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

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934 (Amendment No.)

Filed by the Registrant ☒ Filed by a Party other than the Registrant ☐

Check the appropriate box:

☒ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

☐ Definitive Proxy Statement

☐ Definitive Additional Materials

☐ Soliciting Material Pursuant to §240.14a-12

AILERON THERAPEUTICS, INC.
(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

Payment of Filing Fee (Check the appropriate box):

☒ No fee required.

☐ Fee paid previously with preliminary materials.

☐ Fee computed on table in exhibit required by Item 2(b) per Exchange Act Rules 14a-6(i)(1) and 0-11.

Preliminary Proxy Statement – Subject to Completion

AILERON THERAPEUTICS, INC.
738 Main Street #398
Waltham, Massachusetts 02451
(617) 995-0900

NOTICE OF 2023 ANNUAL MEETING OF STOCKHOLDERS
To Be Held on [●], 2024

Dear Stockholders:

You are cordially invited to attend the 2023 annual meeting of stockholders of Aileron Therapeutics, Inc. to be held on [●], [●], 2024 at [●] a.m., Eastern Standard Time. The annual meeting will be held in a virtual meeting format only via the Internet at www.meetnow.global/MTD5ADS. At our virtual annual meeting, stockholders will be able to attend, vote and submit questions by visiting www.meetnow.global/MTD5ADS. Further information about how to attend the annual meeting online, vote your shares during the meeting and submit questions during the meeting is included in the accompanying proxy statement.

At the annual meeting, stockholders will consider and vote on the following matters:

1. The issuance, in accordance with Nasdaq Listing Rule 5635(a), of our common stock, upon conversion of our outstanding Series X Non-Voting Convertible Preferred Stock;
2. The election of three Class III directors to serve for a term expiring at the 2026 annual meeting of stockholders and until his successor has been duly elected and qualified;
3. The approval of an amendment to the Aileron Therapeutics, Inc. 2021 Stock Incentive Plan to increase the number of shares of our common stock available for issuance thereunder by 3,000,000 shares;
4. The approval of an amendment to our Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of our common from 45,000,000 to 100,000,000;
5. A non-binding, advisory vote to approve named executive officer compensation;
6. A non-binding, advisory vote on the frequency of future advisory votes to approve named executive officer compensation;
7. The ratification of the appointment of Marcum LLP as our independent registered public accounting firm for the fiscal year ended December 31, 2023; and
8. The transaction of any other business that may properly come before the annual meeting or any adjournment or postponement thereof.

Stockholders of record at the close of business on January 18, 2024, will be entitled to notice of and to vote at the annual meeting or any adjournment or postponement thereof.

You can find more information, including the nominees for directors, in the accompanying proxy statement. The board of directors recommends that you vote “FOR of each of proposals one, two, three, four, five and seven and for “one year” for proposal six as outlined in the accompanying proxy statement.

We encourage all stockholders to attend the annual meeting. Whether or not you expect to attend the annual meeting online, please vote your shares to ensure your representation and the presence of a quorum at the annual meeting. Your vote is important regardless of the number of shares you own. If your shares are held in "street name," that is, held for your account by a broker or other nominee, you will receive instructions from the holder of record that you must follow for your shares to be voted. Please review the instructions on each of your voting options described in the proxy statement.

A list of registered stockholders as of the close of business on [●], 2024 will be available for examination by any stockholder for any purpose germane to the annual meeting for a period of 10 days prior to the Annual Meeting. If you wish to view this list, please contact our corporate secretary at Aileron Therapeutics, Inc., 738 Main Street #398, Waltham, Massachusetts 02451, Attention: Corporate Secretary.

Thank you for your ongoing support and continued interest in Aileron Therapeutics, Inc.

By Order of the Board of Directors,

Manuel C. Alves Aivado, M.D., Ph.D.
Chief Executive Officer

Waltham, Massachusetts
January [●], 2024

Important Notice Regarding Internet Availability of Proxy Materials: The attached proxy statement and our 2022 annual report to stockholders, which includes our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and our Annual Report on Form 10-K/A, are available at *www.envisionreports.com*. These documents are also available to any stockholder who wishes to receive a paper copy by calling (866) 641-4276, or by emailing *investorvote@computershare.com* with "Proxy Materials Aileron Therapeutics, Inc." in the subject line, or by submitting a request over the Internet at *www.envisionreports.com/ALRN*.

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Preliminary Proxy Statement – Subject to Completion

738 Main Street #398
Waltham, Massachusetts 02451
(617) 995-0900

PROXY STATEMENT
2023 ANNUAL MEETING OF STOCKHOLDERS
To Be Held on [●], 2024

INFORMATION CONCERNING SOLICITATION AND VOTING

This proxy statement and the proxy card are being furnished in connection with the solicitation of proxies by the board of directors of Aileron Therapeutics, Inc. for use at the annual meeting of stockholders to be held on [●], [●], 2024, at [●] a.m., Eastern Standard Time, and any adjournment thereof, or the annual meeting. The annual meeting will be held in a virtual meeting format only via the Internet at www.meetnow.global/MTD5ADS. At our virtual annual meeting, stockholders will be able to attend, vote and submit questions by visiting www.meetnow.global/MTD5ADS. Stockholders of record do not need to register to attend the annual meeting. Stockholders who hold their shares through an intermediary, such as a bank or broker, who wish to attend the annual meeting must submit proof of their legal proxy reflecting their holdings and their name and email address to our transfer agent no later than 5:00 p.m. Eastern Standard Time on [●], 2024. Stockholders will receive a confirmation of their registration by email after our transfer agent receives their registration materials. Further information about how to attend the annual meeting online, vote your shares during the meeting and submit questions during the meeting is included in this proxy statement.

Except where the context otherwise requires, references to "Aileron Therapeutics," "the Company," "we," "us," "our," and similar terms refer to Aileron Therapeutics, Inc.

The board of directors of Aileron Therapeutics is using this proxy statement to solicit proxies for use at the annual meeting. This proxy statement summarizes information about the proposals to be considered at the meeting and other information you may find useful in determining how to vote. All properly submitted proxies will be voted in accordance with the instructions contained in those proxies.

This proxy statement is dated January [●], 2024 and is first being mailed to stockholders on or about January [●], 2024.

Important Notice Regarding the Availability of Proxy Materials for the Annual Meeting of Stockholders to be Held on [●], 2024:

This proxy statement and our annual report to stockholders for the fiscal year ended December 31, 2022, or the 2022 annual report are available for viewing, printing, and downloading at http://www.envisionreports.com/ALRN.

A copy of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission, or the SEC, and our Annual Report on Form 10-K/A, as filed with the SEC, except for exhibits, will be furnished without charge to any stockholder upon written or oral request to Aileron Therapeutics, Inc., 738 Main Street #398, Waltham, Massachusetts 02451 or by calling (866) 641-4276, by emailing *investorvote@computershare.com* with "Proxy Materials Aileron Therapeutics, Inc." in the subject line, or by submitting a request over the Internet at *www.envisionreports.com/ALRN*. This proxy statement and our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as amended, are also available on the SEC's website at www.sec.gov.

IMPORTANT INFORMATION ABOUT THE ANNUAL MEETING AND VOTING

Q. Why did I receive these proxy materials?

A. Our board of directors has made these materials available to you in connection with the solicitation of proxies for use at our 2023 annual meeting of stockholders to be held on [●], [●], 2024, at [●] a.m., Eastern Standard Time. As a holder of common stock, you are invited to attend the annual meeting online and are requested to vote on the items of business described in this proxy statement. This proxy statement includes information that we are required to provide to you under SEC rules and is designed to assist you in voting your shares.

Q. Why is the 2023 annual meeting of stockholders being held in 2024?

A. As a result of our exploration of a range of strategic alternatives in 2023, and our acquisition of Lung Therapeutics, Inc., a Texas corporation, or Lung, which closed in October 2023 (as discussed in more detail below), we did not hold the 2023 annual meeting of stockholders in 2023, and instead will be holding the 2023 annual meeting on [●], [●], 2024. We intend to hold our 2024 annual meeting of stockholders later this year.

Q. When are this proxy statement and the accompanying materials scheduled to be sent to stockholders?

A. On or about January [●], 2024, we will begin mailing our proxy materials, including the Notice of 2023 Annual Meeting of Stockholders, this proxy statement, the accompanying proxy card or, for shares held in "street name", a voting instruction form.

