diluted Basis immediately prior to such merger, consolidation or other reorganization no longer own at least 50% of the Licensee's common stock on a Fully Diluted Basis after such merger, consolidation or other reorganization; (iii) Licensee sells leases or exchanges, or agrees to sell, lease or exchange, all or substantially all of its assets to any other entity (other than an entity wholly-owned by Licensee); (iv) the grant of any license rights granted to Licensee under the Agreement to any Affiliate that is not a Subsidiary, (v) there is an assignment of the Agreement, or (vi) Board no longer owns at least [**]% of the Licensee's common stock on a Fully Diluted Basis.

"Sell, Sale or Sold" means any transfer or other disposition of Licensed Products or Licensed Services for which consideration is received by Licensee, its Subsidiaries or Sublicensees. A Sale of Licensed Products or Licensed Services will be deemed completed at the time Licensee or its Subsidiary or its Sublicensee receives such consideration.

"Sublicense Agreement" means any agreement or arrangement pursuant to which Licensee (or a Subsidiary or Sublicensee) grants to any third party any of the license rights granted to Licensee under the Agreement.

"Sublicensee" means any entity to whom an express sublicense has been granted under the Patent Rights and/or Technology Rights. For clarity, a third party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product or Licensed Services within its distribution territory or field (i.e., the third party simply functions as a reseller), and who does not pay any consideration to Licensee or a Subsidiary for such wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Sales by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to Section 3.2. This definition does not limit Licensee's rights to grant or authorize sublicenses under the Agreement.

"Subsidiary" means any business entity 100% owned by Licensee, either directly or indirectly.

"Technology Rights" means Licensor's rights in technical information, know-how, processes, procedures, compositions, devices, methods, formulas, protocols, techniques, designs, drawings or data created before the Effective Date by Inventors while employed at the Licensor and within the Field which are not covered by a Valid Claim but which are necessary for practicing inventions claimed in patents and/or patent applications listed in the definition of Patent Rights whether outstanding, expired or abandoned.

"Territory" means worldwide.

"Valid Claim" means a claim of (i) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and un-appealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

2. License Grant and Commercialization

2.1 Grant

(a) Licensor grants to Licensee a royalty-bearing exclusive license under Patent Rights to manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field in the Territory and to perform Licensed Services in the Field in the Territory.

(b) Licensor grants to Licensee a royalty-bearing non-exclusive license under Technology Rights to manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field in the Territory and to perform Licensed Services in the Field in the Territory.

(c) This grant is subject to (i) the payment by Licensee to Licensor of all consideration required under the Agreement, (ii) any rights of, or obligations to, the Government as set forth in Section 11.2 (Government Rights), and (iii) rights retained by Licensor to:

(1) Publish the scientific findings from research related to the Patent Rights; and

(2) Use the Licensed Subject Matter for teaching, research, patient care, education, and other educationally-related purposes; and

(3) Grant rights to, and transfer material embodiments of, the Licensed Subject Matter to other academic institutions or non-profit research institutions for the purposes identified in clauses (1) and (2) above.

(d) Licensor reserves all rights not expressly granted in the Agreement and disclaims the grant of any implied rights to Licensee.

2.2 Subsidiaries

Licensee may extend the license granted herein to any Subsidiary for as long as it remains a Subsidiary, provided that the Subsidiary agrees in writing to be bound by the Agreement to the same extent as Licensee. For the sake of clarity, any specific reference to "Licensee" herein shall include such Subsidiary regardless of whether a specific reference to a "Subsidiary" is made in such provision. Licensee agrees to deliver such written agreement to Licensor within [**] following execution.

2.3 Sublicensing

Licensee has the right to grant Sublicense Agreements under the Licensed Subject Matter consistent with the terms of the Agreement, subject to the following:

(a) A Sublicense Agreement shall not exceed the scope and rights granted to Licensee hereunder. Sublicensee must agree in writing to be bound by the applicable terms and conditions of the Agreement and shall indicate that Licensor is a third party beneficiary of the Sublicense Agreement. In the event of termination of this Agreement, continued sublicense rights shall be governed by Section 7.5(a) (Effect of Termination). Licensee may grant a Sublicensee the right to grant further sub-Sublicense Agreements, in which case such sub-Sublicense Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of the Agreement.

(b) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee, Subsidiary or Sublicensee, and any modification or termination thereof, within [**] following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide Licensor an accurate English translation in addition to a copy of the original agreement.

(c) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Licensor for all of Licensee's duties and obligations contained in the Agreement, including without limitation the payment of running royalties due under Section 3.2 whether or not paid to Licensee by a Sublicensee. Any act or omission of a Sublicensee that would be a breach of the Agreement if performed by Licensee will be deemed to be a breach by Licensee. Each Sublicense Agreement will contain a right of termination by Licensee in the event that the Sublicensee breaches the payment or reporting obligations affecting Licensor or any other terms and conditions of the Sublicense Agreement that would constitute a breach of the Agreement if such acts were performed by Licensee.

2.4 Diligent Commercialization

Licensee by itself or through its Subsidiaries and Sublicensees will use diligent efforts to make Licensed Products and/or Licensed Services (as applicable) commercially available in the Field within the Territory. Without limiting the foregoing, Licensee will:

(a) maintain a bona fide, funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program (all as commercially reasonable) to make License Products and/or Licensed Services commercially available to the public as soon as commercially practicable, and

(b) fulfill the following milestone events by the deadlines indicated:

1. Equity and License Milestones (Clinical)

[**].

2. Equity and License Milestone (Business)

a. Raise funding, in the form of investment capital or grants, equal to at least $[**] by [**]; and

b. Raise funding, in the form of investment capital or grants, equal to at least $[**] by [**], including grants to Licensor utilized for the benefit of the Patent Rights.

If the obligations under this Section 2.4 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b).

3. Compensation

In consideration of rights granted to Licensee, Licensee will pay Licensor the following fees and royalties. All fees and royalties are not refundable and are not creditable against other fees and royalties. Each payment will reference the Agreement number, if any, and will be sent to Licensor's payment and accounting contact in Section 18 (Notices).

3.1 Non-Royalty Payments due from Licensee

(a) *Patent Expenses.* Licensee will reimburse Licensor the amount of $[**] for past patent expenses invoiced as of [**]. This amount is the current estimate for past patent expenses based on invoices received by Licensor through such date. Licensee's obligations to pay all past and future patent expenses pursuant to Section 6 (Patent Expenses and Prosecution) will not be limited by such amount. The past patent expenses will be reimbursed in [**] installments of $[**] remitted to Licensor on [**].

(b) *Milestone Fees.* No milestone fees shall be due under this License.

(c) *Sublicense Fees.* Licensee will pay Sublicense Fees in an amount equal to [**]% of Non-Royalty Sublicensing Consideration on or before the Quarterly Payment Deadline for the Contract Quarter; provided that no Sublicense Fees shall be due for transactions that occur prior to the Sale of Licensee.

(d) *Assignment Fee.* Licensee will pay the assignment fee equal to the greater of [**]% of gross consideration for assignment or $[**] within [**] of the assignment of the Agreement; provided that no Assignment Fees shall be due for transactions that occur prior to the Sale of Licensee.

3.2 Royalties

Prior to the Sale of Licensee, the license granted to Licensee hereunder will be a royalty-free license, and Licensee will not be obligated to pay any royalties to Licensor. After the Sale of Licensee, Licensee will pay a running royalty equal to [**]% of Net Product Sales and Net Service Sales (whether made by Licensee, a Sublicensee or a Subsidiary), in each Contract Quarter following the Sale of Licensee, payable on or before the applicable Quarterly Payment Deadline, subject to the following:

(a) A royalty shall be paid to Licensor hereunder with respect to the Sale of any one unit of Licensed Product or Licensed Service, whether or not more than one Valid Claim is applicable to the Licensed Product or Licensed Service, or the development, manufacture, or performance thereof, subject to the provisions herein, and cover for five (5) years after the expiration of any Patent Rights covering a Licensed Product or Licensed Service, and no royalty payments shall be required with respect to Licensed Product or Service thereafter.

(b) No royalty shall be payable under this Section 3.2 with respect to (i) Sales to a Subsidiary or Sublicensee of a particular unit of Licensed Product that is used by such Subsidiary or Sublicensee to perform a Licensed Service if Licensor is paid a royalty on the Sale of such Licensed Service provided that amount of Sale of such Licensed Service is greater than or equal to sale of particular unit of Licensed Product to end-user, (ii) the Sale of Licensed

Products between or among Licensee, its Subsidiaries, and Sublicensees for re-sale purposes, provided Licensor is paid a royalty with respect to the re-sale provided that amount of Sale of such Licensed Service is greater than or equal to sale of particular unit of the Licensed Service to end-user, or (iii) payments that constitute Non-Royalty Sublicensing Consideration.

(c) Running royalties will pass through to Sublicensees.

3.3 Minimum Royalties

If royalties paid to Licensor do not reach the following minimum royalty amounts: $[**] for the Contract Year ended [**] for the Contract Year ended [**] for the Contract Year ended [**] for the Contract Year ended [**], and $[**] for each Contract Year thereafter, Licensee will pay Licensor on or before the Quarterly Payment Deadline for the last Contract Quarter in the stated period an additional amount equal to the difference between the stated minimum royalty amount and the actual royalties paid to Licensor; provided that no minimum royalty payment shall be due for periods prior to the Sale of Licensee.

3.4 Non-cash Consideration

If Licensee receives or anticipates receipt of non-cash consideration from Sales or Sublicenses, the manner in which Licensor will receive its compensation under the Agreement with respect to such non-cash consideration will be [**].

3.5 Equity Consideration for License Grant

(a) In further consideration of the rights granted to Licensee by Licensor, Licensee has issued Board shares of its common stock and non-convertible preferred stock.

(b) If Licensee transacts any business with an Affiliate of Licensee, including, without limitation, any contract for service or license or transfer of any intellectual property rights or other asset, then either (i) the terms of such business transaction must be no less favorable to the Licensee than those that could be commercially obtained by the Licensee in an arm's length transaction negotiated with an unrelated party, or (ii) the transaction must not affect the interests of Licensor in an adverse manner relative to the effect of the transaction on other shareholders of Licensee, taking into account all interests of such shareholders, including those in capacities other than as shareholders of Licensee.

4. Reports and Plans

The reports specified in this Section 4 will be sent to Licensor's payment and reporting contact identified in Section 18 (Notices). If Licensor requests to have information submitted in a particular format, Licensee will use reasonable efforts to comply with such request.

4.1 Quarterly Payment and Milestone Reports

On or before each Quarterly Payment Deadline, Licensee will deliver to Licensor a true and accurate report, certified by an officer of Licensee, giving such particulars of the business conducted by Licensee, its Subsidiaries and its Sublicensees (including copies of reports provided by Sublicensees and Subsidiaries to Licensee) during the preceding Contract Quarter under the Agreement as necessary for Licensor to account for Licensee's payments, including royalties, hereunder, even if no payments are due. The reports shall continue to be delivered after the termination or expiration of the Agreement until such time as all Licensed Products permitted to be Sold after termination or expiration have been Sold or destroyed. The report shall include:

[**].

4.2 [**] Written Progress Report and Commercialization Plan

Within [**] following the end of [**], Licensee will deliver to Licensor a true and accurate signed written progress report that summarizes (i) Licensee's efforts and accomplishments during the [**] to diligently commercialize Licensed Products and Licensed Services, and (ii) Licensee's development and commercialization plans with respect to Licensed Products and Licensed Services for the next [**]. The report shall also cover such activities by Subsidiaries and Sublicensees.

The report shall contain the following information to the extent relevant to the activities under the Agreement:

[**].

4.3 Government and Economic Development Reporting

If Licensor requests, Licensee will provide information for Licensor's Government and economic development reporting purposes, including the following:

[**].

This information shall be treated as Licensee's Confidential Information; provided that Licensor is entitled to combine such information with similar information from other Licensor licensees and publicly report such combined aggregate information, without identifying Licensee's separate specific applicable numbers. If and when Licensee has more than [**] full-time employees, then no further economic development reports will be required from Licensee.

5. Payment, Records, and Audits

5.1 Payments

All amounts referred to in the Agreement are expressed in U.S. dollars without deductions for taxes, assessments, fees, or charges of any kind. Each payment will reference this Agreement, including agreement number, if any, set forth at the beginning of the Agreement. All payments to Licensor will be made in U.S. dollars by check or wire transfer (Licensee to pay all wire transfer fees) payable to the payee identified in Section 18 and sent to the payment and reporting contact in Section 18 (Notices).

5.2 Sales Outside the U.S.

If any currency conversion shall be required in connection with the calculation of payments hereunder, such conversion shall be made using the rate used by Licensee for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, using the average of the buying and selling exchange rate for conversion between the foreign currency and U.S. Dollars, for current transactions as reported in *The Wall Street Journal* on the last business days of the Contract Quarter to which such payment pertains. Licensee may not make any tax withholdings from payments to Licensor, but Licensor agrees to supply to Licensee, upon written request, appropriate evidence from appropriate U.S. governmental agencies showing that Licensor is a resident of the United States of America for purposes of the U.S. income tax laws and is tax-exempt under such income tax laws.

5.3 Late Payments

Amounts that are not paid when due will accrue a late charge from the due date until paid, at a rate equal to [**]% per month (or the maximum allowed by law, if less).

5.4 Records

For a period of [**] after the Contract Quarter to which the records pertain, Licensee agrees that it and its Subsidiaries and Sublicensees will each keep complete and accurate records of their Sales, Net Product Sales, Net Service Sales, and Non-Royalty Sublicensing Consideration in sufficient detail to enable such payments to be determined and audited.

5.5 Auditing

Licensee and its Subsidiaries will permit Licensor or its representatives, at Licensor's expense, to periodically examine books, ledgers, and records during regular business hours, at Licensee's or its Subsidiary's place of business, on at least [**] advance notice, to the extent necessary to verify any payment or report required under the Agreement. For each Sublicensee, Licensee shall obtain such

audit rights for Licensor or itself. If Licensee obtains such audit rights for itself, it will promptly conduct an audit of the Sublicensee's records upon Licensor's request, and Licensee will furnish to Licensor a copy of the findings from such audit. No more than [**] of Licensee, each Subsidiary, and each Sublicensee shall be conducted under this Section 5.5 in any calendar year. If any amounts due Licensor have been underpaid, then Licensee shall immediately pay Licensor the amount of such underpayment plus accrued interest due in accordance with Section 5.3. If the amount of underpayment is equal to or greater than [**]% of the total amount due for the records so examined, Licensee will pay the cost of such audit. Such audits may, at Licensor's sole discretion, consist of a self-audit conducted by Licensee at Licensee's expense and certified in writing by an authorized officer of Licensee. All information examined pursuant to this Section 5.5 shall be deemed to be the Confidential Information of the Licensee.

6. Patent Expenses and Prosecution

6.1 Patent Expenses

Licensee shall pay for all past documented, out-of-pocket expenses incurred by Licensor for filing, prosecuting, defending and maintaining Patent Rights and related patent searches through the Effective Date of the Agreement, including those identified in Section 3.1(a), and all such future expenses incurred by Licensor, for so long as, and in such countries as the Agreement remains in effect. Licensee will pay all patent expenses (except for the payment called for under Section 3.1(a)), including past expenses that have not been invoiced as of the date indicated in Section 3.1(a) and future expenses, within [**] after Licensee's receipt of an invoice. At the election of Licensor, Licensee will either pay Prosecution Counsel directly for patent expenses or will reimburse Licensor for such patent expenses. Patent expense payment delinquencies (whether owed directly to Prosecution Counsel or to Licensor) will be considered a payment default under Section 7.3(a).

6.2 Direction of Prosecution

Licensor will confer with Licensee to develop a strategy for the prosecution and maintenance of Patent Rights. Licensor will request that copies of all documents prepared by the Prosecution Counsel for submission to governmental patent offices be provided to Licensee for review and comment prior to filing, to the extent practicable under the circumstances. At its discretion, Licensor may allow Licensee to instruct Prosecution Counsel directly, provided, that (a) Licensor will maintain final authority in all decisions regarding the prosecution and maintenance of the Patent Rights, (b) Licensor may revoke this authorization to instruct Prosecution Counsel directly at any time, and (c) the Prosecution Counsel remains counsel to Licensor with an appropriate contract (and shall not jointly represent Licensee unless requested by Licensee and approved by Licensor, and an appropriate engagement letter and conflict waiver are in effect). If Licensee wishes to instruct Prosecution Counsel directly or change Prosecution Counsel, Licensee may request to do so by following Licensor's procedures for such. Licensor reserves in its sole discretion the ability to change Prosecution Counsel and to approve or disapprove any requested changes by Licensee. The Parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will maintain as privileged all information received pursuant to this Section.

6.3 Ownership

All patent applications and patents will be in the name of Licensor (and any co-owner identified in Exhibit A) and owned by Licensor (and such co-owner, if any). No payments due under the Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party.

6.4 Foreign Filings

In addition to the U.S., the Patent Rights shall, subject to applicable bar dates, be pursued in such foreign countries as Licensee so designates in writing to Licensor in sufficient time to reasonably enable the preparation of such additional filings, and in those foreign countries in which Licensor has filed applications prior to the Effective Date. If Licensee does not choose to pursue patent rights in a particular foreign country and Licensor chooses to do so, Licensee shall so notify Licensor and thereafter said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto. Licensor shall have the right to make alternative arrangements with Licensee for upfront payment of foreign patent expenses.

6.5 Withdrawal from Paying Patent Costs

If at any time Licensee wishes to cease paying for any costs for a particular Patent Right or for patent prosecution in a particular jurisdiction, Licensee must give Licensor at least [**] prior written notice and Licensee will continue to be obligated to pay for the patent costs which reasonably accrue during said notice period. Thereafter, said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto.

6.6 U.S. Patent and Trademark Office Entity Size Status

Licensee represents that as of the Effective Date the entity size status of Licensee in accordance with the regulations of the U.S. Patent and Trademark Office is as set forth in Exhibit A. Licensee will inform Licensor in writing on a timely basis of any change in its U.S. Patent and Trademark Office entity size status.

7. Term and Termination

7.1 Term

Unless earlier terminated as provided herein, the term of the Agreement will commence on the Effective Date and continue until 5 years after the last date of expiration or termination of the Patent Rights, or if Technology Rights are licensed and no Patent Rights are applicable, for a term of 25 years.

7.2 Termination by Licensee

Licensee, at its option, may terminate the Agreement by providing Licensor written notice of intent to terminate, which such termination will be effective 90 days following receipt of such notice by Licensor.

7.3 Termination by Licensor

Licensor, at its option, may immediately terminate the Agreement, or any part of Licensed Subject Matter, or any part of Field, or any part of Territory, or the exclusive nature of the license grant, upon delivery of written notice to Licensee of Licensor's decision to terminate, if any of the following occur:

(a) Licensee becomes in arrears in any payments due under the Agreement, and Licensee fails to make the required payment within [**] after delivery of written notice from Licensor; or

(b) Licensee is in breach of any non-payment provision of the Agreement, and does not cure such breach within [**] after delivery of written notice from Licensor; or

(c) Licensor delivers notice to licensee of [**] or more actual breaches of the Agreement in any 12-month period, even in the event that Licensee cures such breaches in the allowed period; or

(d) Licensee or its Subsidiaries or Sublicensee initiates any proceeding or action to challenge the validity, enforceability, or scope of one or more of the Patent Rights, or assist a third party in pursuing such a proceeding or action.

7.4 Other Conditions of Termination

The Agreement will terminate:

(a) Immediately without the necessity of any action being taken by Licensor or Licensee, (i) if Licensee becomes bankrupt, or (ii) Licensee's Board of Directors elects to liquidate its assets or dissolve its business, or (iii) Licensee ceases its business operations, or (iv) Licensee makes an assignment for the benefit of creditors or (v) if the business or assets of Licensee are otherwise placed in the hands of a receiver, assignee or trustee, whether by voluntary act of Licensee or otherwise; or

(b) At any time by mutual written agreement between Licensee and Licensor.

7.5 Effect of Termination

If the Agreement is terminated for any reason:

(a) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided however, if the Sublicense Agreement is for all of the Field for all of the Territory, and the Sublicensee is in good standing and agrees in writing to assume all of the obligations of Licensee and provides Licensor with written notice thereof within [**] after termination of the Agreement, then such Sublicense Agreement shall survive; and

(b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products and performing Licensed Services by the effective date of termination; and

(c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and

(d) Nothing in the Agreement will be construed to release either Party from any obligation that matured prior to the effective date of termination; and

(e) The provisions of Sections 8 (Confidentiality), 9 (Infringement and Litigation), 11 (Representations and Disclaimers), 12 (Limit of liability), 13 (Indemnification), 14 (Insurance), 17 (Use of Name), 18 (Notices), and 19 (General Provisions) will survive any termination or expiration of the Agreement. In addition, the provisions of Sections 3 (Compensation), 4.1 (Quarterly Payment and Milestone Reports), 5 (Payment, Records and Audits), and 6.1 (Patent Expenses) shall survive with respect to all activities and payment obligations accruing prior to the termination or expiration of the Agreement.

8. Confidentiality

8.1 Definition

"Confidential Information" means all information that is of a confidential and proprietary nature to Licensor or Licensee and provided by one Party to the other Party under the Agreement.

8.2 Protection and Marking

Licensor and Licensee each agree that all Confidential Information disclosed in tangible form, and marked "confidential" and forwarded to one by the other, or if disclosed orally, is designated as confidential at the time of disclosure: (i) is to be held in strict confidence by the receiving Party, (ii) is to be used by and under authority of the receiving Party only as authorized in the Agreement, and (iii) shall not be disclosed by the receiving Party, its agents or employees without the prior

written consent of the disclosing Party or as authorized in the Agreement. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights under the Agreement, including without limitation disclosing to Subsidiaries, Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. Each Party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing Party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care.

8.3 Confidentiality of Terms of Agreement

Each Party agrees not to disclose to any third party the terms of the Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of the Agreement: (a) to advisors, actual or potential Sublicensees, acquirers or investors, and others on a need to know basis, in each case, under appropriate confidentiality obligations substantially similar to those of this Section 8; and (b) to the extent necessary to comply with applicable laws and court orders (including, without limitation, The Texas Public Information Act, as may be amended from time to time, other open records laws, decisions and rulings, and securities laws, regulations and guidance). If the Agreement is not for all fields of use, then Licensor may disclose the Field to other potential third party licensees. Notwithstanding the foregoing, the existence of the Agreement shall not be considered Confidential Information.

8.4 Disclosure Required by Court Order or Law

If the receiving Party is required to disclose Confidential Information of another Party hereto, or any terms of the Agreement, pursuant to the order or requirement of a court, administrative agency, or other governmental body or applicable law, the receiving Party may disclose such Confidential Information or terms to the extent required, provided that the receiving Party shall use reasonable efforts to provide the disclosing Party with reasonable advance notice thereof to enable the disclosing Party to seek a protective order and otherwise seek to prevent such disclosure. To the extent that Confidential Information so disclosed does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information protected pursuant to Section 8.