Q. What is the purpose of the annual meeting?

A. At the annual meeting, stockholders will consider and vote on the following matters:

1. The issuance, in accordance with Nasdaq Listing Rule 5635(a), of our common stock, upon conversion of our outstanding Series X Non-Voting Convertible Preferred Stock, or the Series X Preferred Stock, or the Series X Preferred Stock Conversion Proposal (Proposal 1);
2. The election of three Class III directors to serve until the 2026 annual meeting of stockholders and until his successor has been duly elected and qualified (Proposal 2);
3. The approval of an amendment to the Aileron Therapeutics, Inc. 2021 Stock Incentive Plan (the "2021 Plan") to increase the number of shares of our common stock available for issuance thereunder by 3,000,000 shares (Proposal 3);
4. The approval of an amendment to our Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of our common stock from 45,000,000 to 100,000,000 (Proposal 4);
5. A non-binding, advisory vote to approve named executive officer compensation (Proposal 5);
6. A non-binding, advisory vote on the frequency of future advisory votes to approve named executive officer compensation (Proposal 6);
7. The ratification of the appointment of Marcum LLP as our independent registered public accounting firm for the fiscal year ended December 31, 2023, or the Auditor Proposal (Proposal 7); and
8. The transaction of any other business that may properly come before the annual meeting or any adjournment or postponement thereof.

As of the date of this proxy statement, we are not aware of any business to come before the meeting other than the first five items noted above.

Q: How can I attend the annual meeting?

A: The annual meeting will be held in a virtual meeting format only via the Internet. At our virtual annual meeting, stockholders will be able to attend, vote and submit questions by visiting www.meetnow.global/MTD5ADS.

If you are a stockholder of record (i.e., you hold your shares through our transfer agent, Computershare), you do not need to register to attend the annual meeting. Please follow the instructions in the proxy materials.

If you hold your shares through an intermediary, such as a bank, or broker, then you shares are held in "street name" and you must register in advance to attend the annual meeting. In this case, your proxy materials will be sent to you by that organization. The organization holding your shares is considered the stockholder of record for purposes of voting at the annual meeting. To register to attend the annual meeting, you must submit proof of your legal proxy reflecting your holdings and your name and email address to Computershare no later than 5:00 p.m. Eastern Standard Time on [●], 2024. You will receive a confirmation of your registration by email after we receive your registration materials. Requests for registration should be directed to Computershare as follows:

By email: Forward the e-mail from your bank or broker, or attach an image of your legal proxy to:
legalproxy@computershare.com

By mail:
Computershare
ALRN Legal Proxy
P.O. Box 43001
Providence, RI 02940-3001

Q. Who can vote at the annual meeting?

A. To be entitled to vote, you must have been a stockholder of record at the close of business on January 18, 2024, the record date for our annual meeting. There were 4,885,512 shares of our common stock outstanding and entitled to vote at the annual meeting as of the record date.

The holders of Series X Preferred Stock are not entitled to vote on the matters being considered at the annual meeting.

Q. How many votes do I have?

A. Each share of our common stock that you own as of the record date will entitle you to one vote on each matter considered at the annual meeting, except as with respect to Proposal 1 as described below under "What vote is required to approve each matter, and how are votes counted?".

Q. How do I vote?

A. **If you are the "stockholder of record" of your shares**, meaning that your shares are registered in your name in the records of our transfer agent, Computershare Trust Company, N.A., you may vote your shares by proxy prior to the annual meeting or online at the annual meeting as follows:

1. **Online Prior to the annual meeting**: To vote online prior to the annual meeting, please go to the following website: www.envisionreports.com/ALRN. Follow the instructions at that site for submitting your proxy electronically. If you vote online, you do not need to complete and mail your proxy card or vote your proxy by telephone. You must specify how you want your shares voted, or your online vote cannot be completed, and you will receive an error message. You must submit your online proxy before 11:59 p.m., Eastern Standard Time, on [●], 2024, the day before the annual meeting, for your proxy to be valid and your vote to count.

2. **By Telephone**: To vote by telephone, please call (800) 652-VOTE (8683), and follow the instructions provided in the proxy materials. You do not need to complete and mail your proxy card or vote your proxy over the Internet if you vote by telephone. You must specify how you want your shares voted and confirm your vote at the end of the call, or your telephone vote cannot be completed. You must submit your telephonic proxy before 11:59 p.m., Eastern Standard Time, on [●], 2024, the day before the annual meeting, for your proxy to be valid and your vote to count.

3. **By Mail**: To vote by mail, you must request printed copies of the proxy materials and mark, sign and date the proxy card and then mail the proxy card in accordance with the instructions on the proxy card. If you vote by mail, you do not need to vote your proxy over the Internet or telephone. Computershare Trust Company, N.A. must receive the proxy card not later than 5:00 p.m., Eastern Standard Time, on [●], 2024, the day before the annual meeting, for your proxy to be valid and your vote to count. If you return your proxy card but do not specify how you want your shares voted on any particular matter, they will be voted in accordance with the recommendations of our board of directors.

4. **During the annual meeting**: If you attend the annual meeting, you may vote online during the annual meeting. You will need your control number included on your proxy card to be able to vote during the annual meeting. If you vote by proxy prior to the annual meeting and choose to attend the annual meeting online, there is no need to vote again during the annual meeting unless you wish to change your vote.

If your shares are held in "street name," meaning they are held for your account by an intermediary, such as a bank or broker, then you are deemed to be the beneficial owner of your shares, and the bank or broker that holds the shares for you is the record holder and is required to vote the shares it holds on your behalf according to your instructions. The proxy materials and voting and revocation instructions should have been forwarded to you by the bank or broker that holds your shares. To vote your shares, you will need to follow the instructions that your bank or broker provides you. Many brokers solicit voting instructions over the Internet or by telephone. The voting deadlines and availability of telephone and Internet voting for beneficial owners of shares held in "street name" will depend on the voting processes of the bank or broker that holds your shares. Therefore, we urge you to carefully review and follow the voting instructions and any other materials that you receive from that organization.

If you do not give instructions to your bank or broker, we expect that your bank or broker will have discretionary voting authority with respect to Proposals 4 and 7. Accordingly, we expect your bank or broker may vote your shares in its discretion with respect to Proposals 4 and 7, even if you do not give voting instructions on Proposals 4 and 7.

However, under applicable stock exchange rules that regulate voting by registered brokerage firms, brokerage firms do not have discretionary voting authority with respect to Proposals 1, 2, 3, 5 and 6. Accordingly, if you do not give your bank or broker voting instructions on Proposals 1, 2, 3, 5 and 6, your bank or broker may not vote your shares with respect to these matters, and your shares will be counted as "broker non-votes" concerning Proposals 1, 2, 3, 5 and 6. Broker non-votes occur when your bank or broker or other nominee submits a proxy for your shares (because the broker or other nominee has received instructions from you on one or more proposals, but not all proposals, or has not received instructions from you but has discretionary voting authority with respect to a particular matter) but does not indicate a vote for a particular proposal because the broker or other nominee either does not have the authority to vote on that proposal and has not received voting instructions from you or has discretionary authority but chooses not to exercise it.

You are welcome to attend the meeting regardless of whether your shares are held in street name. However, you may not attend the annual meeting if you hold shares in street name unless you register with a legal proxy as described above. You must also obtain a legal proxy executed in your favor from the holder of record (i.e., your bank or broker) to vote shares held in street name during the meeting. A legal proxy is not the form of proxy included with this proxy statement. If you hold your shares in "street name," you must request a legal proxy from your bank, broker, or other nominee to attend the annual meeting or vote during the annual meeting.

Even if you plan to attend the annual meeting, we urge you to vote your shares by proxy in advance of the annual meeting so that if you should become unable to attend the annual meeting, your shares will be voted as directed by you.

Q. Can I change my vote?

A. If your shares are registered directly in your name, you may revoke your proxy and change your vote at any time before the vote is taken at the annual meeting. To do so, you must do one of the following:

1. Vote over the Internet or by telephone prior to the annual meeting as instructed above. Only your latest Internet or telephone vote is counted.
2. Sign and return a new proxy card. Only your latest dated and timely received proxy card will be counted.
3. Attend the annual meeting online and vote during the meeting as instructed above. Attending the annual meeting online will not alone revoke your Internet vote, telephone vote, or proxy card submitted by mail, as the case may be.
4. Give our corporate secretary written notice before or at the meeting that you want to revoke your proxy.