8.5 Copies

Each Party agrees not to copy or record any of the Confidential Information of the other Party, except as reasonably necessary to exercise its rights or perform its obligations under the Agreement, and for archival and legal purposes.

8.6 Continuing Obligations

Subject to the exclusions listed in Section 8.7, the Parties' confidentiality obligations under the Agreement will survive termination of the Agreement and will continue for a period of [**] thereafter.

8.7 Exclusions

Information shall not be considered Confidential Information of a disclosing Party under the Agreement to the extent that the receiving Party can establish by competent written proof that such information:

(a) Was in the public domain at the time of disclosure; or

(b) Later became part of the public domain through no act or omission of the recipient Party, its employees, agents, successors or assigns in breach of the Agreement; or

(c) Was lawfully disclosed to the recipient Party by a third party having the right to disclose it not under an obligation of confidentiality; or

(d) Was already known by the recipient Party at the time of disclosure; or

(e) Was independently developed by the recipient Party without use of the disclosing Party's Confidential Information.

8.8 Copyright Notice

The placement of a copyright notice on any Confidential Information will not be construed to mean that such information has been published and will not release the other Party from its obligation of confidentiality hereunder.

9. Infringement and Litigation

9.1 Notification

If either Licensor's designated office for technology commercialization or Licensee becomes aware of any infringement or potential infringement of Patent Rights, each Party shall promptly notify the other of such in writing.

9.2 Licensee's Enforcement Rights

Licensee shall enforce the Patent Rights against any infringement by a third party. Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by Licensor in providing cooperation or joining as a party as provided in Section 9.4. Any monetary recovery for actual damages or punitive damages in excess of Licensee's documented, third-party expenses in enforcing the Patent Rights and amounts actually reimbursed by Licensee to Licensor under this Section 9.2 shall be shared by Licensee with Licensor in the same manner as Non-Royalty Sublicensing Consideration.

9.3 Licensor's Enforcement Rights

If Licensee does not file suit within six months after a written request by Licensor to initiate an infringement action, then Licensor shall have the right, at its sole discretion, to bring suit to enforce any Patent Right licensed hereunder against the infringing activities, with Licensor retaining all recoveries from such enforcement. If Licensor pursues such infringement action, Licensor may, as part of the resolution of such efforts, grant non-exclusive license rights to the alleged infringer notwithstanding Licensee's exclusive license rights.

9.4 Cooperation between Licensor and Licensee

In any infringement suit or dispute, the Parties agree to cooperate fully with each other. At the request of the Party bringing suit, the other Party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

If it is necessary to name Licensor as a party in such action, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities.

10. Export Compliance

Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic In Arms Regulations (ITAR), and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (a) ITAR and EAR product/service/data-specific requirements; (b) ITAR and EAR ultimate destination-specific requirements; (c) ITAR and EAR end user-specific requirements; (d) Foreign Corrupt Practices Act; and (e) anti-boycott laws and regulations. Licensee will comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information). Licensee certifies that it will not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of applicable U.S. laws and regulations. Licensee will include a provision in its agreements, substantially similar to this Section 10, with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who purchase a Licensed Product, requiring that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.

11. Representations and Disclaimers

11.1 Licensor Representations

Except for the rights, if any, of the Government as set forth in Section 11.2, Licensor represents and warrants to Licensee that to the knowledge of Licensor's designated office for technology commercialization (i) Licensor is the owner or agent of the entire right, title, and interest in and to Patent Rights (other than the right, title and interest of any joint owner identified in Exhibit A), (ii) Licensor has the right to grant licenses hereunder, and (iii) Licensor has not knowingly granted and will not knowingly grant licenses or other rights under the Patent Rights that are in conflict with the terms and conditions in the Agreement.

11.2 Government Rights

Licensee understands that Licensed Subject Matter may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. The Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation. To the extent that there is a conflict between any such agreement, such applicable law or regulation and the Agreement, the terms of such Government agreement, and applicable law or regulation, shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or Sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government.

11.3 Licensor Disclaimers

EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 11.1, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS OR LICENSED SERVICES, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION AS TO WHETHER ANY PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN FIELD. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS

CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS, WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS, OR THE TECHNOLOGY RIGHTS SPECIFICALLY DESCRIBED HEREIN.

11.4 Licensee Representations

By execution of the Agreement, licensee represents, acknowledges, covenants and agrees (a) that Licensee has not been induced in any way by Licensor or its employees to enter into the Agreement, and (b) that Licensee has been given an opportunity to conduct sufficient due diligence with respect to all items and issues pertaining to this Section 11 (Representations and Disclaimers) and all other matters pertaining to the Agreement; and (c) that Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and (d) that Licensee accepts all risks inherent herein. Licensee represents that it is a duly organized, validly existing entity of the form indicated in the preamble to the Agreement, and is in good standing under the laws of its jurisdiction of organization as indicated in the preamble of the Agreement, and has all necessary corporate or other appropriate power and authority to execute, deliver and perform its obligations hereunder.

12. Limit of Liability

IN NO EVENT SHALL LICENSOR, THE UNIVERSITY SYSTEM IT GOVERNS, ITS MEMBER INSTITUTIONS, INVENTORS, REGENTS, OFFICERS, EMPLOYEES, STUDENTS, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. OTHER THAN FOR CLAIMS AGAINST LICENSEE FOR INDEMNIFICATION (SECTION 13) OR FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF LICENSOR'S INTELLECTUAL PROPERTY RIGHTS, LICENSEE WILL NOT BE LIABLE TO LICENSOR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER LICENSEE KNOWS OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. Indemnification

13.1 Indemnification Obligation

Subject to Section 13.2, Licensee agrees to hold harmless, defend and indemnify Licensor, the university system it governs, its member institutions, its Regents, officers, employees, students and agents ("Indemnified Parties") from and against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) (collectively "Liabilities") resulting from claims or demands brought by third parties against an Indemnified Party on account of any injury or death of persons, damage to property, or any other damage or loss arising out of or in connection with the Agreement or the exercise or practice by or under authority of Licensee, its Subsidiaries or their Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product, of the rights granted hereunder.

13.2 Conditions of Indemnification

Licensee shall have no responsibility or obligation under Section 13.1 for any Liabilities to the extent caused by the gross negligence or willful misconduct by Licensor. Obligations to indemnify and hold harmless under Section 13.1 are subject to: (a) the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to the statutory duties of the Texas Attorney General, the Indemnified Party giving Licensee control of the defense and settlement of the claim and demand; and (b) the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to statutory duties of the Texas Attorney General, the Indemnified Party providing the assistance reasonably requested by Licensee, at Licensee's expense.

14. Insurance

14.1 Insurance Requirements

Prior to any Licensed Product being used or Sold (including for the purpose of obtaining Regulatory Approval), and prior to any Licensed Service being performed by Licensee, a Subsidiary, or by a Sublicensee, and for a period of [**] after the Agreement expires or is terminated, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts for the Licensed Product being used or Sold or the Licensed Service being performed. Licensee shall use commercially reasonable efforts to have Licensor, the university system it governs, its member institutions, Regents, officers, employees, and Inventors named as additional insureds. Such commercial general liability insurance shall provide, without limitation: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under the Agreement; and (iii) coverage for litigation costs.

14.2 Evidence of Insurance and Notice of Changes

Upon request by Licensor, Licensee shall provide Licensor with written evidence of such insurance. Additionally, Licensee shall provide Licensor with written notice of at least [**] prior to Licensee cancelling, not renewing, or materially changing such insurance.

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Licensor. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement. For any permitted assignment to be effective, (a) Licensee must be in good standing under this Agreement, (b) Licensee must pay Licensor the assignment fee pursuant to Section 3.1(e), and (c) the assignee must assume in writing (a copy of which shall be promptly provided to Licensor) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original Party to the Agreement.

16. Governmental Markings

16.1 Patent Markings

Licensee agrees that all Licensed Products Sold by Licensee, Subsidiaries, or Sublicensees will be legibly marked with the number of any applicable patent(s) licensed hereunder as part of the Patent Rights in accordance with each country's patent marking laws, including Title 35, U.S. Code, or if such marking is not practicable, shall so mark the accompanying outer box or product insert for Licensed Products accordingly.

16.2 Governmental Approvals and Marketing of Licensed Products and or Licensed Services

Licensee will be responsible for obtaining all necessary governmental approvals for the development, production, distribution, Sale, and use of any Licensed Product or performance of any Licensed Service, at Licensee's expense, including, without limitation, any safety studies. Licensee will have sole responsibility for any warning labels, packaging and instructions as to the use and the quality control for any Licensed Product or Licensed Service.

16.3 Foreign Registration and Laws

Licensee agrees to register the Agreement with any foreign governmental agency that requires such registration and Licensee will pay all costs and legal fees in connection with such registration. Licensee is responsible for compliance with all foreign laws affecting the Agreement or the Sale of Licensed Products and Licensed Services to the extent there is no conflict with United States law, in which case United States law will control.

17. Use of Name

Licensee will not use the name, trademarks or other marks of Licensor (or the name of the university system it governs, its member institutions, any of its Regents or employees) without the advance written consent of Licensor. Licensor may use Licensee's name and logo for annual reports, brochures, website and internal reports without prior consent.

18. Notices

Any notice or other communication of the Parties required or permitted to be given or made under the Agreement will be in writing and will be deemed effective when sent in a manner that provides confirmation or acknowledgement of delivery and received at the address set forth below (or as changed by written notice pursuant to this Section 18).

Licensee Contacts

Contact for Notice:
Attn: Brian Windsor, Ph.D., CEO
P.O. Box 150183
Austin, Texas 78715
Fax: [**]
Phone: [**]
E-mail: [**]

Licensor Contacts

Contact for Notice:
Office of legal Affairs
Attn: Terry Witter
UTHSC-Tyler
11937 US Highway 271
Tyler, Texas 75708-3154
Fax: [**]
Phone: [**]
E-mail:[**]

Accounting and reporting contact:
Checks payable to "The University of Texas Health Science Center - Tyler"
Attn: Accounting
UTHSC-Tyler
11937 US Highway 271
Tyler, Texas 75708-3154
Fax: [**]
Phone: [**]

Notices required under the Agreement may be delivered via E-mail provided such notice is confirmed in writing as indicated. Notices shall be provided to each Party as specified in the "Contact for Notice" address. Each Party shall update the other Party in writing with any changes in such contact information.

19. General Provisions

19.1 Binding Effect

The Agreement is binding upon and inures to the benefit of the Parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.

19.2 Construction of Agreement

Headings are included for convenience only and will not be used to construe the Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of the Agreement; therefore, both Parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted the Agreement.

19.3 Counterparts and Signatures

The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A Party may evidence its execution and delivery of the Agreement by transmission of a signed copy of the Agreement via facsimile or email. In such event, the Party shall promptly provide the original signature page(s) to the other Party.

19.4 Compliance with Laws

Licensee will comply with all applicable federal, state and local laws and regulations, including, without limitation, all export laws and regulations.

19.5 Governing Law

The Agreement will be construed and enforced in accordance with laws of the U.S. and the State of Texas, without regard to choice of law and conflicts of law principles.

19.6 Modification

Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both Parties. No modification will be made by email communications.

19.7 Severability

If any provision hereof is held to be invalid, illegal or unenforceable in any jurisdiction, the Parties hereto shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such other provisions in any other jurisdiction, so long as the essential essence of the Agreement remains enforceable.

19.8 Third Party Beneficiaries

Nothing in the Agreement, express or implied, is intended to confer any benefits, rights or remedies on any entity, other than the Parties and their permitted successors and assigns. However, if there is a joint owner of any Patent Rights identified in Exhibit A (other than Licensee), then Licensee hereby agrees that the following provisions of the Agreement extend to the benefit of the co-owner identified therein (excluding the Licensee to the extent it is a co-owner) as if such co-owner was identified in each reference to the Licensor: the retained rights under clause (b) of Section 2.1; Section 11.3 (Licensor Disclaimers); Section 12 (Limitation of Liability); Section 13 (Indemnification); Section 14.1 (Insurance Requirements); Section 17 (Use of Name); and Section 19.10 (Sovereign Immunity, if applicable).

19.9 Waiver

Neither Party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such Party. No delay or omission of a Party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

19.10 Sovereign Immunity

Nothing in the Agreement shall be deemed or treated as any waiver of Licensor’s sovereign immunity.

19.11 Entire Agreement

The Agreement constitutes the entire Agreement between the Parties regarding the subject matter hereof, and supersedes all prior written or verbal agreements, representations and understandings relative to such matters.

19.12 Claims Against Licensor for Breach of Agreement

Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be subject to Chapter 2260 of the Texas Government Code and that the process provided therein shall be Licensee’s sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Licensor or the State of Texas.

20. No Other Promises and Agreements; Representation by Counsel.

Licensee expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to Licensee in executing the Agreement except those explicitly set forth herein, and that Licensee is not relying upon any statement or representation of Licensor or its representatives. Licensee is relying on Licensee's own judgment and has had the opportunity to be represented by legal counsel. Licensee hereby warrants and represents that Licensee understands and agrees to all terms and conditions set forth in the Agreement.

21. Deadline for Execution by Licensee

If the Agreement is executed first by the Licensor and is not executed by Licensee and received by Licensor at the address and in the manner set forth in Section 18 within 30 days of the date of signature set forth under Licensor's signature below, then the Agreement shall be null and void and of no further effect.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Amended and Restated Patent & Technology License Agreement.

LICENSOR: Board of Regents of The University of Texas System

By /s/ Kirk A. Calhoun
Kirk A. Calhoun, President
The University of Texas Health Science Center at Tyler

Date 12/19/2013

LICENSEE: Lung Therapeutics, Inc.

By /s/ Brian Windsor, PH.D.
Brian Windsor, PH.D.
CEO

Date 12/18/2013

Read and understood by:

By /s/ Steven Idell
Steven Idell, individually

Date 12/19/2013

By /s/ Sreerama Shetty
Sreerama Shetty, individually

Date 12/19/2013

FIRST AMENDMENT
TO
AMENDED AND RESTATED PATENT & TECHNOLOGY LICENSE AGREEMENT

This **First Amendment to Amended and Restated Patent & Technology License Agreement ("Amendment")** is dated effective as of May 4, 2017 ("**Effective Date**"), and is entered into by and between Board of Regents of The University of Texas System, an agency of the State of Texas, on behalf of The University of Texas Health Science Center at Tyler (collectively "Licensor"), and Lung Therapeutics, Inc., a Texas corporation ("Licensee").

Licensor and Licensee entered into that certain Amended and Restated Patent & Technology License Agreement dated effective December 19, 2013 ("Agreement").

Licensor and Licensee now desire to amend the terms of the Agreement as more particularly set forth below:

1. **Section 2.4(b) 1 of the Agreement** is hereby amended and restated in its entirety and will hereafter be and read as follows:

    1. Equity and License Milestones (Clinical)

        [**].

2. Except as provided in this Amendment, all terms used in this Amendment that are not otherwise defined will have the respective meanings ascribed to such terms in the Agreement.

3. This Amendment embodies the entire agreement between Licensor and Licensee with respect to the amendment of the Agreement. In the event of any conflict or inconsistency between the provisions of the Agreement and this Amendment, the provisions of this Amendment will control and govern.

4. Except as otherwise expressly provided herein, the parties do not intend to, and the execution of this Amendment will not, in any manner impair the Agreement, the purpose of this Amendment being simply to amend and ratify the Agreement, as hereby amended and ratified, and to confirm and carry forward the Agreement, as hereby amended, in full force and effect.

IN WITNESS WHEREOF, Licensor and Licensee have executed and delivered this Amendment effective as of the Effective Date.

LICENSOR:

Board of Regents of The University of Texas System

By /s/ Kirk A. Calhoun
Kirk A. Calhoun, President

The University of Texas Health Science Center at Tyler

Date 05/8/2017

LICENSEE:

Lung Therapeutics, Inc.

By /s/ Brian Windsor
Brian Windsor, PH.D., CEO

Date 05/4/2017

Read and understood by:

By /s/ Steven Idell
Steven Idell, individually

Date 05/4/2017

By /s/ Sreerama Shetty
Sreerama Shetty, individually

Date 05/4/2017

Exhibit 10.3

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Patent License Agreement
Agreement No. PM1504101

This Patent License Agreement is between the Licensor and the Licensee identified below (collectively, "Parties", or singly, "Party").

No binding agreement between the Parties will exist until this Patent License Agreement has been signed by both Parties. Unsigned drafts of this Patent License Agreement shall not be considered offers.

Background

Licensor owns or controls Patent Rights. Licensee desires to secure the right and license to use, develop, manufacture, market, and commercialize the Patent Rights. Licensor has determined that such use, development, and commercialization of the Patent Rights is in the public's best interest and is consistent with Licensor's educational and research missions and goals. Licensor desires to have the Patent Rights developed and used for the benefit of Licensee, the inventors, Licensor, and the public.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the Parties hereby agree as follows:

The Terms and Conditions of Patent License attached hereto as Exhibit A are incorporated herein by reference in their entirety (the "Terms and Conditions"). In the event of a conflict between provisions of this Patent License Agreement and the Terms and Conditions, the provisions in this Patent License Agreement shall govern. Unless defined in this Patent License Agreement, capitalized terms used in this Patent License Agreement shall have the meanings given to them in the Terms and Conditions.

The section numbers used in the left hand column in the table below correspond to the section numbers in the Terms and Conditions.

1. Definitions

Effective Date	Date of last signature below.
Licensor	The University of Texas at Austin, on behalf of the Board of Regents of the University of Texas System, an agency of the State of Texas, whose address is 3925 W. Braker Lane, Suite 1.9A (R3500), Austin, Texas 78759.
Licensee	Lung Therapeutics, Inc., a Texas corporation, with its principal place of business at 7500 Rialto Boulevard, Ste. 250, Austin, Texas 78735
Contract Year and Contract Quarters	(Check one box to correspond with Licensee fiscal year and quarters) ☒ Contract Year is 12-month period ending on December 31 and Contract Quarters are 3-month periods ending on March 31, June 30, Sept. 30, Dec. 31. OR ☐ Other: Contract Year is 12-month period ending on (specify): month and day]; Contract Quarters are 3-month periods ending on (specify): [month and day, QI], [month and day, Q2], [month and day, Q3], [month and day, Q4]
Territory	Worldwide
Field	☒ All fields OR ☐ Limited fields

Patent Rights

App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
[**]	[**]	[**]	[**]	[**]

USPTO Entity Status as of Effective Date	**Check one box:** ☒ **Small** ☐ **Large**

2.4. Diligence Milestones

Milestones and deadlines	Milestone Events	Deadlines
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]
	[**]	[**]

3. Compensation

3.1(a)	**Patent expenses**	**Amount and due date** [**]	**based on invoices received as of:** [**]
3.1(b)	**Milestone fees**	**Milestone Events** [**] [**] [**] [**]	**Milestone Fees** [**] [**] [**] [**]
3.1(c)	**Scheduled license fee payments**	$[**] due on [**] for the [**] Contract Year $[**] due on [**] for each Contract Year thereafter	
3.1(d)	**Sublicense Fees**	[**]	
3.1(e)	**Assignment fee**	[**]	
3.1(f)	**FDA Priority Review Voucher**	If Licensee (or its sublicensee or agent) receives a priority review voucher from the US FDA (or any corresponding foreign agency) related to any Licensed Product, and if said voucher is sold or otherwise transferred or monetized (a "Voucher Transfer"), the Licensee shall pay to Licensor a sum equal to [**] percent ([**]%) of all consideration paid in connection with the Voucher Transfer, which sum shall be paid within [**] after the consideration is received by Licensee (or its sublicensee or agent).	
3.2	**Running royalty rate (applies to Net Sales by Licensee, Affiliates and Sublicensees)**	[**]%	

18. Contract Information

Licensee Contacts
Contact for Notice:
Attn: Brian Windsor
7500 Rialto Boulevard Ste. 250
Austin, Texas 78735
Phone[**]
E-mail: [**]

Accounting contact:
Attn: Brian Windsor
7500 Rialto Boulevard Ste. 250
Austin, Texas 78735
Phone: [**]
E-mail: [**]

Patent prosecution contact:
Attn: Brian Windsor
7500 Rialto Boulevard Ste. 250
Austin, Texas 78735
Phone: [**]
E-mail: [**]

Licensor Contacts
Contact for Notice:
Attn: Contract Manager
3925 W. Braker Lane, Suite 1.9A (R3500)
Austin, TX 78759 Fax: [**]
Phone: [**]
E-mail: [**]

Payment and reporting contact:
Checks payable to "The University of Texas at Austin"
Attn: Accounting
3925 W. Braker Lane, Suite 1.9A (R3500)
Austin, TX 78759
Fax: [**]
Phone: [**]
E-mail: [**]

Patent prosecution contact:
Attn: Patents
3925 W. Braker Lane, Suite 1.9A (R3500)
Austin, TX 78759
Fax: [**]
Phone: [**]
E-mail: [**]

For Licensor Administrative Purposes Only
Changes to Standard Form Terms and Conditions 1, ,3.2, 3.3, 3.4, 6.1, 9.1, 9.2, 20.1

20. Special Provision. The Parties hereby agree to the following special provisions set forth in this Section 20 with respect to this Patent License Agreement.

20.1 Milestone Extension Option. Licensee shall have the one-time option to extend all of the deadlines for Milestone Events specified in the above Section 3.2 by [**] by paying the milestone extension fee of $[**]. This option may only be exercised at a time when Licensee is in material compliance with all of its obligations under the Agreement, including having met all milestones with deadlines prior to the date such notice is given (without giving effect to the extension resulting from the exercise of such option). In order to exercise this option, Licensee must provide Licensor written notice of its exercise of this option accompanied by payment of the milestone extension fee. Such notice must contain an affirmation from the Licensee that it is in compliance with all of its obligations under the Agreement, that it is currently Actively Commercializing Licensed Products or Licensed Services and that it reasonably expects to meet the milestone deadlines as extended by the exercise of such option. Upon such payment and exercise each of the future milestones deadline dates shall be extended by [**].

After execution of the [**] milestone extension option, Licensee shall have the one-time option to further extend all of the deadlines for Milestone Events specified in the above Section 3.2 by [**] by paying the milestone extension fee of $[**]. This option may only be exercised at a time when Licensee is in material compliance with all of its obligations under the Agreement, including having met all milestones with deadlines prior to the date such notice is given (without giving effect to the extension resulting from the exercise of such option). In order to exercise this option, Licensee must provide Licensor written notice of its exercise of this option accompanied by payment of the milestone extension fee. Such notice must contain an affirmation from the Licensee that it is in compliance with all of its obligations under the Agreement, that it is currently Actively Commercializing Licensed Products or Licensed Services and that it reasonably expects to meet the milestone deadlines as extended by the exercise of such option. Upon such payment and exercise each of the future milestones deadline dates shall be extended by [**].

20.2 New Inventions resulting from Sponsored Research: In addition to the specific patent applications identified as Patent Rights in Section 1 above, "Licensed Patents" shall also include each new invention of the Licensor made prior to the first anniversary of the Effective Date that meets all of the following criteria (each, a "New Invention"): (a) The invention results from the performance of a Sponsored Research Agreement which is funded by Licensee, in accordance Sponsored Research Agreement UTA 14-001400; (b) Licensee gives written notice to Licensor of Licensee's election to add the invention (and related patent rights) to this Agreement, which notice is received by Licensor within [**] after Licensee has received from Licensor a written disclosure of such invention, which disclosure Licensor shall be obligated to provide promptly following the receipt from the inventor; and (c) Licensee and Licensor execute an amendment to this Agreement adding such additional Patent Rights.

21. No Other Promises and Agreements; Representation by Counsel. Licensee expressly warrants and represents and does hereby state and represent that no promise or agreement which is not herein expressed has been made to Licensee in executing this Patent License Agreement except those explicitly set forth herein and in the Terms and Conditions, and that Licensee is not relying upon any statement or representation of Licensor or its representatives. Licensee is relying on Licensee's own judgment and has had the opportunity to be represented by legal counsel. Licensee hereby warrants and represents that Licensee understands and agrees to all terms and conditions set forth in this Patent License Agreement and said Terms and Conditions.

22. Deadline for Execution by Licensee. If this Patent License Agreement is executed first by the Licensor and is not executed by the Licensee and received by the Licensor at the address and in the manner set forth in Section 18 of the Terms and Conditions within [**] of the date of signature set forth under the Licensor's signature below, then this Patent License Agreement shall be null and void and of no further effect.

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Patent License Agreement.

LICENSOR: THE UNIVERSITY OF TEXAS AT AUSTIN ON BEHALF OF THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

By /s/ Daniel W. Sharp, J.D.
Daniel W. Sharp, J.D.

Associate Vice President for Research and Director, Office of Technology Commercialization

Date 5/21/15

LICENSEE: Lung Therapeutics, Inc.

By /s/ Brian Windsor
Brian Windsor

CEO

Date 5/21/2015

EXHIBIT A

Terms and Conditions of Patent License

These Terms and Conditions of Patent License ("Terms and Conditions") are incorporated by reference into the Patent License Agreement to which they are attached. All Section references in these Terms and Conditions shall be references to provisions in these Terms and Conditions unless explicitly stated otherwise.

1. Definitions

"Affiliate" means any business entity more than 50% owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.

"Agreement" means collectively (i) these Terms and Conditions, and (ii) the Patent License Agreement.

"Contract Quarter" means the three-month periods indicated as the Contract Quarter in Section 1 of the Patent License Agreement, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"Contract Year" means the 12-month periods indicated as the Contract Year in Section 1 of the Patent License Agreement, or any stub period thereof at the commencement of the Agreement or the expiration or termination of the Agreement.

"Effective Date" means the date indicated as the Effective Date in Section 1 of the Patent License Agreement.

"Fair Market Value" means the cash consideration an unaffiliated, unrelated buyer would pay in an arm's length sale of a substantially identical item sold in the same quantity, under the same terms, and at the same time and place.

"Field" means the field indicated as the Field identified in Section 1 of the Patent License Agreement.

"Government" means any agency, department or other unit of the United States of America or the State of Texas.

"Gross Consideration" means all cash and non-cash consideration (e.g., securities).

"Licensed Process' means a method or process whose practice or use is covered by a Valid Claim.

"Licensed Product" means any product or component (i) whose manufacture, use, sale, offer for sale or import is covered by any Valid Claim, or (ii) which is made using a Licensed Process or another Licensed Product.

“Licensed Service” means performance of a service for any consideration using a Licensed Product, or the practice of a Licensed Process. For clarity, research and development of Licensed Products by Licensee, its Affiliates, or a Sublicensee does not constitute a Licensed Service.

“Licensee” means the Party identified as the Licensee in Section 1 of the Patent License Agreement.

“Licensor” means the Party identified as the Licensor in Section 1 of the Patent License Agreement.

“Milestone Fees” means all fees identified as Milestone Fees in Section 3.1(b) of the Patent License Agreement.

“Net Product Sales” means [**].

“Net Sales” means the total of Net Product Sales and Net Service Sales.

“Net Service Sales” means [**].

“Non-Royalty Sublicensing Consideration” means [**].

“Patent License Agreement” means the particular Patent License Agreement to which these Terms and Conditions are attached and incorporated into by reference.

“Patent Rights” means the Licensor’s rights in (a) the patents and patent applications listed in Section 1 of the Patent License Agreement; (b) all non-provisional patent applications that claim priority to any provisional application listed in Section 1 of the Patent License Agreement; and (c) all divisionals, continuations, and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents and/or patent applications, and all reissues, reexaminations, extensions of, and foreign counterparts; and (d) any patents that issue with respect to the aforesaid patent applications. From time to time during the term of the Agreement, upon written agreement by both parties, Licensee and Licensor shall update the list of all patent applications and patents within the Patent Rights.

“Phase I” means a human clinical trial of a Licensed Product, including the initial introduction into humans, the principal purpose of which is to obtain sufficient information about the Product’s pharmacokinetics and pharmacological effects to permit the design of further clinical trials, and be generally consistent with 21 CFR § 312.21(a). Said trial may be conducted in any country.

Phase II means a human clinical trial of a Licensed Product the principal purpose of which is to make a preliminary determination that such Product is safe in a patient population for its intended use and to obtain sufficient information about such Product’s efficacy to permit the design of further clinical trials, and be generally consistent with 21 CFR § 312.21(b). Said trial may be conducted in any country.

"Phase III" means a human clinical trial of a Licensed Product, which trial is designed to: (a) establish that a Licensed Product is safe and efficacious for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Licensed Product in the dosage range to be prescribed; (c) support regulatory approval of such Licensed Product; and (d) be generally consistent with 21 CFR § 312.21(c). Said trial may be conducted in any country.

"Prosecution Counsel" means the law firm or attorney who is handling the prosecution of the Patent Rights. Prosecution Counsel as of the Effective Date is identified in Section 1 of the Patent License Agreement

"Quarterly Payment Deadline" means the day that is [**] after the last day of any particular Contract Quarter.

"Regulatory Approval" means the approval by the Regulatory Authority needed for a particular national jurisdiction to market, sell and use a Licensed Product in that national jurisdiction,

"Regulatory Authority" means the governmental authority responsible for granting any necessary licenses or approvals for the marketing, sale and use of a Licensed Product or Licensed Service in a particular national jurisdiction, including without limitation, the FDA, European Medicines Agency or Koseisho (i.e. the Japanese Ministry of Health and Welfare).

"Sell, Sale or Sold" means any transfer or other disposition of Licensed Products or Licensed Services for which consideration is received by Licensee, its Affiliates or Sublicensees. A Sale of Licensed Products or Licensed Services will be deemed completed at the time Licensee or its Affiliate or its Sublicensee receives such consideration.

"Sublicense Agreement" means any agreement or arrangement pursuant to which Licensee (or an Affiliate or Sublicensee) grants to any third party any license rights of Licensee under the Agreement.

"Sublicense Fee" means the fee specified in Section 3.1(d) of the Patent License Agreement.

"Sublicensee" means any entity to whom an express sublicense has been granted under the Patent Rights. For clarity, a third party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product or Licensed Services within its distribution territory or field (i.e., the third party simply functions as a reseller), and who does not pay any consideration to Licensee or an Affiliate for such wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Sales by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to Section 3.2. This definition does not limit Licensee's rights to grant or authorize sublicenses under the Agreement.

"Territory" means the territory so indicated as the Territory in Section 1 of the Patent License Agreement.

"Valid Claim" means a claim of (i) an issued and unexpired patent included within the Patent Rights unless the claim has been held unenforceable or invalid by the final, un-reversed, and unappealable decision of a court or other government body of competent jurisdiction, has been irretrievably abandoned or disclaimed, or has otherwise been finally admitted or determined to be invalid, un-patentable or unenforceable, whether through reissue, reexamination, disclaimer or otherwise, or (ii) a pending patent application within the Patent Rights to the extent the claim continues to be prosecuted in good faith.

2. License Grant and Commercialization

2.1 Grant

(a) Licensor grants to Licensee a royalty-bearing exclusive license under Patent Rights to manufacture, have manufactured, distribute, have distributed, use, offer for Sale, Sell, lease, loan and/or import Licensed Products in the Field in the Territory and to perform Licensed Services in the Field in the Territory.

(b) This grant is subject to (i) the payment by Licensee to Licensor of all consideration required under the Agreement, (ii) any rights of; or obligations to; the Government as set forth in Section 11.2 (Government Rights), and (iii) rights retained by Licensor to:

(1) Publish the scientific findings from research related to the Patent Rights; and

(2) Manufacture, have manufactured, and use the Patent Rights for teaching, research, patient care, education, and other educationally-related purposes; and

(3) Grant rights to, and transfer material embodiments of, the Patent Rights to other academic institutions or non-profit research institutions for the purposes identified in clauses (1) and (2) above.

(c) Licensor reserves all rights not expressly granted in the Agreement and disclaims the grant of any implied rights to Licensee.

2.2 Affiliates

Licensee may extend the license granted herein to any Affiliate provided that the Affiliate agrees in writing to be bound by the Agreement to the same extent as Licensee. Licensee agrees to deliver such written agreement to Licensor within [**] following execution.

2.3 Sublicensing

Licensee has the right to grant Sublicense Agreements under the Patent Rights consistent with the terms of the Agreement, subject to the following:

(a) A Sublicense Agreement shall not exceed the scope and rights granted to Licensee hereunder. Sublicensee must agree in writing to be bound by the applicable terms and conditions of the Agreement and shall indicate that Licensor is a third party beneficiary and entitled to enforce the terms and conditions of the Sublicense Agreement applicable to the Agreement. In the event of termination of the Agreement, continued sublicense rights shall be governed by Section 7.5(a) (Effect of Termination). Licensee may grant a Sublicensee the right to grant further sub-Sublicense Agreements, in which case such sub-Sublicense Agreements shall be treated as "Sublicense Agreements" and such sub-Sublicensees shall be treated as "Sublicensees" for purposes of the Agreement.

(b) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee, Affiliate or Sublicensee, and any modification or termination thereof, within [**] following the applicable execution, modification, or termination of such Sublicense Agreement. If the Sublicense Agreement is not in English, Licensee shall provide Licensor an accurate English translation in addition to a copy of the original agreement.

(c) Notwithstanding any such Sublicense Agreement, Licensee will remain primarily liable to Licensor for all of the Licensee's duties and obligations contained in the Agreement, including without limitation the payment of running royalties due under Section 3.2 whether or not paid to Licensee by a Sublicensee. Any act or omission of a Sublicensee that would be a breach of the Agreement if performed by Licensee will be deemed to be a breach by Licensee unless Licensee complies with the remaining provisions of this paragraph. Each Sublicense Agreement will contain a right of termination by Licensee in the events that the Sublicensee breaches the payment or reporting obligations affecting Licensor or any other terms and conditions of the Sublicense Agreement that would constitute a breach of the Agreement if such acts were performed by Licensee. In the event of a Sublicensee breach, and if after a reasonable opportunity to cure as provided in thy such Sublicense Agreement (not to exceed [**] for a payment breach and [**] for a non-payment breach), such Sublicensee fails to cure such Sublicensee breach, then the Licensee will terminate the Sublicense Agreement within [**] thereafter, with copy of such written notice of termination to Licensor, unless agreed to in writing otherwise by Licensor.

2.4 Diligent Commercialization

Licensee by itself or; through its Affiliates and Sublicensees will use diligent efforts to make Licensed Products or Licensed Services commercially available in the Field in the Territory. Without limiting the foregoing, Licensee will (a) maintain a reasonably funded, ongoing and active research, development, manufacturing, regulatory, marketing or sales program required to make License Products or Licensed Services commercially available, and (b) fulfill the milestone events specified in Section 2.4 of the Patent License Agreement by the deadlines indicated therein and (c) use diligent and commercially reasonable efforts to perform and complete the plans described in the [**] report submitted pursuant to Section 4.2 ([**] Written Progress Report). If the obligations under this Section 2.4 are not fulfilled, Licensor may treat such failure as a breach in accordance with Section 7.3(b).

3. Compensation

In consideration of rights granted to Licensee, Licensee will pay Licensor the following fees and royalties. All fees and royalties are not refundable and are not creditable against other fees and royalties. Each payment will reference the Patent License Agreement number and will be sent to Licensor's payment and accounting contact in Section 18 (Notices) of the Patent License Agreement.

3.1 Non-Royalty Payments due from Licensee

(a) *Patent Expenses.* Licensee will reimburse Licensor for the past patent expenses stated in Section 3.1(a) of the Patent License Agreement within [**] after the Effective Date. The stated amount is the current estimate for past patent expenses based on invoices received by the Licensor through the stated date. Licensee's obligations to pay all past and future patent expenses pursuant to Section 6 (Patent Expenses and Prosecution) will not be limited by such amount.

(b) *Milestone Fees.* Licensee will pay Milestone Fees indicated in Section 3.1(b) of the Patent License Agreement by the Quarterly Payment Deadline for the Contract Quarter in which the milestone events set forth in Section 3.1(b) of the Patent License Agreement are achieved.

(c) *Scheduled License Fees.* Licensee will pay license fees in the amounts set forth in Sections 3.1(c) of the Patent License Agreement in accordance with the stated schedule.

(d) *Sublicense Fees.* Licensee will pay Sublicense Fees indicated in Section 3.1(d) of the Patent License Agreement on or before the Quarterly Payment Deadline for the Contract Quarter.

(e) *Assignment Fee.* Licensee will pay the assignment fee set forth in Section 3.1(e) of the Patent License Agreement within [**] of the assignment of the Agreement.

(f) *FDA Priority Review Voucher:* If Licensee receives a voucher under the FDA's priority review voucher program, Licensee may sell or otherwise commercialize such voucher, if Licensee pays Licensor [**] percent ([**]%) of all proceeds related to the sale of such voucher within [**] after receipt of such proceeds.

3.2 Royalties

Licensee will pay a running royalty at the rate set forth in Section 3.2 of the Patent License Agreement on Net Sales in each Contract Quarter, payable on or before the Quarterly Payment Deadline for such Contract Quarter, subject to the following:

(a) [**] royalty shall be paid to Licensor hereunder with respect to the Sale of any one unit of Licensed Product or Licensed Service, [**] patent or Valid Claim is applicable to the Licensed Product or Licensed Service, or the development, manufacture, or performance thereof.

(b) No royalty shall be payable under this Section 3.2 with respect to (i) Sales to an Affiliate or Sublicensee of a particular unit of Licensed Product that is used by such Affiliate or Sublicensee to perform a Licensed Service if Licensor is paid a royalty on the Sale of such Licensed Service, (ii) the Sale of Licensed Products between or among Licensee, its Affiliates, and Sublicensees for re-sale purposes, provided Licensor is paid a royalty with respect to the re-sale, or (iii) payments that constitute Non-Royalty Sublicensing Consideration.

3.3 Non-cash Consideration

If Licensee receives or anticipates receipt of non-cash consideration from Sales or Sublicenses, the manner in which Licensor will receive its compensation under the Agreement with respect to such non-cash consideration will be [**].

4. Reports and Plans

The reports specified in this Section 4 will be sent to Licensor's payment and reporting contact identified in Section 18 (Notices) of the Patent License Agreement. If Licensor requests to have information submitted in a particular format, Licensee will use reasonable efforts to comply with such request.

4.1 Quarterly Payment and Milestone Reports

On or before each Quarterly Payment Deadline, Licensee will deliver to Licensor a true and accurate report, certified by an officer of Licensee, giving such particulars of the business conducted by Licensee, its Affiliates and its Sublicensees (including copies of reports provided by Sublicensees and Affiliates to Licensee) during the preceding Contract Quarter under the Agreement as necessary for Licensor to account for Licensee's payments hereunder, even if no payments are due. The reports shall continue to be delivered after the termination or expiration of the Agreement until such time as all Licensed Products permitted to be Sold after termination or expiration have been Sold or destroyed. Licensee shall provide information in sufficient detail to enable the royalties payable hereunder to be determined and to calculate all of the amounts payable under the Agreement. The report shall include:

[**].

4.2 [**] Written Progress Report and Commercialization Plan

Within [**] following the end of [**], Licensee will deliver to Licensor a true and accurate written progress report and commercialization plan, certified by an officer of Licensee, that summarizes (i) Licensee's efforts and accomplishments during the [**] to diligently commercialize Licensed Products and Licensed Services, and (ii) Licensee's development and commercialization plans with respect to Licensed Products and Licensed Services for the next [**]. The report shall also cover such activities by Affiliates and Sublicensees. The report shall contain the following information to the extent relevant to the activities under the Agreement:

[**].

4.3 Government and Economic Development Reporting

If Licensor requests, Licensee will provide information for Licensor's Government and economic development reporting purposes, including the following:

[**].

This information shall be treated as Licensee's Confidential Information; provided that Licensor is entitled to combine such information with similar information from other Licensor licensees and publicly report such combined aggregate information, without identifying Licensee's separate specific applicable numbers. If and when Licensee has more than [**] full-time employees, then no further economic development reports will be required from Licensee.

5. Payment, Records, and Audits

5.1 Payments

All amounts referred to in the Patent License Agreement are expressed in U.S. dollars without deductions for taxes, assessments, fees, or charges of any kind. Each payment will reference the agreement number set forth at the beginning of the Patent License Agreement All payments to Licensor will be made in U.S. dollars by check or wire transfer (Licensee to pay all wire transfer fees) payable to the payee identified in Section 18 of the Patent License Agreement and sent to the payment and reporting contact in Section 18 (Notices) of the Patent License Agreement.

5.2 Sales Outside the U.S.

If any currency conversion shall be required in connection with the calculation of payments hereunder, such conversion shall be made using the rate used by Licensee for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, using the average of the buying and selling exchange rate for conversion between the foreign currency and U.S. Dollars, for current transactions as reported in *The Wall Street Journal* on the last business days of the Contract Quarter to which such payment pertains. Licensee may not make any tax withholdings from payments to Licensor, but Licensor agrees to supply to Licensee, upon written request, appropriate evidence from appropriate U.S. governmental agencies showing that Licensor is a resident of the United States of America for purposes of the U.S. income tax laws and is tax-exempt under such income tax laws.

5.3 Late Payments

Amounts that are not paid when due will accrue a late charge from the due date until paid, at a rate equal to [**]% per month (or the maximum allowed by law, if less).

5.4 Records

For a period of [**] after the Contract Quarter to which the records pertain, Licensee agrees that it and its Affiliates and Sublicensees will each keep complete and accurate records of their Sales, Net Product Sales, Net Service Sales, Milestone Fees, and Non-Royalty Sublicensing Consideration in sufficient detail to enable such payments to be determined and audited.

5.5 Auditing

Licensee and its Affiliates will permit Licensor or its representatives, at Licensor's expense, to periodically examine books, ledgers, and records during regular business hours, at Licensee's or its Affiliate's place of business, on at least [**] advance notice, to the extent necessary to verify any payment or report required under the Agreement. For each Sublicensee, Licensee shall obtain such audit rights for Licensor or itself. If Licensee obtains such audit rights for itself, it will promptly conduct an audit of the Sublicensee's records upon Licensor's request, and Licensee will furnish to Licensor a copy of the findings from such audit. No more than [**] of Licensee, each Affiliate, and each Sublicensee shall be conducted under this Section 5.5 in any calendar year. If any amounts due Licensor have been underpaid, then Licensee shall immediately pay Licensor the amount of such underpayment plus accrued interest due in accordance with Section 5.3. If the amount of underpayment is equal to or greater than [**]% of the total amount due for the records so examined, Licensee will pay the cost of such audit. Such audits may, at Licensor's sole discretion, consist of a self-audit conducted by Licensee at Licensee's expense and certified in writing by an authorized officer of Licensee. All information examined pursuant to this Section 5.5 shall be deemed to be the Confidential Information of the Licensee. Further, whenever Licensee and/or its Affiliates and Sublicensees has its books and records audited by an independent certified public accountant, Licensee and/or its Affiliates and Sublicensees will, within [**] of the conclusion of such audit, provide Licensor with a written statement of said auditor, setting forth the calculation of amounts due to Licensor over the time period audited, as determined from the books and records of the Licensee, Affiliate or Sublicensee; but said auditor does not need to give any audit opinion with said statement.

6. Patent Expenses and Prosecution

6.1 Patent Expenses

Licensee shall pay for all past documented, out-of-pocket expenses incurred by Licensor for filing, prosecuting, enforcing, defending and maintaining Patent Rights and related patent searches through the Effective Date of the Agreement, including those identified in Section 3.1(a) of the Patent License Agreement, and all such future expenses incurred by Licensor, for so long as, and in such countries as the Agreement remains in effect. Licensee will pay all patent expenses (except for the payment called for under Section 3.1(a)), including past expenses that have not been invoiced as of the date indicated in Section 3.1(a) of the Patent License Agreement and future expenses, within [**] after Licensee's receipt of an invoice. At the election of Licensor, Licensee will either pay Prosecution Counsel directly for patent expenses or will reimburse Licensor for such patent expenses. Patent expense payment delinquencies (whether owed directly to Prosecution Counsel or to Licensor) will be considered a payment default under Section 7.3(a).

6.2 Direction of Prosecution

Licensor will confer with Licensee to develop a strategy for the prosecution and maintenance of Patent Rights. Licensor will request that copies of all documents prepared by the Prosecution Counsel for submission to governmental patent offices be provided to Licensee for review and comment prior to filing, to the extent practicable under the circumstances. At its discretion, Licensor may allow Licensee to instruct Prosecution Counsel directly, provided, that (a) Licensor will maintain final authority in all decisions regarding the prosecution and maintenance of the Patent Rights, (b) Licensor may revoke this authorization to instruct Prosecution Counsel directly at any time, and (c) the Prosecution Counsel remains counsel to the Licensor with an appropriate contract (and shall not jointly represent Licensee unless requested by Licensee and approved by Licensor, and an appropriate engagement letter and conflict waiver are in effect). If Licensee wishes to instruct Prosecution Counsel directly or change Prosecution Counsel, Licensee may request to do so by following the Licensor's procedures for such. Licensor reserves in its sole discretion the ability to change Prosecution Counsel and to approve or disapprove any requested changes by Licensee. The Parties agree that they share a common legal interest to get valid enforceable patents and that Licensee will maintain as privileged all information received pursuant to this Section.

6.3 Ownership

All patent applications and patents will be in the name of Licensor (and any co-owner identified in Section 1 of the Patent License Agreement) and owned by Licensor (and such co-owner, if any). No payments due under the Agreement will be reduced as the result of co-ownership interests in the Patent Rights by Licensee or any other party.