If your shares are held in "street name," you may submit new voting instructions by contacting your bank or broker or other nominee. You may also vote online at the annual meeting if you obtain a legal proxy, as described in the answer above.

Q. How do I submit a question at the annual meeting?

A. You may submit a question before and during the annual meeting online by visiting www.meetnow.global/MTD5ADS.

Q. How many shares must be represented to have a quorum and hold the annual meeting?

A. A majority of our shares of common stock outstanding at the record date must be present or represented by proxy to hold the annual meeting. This is called a quorum. To determine whether a quorum exists, we count as present any shares that are voted over the Internet, by telephone, by completing and submitting a proxy card by mail, or that are represented at the meeting. Shares present virtually during the annual meeting will be considered shares of common stock represented at the meeting. Further, for purposes of establishing a quorum, we will count as present any shares that a stockholder holds even if the stockholder votes to abstain or only votes on one of the proposals. In addition, we will count as present any shares counted as broker non-votes for the purpose of establishing a quorum. If a quorum is not present, we expect to adjourn the annual meeting until we obtain a quorum.

Q. What vote is required to approve each matter, and how are votes counted?

A.

Proposal 1 – Approval of Series X Preferred Stock Conversion Proposal

The affirmative vote of the stockholders representing a majority of the votes cast on the matter is required to approve Proposal 1. Shares held in street name by a bank, broker or other nominee who indicate on their proxies that they do not have authority to vote the shares on Proposal 1 will not be counted as votes FOR or AGAINST Proposal 1 and will be treated as broker non-votes. Broker non-votes will have no effect on the voting on Proposal 1. If you vote to ABSTAIN on Proposal 1, your shares will not be voted FOR or AGAINST the proposal and will also not be counted as votes cast of shares voting on Proposal 1. As a result, voting to ABSTAIN will have no effect on the voting on Proposal 1.

Of the shares of our common stock outstanding entitled to vote at the annual meeting, 344,345 shares of common stock were issued in the Lung Acquisition (as defined below under "*Proposal 1 – Lung Acquisition Agreement*") and any votes in favor of Proposal 1 with respect to shares will not count as votes in favor of Proposal 1 pursuant to the listing rules of the Nasdaq Stock Market. In addition, 2,502,346 shares of our common stock were reserved for issuance pursuant to options and warrants assumed in the Lung Acquisition. Any votes in favor of Proposal 1 with respect to shares issued upon exercise of such options and warrants will not count as votes in favor of Proposal 1 pursuant to the listing rules of the Nasdaq Stock Market. Such shares of common stock issued in the Lung Acquisition and reserved for issuance pursuant to options and warrants assumed in the Lung Acquisition may be voted in favor of Proposal 1 for purposes of Delaware law. However, to comply with Nasdaq rules, we will instruct the inspector of elections to conduct a separate tabulation that subtracts the votes represented by these shares from the total number of shares voted on Proposal 1 to determine whether that proposal has been adopted in accordance with applicable Nasdaq rules.

Proposal 2—Election of Class III Directors

A nominee will be elected as a director at the annual meeting if the nominee receives a plurality of the votes cast by stockholders entitled to vote at the annual meeting. Shares held in street name by a bank, broker or other nominee who indicate on their proxies that they do not have authority to vote on the shares on Proposal 2 will not be counted as votes FOR or WITHHELD from any director nominee and will be treated as broker non-votes. Broker non-votes will have no effect on the voting on Proposal 2.

You may:

- vote FOR all nominees;
- vote FOR one or more nominees and WITHHOLD your vote from the other nominee or nominees; or
- WITHHOLD your vote from all nominees.

Votes that are withheld will not be included in the vote tally for the election of directors and will not affect the vote results.

Proposal 3 – Approval of an Amendment to our 2021 Plan to Increase the Number of Shares of our Common Stock Available for Issuance Thereunder by 3,000,000 Shares

The affirmative vote of the stockholders representing a majority of the votes cast on the matter is required to approve Proposal 3. Shares held in street name by a bank, broker or other nominee who indicate on their proxies that they do not have authority to vote the shares on Proposal 3 will not be counted as votes FOR or AGAINST Proposal 3 and will be treated as broker non-votes. Broker non-votes will have no effect on the voting on Proposal 3. If you vote to ABSTAIN on Proposal 3, your shares will not be voted FOR or AGAINST the proposal and will also not be counted as votes cast of shares voting on Proposal 3. As a result, voting to ABSTAIN will have no effect on the voting on Proposal 3.

Proposal 4 – Approval of an Amendment to our Restated Certificate of Incorporation, as Amended, to Increase the Number of Authorized Shares of our Common Stock from 45,000,000 to 100,000,000

The affirmative vote of the stockholders representing a majority of the outstanding shares of our common stock entitled to vote on the matter is required to approve Proposal 4. If your shares are held by a bank, broker or other nominee and you do not timely provide voting instructions with respect to your shares, we expect that your bank, broker or other nominee will have the authority to vote your shares on Proposal 4. If you vote to ABSTAIN on Proposal 4, your shares will not be voted FOR or AGAINST the proposal and will also not be counted as votes cast or shares voting on Proposal 4. Because Proposal 4 requires the affirmative vote of the stockholders representing a majority of the outstanding shares of our common stock entitled to vote on the matter, voting to ABSTAIN will have the same effect as a vote AGAINST Proposal 4.

Proposal 5 – Advisory Vote on the Compensation of our Named Executive Officers

The affirmative vote of the stockholders representing a majority of the votes cast on the matter is required to approve the compensation of our named executive officers as described in this proxy statement. Shares held in street name by a bank, broker or other nominee who indicate on their proxies that they do not have authority to vote the shares on Proposal 5 will not be counted as votes FOR or AGAINST Proposal 5 and will be treated as broker non-votes. Broker non-votes will have no effect on the voting on Proposal 5. If you vote to ABSTAIN on Proposal 5, your shares will not be voted FOR or AGAINST the proposal and will also not be counted as votes cast of shares voting on Proposal 5. As a result, voting to ABSTAIN will have no effect on the voting on Proposal 5.

As an advisory vote, this proposal is not binding. The outcome of this advisory vote will not overrule any decision by us or our board of directors (or any committee thereof). However, our compensation committee and our board of directors value the opinions expressed by our stockholders in their vote on this proposal and will consider the outcome of the vote when making future compensation decisions.

Proposal 6 – Advisory Vote on the Frequency of Future Advisory Votes on the Compensation of our Named Executive Officers

The advisory vote on the frequency of future advisory votes on the compensation of our named executive officers provide a choice among the frequency periods (every one, two or three years).

You may:

- vote ONE YEAR;
- vote TWO YEARS;
- vote THREE YEARS; or
- ABSTAIN from voting on the non-binding resolution.

The frequency period that receives the most votes will be deemed to be the recommendation to our stockholders. Shares held in street name by a bank, broker or other nominee who indicate on their proxies that they do not have authority to vote the shares on Proposal 6 will not be counted as votes FOR or AGAINST Proposal 6 and will be treated as broker non-votes. Broker non-votes will have no effect on the voting on Proposal 6. If you vote to ABSTAIN on Proposal 6, your shares will not be voted FOR or AGAINST the proposal and will also not be counted as votes cast of shares voting on Proposal 6. As a result, voting to ABSTAIN will have no effect on the voting on Proposal 6.

As an advisory vote, this proposal is not binding. Our board of directors will take into consideration the outcome of this vote in determining the frequency of future non-binding advisory votes on the compensation of our named executive officers. However, because this vote is advisory and non-binding, our board of directors may decide that it is in our best interests and those of our stockholders to hold the advisory vote to approve the compensation of our named executive officers more or less frequently.

Proposal 7—Ratification of the Appointment of Independent Registered Public Accounting Firm

The affirmative vote of the stockholders representing a majority of the votes cast on the matter is required ratify Marcum LLP as our independent registered public accounting firm for the year ended December 31, 2023. If your shares are held by a bank, broker or other nominee and you do not timely provide voting instructions with respect to your shares, we expect that your bank, broker or other nominee will have the authority to vote your shares on Proposal 7. If you vote to ABSTAIN on Proposal 7, your shares will not be voted FOR or AGAINST the proposal and will also not be counted as votes cast or shares voting on Proposal 7. As a result, voting to ABSTAIN will have no effect on the voting on Proposal 7.

Q. Who will count the vote?

A. The votes will be counted, tabulated, and certified by Computershare Trust Company, N.A.

Q. How does the board of directors recommend that I vote on the proposals?

A. Our board of directors recommends that you vote:

FOR the approval of the Series X Preferred Stock Conversion Proposal;

FOR the election of the nominees to serve as Class III directors, to serve until the 2026 annual meeting of stockholders, and until his successor has been duly elected and qualified;

FOR the approval of an amendment to our 2021 Plan to increase the number of shares of our common stock available for issuance thereunder by 3,000,000 shares;

FOR the approval of an amendment to our Restated Certificate of Incorporation, as amended, to increase the number of authorized shares of our common stock from 45,000,000 to 100,000,000;

FOR the approval of the compensation of our named executive officers;

FOR a frequency of every one year for the future advisory votes on the compensation of our named executive officers; and

FOR the ratification of the appointment of Marcum LLP as our independent registered public accounting firm for the fiscal year ended December 31, 2023.

Q. Are there other matters to be voted on at the annual meeting?

A. We do not know of any matters that may come before the annual meeting other than Proposals 1, 2, 3, 4, 5, 6 and 7. If any other matters are properly presented at the annual meeting, the persons named in the accompanying proxy intend to vote or otherwise act in accordance with their judgment on the matter.

Q. Where can I find the voting results?

A. We plan to announce preliminary voting results at the annual meeting and will report final voting results in a Current Report on Form 8-K filed with the SEC within four business days following the date of our annual meeting.

Q. What are the costs of soliciting these proxies?

A. We will bear the cost of soliciting proxies. We have retained Alliance Advisors to assist us in the solicitation of proxies for an aggregate fee of approximately $10,000 to $15,000. In addition to solicitation by mail, our directors, officers, and employees may solicit proxies by telephone, e-mail, facsimile, and in person without additional compensation. We may reimburse brokers or persons holding stock in their names, or in the names of their nominees, for their expenses in sending proxies and proxy material to beneficial owners.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than $700.0 million, and our annual revenue was less than $100.0 million during our most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. As a smaller reporting company, we may rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and smaller reporting companies have reduced disclosure obligations regarding executive compensation.

CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This proxy statement contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this proxy statement, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- our plans to develop and commercialize LTI-03 and LTI-01, including the potential benefits thereof;
- 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 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 proxy statement, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

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

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

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 proxy statement. 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 (as defined below). 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.

DESCRIPTION OF THE TRANSACTION

Acquisition of Lung

On October 31, 2023, we acquired Lung pursuant to an Agreement and Plan of Merger, or the Lung Acquisition Agreement, by and among us, AT Merger Sub I, Inc., a Delaware corporation and our wholly owned subsidiary, or First Merger Sub, AT Merger Sub II, LLC, a Delaware limited liability company and our wholly owned subsidiary, or Second Merger Sub, and Lung. Pursuant to the Lung Acquisition Agreement, First Merger Sub merged with and into Lung, pursuant to which Lung was the surviving entity and became 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, the Lung Acquisition. Following the Lung Acquisition, we shifted our operating disease focus to advancing a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications. We continue to maintain our corporate headquarters in Waltham, Massachusetts.

Lung was incorporated on November 13, 2012. We have included a pro forma condensed combined balance sheet as of September 30, 2023, reflecting the net assets acquired as if the net assets were acquired on such date, as *Annex C* to this proxy statement.

Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, we issued to the stockholders of Lung 344,345 shares of common stock and 19,903 shares of newly designated Series X Preferred Stock (as described below under "*—Description of the Series X Preferred Stock*" under Proposal 1). In addition, we assumed (i) all Lung stock options immediately outstanding prior to the First Merger, each becoming an option for our common stock subject to adjustment pursuant to the terms of the Lung Acquisition Agreement, and (ii) all warrants exercisable for Lung common stock immediately outstanding prior to the First Merger, each becoming a warrant to purchase our common stock, subject to adjustment pursuant to the terms of the Lung Acquisition Agreement. Certain holders of Lung stock options and warrants exercisable for Lung common stock agreed that receipt of stockholder approval in favor of Proposal 1 shall be a condition to exercise any options for our common stock or warrants to purchase our common stock, as applicable, issued or granted to such holders in exchange for such options and warrants in connection with the Lung Acquisition. As such, such options and warrants are excluded from the calculation of shares of common stock issued in the Lung Acquisition.

In connection with the execution of the Lung Acquisition Agreement, we and Lung entered into stockholder support agreements, or the Support Agreements, with certain of our directors and officers and our principal stockholder prior to the closing of the Lung Acquisition. The Support Agreements provide that, among other things, each such director, officer or stockholder has agreed to vote or cause to be voted all of the shares of common stock owned by him, her or it in favor of Proposal 1 at the annual meeting or any adjournment or postponement thereof, or in connection with any written consent of the stockholders in connection therewith.

In addition, concurrently and in connection with the execution of the Lung Acquisition Agreement, we entered into lock-up agreements with each individual who was to serve as an officer or as a director of us immediately after the Lung Acquisition and with the officers and directors and the majority stockholder of Lung immediately prior to the Lung Acquisition, pursuant to which each such officer, director 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 officer, director 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 officer, director or stockholder at the closing of the Lung Acquisition and hereafter owned by each such officer, director or stockholder, including those shares issued in the Lung Acquisition, subject to certain customary exceptions.

Financing Transaction

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, and collectively with the Lung Acquisition, the Transactions. The Financing closed on November 2, 2023. The Financing was exempt from registration pursuant to Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering.

The exercise price of the Warrants is $4.89 per share, subject to certain price and share adjustments, including for stock splits, stock dividends, recapitalizations, subdivisions, combinations, noncash distributions and cash dividends. The Warrants are exercisable any time after the later of May 2, 2024 and the date stockholder approval of Proposal 1 is obtained and on or prior to May 2, 2027. Payment for the Warrant Shares upon the exercise of the Warrants may be (i) in cash or (ii) in the event that there is no registration statement available for the resale of the Warrant Shares, by cashless exercise.

Under the terms of the Warrants, we will not effect the exercise of any portion of any Warrant, and a holder will not have the right to exercise any portion of any Warrant, to the extent that after giving effect to such exercise, the holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates), would beneficially own in excess of a percentage elected by the holder up to 19.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may, upon written notice to us, increase or decrease such percentage to any other percentage not in excess of 19.99%; provided that any increase or decrease in such percentage will not be effective until 61 days after such notice is delivered to us.

In connection with the Financing, we entered into a Registration Rights Agreement, or 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 within 90 calendar days following the closing of the Financing, or 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). The Registration Rights Agreement also contains customary terms, including an obligation to indemnify the Investors, their officers, directors, agents, partners, members, managers, stockholders, affiliates and employees under the registration statement from certain liabilities and pay all fees and expenses (excluding any underwriting discounts and selling commissions and all legal fees and expenses of legal counsel for the Investors, except for reasonable and documented fees and expenses in an amount not to exceed $30,000 of the Investors that hold a majority in interest of the registrable securities in connection with the review of the registration statement) incident to our obligations under the Registration Rights Agreement.

Conversion of Preferred Stock

Subject to stockholder approval of Proposal 1 and certain beneficial ownership limitations, each share of Series X Preferred Stock will be convertible into 1,000 shares of common stock. If our stockholders have not approved the conversion of the Series X Preferred Stock into common stock by May 1, 2024 (six months after the closing of the Lung Acquisition), then a holder of 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.

BACKGROUND AND REASONS FOR THE TRANSACTION

As part of its ongoing oversight of our business and affairs, our board of directors, with input from management, regularly reviews our operations and strategy, competitive position, prospects and opportunities with a view to maximizing stockholder value.

In the fourth quarter of 2022, in light of our limited cash resources, our board of directors hired Ladenburg Thalmann & Co., Inc. to act as a strategic advisor to explore acquisition, merger, business combination, in-licensing or other strategic transactions while we continued to conduct our Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer.