6.4 Foreign Filings

In addition to the U.S., the Patent Rights shall, subject to applicable bar dates, be pursued in such foreign countries as Licensee so designates in writing to Licensor in sufficient time to reasonably enable the preparation of such additional filings, and in those foreign countries in which Licensor has filed applications prior to the Effective Date. If Licensee does not choose to pursue patent rights in a particular foreign country and Licensor chooses to do so, Licensor shall so notify Licensee and thereafter said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto. Licensor shall have the right to make alternative arrangements with Licensee for upfront payment of foreign patent expenses.

6.5 Withdrawal from Paying Patent Costs

If at any time Licensee wishes to cease paying for any costs for a particular Patent Right or for patent prosecution in a particular jurisdiction, Licensee must give Licensor at least [**] prior written notice and Licensee will continue to be obligated to pay for the patent costs which reasonably accrue during said notice period. Thereafter, said patent application or patent shall no longer be included in the Patent Rights and Licensee shall have no further rights thereto.

6.6 U.S. Patent and Trademark Office Entity Size Status

Licensee represents that as of the Effective Date the entity size status of Licensee in accordance with the regulations of the U.S. Patent and Trademark Office is as set forth in Section 1 of the Patent License Agreement. Licensee will inform Licensor in writing on a timely basis of any change in its U.S. Patent and Trademark Office entity size status.

6.7 Extension of Patent Term

If a Licensed Product is eligible for extending the term of any patent in the Patent Rights under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or any European, Japanese, or other foreign counterparts of this law, then Licensee shall take all necessary steps with the appropriate regulatory authorities to apply in a timely manner for such an extension of the term for such patent. For example, such application must be made to the USPTO within [**] after the US FDA approves a commercial marketing application for said Licensed Product. Licensee shall prepare and file all documents needed for the application; and Licensee shall take all reasonable actions as may be appropriate to further obtain patent term extension. Licensor shall cooperate and sign such documents as may be reasonably requested by Licensee for the application.

Licensee shall keep Licensor informed as to Licensee’s efforts to prepare and file said application, including giving a written report within [**] after Licensee obtains the applicable marketing approval from the FDA (or foreign counterpart). If Licensee fails to make this required application, then Licensor shall have the option but not the obligation to do so; and if Licensor does elect to file the application, then Licensee shall cooperate and sign such documents as may be needed; and Licensee shall reimburse Licensor’s costs incurred for said application.

7. Term and Termination

7.1 Term

Unless earlier terminated as provided herein, the term of the Agreement will commence on the Effective Date and continue until the last date of expiration or termination of the Patent Rights.

7.2 Termination by Licensee

Licensee, at its option, may terminate the Agreement by providing Licensor written notice of intent to terminate, which such termination effective will be 90 days following receipt of such notice by Licensor.

7.3 Termination by Licensor

Licensor, at its option, may immediately terminate the Agreement, or any part of Patent Rights, or any part of Field, or any part of Territory, or the exclusive nature of the license grant, upon delivery of written notice to Licensee of Licensor's decision to terminate, if any of the following occur:

(a) Licensee becomes in arrears in any payments due under the Agreement, and Licensee fails to make the required payment within [**] after delivery of written notice from Licensor; or

(b) Licensee is in breach of any non-payment provision of the Agreement, and does not cure such breach within [**] after delivery of written notice from Licensor; or

(c) Licensor delivers notice to Licensee of [**] or more actual breaches of the Agreement in any 12-month period, even in the event that Licensee cures such breaches in the allowed period; or

(d) Licensee or its Affiliate or Sublicensee initiates any proceeding or action to challenge the validity, enforceability, or scope of one or more of the Patent Rights, or assist a third party in pursuing such a proceeding or action.

7.4 Other Conditions of Termination

The Agreement will terminate:

(a) Immediately without the necessity of any action being taken by Licensor or Licensee, (i) if Licensee becomes bankrupt or insolvent, or (ii) Licensee's Board of Directors elects to liquidate its assets or dissolve its business, or (iii) Licensee ceases its business operations, or (iv) Licensee makes an assignment for the benefit of creditors or (v) if the business or assets of Licensee are otherwise placed in the hands of a receiver, assignee or trustee, whether by voluntary act of Licensee or otherwise; or

(b) At any time by mutual written agreement between Licensee and Licensor.

7.5 Effect of Termination

If the Agreement is terminated for any reason:

(a) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided however, if the Sublicense Agreement is for all of the Field for all of the Territory, and the Sublicensee is in good standing and agrees in writing to assume all of the obligations of Licensee and provides Licensor with written notice thereof within [**] after termination of the Agreement, then such Sublicense Agreement shall survive; and

(b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products and performing Licensed Services by the effective date of termination; and

(c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and

(d) Nothing in the Agreement will be construed to release either Party from any obligation that matured prior to the effective date of termination; and

(e) The provisions of Sections 8 (Confidentiality), 9 (Infringement and Litigation), 11 (Representations and Disclaimers), 12 (Limit of Liability), 13 (Indemnification), 14 (Insurance), 17 (Use of Name), 18 (Notices), and 19 (General Provisions) will survive any termination or expiration of the Agreement. In addition, the provisions of Sections 3 (Compensation), 4.1 (Quarterly Payment and Milestone Reports), 5 (Payment, Records and Audits), and 6.1 (Patent Expenses) shall survive with respect to all activities and payment obligations accruing prior to the termination or expiration of the Agreement.

8. Confidentiality

8.1 Definition

"Confidential Information" means all information that is of a confidential and proprietary nature to Licensor or Licensee and provided by one Party to the other Party under the Agreement.

8.2 Protection and Marking

Licensor and Licensee each agree that all Confidential Information disclosed in tangible form, and marked "confidential" and forwarded to one by the other, or if disclosed orally, is designated as confidential at the time of disclosure: (i) is to be held in strict confidence by the receiving Party, (ii) is to be used by and under authority of the receiving Party only as authorized in the Agreement, and (iii) shall not be disclosed by the receiving Party, its agents or employees without the prior written consent of the disclosing Party or as authorized in the Agreement. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights under the Agreement, including without limitation disclosing to Affiliates, Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. Each Party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing Party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care.

8.3 Confidentiality of Terms of Agreement

Each Party agrees not to disclose to any third party the terms of the Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of the Agreement: (a) to advisors, actual or potential Sublicensees, acquirers or investors, and others on a need to know basis, in each case, under appropriate confidentiality obligations substantially similar to those of this Section 8; and (b) to the extent necessary to comply with applicable laws and court orders {including, without limitation, The Texas Public Information Act, as may be amended from time to time, other open records laws, decisions and rulings, and securities laws, regulations and guidance). If the Agreement is not for all fields of use, then Licensor may disclose the Field to other potential third party licensees. Notwithstanding the foregoing, the existence of the Agreement shall not be considered Confidential Information.

8.4 Disclosure Required by Court Order or Law

If the receiving Party is required to disclose Confidential Information of another Party hereto, or any terms of the Agreement, pursuant to the order or requirement of a court, administrative agency, or other governmental body or applicable law, the receiving Party may disclose such Confidential Information or terms to the extent required, provided that the receiving Party shall use reasonable efforts to provide the disclosing Party with reasonable advance notice thereof to enable the disclosing Party to seek a protective order and otherwise seek to prevent such disclosure. To the extent that Confidential Information so disclosed does not become part of the public domain by virtue of such disclosure, it shall remain Confidential Information protected pursuant to Section 8.

8.5 Copies

Each Party agrees not to copy or record any of the Confidential Information of the other Party, except as reasonably necessary to exercise its rights or perform its obligations under the Agreement, and for archival and legal purposes.

8.6 Continuing Obligations

Subject to the exclusions listed in Section 8.7, the Parties' confidentiality obligations under the Agreement will survive termination of the Agreement and will continue for a period of [**] thereafter.

8.7 Exclusions

Information shall not be considered Confidential Information of a disclosing Party under the Agreement to the extent that the receiving Party can establish by competent written proof that such information:

(a) Was in the public domain at the time of disclosure; or

(b) Later became part of the public domain through no act or omission of the recipient Party, its employees, agents, successors or assigns in breach of the Agreement; or

(c) Was lawfully disclosed to the recipient Party by a third party having the right to disclose it not under an obligation of confidentiality; or

(d) Was already known by the recipient Party at the time of disclosure; or

(e) Was independently developed by the recipient Party without use of the disclosing Party's Confidential Information.

8.8 Copyright Notice

The placement of a copyright notice on any Confidential Information will not be construed to mean that such information has been published and will not release the other Party from its obligation of confidentiality hereunder.

9. Infringement and Litigation

9.1 Notification

If either Licensee or Licensor's designated office for technology commercialization becomes aware of any infringement or potential infringement of Patent Rights in the Field in the Territory, such Party shall give prompt written notice to the other Party of such infringement.

9.2 Enforcement Against Infringer.

Licensor shall have the right, but no obligation, to enforce the Patent Rights against any infringement by a third party. Licensor shall confer with Licensee and give due consideration to Licensee's input concerning any such enforcement action. If an action is to be commenced, Licensor and Licensee will endeavor to reach mutual agreement as to how best (i) to prosecute, manage, and fund such action, and (ii) to allocate equitably any net recovery resulting from such action. Licensee is not entitled to commence any enforcement action against an infringer unless Licensor expressly approved in writing for Licensee to do so, which approval may not be unreasonably withheld. If an enforcement action is to be commenced, both Parties agree to cooperate fully with each other and to permit reasonable access to all relevant personnel, records, papers, information, samples, specimens, etc., relevant to the action.

9.3 Cooperation between Licensor and Licensee

In any infringement suit or dispute, the Parties agree to cooperate fully with each other. At the request of the Party bringing suit, the other Party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

If it is necessary to name Licensor as a party in such action, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Texas Attorney General regarding retention of outside counsel for state entities.

10. Export Compliance

Licensee understands that the Arms Export Control Act (AECA), including its implementing International Traffic In Arms Regulations (TEAR), and the Export Administration Act (EAA), including its Export Administration Regulations (EAR), are some (but not all) of the laws and regulations that comprise the U.S. export laws and regulations. Licensee further understands that the U.S. export laws and regulations include (but are not limited to): (a) ITAR and EAR product/service/data-specific requirements; (b) ITAR and EAR ultimate destination-specific requirements; (c) ITAR and EAR end user-specific requirements; (d) Foreign Corrupt Practices Act; and (e) anti-boycott laws and regulations. Licensee will comply with all then-current applicable export laws and regulations of the U.S. Government (and other applicable U.S. laws and regulations) pertaining to the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information). Licensee certifies that it will not, directly or indirectly, export (including any deemed export), nor re-export (including any deemed re-export) the Licensed Products and Licensed Services (including any associated products, items, articles, computer software, media, services, technical data, and other information) in violation of applicable U.S. laws and regulations. Licensee will include a provision in its agreements, substantially similar to this Section 10, with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who purchase a Licensed Product, requiring that these parties comply with all then-current applicable U.S. export laws and regulations and other applicable U.S. laws and regulations.

11. Representations and Disclaimers

11.1 Licensor Representations

Except for the rights, if any, of the Government as set forth in Section 11.2, Licensor represents and warrants to Licensee that to the knowledge of Licensor's designated office for technology commercialization (i) Licensor is the owner or agent of the entire right, title, and interest in and to Patent Rights (other than the right, title and interest of any joint owner identified in Section 1 of the Patent License Agreement), (ii) Licensor has the right to grant licenses hereunder, and (iii) Licensor has not knowingly granted and will not knowingly grant licenses or other rights under the Patent Rights that are in conflict with the terms and conditions in the Agreement.

11.2 Government Rights

Licensee understands that Patent Rights may have been developed under a funding agreement with Government and, if so, that Government may have certain rights relative thereto. The Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation. To the extent that there is a conflict between any such agreement, such applicable law or regulation and the Agreement, the terms of such Government agreement, and applicable law or regulation, shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or Sold in the U.S. will be manufactured substantially in the U.S., unless a written waiver is obtained in advance from the U.S. Government.

11.3 Licensor Disclaimers

EXCEPT AS SPECIFICALLY SET FORTH IN SECTION 11.1, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS OR LICENSED SERVICES, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION AS TO WHETHER ANY PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN FIELD. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS, WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS. LICENSOR HAS NO OBLIGATION TO FURNISH TO LICENSEE ANY KNOW-HOW, TECHNOLOGY OR TECHNOLOGICAL INFORMATION.

11.4 Licensee Representation

By execution of the Agreement, Licensee represents, acknowledges, covenants and agrees (a) that Licensee has not been induced in any way by Licensor or its employees to enter into the Agreement, and (b) that Licensee has been given an opportunity to conduct sufficient due diligence with respect to all items and issues pertaining to this Section 11 (Representations and Disclaimers) and all other

matters pertaining to the Agreement; and (c) that Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and (c) that Licensee accepts all risks inherent herein. Licensee represents that it is a duly organized, validly existing entity of the form indicated in Section 1 of the Patent License Agreement, and is in good standing under the laws of its jurisdiction of organization as indicated in Section 1 of the Patent License Agreement, and has all necessary corporate or other appropriate power and authority to execute, deliver and perform its obligations hereunder.

12. Limit of Liability

IN NO EVENT SHALL LICENSOR, THE UNIVERSITY SYSTEM IT GOVERNS, ITS MEMBER INSTITUTIONS, INVENTORS, REGENTS, OFFICERS, EMPLOYEES, STUDENTS, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES. OTHER THAN FOR CLAIMS AGAINST LICENSEE FOR INDEMNIFICATION (SECTION 13) OR FOR MISUSE OR MISAPPROPRIATION OR INFRINGEMENT OF LICENSOR'S INTELLECTUAL PROPERTY RIGHTS, LICENSEE WILL NOT BE LIABLE TO LICENSOR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER LICENSEE KNOWS OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES.

13. Indemnification

13.1 Indemnification Obligation

Subject to Section 13.2, Licensee agrees to hold harmless, defend and indemnify Licensor, the university system it governs, its member institutions, its Regents, officers, employees, students and agents ("Indemnified Parties") from and against any liabilities, damages, causes of action, suits, judgments, liens, penalties, fines, losses, costs and expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) (collectively "Liabilities") resulting from claims or demands brought by third parties against an Indemnified Party on account of any injury or death of persons, damage to property, or any other damage or loss arising out of or in connection with the Agreement or the exercise or practice by or under authority of Licensee, its Affiliates or their Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product, of the rights granted hereunder.

13.2 Conditions of Indemnification

licensee shall have no responsibility or obligation under Section 13.1 for any Liabilities to the extent caused by the gross negligence or willful misconduct by Licensor. Obligations to indemnify, and hold harmless under Section 13.1 are subject to: (a) to the extent authorized by the Texas Constitution and the laws of the State of Texas, and subject to the statutory duties of the Texas Attorney General, the Indemnified Party giving Licensee control of the defense and settlement of the claim and demand; and (b) to the extent authorized by the Texas Constitution and the laws of the State of Texas and subject to statutory duties of the Texas Attorney General, the Indemnified Party providing assistance reasonably requested by Licensee, at Licensee's expense.

14. Insurance

14.1 Insurance Requirements

Prior to any Licensed Product being used or Sold (including for the purpose of obtaining regulatory approvals), and prior to any Licensed Service being performed by Licensee, an Affiliate, or by a Sublicensee, and for a period of [**] after the Agreement expires or is terminated, Licensee shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable and appropriate amounts for the Licensed Product being used or Sold or the Licensed Service being performed. Licensee shall use commercially reasonable efforts to have Licensor, the university system it governs, its member institutions, Regents, officers, employees, students and agents named as additional insureds. Such commercial general liability insurance shall provide, without limitation: (i) product liability coverage; (ii) broad form contractual liability coverage for Licensee's indemnification under the Agreement; and (iii) coverage for litigation costs.

14.2 Evidence of Insurance and Notice of Changes

Upon request by Licensor, Licensee shall provide Licensor with written evidence of such insurance. Additionally, Licensee shall provide Licensor with written notice of at least [**] prior to Licensee cancelling, not renewing, or materially changing such insurance.

15. Assignment

The Agreement may not be assigned by Licensee without the prior written consent of Licensor, which consent will not be unreasonably withheld. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement. For any permitted assignment to be effective, (a) Licensee must be in good standing under this Agreement, (b) the Licensee must pay Licensor the assignment fee pursuant to Section 3.1(e), and (c) the assignee must assume in writing (a copy of which shall be promptly provided to Licensor) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original Party to the Agreement.

16. Governmental Markings

16.1 Patent Markings

Licensee agrees that all Licensed Products Sold by Licensee, Affiliates, or Sublicensees will be legibly marked with the number of any applicable patent(s) licensed hereunder as part of the Patent Rights in accordance with each country's patent marking laws, including Title 35, U.S. Code, or if such marking is not practicable, shall so mark the accompanying outer box or product insert for Licensed Products accordingly.

16.2 Governmental Approvals and Marketing of Licensed Products and or Licensed Services

Licensee will be responsible for obtaining all necessary governmental approvals for the development, production, distribution, Sale, and use of any Licensed Product or performance of any Licensed Service, at Licensee's expense, including, without limitation, any safety studies. Licensee will have sole responsibility for any warning labels, packaging and instructions as to the use and the quality control for any Licensed Product or Licensed Service.

16.3 Foreign Registration and Laws

Licensee agrees to register the Agreement with any foreign governmental agency that requires such registration; and Licensee will pay all costs and legal fees in connection with such registration. Licensee is responsible for compliance with all foreign laws affecting the Agreement or the Sale of Licensed Products and Licensed Services to the extent there is no conflict with United States law, in which case United States law will control.

17. Use of Name

Licensee will not use the name, trademarks or other marks of Licensor (or the name of the university system it governs, its member institutions, .any of its Regents or employees) without the advance written consent of Licensor. Licensor may use Licensee's name and logo for annual reports, brochures, website, and internal reports without prior consent.

18. Notices

Any notice or other communication of the Parties required or permitted to be given or made under the Agreement will be in writing and will be deemed effective when sent in a manner that provides confirmation or acknowledgement of delivery and received at the address set forth in Section 18 of the Patent License Agreement (or as changed by written notice pursuant to this Section 18). Notices required under the Agreement may be delivered via E-mail provided such notice is confirmed in writing as indicated.

Notices shall be provided to each Party as specified in the "Contact for Notice" address set forth in Section 18 of the Patent License Agreement. Each Party shall update the other Party in writing with any changes in such contact information.

19. General Provisions

19.1 Binding Effect

The Agreement is binding upon and inures to the benefit of the Parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.

19.2 Construction of Agreement

Headings are included for convenience only and will not be used to construe the Agreement. The Parties acknowledge and agree that both Parties substantially participated in negotiating the provisions of the Agreement; therefore, both Parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one Party than the other Party, regardless of which Party primarily drafted the Agreement.

19.3 Counterparts and Signatures

The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A Party may evidence its execution and delivery of the Agreement by transmission of a signed copy of the Agreement via facsimile or email.

19.4 Compliance with Laws

Licensee will comply with all applicable federal, state and local laws and regulations, including, without limitation, all export laws and regulations.

19.5 Governing Law

The Agreement will be construed and enforced in accordance with laws of the U.S. and the State of Texas, without regard to choice of law and conflicts of law principles.

19.6 Modification

Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both Parties. No modification will be made by email communications.

19.7 Severability

If any provision hereof is held to be invalid, illegal or unenforceable in any jurisdiction, the Parties hereto shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties, and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such other provisions in any other jurisdiction, so long as the essential essence of the Agreement remains enforceable.

19.8 Third Party Beneficiaries

Nothing in the Agreement, express or implied, is intended to confer any benefits, rights or remedies on any entity, other than the Parties and their permitted successors and assigns. However, if there is a joint owner of any Patent Rights identified in Section 1 of the Patent License Agreement (other than Licensee), then Licensee hereby agrees that the following provisions of these Terms and Conditions extend to the benefit of the co-owner identified therein (excluding the Licensee to the extent it is a co-owner) as if such co-owner was identified in each reference to the Licensor: the retained rights under clause (b) of Section 2.1; Section 11.3 (Licensor Disclaimers); Section 12 (Limitation of Liability); Section 13 (Indemnification); Section 14.1 (Insurance Requirements); Section 17 (Use of Name); and Section 19.10 (Sovereign Immunity, if applicable).

19.9 Waiver

Neither Party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such Party. No delay or omission of a Party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

19.10 Sovereign Immunity

Nothing in the Agreement shall be deemed or treated as any waiver of Licensor's sovereign immunity.

19.11 Entire Agreement

The Agreement constitutes the entire Agreement between the Parties regarding the subject matter hereof, and supersedes all prior written or verbal agreements, representations and understandings relative to such matters.

19.12 Claims Against Licensor for Breach of Agreement

Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be subject to Chapter 2260 of the Texas Government Code and that the process provided therein shall be Licensee's sole and exclusive process for seeking a remedy for any and all alleged breaches of the Agreement by Licensor or the State of Texas.

19.13 Grant of Security Interest

Licensee hereby grants to Licensor a security interest in and to Licensee's rights under the Patent License Agreement, as collateral security for the payment by Licensee of any and all sums which may be owed from time to time by Licensee to Licensor. Licensor shall have all rights of a secured party as specified in the Texas Uniform Commercial Code relative to this security interest and the enforcement thereof. Licensee hereby authorizes Licensor to file with the appropriate governmental agencies appropriate UCC-1 financing statements to evidence this security interest.

— END OF EXHIBIT A —

AMENDMENT #1 TO PATENT LICENSE AGREEMENT

This Amendment #1 to the Patent License Agreement ("Amendment") is made and entered into as of date of last signature below ("Amendment Effective Date") by and between Lung Therapeutics, Inc., a Texas corporation, with its principal place of business at 7500 Rialto Boulevard, Ste. 250, Austin, Texas 78735, ("Licensee") and the Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas.

Background

A. The Board and Licensee entered into a Patent License Agreement (UTA Agreement No. PM1504101) with an Effective Date of May 21, 2015, (the "Patent License Agreement"). Capitalized terms used herein without definition shall have meanings given to them in the Patent License Agreement.

B. The Board and Collaborators now wish to amend the Consortium Agreement as set forth below.

NOW, THEREFORE, it is hereby agreed as follows:

1. Milestones. Section 2.4 Milestone Event 2, [**] with a deadline of [**], as set forth in Section 2.4 and elsewhere in the Patent License Agreement is hereby deleted and replaced with [**]with a deadline of [**]. For the sake of clarity, this amendment does not trigger Section 20.1 Milestone Extension Option, and the milestone extension fee of $[**] is not due.

2. Agreement in Full Force and Effect. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Patent License Agreement shall continue in full force and effect as provided therein.

IN WITNESS WHEREOF, the Board and Licensee have entered into this Amendment effective as of the date first set forth above.