In February 2023, we announced that a review of initial data from our Phase 1b chemoprotection trial of ALRN-6924 in patients with p53-mutated breast cancer showed that patients in the trial experienced severe neutropenia (Grade 4) and alopecia. Based on these findings, we announced that we were terminating our Phase 1b breast cancer trial and further development of ALRN-6924. We also announced that we were exploring a range of strategic alternatives to maximize stockholder value and were shifting our focus toward conserving our resources as we explored strategic alternatives. As part of this strategic process, Ladenburg Thalmann & Co., Inc. focused its process on the exploration of reverse merger candidates.

As part of the process to explore strategic options, our financial advisor contacted approximately 200 companies regarding a potential transaction with us. As part of the outreach process (and at different periods during the strategic process), we received proposals from twenty-one companies. During the strategic process between March 2023 and August 2023, the Company sent term sheets to 11 companies and negotiated terms with each.

After reviewing the relative merits of each of these potential strategic alternatives, and discussions with several candidates, including material discussions with ten other companies at different stages of the strategic process, the board of directors determined that the acquisition of Lung offered the best reasonably available alternative for the Company and its stockholders. Following this determination by the board of directors, the Company's senior management and its financial advisors engaged in expanded and more detailed discussions with Lung.

To facilitate the completion of the parties' confirmatory due diligence of each other and the negotiation of the Lung Acquisition Agreement, the Company and Lung entered into a term sheet on September 6, 2023 after negotiating certain key economic and other material transaction terms, including the respective valuation of each party and other components of the exchange ratio, key components of the definition of net cash to be set forth in the Lung Acquisition Agreement and certain closing conditions. The term sheet included a binding exclusivity provision obligating each party to negotiate exclusively with the other for a period of 30 days.

On October 31, 2023, following the approval of our board of directors, we and Lung entered into the Lung Acquisition Agreement, pursuant to which the Company had a deemed enterprise value of approximately $17.8 million (representing our estimated net cash as of an agreed-upon date plus an agreed-upon premium of $10.0 million) and Lung had a deemed enterprise value of $90.0 million, which resulted in our pre-closing stockholders retaining approximately 16.5% of the combined company, on an as-converted-to-common-stock basis, and before giving effect to the Financing.

Also on October 31, 2023, our board of directors approved the Financing, at the same implied equity value per share of approximately $3.91 per share, which resulted in our pre-closing stockholders retaining approximately 14.3% of the combined company, while Lung equity holders received approximately 72.3% of the combined company and the investors in the Financing received approximately 13.4% of the combined company, in each case on an as-converted-to-common-stock basis, but excluding any potential exercise of the Warrants.

In approving the Lung Acquisition and the Financing, or the Transactions, the board of directors considered the benefits and risks of the Transactions compared to other alternatives, including other potential acquisitions and business development opportunities reviewed by the board and the opportunities and risks presented with the

Transactions, the other proposals received by us in connection with the process conducted by our board of directors, other potential business development opportunities reviewed by our board of directors, the potential liquidation of our company and the opportunities and risks associated with the Transactions. In particular, the board of directors considered the following events, facts and circumstances in approving the Transactions:

- Our board of directors' belief that, as a result of arm's length negotiations with Lung, the Company and its management team negotiated the most favorable equity split for Company stockholders that Lung was willing to agree to, and that the terms of the Lung Acquisition Agreement included the most favorable terms to the Company in the aggregate to which Lung was willing to agree.
- Our board of directors' belief that, with the Transactions, the Company would have sufficient resources to fund the near-term development of the combined Company's pipeline and generate initial data from the ongoing clinical trial of LTI-03, a novel Cav1-related peptide with a dual mechanism targeting both alveolar epithelial cell survival as well as inhibition of profibrotic signaling being developed for the treatment of idiopathic pulmonary fibrosis, or IPF.
- Our board of directors' belief, based in part on a scientific diligence and analysis process conducted by the Company's management and reviewed with the board of directors, that Lung's lead product candidate, LTI-03, represented a meaningful treatment option for affected patients.
- Our board of directors' belief, after a thorough review of strategic alternatives and discussions with Company senior management, financial advisors and legal counsel, that the Lung Acquisition was more favorable to the Company's stockholders than the potential value that might have resulted from other strategic options available to the Company, including a liquidation of the Company and the distribution of any available cash.
- Our board of directors' belief that the structure of the Lung Acquisition, including the issuance of common stock and Series X Preferred Stock at a simultaneous sign and close of the Lung Acquisition, or the Acquisition Structure, instead of a structure in which the closing of the Lung Acquisition would be conditioned on receipt of approval of the issuance of common stock in the Lung Acquisition by our pre-closing stockholders, or the Traditional Structure, was beneficial to our stockholders. In the Traditional Structure, we would have had less cash at the closing of the Lung Acquisition than we did at the closing of the Acquisition Structure, which would have resulted in a less favorable equity split for our pre-closing stockholders as compared to the Lung equity holders. In addition, our board believed that our ability to consummate the Lung Acquisition Structure with more cash at closing made us a more attractive merger candidate (and thus able to attract better terms and more attractive counterparties such as Lung) and a more attractive investment for purchasers in the Financing.

After giving consideration to these and other factors, the board of directors approved the Transactions, which the board of directors believes better positions the Company for long-term success.

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

We intend to file a copy of the Taiho Agreement, as defined below, as an exhibit to a Current Report on Form 8-K with the SEC prior to filing the definitive proxy statement for the annual meeting.

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

We intend to file copies of the UTHSCT Agreement, UT Austin 6607 Agreement, the MUSC Agreement and the Vivarta Agreement, each as defined below, as exhibits to a Current Report on Form 8-K with the SEC prior to filing the definitive proxy statement for the annual meeting.

Agreement with the University of Texas Health Science Center at Tyler

In June 2013, Lung entered into a patent and technology license agreement with the Board of Regents of the University of Texas System, or UT System, on behalf of University of Texas Health Science Center at Tyler, or

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

In consideration of the UTHSCT Agreement, we granted UT System (via UTHSCT and UT Horizon Fund affiliates) (i) 2,000,000 shares of Lung common stock and (ii) 400,000 shares of Lung non-convertible preferred stock. On February 6, 2015, UT System exchanged the 400,000 shares of Lung non-convertible preferred stock for 4,000,000 shares of Lung common stock. In addition, Lung agreed to pay past and ongoing patent expenses, and we owe UTHSCT sublicensing fees, assignment fees, and single digit royalties on worldwide net product sales, with fixed minimum royalty payments that started in 2015.

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

We may terminate the UTHSCT Agreement for convenience with 90 days' notice. UTHSCT may also terminate the UTHSCT Agreement, but only if we breach the terms of the agreement.

Agreement with the University of Texas at Austin

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

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

Pursuant to the UT Austin 6607 Agreement, we are required to use diligent efforts to commercialize the licensed products, including maintaining active research and development, regulatory, marketing and sales program. Moreover, we are required to meet certain development and regulatory milestones by specific dates. We may terminate the UT Austin 6607 Agreement for convenience with 90 days' notice. UT Austin may also terminate the UT Austin 6607 Agreement, but only if we breach the terms of the agreement.

Agreement with Medical University of South Carolina

In March 2016, Lung entered into a license agreement with Medical University of South Carolina Foundation for Research Development, or MUSC. Pursuant to this license agreement with MUSC, or the MUSC Agreement, we have patent rights related to protecting against lung fibrosis by up regulating Cav1. The MUSC Agreement granted (i) a royalty-bearing, exclusive license under the patent rights to make, use and sell the license product;

and (ii) a sublicensing right that allows us to grant sublicenses to affiliates and third parties to use the licensed product in the field of use and approved territories outlined in the agreement. In September 2018, the agreement was amended and restated to include definitions of related methods, related products and related rights.

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

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

We may terminate the MUSC Agreement for convenience by providing a written notice to MUSC effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract.

Agreement with Vivarta Therapeutics LLC

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

In consideration for the Vivarta Agreement, Lung agreed to grant Vivarta a warrant to purchase an aggregate of 75,000 shares of Lung common stock for $0.12 per share, to pay a license fee of $10,000 upon the Vivarta Agreement effective date and $40,000 within 30 days of the receipt of a positive freedom to operate analysis from legal counsel. Lung also agreed to pay patent expenses, milestone fees upon certain development and regulatory milestone events, sublicense fees, assignment fees and low single digit royalties on net sales.