THE UNIVERSITY OF TEXAS AT AUSTIN
ON BEHALF OF THE BOARD OF REGENTS
OF THE UNIVERSITY OF TEXAS SYSTEM

By: /s/ Daniel W. Sharp
Daniel W. Sharp, J.D.
Associate Vice President for Research and
Director, Office of Technology
Commercialization
Date: 01/26/2017

LICENSEE: Lung Therapeutics, Inc

By: /s/ Brian Windsor
Name: Brian Windsor, PhD
Title: CEO
Date: 01/26/2017

The University of Texas at Austin Licensee: Lung Therapeutics UTA
No.: Agreement No. PM1504102

AMENDMENT #2 TO PATENT LICENSE AGREEMENT

This Amendment #2 to the Patent License Agreement ("Amendment") is made and entered into as of the date of last signature below ("Amendment Effective Date") by and between Lung Therapeutics, Inc., a Texas corporation, with its principal place of business at 2801 Via Fortuna, Suite 425, Austin, Texas 78746, ("Licensee") and the Board of Regents ("Board") of the University of Texas System ("System"), an agency of the State of Texas.

Background

A. The Board and Licensee entered into a Patent License Agreement (UTA Agreement No. PM1504101 with an Effective Date of May 21, 2015, and the Board and Licensee entered into Amendment #1 to the Patent License Agreement with an effective date of February 14th, 2017 (the "Patent License Agreement"). Capitalized terms used herein without definition shall have meanings given to them in the Patent License Agreement.

B. The Board and Licensee now wish to amend the Patent License Agreement as set forth below.

NOW, THEREFORE, it is hereby agreed as follows:

1. Patent Rights: The Exclusive Patent Rights are hereby supplemented to include the patent application listed in Table 1 below:

Table 1

Patent No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; If Y, with whom?)	Prosecution Counsel
[**]	[**]	[**]	[**]	[**]

2. Agreement in Full Force and Effect. Except as expressly provided in this Amendment, all other terms, conditions and provisions of Patent License Agreement shall continue in full force and effect as provided therein.

[SIGNATURE PAGE TO FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Amendment.

THE UNIVERSITY OF TEXAS AT AUSTIN ON BEHALF OF THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

By: /s/ Les Nichols

Les Nichols
Interim Director, Office of Technology Commercialization
The University of Texas at Austin

Date: 11/19/2018

LICENSEE: Lung Therapeutics, Inc.

By: /s/ Brian Windsor

Name: Brian Windsor, PhD

Title: CEO

Date: 11/12/18

AMENDMENT #3 TO PATENT LICENSE AGREEMENT

This Amendment #3 to the Patent License Agreement ("Amendment") is made and entered into as of June 20, 2019 ("Amendment Effective Date") by and between Lung Therapeutics, Inc., ("Licensee") and the Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas.

Background

A. The Board and Licensee entered into a Patent License Agreement (UTA Agreement No. PM1504101) with an Effective Date of May 21, 2015, and amended by Amendment #1 (UTA Agreement No. PA 15 04102), with an effective date of February 14, 2017, and amended by Amendment #2 (UTA Agreement No. PA1504103) with an effective date of November 14, 2018 (the "Patent License Agreement"). Capitalized terms used herein without definition shall have meanings given to them in the Patent License Agreement.

B. The Board and Licensee now wish to amend the Patent License Agreement as set forth below.

NOW, THEREFORE, it is hereby agreed as follows:

1. The definition of Patent Rights is hereby amended to add the Board's rights in the following:

App. No./ Date of Filing	Title	Inventor(s)	Jointly Owned? (Y/N; if Y, with whom?)	Prosecution Counsel
[**]	[**]	[**]	[**]	[**]

2. Milestone Event 3 as set forth in Section 2.4

[**] [**]

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

[**] [**]

3. Milestone Event 1 as set forth in Section 3.1(b)

[**] [**]

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

[**] [**]

4. Agreement in Full Force and Effect. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Patent License Agreement shall continue in full force and effect as provided therein.

IN WITNESS WHEREOF, the Board and Licensee have entered into this Amendment effective as of the date first set forth above.

THE UNIVERSITY OF TEXAS AT AUSTIN
ON BEHALF OF THE BOARD OF
REGENTS OF THE UNIVERSITY OF
TEXAS SYSTEM

By: /s/ Les Nichols
Les Nichols
Interim Director, Office of Technology
Commercialization
Date: 09/06/19

Lung Therapeutics, Inc.

By: /s/ Brian Windsor
Name: Brian Windsor, PhD
Title: CEO
Date: 09/10/19

AMENDMENT #4 TO PATENT LICENSE AGREEMENT

This Amendment #4 to the Patent License Agreement ("Amendment") is made and entered into as of the date of last signature below ("Amendment Effective Date") by and between Lung Therapeutics, Inc. ("Licensee") and the Board of Regents ("Board") of The University of Texas System, an agency of the State of Texas.

Background

A. Board and Licensee entered into a Patent License Agreement (UTA Agreement No. PM1504101) with an effective date of May 21, 2015, and amended by Amendment #1 (UTA Agreement No. PA1504102), with an effective date of February 14, 2017, amended by Amendment #2 (UTA Agreement No. PA1504103) with an effective date of November 14, 2018, and amended by Amendment #3 (UTA Agreement No. PA1504104) with an effective date of June 20, 2019 (the "Patent License Agreement"). Capitalized terms used herein without definition shall have meanings given to them in the Patent License Agreement.

B. Board and Licensee now wish to amend the Patent License Agreement as set forth below.

NOW, THEREFORE, it is hereby agreed as follows:

1. Milestone Event 5 as set forth in Section 2.4

5. [**]	[**]

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

5. [**]	[**]

2. Milestone Event 6 as set forth in Section 2.4

6. [**]	[**]

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

6. [**]	[**]

3. Milestone Event 2 as set forth in Section 3.1(b)

2. [**]	$[**]

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

2. [**]	[**]

4. Section 3.1(b) of the Terms and Conditions of Patent License

(b) *Milestone Fees*. Licensee will pay Milestone Fees indicated in Section 3.1(b) of the Patent License Agreement by the Quarterly Payment Deadline for the Contract Quarter in which the milestone events set forth in Section 3.1(b) of the Patent License Agreement are achieved.

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

(b) *Milestone Fees*. Licensee will pay Milestone Fees indicated in Section 3.1(b) of the Patent License Agreement by the Quarterly Payment Deadline for the Contract Quarter in which the milestone events set forth in Section 3.1(b) of the Patent License Agreement are achieved, with the exception of the Milestone Fee for Milestone 2 that will be paid by [**].

5. Milestone Event 3 as set forth in Section 3.1(b)

3. [**]	$[**]

and elsewhere in the Patent License Agreement is hereby deleted and replaced with

3. [**]	$[**]

6. Agreement in Full Force and Effect. Except as expressly provided in this Amendment, all other terms, conditions and provisions of the Patent License Agreement shall continue in full force and effect as provided therein.

IN WITNESS WHEREOF, the Board and Licensee have entered into this Amendment effective as of the date of the last signature below.

THE UNIVERSITY OF TEXAS AT AUSTIN
ON BEHALF OF THE BOARD OF
REGENTS OF THE UNIVERSITY OF
TEXAS SYSTEM

By: /s/ Les Nichols
Les Nichols
Interim Director, Office of Technology Commercialization
Date: 04/28/23

Lung Therapeutics, Inc.

By: /s/ Brian Windsor
Name: Brian Windsor, PhD
Title: CEO
Date: 04/28/23

Exhibit 10.4

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDED AND RESTATED LICENSE AGREEMENT
by and between
MUSC FOUNDATION FOR RESEARCH DEVELOPMENT
and
LUNG THERAPEUTICS, INC.

THIS AMENDED AND RESTATED AGREEMENT, (the "Agreement") effective as of September 1, 2018 (the "Amendment Date"), is entered into by and between Lung Therapeutics, Inc., having and address at 2801 Via Fortuna, Suite 425, Austin, TX 78746 (herein called "Licensee"), and MUSC Foundation for Research Development, a 501(c)(3) South Carolina not for profit corporation, having its principal place of business at 135 Cannon Street, Suite 101L, Charleston, SC 29425 (herein called "Licensor"). Licensee and Licensor are sometimes hereinafter referred to collectively as the "Parties" or individually as a "Party".

In consideration of the mutual promises and covenants contained herein, the Parties hereby agree as follows:

ARTICLE I

BACKGROUND

Section 1.1. Licensor desires that its inventions be transferred to the private sector through licenses to facilitate the commercial development of products and processes for public use and benefit.

Section 1.2. Licensor has certain patent rights as defined herein and is willing to grant licenses to Licensee pursuant to the terms of this Agreement.

Section 1.3. Licensee acquired certain license rights pursuant to the terms of that certain License Agreement between Licensor and Licensee, effective March 30, 2016 (the "Original Agreement"), in order to develop methods and marketable products for ultimate public use and benefit by practicing the inventions licensed in this Agreement.

Section 1.4. The Parties now wish to amend and restate the Original Agreement in its entirety as set forth in this Agreement.

ARTICLE II

DEFINITIONS

As used in this Agreement, each underlined word or phrase below shall have the meaning given after it:

Section 2.1. Affiliate. Any corporation, partnership, limited liability company, joint venture or other entity which now or hereafter directly or indirectly controls, is controlled by, or is under common control with a Party. For this purpose, "control" in an Affiliate requires ownership of greater than fifty percent (50%) of: (i) voting stock of a company which issued voting stock, or (ii) ownership interest in any other enterprise. An Affiliate shall only be considered an Affiliate for so long as such control exists.

Section 2.2. Effective Date. March 30, 2016.

Section 2.3. Field of Use. All uses of the Patent Rights.

Section 2.4. First Commercial Sale. The first sale of any Licensed Product or Licensed Methods, or Related Product or Related Method, by Licensee or its sublicensees, following approval of its marketing by the appropriate governmental agency for the country in which the sale is to be made or, when governmental approval is not required, the first sale in that country.

Section 2.5. Inventors. [**]

Section 2.6. Licensed Methods. Any and all methods whose practice or use, but for the licenses granted herein, would infringe or would constitute indirect infringement (including contributory or induced infringement) of a Valid Claim (as defined below).

Section 2.7. Licensed Products. Any and all products the manufacture, use, sale, offer for sale, or import of which, but for the licenses granted herein, would infringe or would constitute indirect infringement (including contributory or induced infringement) ofa Valid Claim (as defined below).

Section 2.8. MUSC Entities. Licensor and The Medical University of South Carolina ("MUSC"), MUSC Physicians, the Medical University Hospital Authority, MUSC Health, the MUSC Foundation, and all entities within MUSC which are under the control of the Board of Trustees of MUSC, and all faculty members, employees, trainees, fellows, research associates, students, directors, trustees and agents of said organizations.

Section 2.9. Net Selling Price.

[**].

Section 2.10 Other Sublicense Revenues. [**]

Section 2.11. Patent Rights. [**]

Section 2.12. Related Methods. Any and all methods, other than the Licensed Methods, whose practice or use relate to the Related Rights.

Section 2.13. Related Products. Any and all products, other than the Licensed Products, the manufacture, use, sale, offer for sale, or import of which relate to the Related Rights.

Section 2.14. Related Rights. Intellectual property rights, other than the Patent Rights, related to a Caveolin-1 peptide that are licensed to or owned by Licensor.

Section 2.15. Term. As defined in Section 8.1 hereof.

Section 2.16. Territory. Worldwide.

Section 2.17. Valid Claim. With respect to a particular country, a claim of

(a) an issued and unexpired patent of the Patent Rights in such country that (i) has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal; (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country; and (iii) provides exclusive and enforceable rights with respect to the sale or practice of a Licensed Product or Licensed Methods, as the case may be, in such country; or

(a) a pending patent application of the Patent Rights that has been pending without determination of final grant (i.e., after the conclusion of any opposition proceeding) or issuance for less than [**] from the date of filing.

ARTICLE III

LICENSE GRANT

Section 3.1. Grant. The Licensor hereby grants to the Licensee and its Affiliates, within the Field of Use, for the Term of this Agreement as set forth in Section 8.1 an exclusive license, with the right to sublicense under the terms contained herein, in the Territory, under the Patent Rights to make, have made, use, offer to sell, sell, have sold, and import Licensed Products and to practice and use Licensed Methods.

Section 3.2. Sublicense.

(a) Licensor hereby grants to Licensee the right to grant sublicenses in accordance with the terms of this Agreement, subject to approval by Licensor, such approval not to be unreasonably withheld. Licensor shall have [**] to review proposed sublicenses and respond to Licensee. Licensee shall require each approved sublicensee to keep records and render reports as required in Sections 4.3, 6.1 and 6.9 and maintain insurance as required in Section 9.7. Licensee may not grant sublicensees the right to grant sublicenses or the right to enforce Patent Rights. Except as expressly provided in this Section 3.2(a), all sublicenses shall have terms and conditions no less restrictive than those in this Agreement. Licensee shall include in each sublicense agreement a provision that identifies Licensor as an intended beneficiary thereof. Licensee shall deliver to Licensor a true copy of each sublicense within [**] after it is executed; *provided, however,* that Licensee may redact from such copy any confidential or proprietary information of Licensee or its sublicensee that is not necessary for Licensor to ascertain Licensee's compliance with this Agreement.

(b) Termination under any of the provisions of this Agreement shall terminate all sublicenses that may have been granted by Licensee, provided that any sublicensee may elect to continue its sublicense by advising Licensor in writing, within [**] of the sublicensee's receipt of written notice of such termination, of its election, which written notice of election shall include such sublicensee's express agreement to be bound to Licensor by the terms of the sublicense agreement, subject to the following: (i) Licensor shall not have any obligations to such sublicensee other than Licensor's obligations to Licensee as set forth in this Agreement; and (ii) such sublicense agreement shall be subordinate in all respects to the applicable provisions of this Agreement; *provided, however,* that the scope of such sublicensee's direct license from Licensor shall be as set forth in the sublicense agreement and such sublicensee's financial obligations to Licensor shall be those set forth in the sublicense agreement (and not those set forth in this Agreement), except that the sublicensee shall assume Licensee's patent cost reimbursement obligations under this Agreement with respect to those of the Patent Rights that are covered by such sublicense agreement.

(c) Any sublicense granted hereunder by Licensee shall be reasonable and for fair market value. With the exception of Related Rights, an agreement granting a sublicense hereunder shall not include the grant of other rights held by the Licensee or any third party. Licensee shall be responsible for all actions and conduct of sublicensees with respect to obligations imposed by this Agreement on Licensee.

Section 3.3. Reservation of Rights. Licensor expressly reserves and retains for itself, and the right to grant to: (i) the MUSC Entities and their not for profit research collaborators, a non-exclusive license under the Patent Rights, to make and use Licensed Products and to practice and use Licensed Methods, solely for educational and research purposes; and (ii) the MUSC Entities, to sell to patients or other MUSC Entities and offer to sell to patients or other MUSC Entities Licensed Products and to practice and use Licensed Methods, solely for educational, research, and medical care purposes, but not otherwise. The rights extended under this section for medical care purposes shall be limited to patient care provided by the MUSC Entities. Further, nothing contained herein shall be deemed to require Licensee to provide Licensed Products or Licensed Methods to MUSC Entities at below the average Net Selling Price for such Licensed Products or Licensed Methods.

Section 3.4. Bayh-Dole. Licensee acknowledges that for all Patent Rights licensed under this Agreement which were funded by the U.S. federal government, (i) the U.S. federal government shall retain a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention claimed, (ii) that the license granted to Improvements shall also be subject to any overriding rights of, or requirements imposed by, the U.S. Government as set forth in 35 U.S.C. §§ 200-212, and the regulations promulgated thereunder, as amended, or any successor statutes or regulations ("Bayh-Dole Act"), and (iii) Licensee shall fulfill its obligations with regards to the Bayh-Dole Act.

ARTICLE IV

DILIGENCE

Section 4.1. Diligence.

(a) General: Licensee, upon the execution of this Agreement, shall diligently proceed with the development, manufacture, and sale of Licensed Products or Related Products, and the use and practice of Licensed Methods or Related Methods, and shall earnestly and with commercially reasonable effort endeavor to market the same within a reasonable time after execution of this Agreement and in quantities sufficient to meet the market demands therefor.

(b) Specific Diligence Provisions: Licensee shall be obligated to perform and complete by the date specified the following specific diligence provisions in order to maintain the license granted under this Agreement; provided, however, that Licensee can extend each specific diligence provision (i) and (ii) below by [**] with a payment to Licensor of $[**] per specific diligence provision, and for an additional [**], with the written consent of Licensor, with a payment to Licensor of $[**]:

(i) [**]; and

(ii) [**].

(iii) [**].

Section 4.2. Approvals. Licensee shall obtain all necessary governmental approvals for the manufacture, use and sale of Licensed Products and the practice and use of Licensed Methods.

Section 4.3. Progress Reports. Licensee shall submit to Licensor [**] progress reports, commencing on [**], detailing Licensee's activities related to the development and testing of all Licensed Products and Licensed Methods, including a summary of results thereof, and Licensee's efforts to obtain governmental approvals necessary for marketing. All information provided in this Section 4.3 shall be deemed to be Confidential Information.

ARTICLE V

LICENSE AND ROYALTY CONSIDERATION

Section 5.1. License Fee. Licensee paid Licensor [**] dollars ($[**]) at the Effective Date. Licensee has also paid Licensor [**] dollars ($[**]) for reimbursement of patent prosecution expenses for the Patent Rights incurred by Licensor prior to the Effective Date.

Section 5.2. Royalty on Sales. Licensee shall pay, or cause to be paid, to Licensor royalties of [**] percent ([**]%) of Net Selling Price of the Net Selling Price for the sale or disposition of Licensed Products or services using Licensed Methods in the U.S.

If Licensee (or its Affiliate or sublicensee) obtains a license under patent rights of a third party that are necessary for the manufacture, use or sale of a Licensed Product or Licensed Method in a country, then Licensee shall be entitled to offset [**]% of the royalties actually paid by Licensee (or its Affiliate or sublicensee) to such third party with respect to sales of such Licensed Product or Licensed Method in such country in a calendar quarter against the running royalties due to Licensor hereunder with respect to the Net Selling Price of such Licensed Product or Licensed Method (as applicable) in such country in such calendar quarter, provided that the royalties payable to Licensor with respect to such Licensed Product or Licensed Method in such country in a calendar quarter may not be reduced by more than [**]% as a result of any and all such offsets in the aggregate.

Section 5.3. Single Royalty. Nothing herein contained shall obligate Licensee to pay or cause to be paid to Licensor more than one royalty on any unit of Licensed Product or Licensed Methods.

Section 5.4. Sublicense Payments.

(a) With respect to royalties in connection with a sublicensee's sale of Licensed Products or Licensed Methods ("Sublicensee Royalties"), Licensee shall pay to Licensor an amount equal to the royalty Licensor would have received from Licensee under Section 5.2 if such sale had been made by Licensee. Such payments shall be made within [**] of receipt from sublicensee by Licensee.

(b) [**]:

(i) [**];

(ii) [**]; and

(iii) [**].

Section 5.5. Minimum Royalties. Commencing on the third anniversary of the Effective Date and on each subsequent anniversary of the Effective Date, Licensee shall pay to Licensor a minimum royalty payment in accordance with the following schedule:

(a) [**] dollars ($[**]) on the [**] anniversary of the Effective Date; and

(b) [**] dollars ($[**]) on the [**] anniversary of the Effective Date and every anniversary thereafter.

[**].

Section 5.6. Milestone Payment. Licensee shall pay Licensor within [**] of the designated event the sums set forth as follows:

(a) [**];

(b) [**];

(c) [**];

(d) [**].

For clarity, each of the foregoing milestone payments shall be payable only onetime, [**].

Section 5.7. Transaction Fee.

(a) Upon the occurrence of a Liquidation Event (as defined below), Licensee will pay Licensor a fee equal to [**]. Licensor will pay the Transaction Fee, when and if payable, within [**] after the closing of a Liquidation Event; *provided, however,* that Licensee will pay any amounts due for [**] with respect to a Liquidation Event within [**] after [**].

(b) The Transaction Fee shall be in the form of [**]. Notwithstanding the foregoing, in the event that the form of

(c) For purposes of this Section 5.7:

(i) [**].

(ii) [**].

(iii) The method of valuation of securities subject to investment letters or other similar restrictions on free marketability shall take into account an appropriate discount from the market value as determined pursuant to clause (A) or (B) above so as to reflect the approximate fair market value thereof.

(iv) For securities for which there is .no active public market, the value shall be the fair market value thereof as determined (A) in good faith by the Board of Directors of Licensee, as approved by Licensor, such approval not to be unreasonably withheld, or (B) by a third party appraiser appointed and paid for by Licensee.

(v) "Liquidation Event" means [**].

(vi) [**].

Section 5.8. Non-refundable. With the exception of payments made in error by Licensee for amounts that are not due under this Agreement, all payments made to Licensor under this Agreement are non-refundable.

ARTICLE VI

PAYMENTS

Section 6.1. Royalty Reports Due Dates. Commencing with the period including either the first sublicense agreement or the First Commercial Sale, whichever is first to occur, Licensee agrees to make written reports to Licensor quarterly within [**] after the first days of each January, April, July, and October during the Term of this Agreement ("Royalty Reports"). If no amount due has accrued during any reporting period, a written statement to that effect shall be provided.

Section 6.2. Royalty Report Contents. Royalty Reports, which shall be deemed Confidential Information under Section 10.9, shall detail the number, description, and aggregate Net Selling Prices of the Licensed Products and/or Licensed Methods sold and Licensed Products or Licensed Methods Otherwise Disposed of during the preceding three (3) calendar months for which a royalty is payable as provided in Article V and Sublicense Revenue as provided in Section 5.6. The Royalty Report shall also set forth in aggregate [**].

Section 6.3. Payment of Royalties. Concurrently with the submission of each such report, Licensee shall pay to Licensor royalties at the rate specified in Article V of this Agreement on the Licensed Products and Licensed Methods included therein, as well as Sublicense Revenue.

Section 6.4. Place of Payment and Conversion. All monies due Licensor shall be payable in United States funds at Charleston, South Carolina. When Licensed Products or Licensed Methods are sold for monies other than United States dollars, the earned royalties shall first be determined in the foreign currency of the country in which such Licensed Products or Licensed Methods were sold and then converted into equivalent United States funds. The exchange rate shall be that reported in the Wall Street Journal on the last business day of the reporting period.

Section 6.5. Foreign Taxes. Any tax for the account of Licensor required to be withheld by Licensee under the laws of any foreign country, may be deducted by Licensee from any royalty due hereunder and shall be promptly paid by Licensee for and on behalf of Licensor to the appropriate governmental authority, and Licensee shall furnish Licensor with proof of payment of such tax. Licensee shall be responsible for all bank transfer charges.

Section 6.6. Term of Royalty Payment Obligation. On a Licensed Product-by-Licensed Product or Licensed Method-by-Licensed Method and country-by-country basis, the obligation to pay royalties shall begin on the First Commercial Sale of a Licensed Product or Licensed Method in a country and expire upon the expiration (including, for such purpose, revocation, unappealable determination of unenforceability or invalidity,

abandonment, disclaimer, denial, or admission of unenforceability or invalidity, all as set forth in the definition of Valid Claim) of the last-to-expire Valid Claim of the Patent Rights covering the manufacture, use, sale, offer for sale, or import of such Licensed Product or Licensed Method in such country. For clarity, no royalty shall be payable with respect to a Licensed Product or Licensed Method in a country if, at the time of sale in such country, no Valid Claim of the Patent Rights covers any of the manufacture, use, sale, offer for sale and import of such Licensed Product or Licensed Method in such country. [**]. A Patent Right shall be deemed to expire at midnight of the latest time zone of the country of issue of the day of expiration. The Transaction Fee paid to Licensor pursuant to Section 5.7 shall be fully creditable against future royalties owed under Section 5.2.

Section 6.7. Termination Report. Licensee agrees to submit a written Royalty Report and payment to the Licensor within [**] after the date of any termination of this Agreement if the Licensee continues to sell Licensed Product and Licensed Methods in accordance with Section 8.5 of this Agreement, otherwise within [**] after the date of any termination of this Agreement, on which royalty is payable hereunder but that were not previously reported to Licensor.

Section 6.8. Late Payments. In the event any payment due hereunder is not received by Licensor within [**] of the date due, Licensee shall pay to Licensor interest charges calculated from the due date until such payment is paid at a rate equal to the lesser of (i) the prime rate as reported in The Wall Street Journal on the date such payment is due, plus an additional [**] percent per annum ([**]%), or (ii) the maximum rate allowed under applicable law.

Section 6.9. Records and Audits. Licensee shall keep or cause to be kept accurate records in sufficient detail to enable the calculation of all payments payable hereunder to be determined. All such records shall be deemed to be Confidential Information of Licensee subject to the terms and conditions of Section 10.9 hereof. During the Term and for a period of [**] following the termination of this Agreement, upon the request of Licensor (but not more frequently than [**]) an independent public accountant selected and paid by Licensor, and approved by Licensee, such approval not to be umeasonably denied, shall be allowed access, during ordinary business hours, to such records pertaining to the preceding [**] solely to verify the accuracy of royalty payments made or payable hereunder. The Parties shall mutually determine a general strategy for such audit in advance of its conduct. If any audit performed under this Section 6.9 shall indicate that any payment due hereunder was underpaid, Licensee shall promptly pay to Licensor the amount of such underpayment plus interest calculated from the due date until such underpayment is paid, at a rate equal to that specified in Section 6.8. If any audit performed under this Section 6.9 shall indicate that any payment due hereunder was overpaid, Licensor shall be entitled to a credit against future payments in the amount of such overpayment without interest. If any audit performed under this Section 6.9 shall indicate that any payment hereunder was in error to Licensor's detriment by more than [**] percent ([**]%) for any calendar year, Licensee shall pay the cost of such audit.

ARTICLE VII

PATENT PROSECUTION AND ENFORCEMENT

Section 7.1. Prosecution and Maintenance. Licensor shall apply for, seek issuance of, and maintain, during the Term of this Agreement, the Patent Rights within the Fields of Use, owned or controlled, in the United States as requested and paid for by Licensee. Prosecuting attorneys represent the Licensor and the Inventors, and shall take instruction from Licensor (after Licensor's consultation with Licensee). Licensee,

at its expense, may hire separate counsel to represent Licensee. Licensor shall cause the prosecuting attorneys, the selection of which shall be reasonably acceptable to Licensee, to provide timely copies to Licensee of all communications to and from the applicable patent offices concerning prosecution of the Patent Rights within the Fields of Use, and consult with Licensee concerning such prosecution. All such communications and consultations between the prosecuting attorneys, the Parties and/or the Inventors regarding the Patent Rights and preparation, filing, prosecution and/or maintenance of the patents and/or patent applications relating thereto shall be deemed Confidential Information under Section 10.9. In addition, the Parties acknowledge and agree that the interests of the Parties with regard to the Patent Rights and preparation, filing, prosecution and/or maintenance of the patents and/or patent applications relating thereto, are aligned and are legal in nature. The Parties agree and acknowledge that the Parties have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege, including, but not limited to, privilege under the common interest doctrine or any related doctrine.

Section 7.2. Expenses for Prosecution and Maintenance.

(a) Licensee shall pay for all reasonable patent filing, prosecution, and maintenance fees and legal expenses for the Patent Rights in the United States and in such foreign countries as requested by Licensee. Licensee shall make said payments to Licensor within [**] of receipt of an invoice from Licensor or prosecuting attorneys with said invoice including copies of the billing statements from the prosecuting attorneys. Licensor shall have the right to require reasonable advance payment or retainer by Licensee to prosecuting attorneys. In the event that advance payment or retainer is required, Licensor shall provide documentation of such request to Licensee who shall pay the required advance payment or retainer within [**] of receipt of such documentation from Licensor.

(b) Licensee shall notify Licensor of a decision to discontinue paying for prosecution or maintenance of an application or patent of the Patent Rights in a country at least [**] in advance of any applicable patent prosecution or maintenance deadline. Licensee's decision to discontinue prosecution or maintenance of an application or patent of the Patent Rights in a country shall terminate Licensee's grant in Section 3.1 to such Patent Right in such country. Licensor shall have the option but not the obligation to prosecute or maintain such Licensee discontinued application or patent at Licensor's expense.

Section 7.3. Interference. The Parties agree that inter partes reexamination type proceedings and/or interference actions conducted within the applicable patent office shall be considered part of prosecution.

Section 7.4. Prosecution of Infringement and Patent Defense.

(a) Infringement. If either Party learns of (i) any infringement or potential infringement of the Patent Rights in the Field of Use by a third party and/or (ii) any claim by a third party that a patent of the Patent Rights in the Field of Use is invalid, it shall promptly notify the other Party. In that event, as long as Licensee enjoys the exclusive license granted under Section 3.1 herein, Licensee shall have the first right, but not the obligation, at its own expense, to prosecute such infringement or to compromise or settle such claim (an "Action"). In the event that Licensee cannot prosecute or defend such Action in its own name, Licensor agrees to sign and deliver to Licensee the documents necessary for Licensee to prosecute or defend such Action in the name of Licensor. Licensee shall not compromise or settle such Action in any way that directly and adversely affects the scope, validity or enforceability of the Patent Rights, without the Licensor's prior written consent, which consent shall not be unreasonably withheld or delayed. Licensor shall reasonably

cooperate with Licensee in connection with such Action, at Licensee's expense. Any recovery that Licensee receives from such Action or the compromise or settlement thereof, shall be used to first reimburse Licensee for its out of pocket costs of prosecuting or defending the Action (but not such expenses as employee salary or overhead). The sum remaining after deduction of Licensee's out of pocket expenses shall be treated as follows: (a) for any recovery which is based upon lost sales or lost profits, Licensee shall pay to Licensor royalties in accordance with Section 5.2, based upon the Net Selling Price used to compute the recovery and (b) for any recovery based upon treble damages, Licensee shall pay Licensor [**] percent ([**]%) of the recovery. If Licensee elects to not pursue an Action, Licensor may, but shall not be required, to pursue such Action on its own, at its own expense, keeping any proceeds from such Action for itself.

(b) Defense. In the event that a legal proceeding is instituted which challenges the validity of all or a portion of the Patent Rights, and such proceeding is a result of action or conduct of the Licensee, the Licensee shall have the obligation to provide, at its own expense, a reasonable defense of the challenged Patent Rights, with counsel reasonably acceptable to the Licensor. In no event shall the Licensee take or fail to take a course of action in the defense which shall cause a loss of all or part of the Patent Rights without the Licensor's prior written consent, which consent shall not be unreasonably withheld or delayed.

(c) Licensor obligations. Licensor has no obligation to bring an action for infringement of the Patent Rights or to defend any action challenging the validity of the Patent Rights, excepting for its obligation to cooperate with an action by the Licensee under Section 7.4(a).

Section 7.5. Assertion of Invalidity of Patent Rights.

(a) In the event Licensee intends to assert in any forum that any of the Patent Rights are invalid, unenforceable, or unpatentable, Licensee shall, not less than ninety (90) days prior to making any such assertion, provide to Licensor a complete written disclosure of each and every basis then known to Licensee for such assertion and, with such disclosure, shall provide Licensor with a copy of any document or publication upon which Licensee intends to rely in support of such assertion. Licensee's failure to comply with this provision shall constitute a material breach of this Agreement.

(b) Assertion by Licensee, subsequent to the date of its execution of this Agreement, of the invalidity or unenforceability of any claim of any Patent Rights in a declaratory judgment action may, at the option of Licensor, be conclusively presumed to constitute Licensee's termination of this Agreement, as of the filing date of the declaratory judgment action, of its license in respect to such claim and of its obligation under this Agreement for payment of royalties in respect to Licensee's future operations under the claim (but not under any other claim).

ARTICLE VIII

TERM AND TERMINATION

Section 8.1. Term. This Agreement shall continue in force from the Effective Date until the expiration, abandonment, or invalidation of the last Valid Claim in the Field of Use of the Patent Rights, unless the Agreement is terminated earlier as provided for herein (the "Term").

Section 8.2. Termination by Licensee. Licensee may terminate this Agreement, and the rights and licenses granted hereunder, effective at any time by giving ninety (90) days prior notice to Licensor.

Section 8.3. Termination for Breach. In the event a Party shall be in default or breach of any material provision of this Agreement ("Breaching Party"), the other Party ("Non-Breaching Party") may give written notice of such default or breach ("Notice of Default"). If the Breaching Party fails to cure the default or breach set forth in the Notice of Default within [**], the Non-Breaching Party may elect to terminate this Agreement at any time thereafter that is within [**] of the Notice of Default by sending a notice ("Notice of Termination") which shall be effective upon the date such Notice of Termination is sufficiently given pursuant to Section 10.3.

Section 8.4. Effect of Termination. Termination of this Agreement shall not release either Party from its obligations accrued prior to the effective date of termination nor deprive either Party from any rights that survive termination as described in Section 8.6.

Section 8.5. Disposition of Inventory. Upon termination of this Agreement under Section 8.2 or, if the Licensor is the Breaching Party, under Section 8.3, Licensee shall have the privilege of disposing of all previously made or partially made Licensed Products or, if tangible, Licensed Methods within a period of [**] after termination. If termination is pursuant to Section 8.2, the sale of such Licensed Products or Licensed Methods shall be subject to the terms of this Agreement including, but not limited to, the payment of royalties earned under Section 5.2 at the rate and amount, and at the time provided herein and the rendering of reports thereon. If termination is pursuant to Section 8.3 where Licensor is alleged to be the Breaching Party and Licensor disputes the allegation, the payment of royalties earned under Section 5.2 shall be paid at the rate and amount, and at the time provided herein along with rendering of reports thereon into an escrow account controlled by an escrow agent mutually acceptable to the parties pending resolution of the dispute.

Section 8.6. Survival. The provisions of Articles V and VI shall survive termination of this Agreement, to the extent necessary, and for the time required, to effectuate the payments and obligations of Licensee which arise out of Licensee's use of its disposition of inventory rights under Section 8.5. To the extent necessary to effectuate the other surviving provisions the definitions of Article II shall survive termination or expiration of this Agreement. The provisions of Sections 6.9, 7.4(b), 8.4, 8.5, 8.6, 9.3, 9.4, 9.5, 9.6, 9.7 for a period of [**] from the later of the date of the last sale of a Licensed Product or Licensed Methods or the date of termination, 9.8, 10.3, 10.4 10.6, 10.8, 10.9, and 10.13, to the extent applicable, shall survive any termination of this Agreement.

Section 8.7. Cumulative Rights and Remedies. Any right to terminate this Agreement shall be in addition to and not in lieu of all other rights or remedies that the Party giving notice of termination may have at law or in equity or otherwise.

Section 8.8. Amicable Dispute Resolution. Any controversy or dispute arising out of or in connection with this Agreement, its interpretation, performance, or termination, but excluding validity or enforceability of Patent Rights, that the Parties are unable to resolve within [**] after written notice by one Party to the other of the existence of such controversy or dispute shall be referred to mediation. Unless the Parties agree otherwise, the mediation shall be conducted in accordance with the International Chamber of Commerce Amicable Dispute Resolution rules in effect on the date of the written notice of the existence of such controversy or dispute by a mediator mutually selected by the Parties. Within [**] after the mediator has been selected as provided above, both Parties and their respective attorneys shall meet with the mediator for one mediation session of at least [**], it being agreed that each Party representative attending such mediation session shall be a corporate officer or member of the board of directors with authority to settle the dispute. If the dispute cannot be settled at such mediation session or at any mutually agreed continuation thereof, either party may give the other and the mediator a written notice declaring the mediation process at an end.

ARTICLE IX

REPRESENTATIONS, WARRANTIES AND INDEMNIFICATION

Section 9.1. Licensor Representations and Warranties. Licensor represents and warrants to Licensee as follows:

(a) Licensor has the right, power and authority to enter into this Agreement, and has complied with all corporate formalities required for the execution of this Agreement;

(b) Licensor has received the necessary rights as of the Effective Date (including any necessary assignment or other transfer of intellectual property rights) from all necessary parties including the MUSC Entities, to enter in this Agreement; and

(c) Licensor has, if applicable, carried out the necessary steps to obtain title to any inventions subject to the Bayh-Dole Act as of the Effective Date.

Section 9.2. Licensee Representations and Warranties. Licensee represents and warrants to Licensor that it has the right, power and authority to enter into this Agreement, and has complied with all corporate formalities required for the execution of this Agreement.

Section 9.3. Warranty Limitation. **LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE SET FORTH IN SECTION 9.1, EXTENDS NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITY WHATSOEVER WITH RESPECT TO THE USE, SALE, OR OTHER DISPOSITION BY LICENSEE, AFFILIATES, SUBLICENSEES, ITS VENDEES, OR OTHER TRANSFEREES OF PRODUCTS OR METHODS INCORPORATING, MADE BY, PRACTICED OR USED PURSUANT TO (i) PATENT RIGHTS LICENSED UNDER THIS AGREEMENT OR (ii) INFORMATION, IF ANY, FURNISHED UNDER THIS AGREEMENT.** MUSC Entities shall have no liability whatsoever to Licensee, Licensee's Affiliates, sublicensees, or any other person or entity for or on account of any injury, loss, or damage, of any kind or nature, sustained by, any damage assessed or asserted against, or any other liability incurred by or imposed on Licensee, Licensee's Affiliates, sublicensee, or any other person arising out of or in connection with or resulting from (i) the manufacture, use, import, or sale of any Licensed Product or Licensed Methods, or the practice of the Patent Rights by Licensee, its distributors, its affiliates or its customers; or **(ii) any advertising or other promotional activities with respect to any of the foregoing by Licensee, its distributors, its affiliates or its customers.**

Section 9.4. Negation of Implications. Nothing in this Agreement shall be construed as (i) a warranty or representation by Licensor as to the validity or scope of any Patent Rights; (ii) a warranty or representation by Licensor that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties; (iii) granting by implication, estoppel, or otherwise any licenses or rights under patents of Licensor other than the Patent Rights in the Field of Use, regardless of whether such other patents are dominant of or subordinate to any Patent Rights; (iv) an obligation of Licensor to furnish any know-how; or (v) an obligation of Licensor to bring or prosecute actions or suits against third parties for patent infringement except as provided in Section 7.4.

Section 9.5. Damage Limitation. In no event shall either Party be liable to the other Party for any incidental, special or consequential damages resulting from the exercise of the license granted pursuant to this Agreement or due to any breach of this Agreement.

Section 9.6. Product Specifications and Warranties. MUSC Entities assume no responsibility for the product specifications, manufacture, sale or end-use of any Licensed Product or Licensed Methods which is manufactured by, or for, or sold, or otherwise disposed of by Licensee, Affiliates, or sublicensees. All warranties made or to be made, if any, in connection with Licensed Product or Licensed Methods shall be made by Licensee and none of such warranties shall directly or by implication obligate in any way the MUSC Entities.

Section 9.7. Insurance.

(a) Licensee and sublicensees shall carry general liability insurance m an amount of $[**] upon the Effective Date.

(b) Prior to the first use of a Licensed Product or Licensed Methods in humans and continuing through any time that the Licensed Product or Licensed Methods is used in humans for experimental purposes prior to first commercial sale, regardless of the jurisdiction or territory in which the first commercial sale occurs, Licensee, at its sole cost and expense, shall insure such party's activities in connection with its exercise of rights under this Agreement, through clinical trial insurance and obtain, keep in force, and maintain insurance in appropriate amounts within industry standards.

(c) Prior to first commercial sale of a Licensed Product or Licensed Methods, regardless of the jurisdiction or territory in which the first commercial sale occurs, and continuing through a period [**] following the termination of this Agreement, Licensee, at its sole cost and expense, shall insure such party's activities in connection with its exercise of rights under this Agreement through product liability insurance and obtain, keep in force, and maintain insurance in appropriate amounts within industry standards.

The coverage and limits referred to in 9.7(a), 9.7(b), and 9.7(c) above shall not in any way limit the liability of Licensee. Licensee shall furnish Licensor with certificates of insurance evidencing compliance with all requirements. Such insurance shall: (a) provide for [**] advance written notice to Licensor of any reduction of coverage; (b) indicate that Licensor has been endorsed as an additional insured under the coverage required herein; and (c) include a provision that the coverage shall be primary and shall not participate with nor shall be excess over any valid and collective insurance or program of self-insurance carried or maintained by Licensee.

Section 9.8. Indemnification. Licensee shall defend, indemnify and hold harmless MUSC Entities (each individually an "Indemnified Party," and collectively the "Indemnified Parties"), from and against any and all liabilities, losses, damages, costs or expenses (including reasonable attorneys' fees) (individually a "Liability" and collectively the "Liabilities") arising from a third-party demand, claim or action to the extent such demand, claim or action results from Licensee's, Affiliate's, or sublicensee's development, manufacture, import, use, offer to sell or sale of Licensed Products or Licensed Methods pursuant to this Agreement; provided, however, that Licensee shall have no obligation under this Section 9.8 to the extent a Liability results or arises from the gross negligence or willful misconduct of an Indemnified Party. Each Party shall promptly notify

the other of any claim or action giving rise to Liabilities subject to the provisions of this Section 9.8. Licensee shall have the right, as allowed by applicable law, to defend, settle or compromise any such demand, claim or action, at its cost and expense, and shall keep Licensor informed of developments with respect to any such demand, claim or action. Licensor shall cooperate and shall cause the Indemnified Parties to cooperate with Licensee in the defense, settlement or compromise of any such demand, claim or action. Licensee shall not settle or compromise any such demand, claim or action in a manner that admits any wrongdoing by or imposes any restrictions or obligations on an Indemnified Party, without the prior consent of such Indemnified Party, which consent shall not be unreasonably withheld.

ARTICLE X

GENERAL PROVISIONS

Section 10.1. No Waiver. No failure on the part of either Party to exercise, and no delay in exercising, any right shall be construed as a waiver thereof, nor shall any single or partial exercise by either Party of any right preclude any other future exercise thereof or the exercise of any other right.

Section 10.2. Force Majeure. If the performance of this Agreement or of any obligation hereunder (other than an obligation to make payments hereunder) is prevented, restricted or interfered with by reason of any acts or circumstances beyond the reasonable control of the obligated Party, the obligated Party shall be excused from such performance to the extent of such prevention, restriction or interference; provided, however, the obligated Party shall promptly advise the other Party of the existence of such prevention, restriction or interference, shall use its best efforts to avoid or remove such causes of nonperformance and shall continue performance hereunder whenever such causes are removed. Any nonperformance or delay of Licensee subject to this paragraph that is in excess of [**] shall constitute cause for immediate termination by Licensor of this Agreement upon written notice to Licensee and not subject to Sections 8.8 and 8.9.

Section 10.3. Notices. All notices, reports, requests or demands required or permitted under this Agreement shall be sent by certified mail or by facsimile, with confirmed transmission, properly addressed to the respective Parties as follows:

If to Licensor:
MUSC Foundation for Research Development
135 Cannon Street, Suite 101 L
Charleston, South Carolina 29425
Attn: Executive Director
Facsimile: [**]
Email: [**]

If to Licensee:
Lung Therapeutics, Inc.
2801 Via Fortuna, Suite 425
Austin, Texas 78746
Facsimile:
Email: [**]

or to such addresses as the Parties hereto may designate for such purposes during the Term. Notices shall be deemed to have been sufficiently given or made: (i) if by facsimile with confirmed transmission, when performed, and (ii) if by air courier upon receipt by the Party. Communications via email shall not constitute Notice under this Agreement, unless the Parties agree in writing to such acceptance.

Section 10.4. Independent Contractors. No agency, partnership or joint venture 1s hereby established; each Party shall act hereunder as an independent contractor. Neither Licensor nor Licensee shall enter into, or incur, or hold itself out to third parties as having authority to enter into or incur on behalf of the other Party any contractual obligations, expenses or liabilities whatsoever.

Section 10.5. Assignment. The rights and licenses granted by Licensor in this Agreement are personal to Licensee and may not be assigned or otherwise transferred (other than by sublicense in accordance with the terms hereof) without the written consent of Licensor, which consent may be given in the sole discretion of Licensor. The preceding sentence notwithstanding, Licensee may, without Licensor's consent, assign this Agreement and the license granted herein to an Affiliate or in conjunction with a merger or the sale or transfer of all of the assets associated with Licensee's performance under this Agreement. In no event, however, shall this Agreement be assigned to or run in favor of a person who or entity that, prior to the date of this Agreement, was engaged in substantial production or sale of Licensed Products or Licensed Methods. Notwithstanding any provision to the contrary, Licensor has the right to assign this Agreement to any of the MUSC Entities.

Section 10.6. Marking. Licensee shall mark or cause to be marked the Licensed Products and, if tangible, Licensed Methods, made, imported, used, offered for sale or sold pursuant to this Agreement with such references to the Patent Rights as are required by the applicable laws of the territories in which such Licensed Products or Licensed Methods are made, imported, used, offered for sale or sold.

Section 10.7. No Third-Party Beneficiary. Nothing in this Agreement, express or implied, is intended to confer on any person other than the Parties hereto, Licensee's Affiliates, and the MUSC Entities, or their respective permitted successors and assigns, any benefits, rights or remedies.

Section 10.8. Publicity. Nothing contained in this Agreement shall be construed as conferring any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either Party by the other Party (including contraction, abbreviation or simulation of any of the foregoing) without prior written approval, which approval may be given in the sole discretion of Party owning such intellectual property. Approval by e-mail shall constitute "written approval." Unless required by law, the use of the name of any MUSC Entity is expressly prohibited without prior written approval.