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

We may terminate the Vivarta Agreement for convenience by providing a written notice to Vivarta effective 90 days following the receipt of notice, and either party may terminate the agreement for a breach of contract.

Intellectual Property

Overview

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

Our commercial success may depend in part on our ability to: obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using,

selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable licenses, patents, or trade secrets that cover these activities. In some cases, enforcement of these rights may depend on third party licensors. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same.

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.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS OF LUNG THERAPEUTICS, INC.

The following discussion and analysis of Lung's financial condition and results of operations should be read together with Lung's audited consolidated financial statements and the related notes for the years ended December 31, 2022 and 2021, and Lung's unaudited condensed consolidated financial statements and related notes for the nine months ended September 30, 2023 and 2022, attached as Annex A and Annex B to this proxy statement, respectively. These unaudited condensed consolidated financial statements have not been audited or reviewed by an independent accountant.

The Lung Acquisition and Financing Transaction

On October 31, 2023, Lung entered into the Merger Agreement with the Company, First Merger Sub and Second Merger Sub. On that same day, Lung was acquired by the Company in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, First Merger Sub merged with and into Lung, with Lung surviving as a wholly owned subsidiary of the Company, and, immediately following the First Merger, Lung merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity. Following the completion of the Lung Acquisition, the business conducted by Lung became primarily the business conducted by the Company, which is developing novel therapies for the treatment of orphan pulmonary and fibrosis indications that have no approved or limited effective treatments. The Lung Acquisition was intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Code.

Under the terms of the Lung Acquisition Agreement, at the closing of the Lung Acquisition, the Company issued to the stockholders of Lung 344,345 shares of common stock of the Company and 19,903 shares of Series X Preferred Stock of the Company (as described below under "*—Description of the Series X Preferred Stock*" under Proposal 1). In addition, the Company assumed (i) all Lung stock options immediately outstanding prior to the First Merger, each becoming an option for its common stock subject to adjustment pursuant to the terms of the Lung Acquisition Agreement, and (ii) all warrants exercisable for Lung common stock immediately outstanding prior to the First Merger, each becoming a warrant to purchase its common stock, subject to adjustment pursuant to the terms of the Lung Acquisition Agreement.

Immediately following the closing of the Lung Acquisition, the Company entered into a Stock and Warrant Purchase Agreement with a group of accredited investors led by Bios Partners, the majority stockholder of Lung prior to the closing of the Lung Acquisition, pursuant to which the Company issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants to purchase up to an aggregate of 2,353,500 shares of common stock 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. The Financing closed on November 2, 2023. For additional information, see the "*—Description of the Transaction – Financing Transaction*" section of this proxy statement.

Overview

Prior to its acquisition by the Company, Lung was a privately held 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. As of the date of the Lung Acquisition, Lung had two product candidates in clinical development, LTI-03 and LTI-01, and multiple candidates in preclinical development focused on fibrosis indications. As of the date of the Lung Acquisition, Lung's pipeline included:

- LTI-03, a peptide, for which Lung is 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.

Lung devoted all of its focus and financial resources to organizing and staffing its company so that it could engage in business planning and capital raising, discovering, identifying and developing potential product candidates, securing related intellectual property rights, and conducting clinical trials and preclinical studies of its product candidates. As of the date of the Lung Acquisition, Lung had not completed the development of any of its product candidates, had not generated any revenue from product sales and had never generated an operating profit.

Lung funded its operations primarily with outside capital (e.g., proceeds from the sale of preferred stock and simple agreements for future equity, or SAFEs), however, Lung has incurred significant losses since the commencement of its operations. Lung's operating losses were $15.2 million and $11.2 million for the nine months ended September 30, 2023 and 2022, respectively, and $19.0 million and $9.9 million for the years ended December 31, 2022 and 2021, respectively. In addition, Lung had an accumulated deficit of $78.6 million as of September 30, 2023. As of September 30, 2023, Lung had cash and cash equivalents of $20.0 thousand. As of the date of the Lung Acquisition, Lung had financed its operations primarily through private placements of convertible preferred stock, an upfront payment received from a licensing agreement, and sales of marketable equity securities in TFF Pharmaceuticals, Inc., or TFF. From inception through September 30, 2023, these income sources generated total gross proceeds of approximately $108.8 million.

Components of Lung's Results of Operations

Licensing Revenue

As of the date of the Lung Acquisition, Lung had not generated any revenue from product sales.

In November 2020, Lung entered into a license agreement with Taiho Pharmaceutical Co. Ltd., or Taiho, pursuant to which it collaborates with Taiho regarding the development and potential commercialization of its product candidate, LTI-01, in Japan, or the License Agreement. Under the License Agreement, Lung granted Taiho an exclusive, royalty-bearing license to develop, seek regulatory approval for, and commercialize LTI-01 in Japan. Lung is obligated to conduct all development activities for LTI-01 through regulatory approval in the U.S. or other markets.

Lung determined that its combined performance obligation under the License Agreement is satisfied over time and further concluded that it would utilize a cost-based input method to measure its progress toward completion of this performance obligation and to calculate the corresponding amount of revenue to recognize each period. In applying the cost-based input method of revenue recognition, Lung used actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. Lung recognized revenue based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires Lung to make estimates of costs to complete its performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

In consideration for the exclusive, royalty-bearing license and other rights contained in the License Agreement, Taiho agreed to make a non-refundable, non-creditable payment to Lung of $5.0 million. This upfront payment, deemed a partial reimbursement of past and future development costs for LTI-01, was received by Lung in February 2021. The License Agreement also provides that Lung is eligible to receive an additional milestone payment of $10.0 million.

In addition, Lung is entitled to receive royalties on net sales of LTI-01 in Japan during the period commencing on the first commercial sale of LTI-01 in Japan and ending upon the later of: (a) ten years from the date of first commercial sale of LTI-01 in Japan; and (b) expiration of the last-to-expire valid claim of its patents covering the manufacture, use or sale or exploitation of LTI-01 in Japan.

Lung's management evaluated the License Agreement under ASC 606, *Revenue from Contracts with Customers*, or ASC 606, and determined that there is one combined performance obligation. It consists of the license and data transfer, the research and development services in which Lung is required to use commercially reasonable efforts to further the development of LTI-01, including execution of the necessary clinical trials, and supply of all clinical products during the term of the Agreement. These deliverables are non-contingent in nature.

Lung's assessment of the transaction price included an analysis of amounts it expected to receive, which at contract inception consisted of the non-refundable, upfront payment of $5.0 million that Lung received in February 2021. Lung considered this non-refundable fee of $5.0 million to be the initial transaction price.

Management also determined that the milestone payment of $10.0 million under the License Agreement is variable consideration under ASC 606 which needs to be added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of milestones, such as the regulatory approvals which are generally not within Lung's control, Lung will not consider achievement of this milestone to be probable until the uncertainty associated with such milestone has been resolved. When it is probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which Lung recognizes revenue. As of September 30, 2023 and 2022, and as of December 31, 2022 and 2021, no milestones had been achieved under the License Agreement.

Lung recognized royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). As of September 30, 2023 and 2022, and as of December 31, 2022 and 2021 no royalty revenue has been recognized.

For the nine months ended September 30, 2023 and 2022, Lung recognized revenue totaling $0.2 million and $0.8 million, respectively, from the License Agreement. As of September 30, 2023 and December 31, 2022, Lung recorded current deferred revenue of $0 and $0.4 million, and noncurrent deferred revenue of $2.7 million and $2.5 million, respectively, on its consolidated balance sheets.

For the years ended December 31, 2022 and 2021, Lung recognized revenue totaling $0.7 million and $0.6 million, respectively, from the License Agreement. As of December 31, 2022 and 2021, Lung recorded current deferred revenue of $0.4 million and $1.6 million, and noncurrent deferred revenue of $2.5 million and $2.0 million, respectively, on its consolidated balance sheets.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of Lung's product candidates. Lung records research and development expenses when these costs are incurred. Such expenses include:

- employee-related costs, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the clinical development of its product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of manufacturing product candidates for use in its clinical trials and preclinical studies, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;

- expenses incurred in connection with the preclinical development of its product candidates, including outsourced professional scientific development services, consulting research fees and payments made under sponsored research arrangements with third parties;
- facilities and other expenses, which include direct or allocated expenses for rent and maintenance of facilities;
- costs related to compliance with regulatory requirements; and
- payments made under third-party licensing agreements.

Lung tracked its direct research and development expenses on a program-by-program basis. These direct costs consist primarily of external costs such as fees paid to outside consultants, CROs, CMOs, clinical trial sites and research laboratories in connection with its preclinical activities, formulation development, manufacturing, and clinical development activities. These expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to Lung by its service providers or its estimate of the level of service that has been performed at each reporting date. Lung does not allocate employee-related costs, including stock-based compensation, or facility expenses, including rent or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. Lung uses internal resources primarily to conduct and manage its research and development activities, preclinical development, manufacturing, and clinical development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits and stock-based compensation expenses for personnel in executive, finance and administrative functions. General and administrative expenses also include facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services.

Gains from Affiliate

Pursuant to a contribution agreement executed on January 24, 2018, Lung's wholly owned subsidiary, TFF, was spun out into a separate company, whereby Lung received 4,000,000 shares of TFF's common stock in exchange for providing TFF with certain intellectual property assets licensed by Lung from the University of Texas. Lung applied the equity method of accounting to its investment in TFF as Lung determined that it exercised significant influence over the operating and financial policies of TFF. Based on TFF's history of losses, Lung had previously concluded that its share of TFF's net losses under the equity method was greater than the carrying value of the investment. As a result, in 2019, Lung wrote down its investment in TFF to $0 and suspended further recognition of its share of losses incurred by TFF.

In 2020, Lung sold 1,050,000 shares of common stock of TFF at an average of $13.90 per share, generating proceeds of $14.0 million. In March 2021, Lung sold 715,000 shares of common stock of TFF at an average price of $14.00 per share, generating proceeds of $9.4 million, net of commissions and other direct selling expenses.

In January 2022, Lung entered into a variable price forward sales contract with Jefferies LLC to sell 962,000 shares of common stock of TFF based upon the daily volume-weighted average price during the three-month period ended March 31, 2022, plus a premium applied over the term of the contract. On April 1, 2022, the contract was consummated and as a result, Lung received total cash proceeds of $6.2 million from the sale of these shares. In April 2022, Lung sold 500,000 additional shares of common stock of TFF to Bios Special Opportunity Fund, LP, a related party, at a price of $6.43 per share, generating net proceeds of $3.2 million.

Lung recorded gains from the sale of these shares of $0 and $9.4 million that are reflected under "Gain from sale of equity securities in TFF" on its condensed consolidated statements of operations and comprehensive loss for

the nine months ended September 20, 2023 and 2022, respectively. As of September 30, 2023 and December 31, 2022, Lung owned 773,000 shares of TFF common stock. On December 19, 2023, TFF effected a 1-for-25 reverse stock split.

Other Income, Net

Interest and Other Income

Interest income primarily consists of interest income generated from Lung's investments in interest-bearing money market accounts. Other net income consists of miscellaneous income that is unrelated to Lung's core operations.

Results of Operations

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes Lung's results of operations for the nine months ended September 30, 2023 and 2022, respectively (in thousands):

	Nine Months Ended September 30,		Change	
	2023	2022		
Licensing revenue	$ 153	$ 766	$ (613)	(80)%
Operating expenses:				
Research and development	(10,861)	(16,105)	5,244	(33)%
General and administrative	(4,525)	(5,287)	762	(14)%
Total operating expenses	(15,386)	(21,392)	6,006	(28)%
Loss from operations before gains from affiliate	(15,233)	(20,626)	5,393	(26)%
Gains from sale of equity securities in TFF	—	9,400	(9,400)	(100)%
Loss from operations	(15,233)	(11,226)	(4,007)	36%
Other income, net:				
Interest income, net	76	42	34	81%
Total other income, net	76	42	34	81%
Net loss	$(15,157)	$(11,184)	$(3,973)	36%

Revenue

Licensing revenue of $0.2 million and $0.8 million for the nine months ended September 30, 2023 and 2022, respectively, consisted of revenue recognized from the License Agreement.

Research and Development Expenses

The following table summarizes Lung's research and development expenses for the nine months ended September 30, 2023 and 2022, respectively (in thousands):

	Nine Months Ended September 30,		Change	
	2023	2022		
Employee related expenses	$ 3,275	$ 3,481	$ (206)	(6)%
Direct research and development expense by program				
LTI-01	2,370	8,964	(6,594)	(74)%
LTI-03	5,194	3,500	1,694	48%
Other expenses	22	160	(138)	(86)%
Total research and development expenses	$10,861	$16,105	$(5,244)	(33)%

Research and development expenses were $10.9 million and $16.1 million for the nine months ended September 30, 2023 and 2022, respectively. The decrease of $5.2 million in 2023 compared to 2022 was primarily driven by the impact of $6.6 million of lower direct program costs for LTI-01 as a result of the completion of the Phase 2a clinical study and drug substance manufacture, combined with a decrease in employee related expenses of $0.2 million that was driven by a lower employee headcount and the decrease in other expenses of $0.1 million. These decreases were partially offset by an increase of $1.7 million in direct program costs for LTI-03 due to higher clinical expenses for the Phase 1b clinical trial and higher preclinical expenses for long term toxicology studies.

General and Administrative Expenses

The following table summarizes Lung's general and administrative expenses for the nine months ended September 30, 2023 and 2022, respectively (in thousands):

	Nine Months Ended September 30,		Change	
	2023	2022		
Employee related expenses	$ 1,942	$ 1,947	$ (5)	— %
Professional fees for services	1,774	2,445	(671)	(27)%
Facilities and other expenses	809	895	(86)	(10)%
Total general and administrative expenses	$ 4,525	$ 5,287	$(762)	(14)%

General and administrative expenses were $4.5 million for the nine months ended September 30, 2023 compared to $5.3 million for the nine months ended September 30, 2022. The decrease of $0.8 million was primarily due to lower professional fees for services that were largely driven by a $1.2 million write-off in 2022 of previously deferred direct offering and other financing-related costs following a determination by management that the underlying financing transactions would no longer be pursued, partially offset by the impact of higher legal and other professional fees.

Gains from Affiliate

The gain from sale of equity securities in TFF of $0 and $9.4 million for the nine months ended September 30, 2023 and 2022, respectively, was a result of the sale of 962,000 shares of common stock of TFF on April 1, 2022, for net proceeds of $6.2 million to third parties and the sale of 500,000 additional shares of common stock of TFF on April 1, 2022 to Bios Special Opportunity Fund, LP, a related party, at a price of $6.43 per share, generating net proceeds of $3.2 million. Lung did not sell any TFF common stock during the nine months ended September 30, 2023.

Other Income, Net

Total other income, net was $0.1 million and $0.04 million for the nine months ended September 30, 2023 and 2022, respectively.

Income Tax

The provision for income taxes consists primarily of income taxes related to federal and state jurisdictions in which Lung conducts business. Lung maintains a full valuation allowance on its federal and state deferred tax assets as management has concluded that it is more likely than not that the deferred assets will not be utilized.

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes Lung's results of operations for the years ended December 31, 2022 and 2021, respectively (in thousands):

	Year Ended December 31,		Change	
	2022	2021		
Licensing revenue	$ 688	$ 556	$ 132	24%
Operating expenses:				
Research and development	(22,465)	(15,397)	(7,068)	46%
General and administrative	(6,763)	(4,720)	(2,043)	43%
Total operating expenses	(29,228)	(20,117)	(9,111)	45%
Loss from operations before gains from affiliate	(28,540)	(19,561)	(8,979)	46%
Gains from sale of equity securities in TFF	9,400	9,373	27	0.3%
Loss from operations	(19,140)	(10,188)	(8,952)	88%
Other income, net:				
Gain on extinguishment of PPP loan	—	253	(253)	(100)%
Interest income, net	99	30	69	230%
Other income, net	—	2	(2)	(100)%
Total other income, net	99	285	(186)	(65)%
Net loss	$(19,041)	$ (9,903)	$(9,138)	92%

Revenue

Licensing revenue of $0.7 million and $0.6 million for the years ended December 31, 2022 and 2021, respectively, consisted of revenue recognized from the License Agreement.