Section 10.9. Confidential Information. For the purpose of this Agreement, the term "Confidential Information" shall mean any information disclosed by either Party to the other pursuant to this Agreement. Each Party (i) shall hold Confidential Information it has received in confidence during the Term and for a period of [**] thereafter; (ii) shall use such Confidential Information only for performance of its obligations under this Agreement; and (iii) shall not disclose such Confidential Information to third parties without the consent of the disclosing Party. In the event that Confidential Information must be disclosed to individuals such as employees, agents, or affiliates in order to effectuate the development and commercialization of Licensed Products or Licensed Methods pursuant to this Agreement, each such individual must be bound by an obligation of confidentiality substantially the same as this Section 10.9. Licensor shall specifically be allowed to disclose Confidential Information to the MUSC Entities as required to comply with Licensor's reporting obligations to MUSC, provided that such Confidential Information shall be reported and maintained in a confidential manner. For the purposes of this Agreement, Confidential Information shall not include information that:

(a) was known to the receiving Party or its Affiliates prior to disclosure by the disclosing Party (other than through disclosure on a confidential basis by the disclosing Party or its Affiliates) as evidenced by the receiving Party's or its Affiliate's prior written records;

(b) is disclosed to the receiving Party or its Affiliates by a third party, except if such disclosure is made on a confidential basis or in violation of a confidentiality obligation to the disclosing Party or its Affiliates;

(c) is or becomes public knowledge other than by the receiving Party's breach of this confidentiality obligation;

(d) the receiving Party must disclose to government authorities for the purpose of seeking marketing approval of Licensed Products or Licensed Methods pursuant to this Agreement, but only after giving adequate advance notice to the disclosing Party;the receiving Party must disclose in connection with filing or prosecuting any patent application within the scope of the Patent Rights;

(e) the receiving Party or its Affiliates independently develops or discovers without use of or reference to the Confidential Information as evidenced by written records; or

(f) the receiving Party must disclose, pursuant to a requirement of law, provided the receiving Party has given the disclosing Party prompt notice of such fact, so the disclosing Party may obtain a protective order or other appropriate remedy concerning any such disclosure and/or waive compliance with the confidentiality obligations of this Section I 0.9. The receiving Party shall fully cooperate with the disclosing Party in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, or the disclosing Party waives such compliance, the receiving Party shall make such disclosure, but only to the extent such disclosure is legally required, and shall use its best efforts to have confidential treatment accorded to the disclosed Confidential Information.

All Confidential Information shall be returned to the disclosing Party by the receiving Party upon request by the disclosing Party upon the termination of this Agreement, with the exception of a single copy to be retained by the receiving Party in a confidential file for the purpose of determining compliance with this confidentiality obligation.

Section 10.10. Counterparts. This Agreement may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Agreement.

Section 10.11. No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

Section 10.12. Headings. The headings and titles to the Articles and Sections of this Agreement are inserted for convenience only and shall not be deemed a part hereof or affect the construction or interpretation of any provision herein.

Section 10.13. Governing Law. This Agreement, including all matters of construction, validity, and performance, shall be governed by and construed and enforced in accordance with the laws of the State of South Carolina, as applied to contracts made, executed, and to be fully performed in such state by citizens of such state, without regard to its conflict of law rules, except that questions affecting the construction and effect of any Patent Rights shall be determined by the law of the country in which the patent was granted or is being prosecuted. The Parties hereto agree that the exclusive jurisdiction and venue for any action brought between the parties under this Agreement shall be the state courts of South Carolina and the federal courts of the District of South Carolina, and each of the Parties hereby agrees and submits itself to the exclusive jurisdiction and venue of such courts for such purpose.

Section 10.14. Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with the law of any applicable jurisdiction, the validity of the remaining parts or provisions shall not be affected by such holding. In the event a part or provision of this Agreement held unenforceable or in conflict with law affects consideration to either Party, the Parties agree to negotiate in good faith amendment of such part or provision m a manner consistent with the intention of the Parties as expressed in this Agreement.

Section 10.15. Interpretation. The use in this Agreement of the term "including" means "including, without limitation." Unless otherwise specifically stated, the words "herein," "hereof," "hereunder," and other words of similar import refer to this Agreement as a whole, and not to any particular section, subsection, paragraph, subparagraph or clause contained in this Agreement.

Section 10.16. Integration. This Agreement constitutes the entire agreement between the Parties hereto relating to the subject matter hereof and supersedes all prior and contemporaneous negotiations, agreements, representations, understandings and commitments with respect thereto. No terms or provisions of this Agreement shall be varied, extended or modified by any prior or subsequent statement, conduct or act of either of the Parties, except by a written instrument specifically referring to and executed in the same manner as this Agreement.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the Parties have hereunto set their hands and seals and duly executed this Agreement the day and year set forth below.

"Licensee"	"Licensor"
LUNG THERAPEUTICS, INC.	MUSC FOUNDATION FOR RESEARCH DEVELOPMENT
/s/ Brian Windsor	/s/ Michael Rusnak
Brian Windsor Chief Executive Officer	Michael Rusnak Executive Director
Date: 02/15/19	Date: 02/22/19

Exhibit 10.5

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

LICENSE AGREEMENT
by and between
VIVARTA THERAPEUTICS, L.L.C.
and
LUNG THERAPEUTICS, INC.

THIS LICENSE AGREEMENT, (the "Agreement") effective as of March 8, 2018, (the "Effective Date") is entered into by and between Lung Therapeutics, Inc., having and address at 2801 Via Fortuna, Suite 425, Austin, TX 78746 (herein called "Licensee"), and Vivarta Therapeutics, L.L.C., a North Carolina limited liability company, having its principal place of business at 203 Woodside Glen Place, Cary, NC 27519 (herein called "Licensor"). Licensee and Licensor are sometimes hereinafter referred to collectively as the "Parties" or individually as a "Party".

In consideration of the mutual promises and covenants contained herein, the Parties hereby agree as follows:

ARTICLE I

BACKGROUND

Section 1.1. Licensor desires that its inventions be transferred to Licensee to facilitate the commercial development of products and processes related to those inventions for public use and benefit.

Section 1.2. Licensor has certain intellectual property rights as defined herein and is willing to grant licenses to Licensee pursuant to the terms of this Agreement.

Section 1.3. Licensee wishes to acquire certain license rights pursuant to the terms of this Agreement in order to develop methods and marketable products for ultimate public use and benefit by practicing the inventions licensed in this Agreement.

ARTICLE II

DEFINITIONS

As used in this Agreement, each underlined word or phrase below shall have the meaning given after it:

Section 2.1. Affiliate. Any corporation, partnership, limited liability company, joint venture or other entity that now or hereafter directly or indirectly controls, is controlled by, or is under common control with a Party. For this purpose, "control" in an Affiliate requires ownership of greater than fifty percent (50%) of: (i) voting stock of a company that issued voting stock, or (ii) ownership interest in any other enterprise. An Affiliate shall only be considered an Affiliate for so long as such control exists.

Section 2.2. Fields of Use. All fields of use of the Licensed Intellectual Property.

Section 2.3. First Commercial Sale. The first sale of any Licensed Product or Licensed Methods by Licensee or its sublicensees, following approval of its marketing by the appropriate governmental agency for the country in which the sale is to be made or, when governmental approval is not required, the first sale in that country.

Section 2.4. Intellectual Property. (i) Any patent or patent application, in any one or more countries; including, but not limited to: (A) any provisional, divisional, continuation, continuation-in-part, reexamination, reissue, extension, substitute or renewal thereof; (B) any application or patent that claims priority therefrom; (C) any foreign counterpart thereof; or (D) any underlying invention described therein; (E) any utility model or application therefor; (F) any industrial model or application therefor; (G) any certificate of invention or application therefor; (ii) any trade secret, know-how or other similar proprietary intellectual property protection or intangible legal right or interest in any one or more countries; or (iii) any other intellectual property, irrespective of whether patentable, including, but not limited to (A) any copyrights, (B) any moral right of authorship; or (C) any publicity or privacy right.

Section 2.5. Inventor. Dale Christensen, an individual resident in Cary, North Carolina.

Section 2.6. Licensed Intellectual Property. All Intellectual Property relating to epithelial sodium channel inhibitors and methods to treat pulmonary disease.

Section 2.7. Licensed Methods. Any and all methods whose practice or use, but for the licenses granted herein, would infringe or would constitute indirect infringement (including contributory or induced infringement) of the Licensed Intellectual Property.

Section 2.8. Licensed Products. Any and all products the manufacture, use, sale, offer for sale, or import of which, but for the licenses granted herein, would infringe or would constitute indirect infringement (including contributory or induced infringement) of the Licensed Intellectual Property.

Section 2.9. Net Selling Price.

[**]

Section 2.10. Other Sublicense Revenues. [**]

Section 2.11. Term. As defined in Section 8.1 hereof.

Section 2.12. Territory. Worldwide.

Section 2.13. Valid Claim. With respect to a particular country, a claim of:

(a) an issued and unexpired patent of the Licensed Intellectual Property in such country that (i) has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken or has been taken within the time allowed for appeal; (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country; and (iii) provides exclusive and enforceable rights with respect to the sale or practice of a Licensed Product or Licensed Methods, as the case may be, in such country; or

(b) a pending patent application of the Licensed Intellectual Property that has been pending without determination of final grant *(i.e.,* after the conclusion of any opposition proceeding) or issuance for less than [**] from the date of filing.

ARTICLE III

LICENSE GRANT

Section 3.1. Grant. The Licensor hereby grants to the Licensee and its Affiliates, within the Field of Use, for the Term of this Agreement as set forth in Section 8.1 an exclusive license even as against the Licensor, with the right to sublicense under the terms contained herein, in the Territory, under the Licensed Intellectual Property to make, have made, use, offer to sell, sell, have sold, and import Licensed Products and to practice and use Licensed Methods.

Section 3.2. Sublicense.

(a) Licensor hereby grants to Licensee the right to grant sublicenses through multiple tiers of sublicense in accordance with the terms of this Agreement. Licensee shall require each sublicensee to keep records and render reports as required in Sections 4.3, 6.1 and 6.9 and maintain insurance as required in Section 9.7. Except as expressly provided in this Section 3.2(a), all sublicenses shall have terms and conditions no less restrictive than those in this Agreement. Licensee shall include in each sublicense agreement a provision that identifies Licensor as an intended beneficiary thereof. Licensee shall deliver to Licensor a true copy of each sublicense within [**] after it is executed; *provided, however,* that Licensee may redact from such copy any confidential or proprietary information of Licensee or its sublicensee that is not necessary for Licensor to ascertain Licensee's compliance with this Agreement.

(b) Termination under any of the provisions of this Agreement shall terminate all sublicenses that may have been granted by Licensee, provided that any sublicensee may elect to continue its sublicense by advising Licensor in writing, within [**] of the sublicensee' s receipt of written notice of such termination, of its election, which written notice of election shall include such sublicensee's express agreement to be bound to Licensor by the terms of the sublicense agreement, subject to the following: (i) Licensor shall not have any obligations to such sublicensee other than Licensor's obligations to Licensee as set forth in this Agreement; and (ii) such sublicense agreement shall be subordinate in all respects to the applicable provisions of this Agreement; *provided, however,* that the scope of such sublicensee's direct license from Licensor shall be as set forth in the sublicense agreement and such sublicensee's financial obligations to Licensor shall be those set forth in the sublicense agreement (and not those set forth in this Agreement), except that the sublicensee shall assume Licensee's patent cost reimbursement obligations under this Agreement with respect to those of the Licensed Intellectual Property that are covered by such sublicense agreement.

(c) Any sublicense granted hereunder by Licensee shall be reasonable and for fair market value. Licensee shall be responsible for all actions and conduct of sublicensees with respect to obligations imposed by this Agreement on Licensee. If any agreement granting a sublicense hereunder also includes the grant of a license or sublicense under patent or other intellectual property rights owned by Licensee or licensed to Licensee by a third party (collectively, "Non-Vivarta Intellectual Property"), the Other Sublicense Revenues received by Licensee under such sublicense shall be fairly and equitably allocated between the Licensed Intellectual Property arid the Non-Vivarta Intellectual Property in a manner that reflects the respective contributions to the total combined value of the Licensed Intellectual Property and the Non-Vivarta Intellectual Property, which allocation shall be mutually agreed by the parties in writing (such agreement not to be unreasonably withheld or delayed), and only the portion of such Other Sublicense Revenues that is so allocated to the Licensed Intellectual Property shall be considered "Other Sublicense Revenues" for purposes of Section 5.4(b).

ARTICLE IV

DILIGENCE

Section 4.1. Diligence. Licensee, upon the execution of this Agreement, shall diligently proceed with the development, manufacture, and sale of Licensed Products and the use and practice of Licensed Methods, and shall earnestly and with commercially reasonable effort endeavor to market the same within a reasonable time after execution of this Agreement and in quantities sufficient to meet the market demands therefor.

Section 4.2. Approvals. Licensee shall obtain all necessary governmental approvals for the manufacture, use and sale of Licensed Products and the practice and use of Licensed Methods.

ARTICLE V

LICENSE AND ROYALTY CONSIDERATION

Section 5.1. License Fee. Licensee will pay Licensor ten thousand dollars ($10,000) at the Effective Date. Licensee will also pay Licensor forty thousand dollars ($40,000) within thirty (30) days following Licensee's receipt of a positive Freedom to Operate (FTO) analysis from Licensee's legal counsel.

Section 5.2. Royalty on Sales. Licensee shall pay, or cause to be paid, to Licensor royalties on the Net Selling Price of Licensed Products and Licensed Methods sold or disposed of by Licensee or its Affiliates in the amount of [**] percent ([**]%) of Net Selling Price. If Licensee (or its Affiliate or sublicensee) obtains a license under intellectual property rights of a third party that are necessary for the manufacture, use or sale of a Licensed Product or Licensed Method in a

country, then Licensee shall be entitled to offset [**]% of the royalties actually paid by Licensee (or its Affiliate or sublicensee) to such third party with respect to sales of such Licensed Product or Licensed Method in such country in a calendar quarter against the running royalties due to Licensor hereunder with respect to the Net Selling Price of such Licensed Product or Licensed Method (as applicable) in such country in such calendar quarter, provided that the royalties payable to Licensor with respect to such Licensed Product or Licensed Method in such country in a calendar quarter may not be reduced by more than [**]% as a result of any and all such offsets in the aggregate.

Section 5.3. Single Royalty. Nothing herein contained shall obligate Licensee to pay or cause to be paid to Licensor more than one royalty on any unit of Licensed Product or Licensed Methods.

Section 5.4. Sublicense Payments.

(a) With respect to royalties m connection with a sublicensee's sale of Licensed Products or Licensed Methods ("Sublicensee Royalties"), Licensee shall pay to Licensor an amount equal to the royalty Licensor would have received from Licensee under Section 5.2 if such sale had been made by Licensee. Such payments shall be made within [**] of receipt from sublicensee by Licensee.

(b) Licensee shall pay to Licensor a percentage of all Other Sublicense Revenues received (or, where Non-Vivarta Intellectual Property is licensed or sublicensed in conjunction with the grant of a sublicense under the Licensed Intellectual Property, the applicable allocation of Other Sublicense Revenues received as determined in accordance with the definition of "Other Sublicense Revenues"). The percentage paid by Licensee to Licensor of all Other Sublicense Revenues (or the applicable allocation thereof) will be calculated in accordance with the following schedule:

(i) [**] percent ([**]%) for sublicenses granted prior to [**];

(ii) [**] percent ([**]%) for sublicenses granted prior to [**];

(iii) [**] percent [**]%) for sublicenses granted after [**];

(iv) [**] percent ([**]%) for sublicenses granted after [**]; and

(v) [**] percent ([**]%) for sublicenses granted after [**].

Section 5.5. Milestone Payment. Licensee shall pay Licensor within [**] of the first achievement of the designated event the corresponding sum set forth below:

[**].

For clarity, each of the foregoing milestone payments shall be payable only one time, for the first achievement of the applicable milestone event by the first License Product to achieve such milestone event.

Section 5.6. Warrant Issuance. Licensee agrees to issue to Licensor at the Effective Date a ten-year warrant to purchase an aggregate of 75,000 shares of Licensor's Common Stock, par value $0.0001, for $0.12 per share.

ARTICLE VI

PAYMENTS

Section 6.1. Royalty Reports Due Dates. Commencing with the period including either the first sublicense agreement or the First Commercial Sale, whichever is first to occur, Licensee agrees to make written reports to Licensor quarterly within [**] after the first day of each calendar quarter each January, April, July, and October during the Term of this Agreement ("Royalty Reports"). If no amount due has accrued during any reporting period, a written statement to that effect shall be provided.

Section 6.2. Royalty Report Contents. Royalty Reports, which shall be deemed Confidential Information under Section 10.9, shall detail (i) the number, description, and aggregate Net Selling Prices of the Licensed Products and/or Licensed Methods sold during the preceding calendar quarter for which a royalty is payable as provided in Article V and (ii) Other Sublicense Revenue as provided in Section 5.4. The Royalty Report shall also set forth in aggregate (i) actual amounts received by Licensee or its sublicensees for Licensed Products and/or Licensed Methods, during the preceding quarter in each country in which Licensed Products and/or Licensed Methods were sold, segmented on a country-by-country basis; (ii) deductions itemized by category from such actual amounts paid to arrive at Net Selling Prices; (iii) the currency conversion rate used and the U.S. dollar-equivalent of such Net Selling Prices; (iv) the calculation of royalties thereon; (v) any deductions or royalty offsets allowed hereunder; and (vi) all Other Sublicense Revenues and the calculation of amount due to Licensor thereunder; *provided, however,* that in the case of actual amounts paid and deductions from such actual amounts paid for the Net Selling Price of Licensed Products sold by a sublicensee, if such sublicensee does not account for or report actual amounts paid or deductions from actual amounts paid on a product-by-product and country-by-country basis in certain regions, or does not account for or report deductions from such amounts on an itemized basis, then, in each case, Licensee's report regarding such sublicensee's actual amounts paid, deductions from actual amounts paid, and Net Sales need contain only the same level of detail that is reported to Licensee by such sublicensee.

Section 6.3. Payment of Royalties. Concurrently with the submission of each such report, Licensee shall pay to Licensor royalties at the rate specified in Article V of this Agreement on the Licensed Products and Licensed Methods included therein, as well as Sublicense Revenue**.**

Section 6.4. Place of Payment and Conversion. All monies due Licensor shall be payable in United States funds at Cary, North Carolina. When Licensed Products or Licensed Methods are sold for monies other than United States dollars, the earned royalties shall first be determined in the foreign currency of the country in which such Licensed Products or Licensed Methods were sold and then converted into equivalent United States funds. The exchange rate shall be the rate used by the reporting party (i.e., Licensee or its Affiliate or sublicensee) for its financial reporting purposes in accordance with Generally Accepted Accounting Principles (or foreign equivalent) or, in the absence of such rate, that reported in the Wall Street Journal on the last business day of the reporting period.

Section 6.5. Foreign Taxes. Any tax for the account of Licensor required to be withheld by Licensee under the laws of any foreign country, may be deducted by Licensee from any royalty due hereunder and shall be promptly paid by Licensee for and on behalf of Licensor to the appropriate governmental authority, and Licensee shall furnish Licensor with proof of payment of such tax. Licensee shall be responsible for all bank transfer charges.

Section 6.6. Term of Royalty Payment Obligation. On a Licensed Product-by-Licensed Product or Licensed Method-by-Licensed Method and country-by-country basis, the obligation to pay royalties shall begin on the first commercial sale of a Licensed Product or Licensed Method in a country and expire upon the earlier of twenty (20) years after the Effective Date or the expiration (including, for such purpose, revocation, unappealable determination of unenforceability or invalidity, abandonment, disclaimer, denial, or admission of unenforceability or invalidity, all as set forth in the definition of Valid Claim) of the last-to-expire Valid Claim of the Licensed Intellectual Property covering the manufacture, use, sale, offer for sale, or import of such Licensed Product or Licensed Method in such country. For clarity, no royalty shall be payable with respect to a Licensed Product or Licensed Method in a country if, at the time of sale in such country, no Valid Claim of the Licensed Intellectual Property covers any of the manufacture, use, sale, offer for sale and import of such Licensed Product or Licensed Method in such country. Upon expiration

of Licensee's obligation to pay royalties with respect to a Licensed Product or Licensed Method in a country, the license granted to Licensee hereunder with respect to such Licensed Product or Licensed Method in such country shall become royalty-free, fully-paid, irrevocable and perpetual; provided, however, that royalties accrued but not paid prior to such expiration shall be payable with the next report made under the provisions of this Article VI.

Section 6.7. Termination Report. Licensee agrees to submit a written Royalty Report and payment to the Licensor within [**] after the date of any termination of this Agreement if the Licensee continues to sell Licensed Product and Licensed Methods in accordance with Section 8.5 of this Agreement, otherwise within [**] after the date of any termination of this Agreement, on which royalty is payable hereunder but that were not previously reported to Licensor.

Section 6.8. Late Payments. In the event any payment due hereunder is not received by Licensor within [**] of the date due, Licensee shall pay to Licensor interest charges calculated from the due date until such payment is paid at a rate equal to the lesser of (i) the prime rate as reported in The Wall Street Journal on the date such payment is due, plus an additional [**] percent per annum ([**]%), or (ii) the maximum rate allowed under applicable law.

Section 6.9. Records and Audits. Licensee shall keep or cause to be kept accurate records in sufficient detail to enable the calculation of all payments payable hereunder to be determined. All such records shall be deemed to be Confidential Information of Licensee subject to the terms and conditions of Section 10.9 hereof. During the Term and for a period of [**] following the termination of this Agreement, upon the request of Licensor (but not more frequently than [**]) an independent public accountant selected and paid by Licensor, and approved by Licensee, such approval not to be unreasonably denied, shall be allowed access, during ordinary business hours, to such records pertaining to the preceding [**] solely to verify the accuracy of royalty payments made or payable hereunder. The Parties shall mutually determine a general strategy for such audit

in advance of its conduct. If any audit performed under this Section 6.9 shall indicate that any payment due hereunder was underpaid, Licensee shall promptly pay to Licensor the amount of such underpayment plus interest calculated from the due date until such underpayment is paid, at a rate equal to that specified in Section 6.8. If any audit performed under this Section 6.9 shall indicate that any payment due hereunder was overpaid, Licensor shall be entitled to a credit against future payments in the amount of such overpayment without interest. If any audit performed under this Section 6.9 shall indicate that any payment hereunder was in error to Licensor's detriment by more than [**] percent ([**] %) for any calendar year, Licensee shall pay the cost of such audit.

ARTICLE VII

PATENT PROSECUTION AND ENFORCEMENT

Section 7.1. Prosecution and Maintenance. Licensor shall apply for, seek issuance of, and maintain, during the Term of this Agreement, the Licensed Intellectual Property within the Fields of Use, owned or controlled, in the United States, and in such foreign countries as requested by Licensee, as requested and paid for by Licensee. Prosecuting attorneys jointly represent the Licensor and Licensee, and shall take instruction from Licensee (after Licensee's consultation with Licensor). In the event that the Licensor and Licensee disagree about the instructions to the prosecuting attorneys, Licensor shall in all instances defer to Licensee so long as claims are not reduced by Licensee except as required by patent examiners for the express purpose of issuance of claims. Licensor, at its expense, may hire separate counsel to represent Licensor. Licensee shall cause the prosecuting attorneys, the selection of which shall be reasonably acceptable to Licensor, to provide timely copies to Licensor of all communications to and from the applicable patent offices concerning prosecution of the Licensed Intellectual Property within the Fields of Use, and consult with Licensor concerning such prosecution. All such communications and consultations between the prosecuting attorneys, the Parties and/or the Inventor regarding the Licensed Intellectual

Property and preparation, filing, prosecution and/or maintenance of the patents and/or patent applications relating thereto shall be deemed Confidential Information under Section 10.9. In addition, the Parties acknowledge and agree that the interests of the Parties with regard to the Licensed Intellectual Property and preparation, filing, prosecution and/or maintenance of the patents and/or patent applications relating thereto, are aligned and are legal in nature. The Parties agree and acknowledge that the Parties have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege, including, but not limited to, privilege under the common interest doctrine or any related doctrine.

Section 7.2. Expenses for Prosecution and Maintenance.

(a) Licensee shall pay all patent filing, prosecution, and maintenance fees and legal expenses for the Licensed Intellectual Property in the United States and in such foreign countries as determined by Licensee. Licensee shall make said payments within [**] of receipt of the billing statements from the prosecuting attorneys.

(b) Licensee shall notify Licensor of a decision to discontinue paying for prosecution or maintenance of an application or patent of the Licensed Intellectual Property in a country at least [**] in advance of any applicable patent prosecution or maintenance deadline. Licensee's decision to discontinue prosecution or maintenance of an application or patent of the Licensed Intellectual Property in a country shall terminate Licensee's grant in Section 3.1 to such Licensed Intellectual Property in such country. Licensor shall have the option but not the obligation to prosecute or maintain such Licensee discontinued application or patent at Licensor's expense.

Section 7.3. Interference. The Parties agree that inter partes reexamination type proceedings and/or interference actions conducted within the applicable patent office shall be considered part of prosecution.

Section 7.4. Prosecution oflnfringement and Patent Defense.

(a) Infringement. If either Party learns of (i) any infringement or potential infringement of the Licensed Intellectual Property in the Field of Use by a third party and/or (ii) any claim by a third party that a patent of the Licensed Intellectual Property in the Field of Use is invalid, it shall promptly notify the other Party. In that event, as long as Licensee enjoys the exclusive license granted under Section 3.1 herein, Licensee shall have the first right, but not the obligation, at its own expense, to prosecute such infringement or to compromise or settle such claim (an "Action"). If Licensee cannot prosecute or defend such Action in its own name, Licensor agrees to sign and deliver to Licensee the documents necessary for Licensee to prosecute or defend such Action in the name of Licensor. Licensee shall not compromise or settle such Action in any way that directly and adversely affects the scope, validity or enforceability of the Licensed Intellectual Property, without the Licensor's prior written consent, which consent shall not be umeasonably withheld or delayed. Licensor shall reasonably cooperate with Licensee in connection with such Action, at Licensee's expense. Any recovery that Licensee receives from such Action or the compromise or settlement thereof, shall be used to first reimburse Licensee for its out of pocket costs of prosecuting or defending the Action (but not such expenses as employee salary or overhead). The sum remaining after deduction of Licensee's out of pocket expenses shall be treated as follows: (a) for any recovery which is based upon lost sales or lost profits, Licensee shall pay to Licensor royalties in accordance with Section 5.2, based upon the Net Selling Price used to compute the recovery and (b) for any recovery based upon treble damages, Licensee shall pay Licensor [**] percent ([**]%) of the recovery. If Licensee elects to not pursue an Action, Licensor may, but shall not be required, to pursue such Action on its own, at its own expense, keeping any proceeds from such Action for itself.

(b) Defense. If a legal proceeding is instituted that challenges the validity of all or a portion of the Licensed Intellectual Property, and such proceeding is a direct result of action or conduct of the Licensee, the Licensee shall have the obligation to provide, at its own expense, a reasonable defense of the challenged Licensed Intellectual Property, with counsel reasonably acceptable to the Licensor. In no event shall the Licensee take or fail to take a course of action in the defense which shall cause a loss of all or part of the Licensed Intellectual Property without the Licensor's prior written consent, which consent shall not be unreasonably withheld or delayed.

(c) Licensor Obligations. Licensor has no obligation to bring an action for infringement of the Licensed Intellectual Property or to defend any action challenging the validity of the Licensed Intellectual Property, excepting for its obligation to cooperate with an action by the Licensee under Section 7.4(a).

Section 7.5. Assertion of lnvalidity of Licensed Intellectual Property.

(a) In the event Licensee intends to assert in any forum that any of the Licensed Intellectual Property is invalid, unenforceable, or unpatentable, Licensee shall, not less than [**] prior to making any such assertion, provide to Licensor a complete written disclosure of each and every basis then known to Licensee for such assertion and, with such disclosure, shall provide Licensor with a copy of any document or publication upon which Licensee intends to rely in support of such assertion. Licensee's failure to comply with this provision shall constitute a material breach of this Agreement.

(b) Assertion by Licensee, subsequent to the date of its execution of this Agreement, of the invalidity or unenforceability of any claim of any Licensed Intellectual Property in a declaratory judgment action may, at the option of Licensor, be conclusively presumed to constitute Licensee's termination of this Agreement, as of the filing date of the declaratory judgment action, of its license in respect to such claim and of its obligation under this Agreement for payment of royalties in respect to Licensee's future operations under the claim (but not under any other claim).

ARTICLE VIII

TERM AND TERMINATION

Section 8.1. Term. This Agreement shall continue in force from the Effective Date until the Agreement is terminated as provided for herein (the "Term").

Section 8.2. Termination by Licensee. Licensee may terminate this Agreement, and the rights and licenses granted hereunder, effective at any time by giving ninety (90) days prior notice to Licensor.

Section 8.3. Termination for Breach. In the event a Party shall be in default or breach of any material provision of this Agreement ("Breaching Party"), the other Party ("Non-Breaching Party") may give written notice of such default or breach ("Notice of Default"). If the Breaching Party fails to cure the default or breach set forth in the Notice of Default within [**], the Non-Breaching Party may elect to terminate this Agreement at any time thereafter that is within [**] of the Notice of Default (and prior to the Breaching Party's cure of the applicable default or breach if cured within such [**] period) by sending a notice ("Notice of Termination") which shall be effective upon the date such Notice of Termination is sufficiently given pursuant to Section 10.3. For clarity, the Non-Breaching Party shall not have the right to send a Notice of Termination after the Breaching Party's cure of the applicable default or breach.

Section 8.4. Effect of Termination. Termination of this Agreement shall not release either Party from its obligations accrued prior to the effective date of termination nor deprive either Party from any rights that survive termination as described in Section 8.6.

Section 8.5. Disposition of Inventory. Upon any termination of this Agreement prior to its expiration, Licensee shall have the privilege of disposing of all previously made or partially made Licensed Products or, if tangible, Licensed Methods within a period of [**] after termination. The sale of such Licensed Products or Licensed Methods shall be subject to the terms of this Agreement including, but not limited to, the payment of royalties earned under Section 5.2 at the rate and amount, and at the time provided herein and the rendering of reports thereon.

Section 8.6. Survival. Termination or expiration of this Agreement for any reason shall not release either Party from any liabilities or obligations set forth in this Agreement that either (i) the Parties have expressly agreed shall survive any such termination or expiration, or (ii) remain to be performed or by their nature would be intended to be applicable following any such termination or expiration.

Section 8.7. Cumulative Rights and Remedies. Any right to terminate this Agreement shall be in addition to and not in lieu of all other rights or remedies that the Party giving notice of termination may have at law or in equity or otherwise.

Section 8.8. Amicable Dispute Resolution. Any controversy or dispute arising out of or m connection with this Agreement, its interpretation, performance, or termination, but excluding validity or enforceability of Licensed Intellectual Property, that the Parties are unable to resolve within [**] after written notice by one Party to the other of the existence of such controversy or dispute shall be referred to mediation. Unless the Parties agree otherwise, the mediation shall be conducted in accordance with the International Chamber of Commerce Amicable Dispute Resolution rules in effect on the date of the written notice of the existence of such controversy or dispute by a mediator mutually selected by the Parties. Within [**] after the mediator has been selected as provided above, both Parties and their respective attorneys shall meet with the mediator for one mediation session of at least [**], it being agreed that each Party representative attending such mediation session shall be a corporate officer or member of the board of directors with authority to settle the dispute. If the dispute cannot be settled at such mediation session or at any mutually agreed continuation thereof, either party may give the other and the mediator a written notice declaring the mediation process at an end.

ARTICLE IX

REPRESENTATIONS, WARRANTIES AND INDEMNIFICATION

Section 9.1. Licensor Representations and Warranties. Licensor represents and warrants to Licensee as follows:

(a) Licensor has the right, power and authority to enter into this Agreement, and has complied with all corporate formalities required for the execution of this Agreement;

(b) Licensor is the sole and exclusive owner of all right, title and interest in and to the Licensed Intellectual Property, and Licensor has the right to grant and assign, as applicable, to Licensee all rights and licenses granted and assigned, as applicable, under this Agreement;

(c) Licensor has good title to the Licensed Intellectual Property, free and clear of all liens, claims, security interests, pledges and other encumbrances, including without limitation any liens, claims, security interests, pledges and other encumbrances of Inventor's former employer, Spyryx Biosciences, Inc.;

(d) Licensor is not a party to any agreement that conflicts with this Agreement, and Licensor has not granted to any third party any right, license, or privilege that conflicts with, or that would be breached or otherwise violated by, this Agreement;

(e) Licensor is an Accredited Investor (as defined in Rule 501 of Regulation D promulgated under the Securities Act of 1933, as amended).

Section 9.2. Licensee Representations and Warranties. Licensee represents and warrants to Licensor that it has the right, power and authority to enter into this Agreement, and has complied with all corporate formalities required for the execution of this Agreement.

Section 9.3. Warranty Limitation. LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE SET FORTH IN SECTION 9.1, EXTENDS NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND ASSUMES NO RESPONSIBILITY WHATSOEVER WITH RESPECT TO THE USE, SALE, OR OTHER DISPOSITION BY LICENSEE, AFFILIATES, SUBLICENSEES, ITS VENDEES, OR OTHER TRANSFEREES OF PRODUCTS OR METHODS INCORPORATING, MADE BY, PRACTICED OR USED PURSUANT TO (i) LICENCED INTELLECTUAL PROPERTY LICENSED UNDER THIS AGREEMENT OR (ii) INFORMATION, IF ANY, FURNISHED UNDER THIS AGREEMENT. Licensor shall have no liability whatsoever to Licensee, Licensee's Affiliates, sublicensees, or any other person or entity for or on account of any injury, loss, or damage, of any kind or nature, sustained by, any damage assessed or asserted against, or any other liability incurred by or imposed on Licensee, Licensee's Affiliates, sublicensee, or any other person arising out of or in connection with or resulting from (i) the manufacture, use, import, or sale of any Licensed Product or Licensed Methods, or the practice of the Licensed Intellectual Property by Licensee, its distributors, its affiliates or its customers; or (ii) any advertising or other promotional activities with respect to any of the foregoing by Licensee, its distributors, its affiliates or its customers.

Section 9.4. Negation of lmplications. Nothing in this Agreement shall be construed as (i) a warranty or representation by Licensor as to the validity or scope of any Licensed Intellectual Property; (ii) a warranty or representation by Licensor that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or shall be free from infringement of patents of third parties; or (iii) an obligation of Licensor to bring or prosecute actions or suits against third parties for patent infringement except as provided in Section 7.4.

Section 9.5. Damage Limitation. In no event shall either Party be liable to the other Party for any incidental, special or consequential damages resulting from the exercise of the license granted pursuant to this Agreement or due to any breach of this Agreement.

Section 9.6. Product Specifications and Warranties. Licensor assumes no responsibility for the product specifications, manufacture, sale or end-use of any Licensed Product or Licensed Methods that are manufactured by, or for, or sold, or otherwise disposed of by Licensee, Affiliates, or sublicensees. All warranties made or to be made, if any, in connection with Licensed Product or Licensed Methods shall be made by Licensee and none of such warranties shall directly or by implication obligate in any way Licensor.

Section 9.7. Insurance.

(a) Licensee and sublicensees shall carry general liability msurance m an amount of $[**] upon the Effective Date.

(b) Prior to the first use of a Licensed Product or Licensed Methods in humans and continuing through any time that the Licensed Product or Licensed Methods is used in humans for experimental purposes prior to first commercial sale, regardless of the jurisdiction or territory in which the first commercial sale occurs, Licensee, at its sole cost and expense, shall insure such party's activities in connection with its exercise of rights under this Agreement, through clinical trial insurance and obtain, keep in force, and maintain insurance in appropriate amounts within industry standards.

(c) Prior to first commercial sale, regardless of the jurisdiction or territory in which the first commercial sale occurs, and continuing through a period [**] following the termination of this Agreement, Licensee, at its sole cost and expense, shall insure such party's activities in connection with its exercise of rights under this Agreement through product liability insurance and obtain, keep in force, and maintain insurance in appropriate amounts within industry standards.

Section 9.8. Indemnification. Licensee shall defend, indemnify and hold harmless Licensor and its Affiliates (each individually an "Indemnified Party," and collectively the "Indemnified Parties"), from and against any and all liabilities, losses, damages, costs or expenses (including reasonable attorneys' fees) (individually a "Liability" and collectively the "Liabilities") arising from a third-party demand, claim or action to the extent such demand, claim or action results from Licensee's, Affiliate's, or sublicensee's development, manufacture, import, use, offer to sell or sale of Licensed Products or Licensed Methods pursuant to this Agreement; *provided, however,* that Licensee shall have no obligation under this Section 9.8 to the extent a Liability results or arises from the negligence or willful misconduct of an Indemnified Party. Each Party shall promptly notify the other of any claim or action giving rise to Liabilities subject to the provisions of this Section 9.8. Licensee shall have the right, as allowed by applicable law, to defend, settle or compromise any such demand, claim or action, at its cost and expense, and shall keep Licensor informed of developments with respect to any such demand, claim or action. Licensor shall cooperate and shall cause the Indemnified Parties to cooperate with Licensee in the defense, settlement or compromise of any such demand, claim or action. Licensee shall not settle or compromise any such demand, claim or action in a manner that admits any wrongdoing by or imposes any restrictions or obligations on an Indemnified Party, without the prior consent of such Indemnified Party, which consent shall not be unreasonably withheld.

ARTICLEX

GENERAL PROVISIONS

Section 10.1. No Waiver. No failure on the part of either Party to exercise, and no delay in exercising, any right shall be construed as a waiver thereof, nor shall any single or partial exercise by either Party of any right preclude any other future exercise thereof or the exercise of any other right.

Section 10.2. Force Majeure. If the performance of this Agreement or of any obligation hereunder (other than an obligation to make payments hereunder) is prevented, restricted or interfered with by reason of any acts or circumstances beyond the reasonable control of the obligated Party, the obligated Party shall be excused from such performance to the extent of such prevention, restriction or interference; *provided, however,* the obligated Party shall promptly advise the other Party of the existence of such prevention, restriction or interference, shall use its best efforts to avoid or remove such causes of nonperformance and shall continue performance hereunder whenever such causes are removed.

Section 10.3. Notices. All notices, reports, requests or demands required or permitted under this Agreement shall be sent by certified mail or by air courier, properly addressed to the respective Parties as follows:

If to Licensor:

Vivarta Therapeutics, L.L.C.
203 Woodside Glen Place
Cary, North Carolina 27519
Email: [**]

If to Licensee:

Lung Therapeutics, Inc.
2801 Via Fortuna, Suite 425
Austin, Texas 78746
Email: [**]

or to such addresses as the Parties hereto may designate for such purposes during the Term. Notices shall be deemed to have been sufficiently given or made upon receipt by the Party. Communications via email shall not constitute Notice under this Agreement, unless the Parties agree in writing to such acceptance.

Section 10.4. Independent Contractors. No agency, partnership or joint venture 1s hereby established; each Party shall act hereunder as an independent contractor. Neither Licensor nor Licensee shall enter into, or incur, or hold itself out to third parties as having authority to enter into or incur on behalf of the other Party any contractual obligations, expenses or liabilities whatsoever.

Section 10.5. Assignment. Licensee shall have the right, without the consent of Licensor, to assign or transfer this Agreement or any or all of its rights hereunder to any person, provided that such person expressly assumes the relevant and corresponding obligations of this Agreement. Any assignment in derogation of the foregoing shall be void.

Section 10.6. Marking. Licensee shall mark or cause to be marked the Licensed Products and, if tangible, Licensed Methods, made, imported, used, offered for sale or sold pursuant to this Agreement with such references to the Licensed Intellectual Property as are required by the applicable laws of the territories in which such Licensed Products or Licensed Methods are made, imported, used, offered for sale or sold.

Section 10.7. No Third-Party Beneficiary. Nothing m this Agreement, express or implied, is intended to confer on any person other than the Parties hereto, Licensee's Affiliates, and Licensor's Affiliates, or their respective permitted successors and assigns, any benefits, rights or remedies.

Section 10.8. Publicity. Nothing contained in this Agreement shall be construed as conferring any right to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of either Party by the other Party (including contraction, abbreviation or simulation of any of the foregoing) without prior written approval, which approval may be given in the sole discretion of Party owning such intellectual property. Approval by e-mail shall constitute "written approval."

Section 10.9. Confidential Information. For the purpose of this Agreement, the term "Confidential Information" shall mean, with respect to a Party, any information disclosed by such Party (for such purpose, the "Disclosing Party") to the other Party (the "Receiving Party") pursuant to this Agreement. The Receiving Party (i) shall hold Confidential Information it has received in confidence during the Term and for a period of [**] thereafter; (ii) shall use such Confidential Information only for performance of its obligations under this Agreement; and (iii) shall not disclose such Confidential Information to third parties without the consent of the Disclosing Party. If Confidential Information of Licensor must be disclosed by Licensee to individuals such as employees, agents, or Affiliates to effectuate the development and commercialization of Licensed Products or Licensed Methods pursuant to this Agreement, each such individual must be bound by an obligation of confidentiality substantially the same as this Section 10.9. For the purposes of this Agreement, Confidential Information shall not include information that:

(a) was known to the Receiving Party or its Affiliates prior to disclosure by the Disclosing Party (other than through disclosure on a confidential basis by the Disclosing Party or its Affiliates) as evidenced by the Receiving Party's or its Affiliate's prior written records;

(b) is disclosed to the Receiving Party or its Affiliates by a third party, except if such disclosure is made on a confidential basis or in violation of a confidentiality obligation to the Disclosing Party or its Affiliates;

(c) is or becomes public knowledge other than by the Receiving Party's breach of this confidentiality obligation;

(d) in the case of Licensee as the Receiving Party, must be disclosed to government authorities for the purpose of seeking marketing approval of Licensed Products or Licensed Methods pursuant to this Agreement;

(e) the Receiving Party must disclose in connection with filing or prosecuting any patent application within the scope of the Licensed Intellectual Property; or

(f) the Receiving Party or its Affiliates independently develops or discovers without use of or reference to the Confidential Information as evidenced by written records.

In addition, the Receiving Party shall not be prohibited from disclosing Confidential Information that it must disclose, pursuant to a requirement of law, provided the Receiving Party has given the Disclosing Party prompt notice of such fact, so the Disclosing Party may obtain a protective order or other appropriate remedy concerning any such disclosure and/or waive compliance with the confidentiality obligations of this Section 10.9. The Receiving Party shall fully cooperate with the Disclosing Party in connection with the Disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, or the Disclosing Party waives such compliance, the Receiving Party shall make such disclosure, but only to the extent such disclosure is legally required, and shall use reasonable efforts to have confidential treatment accorded to the disclosed Confidential Information.

All Confidential Information shall be returned to the Disclosing Party by the Receiving Party upon request by the Disclosing Party upon the termination of this Agreement, with the exception of a single copy to be retained by the Receiving Party in a confidential file for the purpose of determining compliance with this confidentiality obligation.

Section 10.10. Counterparts. This Agreement may be signed in any number of counterparts with the same effect as if the signatures to each counterpart were upon a single instrument, and all such counterparts together shall be deemed an original of this Agreement.

Section 10.11. No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

Section 10.12. Headings. The headings and titles to the Articles and Sections of this Agreement are inserted for convenience only and shall not be deemed a part hereof or affect the construction or interpretation of any provision herein.

Section 10.13. Governing Law. This Agreement, including all matters of construction, validity, and performance, shall be governed by and construed and enforced in accordance with the laws of the State of New York, as applied to contracts made, executed, and to be fully performed in such state by citizens of such state, without regard to its conflict of law rules, except that questions affecting the construction and effect of any Licensed Intellectual Property shall be determined by the law of the country in which the patent was granted or is being prosecuted. The Parties hereto agree that the exclusive jurisdiction and venue for any action brought between the parties under this Agreement shall be the state courts or federal courts of New York, and each of the Parties hereby agrees and submits itself to the exclusive jurisdiction and venue of such courts for such purpose.

Section 10.14. Severability. Should any part or provision of this Agreement be held unenforceable or in conflict with the law of any applicable jurisdiction, the validity of the remaining parts or provisions shall not be affected by such holding. In the event a part or provision of this Agreement held unenforceable or in conflict with law affects consideration to either Party, the Parties agree to negotiate in good faith amendment of such part or provision in a manner consistent with the intention of the Parties as expressed in this Agreement.

Section 10.15. Interpretation. The use in this Agreement of the term “including” means “including, without limitation.” Unless otherwise specifically stated, the words “herein,” “hereof,” “hereunder,” and other words of similar import refer to this Agreement as a whole, and not to any particular section, subsection, paragraph, subparagraph or clause contained in this Agreement.

Section 10.16. Integration. This Agreement constitutes the entire agreement between the Parties hereto relating to the subject matter hereof and supersedes all prior and contemporaneous negotiations, agreements, representations, understandings and commitments with respect thereto. No terms or provisions of this Agreement shall be varied, extended or modified by any prior or subsequent statement, conduct or act of either of the Parties, except by a written instrument specifically referring to and executed in the same manner as this Agreement.

SIGNATURE PAGE TO FOLLOW

IN WITNESS WHEREOF, the Parties have hereunto set their hands and seals and duly executed this Agreement the day and year set forth below.

"Licensee"	"Licensor"
LUNG THERAPEUTICS, INC.	VIVARTA THERAPEUTICS, LLC
/s/ Brian Windsor	/s/ Dale Christensen
Brian Windsor	Dale Christensen
Chief Executive Officer Date: 03/08/2018	Manager Date 08 Mar 2018