Research and Development Expenses

The following table summarizes Lung's research and development expenses for the years ended December 31, 2022 and 2021, respectively (in thousands):

	Year Ended December 31,		Change	
	2022	2021		
Employee related expenses	$ 4,484	$ 2,887	$1,597	55%
Direct research and development expense by program				
LTI-01	12,582	8,014	4,568	57%
LTI-03	5,151	4,014	1,137	28%
Other expenses	248	482	(234)	(49)%
Total research and development expenses	$22,465	$15,397	$7,068	46%

Research and development expenses were $22.5 million and $15.4 million for the years ended December 31, 2022 and 2021, respectively. The increase of $7.1 million was primarily driven by $4.6 million of higher direct program costs for LTI-01 as a result of higher manufacturing expenses to produce a drug substance, and a $1.6 million increase of employee related expenses that was driven largely by a higher employee headcount to support the growth and development of Lung's programs. In addition, direct program costs for LTI-03 increased by $1.1 million due primarily to higher expenses for preclinical toxicology studies, Phase 1a and Phase 1b clinical trial costs, and the necessary manufacturing activities to support those studies and trials, partially offset by the decrease in other research and development expenses.

General and Administrative Expenses

The following table summarizes Lung's general and administrative expenses for the years ended December 31, 2022 and 2021, respectively (in thousands):

	Year Ended December 31,		Change	
	2022	2021		
Employee related expenses	$2,518	$2,045	$ 473	23.1%
Professional fees for services	3,059	2,080	979	47%
Facilities and other expenses	1,186	595	591	99%
Total general and administrative expenses	$6,763	$4,720	$2,043	43%

General and administrative expenses were $6.8 million and $4.7 million for the years ended December 31, 2022 and 2021, respectively. The increase of $2.0 million was primarily driven by the $1.5 million increase in direct offering and other financing costs from the write-off of previously incurred financing-related costs, by the $0.5 million increase in employee related expenses from Lung's increased employee headcount and by the $0.6 million increase of meals, travel and other expenses due to increased corporate domestic and international travel in 2022, the increase in spend on corporate subscriptions and the increase in adoption of lease accounting in 2022, that was partially offset by a $0.6 million decrease in professional fees primarily from lower expenses for legal and employee search services.

Gains from Affiliate

The gain from sale of equity securities in TFF of $9.4 million for the year ended December 31, 2022, was a result of the sale of 962,000 shares of common stock of TFF to third parties on April 1, 2022 for the net proceeds of $6.2 million and the sale of 500,000 additional shares of common stock of TFF on April 1, 2022 to Bios Special Opportunity Fund, LP, a related party, at a price of $6.43 per share, generating net proceeds of $3.2 million. The gain from sale of equity securities in TFF of $9.4 million for the year ended December 31, 2021, was a result of the sale in March 2021 of 715,000 shares of common stock of TFF at an average price of $14.00 per share, net of direct transaction expenses of $0.6 million.

Other Income, Net

Total other income, net was $0.1 million and $0.3 million for the years ended December 31, 2022 and 2021, respectively.

Income Tax

The provision for income taxes consists primarily of income taxes related to federal and state jurisdictions in which Lung conducts business. Lung maintains a full valuation allowance on its federal and state deferred tax assets as management has concluded that it is more likely than not that the deferred assets will not be utilized.

Liquidity and Capital Resources

Sources of Liquidity

Since its inception, Lung had not generated any revenue from product sales and has incurred significant operating losses and negative cash flows from its operations. As of the date of the Lung Acquisition, Lung had funded its operations primarily through private placements of convertible preferred stock, an upfront payment received from a licensing agreement, sales of marketable equity securities in TFF, issuance of SAFEs and convertible promissory notes. Through September 30, 2023, these income sources generated total gross proceeds of approximately $108.8 million, including gross proceeds totaling $34.0 million generated from sales of common stock of TFF, gross proceeds totaling $21.5 million generated from sales of SAFEs, and $5.0 million of upfront payment under the License Agreement. As of September 30, 2023, Lung had cash and cash equivalents in the amount of $20.0 thousand.

Cash Flows for the Years Ended December 31, 2022 and 2021

The following table summarizes Lung's sources and uses of cash for each of the periods presented (in thousands):

	Nine Months Ended September 30,		Year Ended December 31,	
	2023	2022	2022	2021
Net cash flows used in operating activities	$(12,581)	$(17,355)	$(21,769)	$(20,675)
Net cash flows provided by investing activities	—	9,400	9,400	9,368
Net cash flows provided by (used in) financing activities	720	13,439	12,767	(351)
Net (decrease) increase in cash and cash equivalents	$(11,861)	$ 5,484	$ 398	$(11,658)

Operating Activities

For the nine months ended September 30, 2023, net cash used in operating activities consisted of a net loss of $15.2 million, partially offset by a decrease in net operating assets and liabilities of $2.2 million and net non-cash operating expenses of $0.4 million. The decrease in net operating assets and liabilities was primary attributable to a decrease in prepaid expenses and other current assets of $0.6 million, an increase in accounts payable of $1.6 million and an increase in accrued expenses and other current liabilities of $0.2 million, partially offset by a decrease in deferred revenue of $0.2 million. The non-cash operating expenses consisted mainly of stock-based compensation expense of $0.3 million and amortization of right-of-use lease assets of $0.1 million.

For the nine months ended September 30, 2022, net cash used in operating activities consisted of a net loss of $11.2 million and net non-cash operating expenses of $9.0 million, partially offset by a decrease in net operating assets and liabilities of $2.8 million. The decrease in net operating assets and liabilities was primary attributable to a decrease in prepaid expenses and other current assets of $4.2 million and increase in accounts payable of $0.7 million, partially offset by a decrease in deferred revenue of $0.8 million and a decrease in accrued expenses and other current liabilities of $1.3 million. The non-cash operating expenses consisted mainly of gains from sale of equity securities in TFF of $9.4 million, partially offset by stock-based compensation expense of $0.3 million and amortization of right-of-use lease assets of $0.1 million.

For the year ended December 31, 2022, net cash used in operating activities consisted of a net loss of $19.0 million and net non-cash operating expenses of $7.8 million, partially offset by a decrease in net operating assets and liabilities of $5.0 million. The decrease in net operating assets and liabilities was primary attributable to a decrease in prepaid expenses and other current assets of $5.4 million and an increase in accounts payable of

$1.1 million, partially offset by a decrease in deferred revenue of $0.7 million, a decrease in operating lease liability of $0.2 million and a decrease in accrued expenses and other current liabilities of $0.6 million. The non-cash operating expenses consisted mainly of gains from sale of equity securities in TFF of $9.4 million, partially offset by deferred financing costs written off of $1.0 million, stock-based compensation expense of $0.4 million and amortization of right-of-use lease assets of $0.2 million.

For the year ended December 31, 2021, net cash used in operating activities consisted of a net loss of $9.9 million, net non-cash operating expenses of $9.4 million, and an increase in net operating assets and liabilities of $1.4 million. The increase in net operating assets and liabilities was primary attributable to increase in prepaid expenses and other current assets of $6.4 million and an increase in accrued expenses and other current liabilities of $0.9 million, partially offset by an increase in accounts receivable due from a licensing partner of $5.0 million, a decrease in accounts payable of $0.3 million and a decrease in deferred revenue of $0.6 million. The non-cash operating expenses consisted mainly of gains from sale of equity securities in TFF of $9.4 million and gain on extinguishment of a Paycheck Protection Program loan of $0.3 million, partially offset by stock-based compensation expense of $0.3 million.

Investing Activities

In the nine months ended September 30, 2023, were there no investing activities.

For the nine months ended September 30, 2022, net cash provided by investing activities consisted of $9.4 million of net proceeds from sale of marketable securities in TFF.

For the year ended December 31, 2022 and 2021, net cash provided by investing activities consisted of $9.4 million of net proceeds from sale of marketable securities in TFF to a related party.

Financing Activities

For the nine months ended September 30, 2023, net cash provided by financing activities consisted of $0.7 million of proceeds from the issuance of convertible promissory notes.

For the nine months ended September 30, 2022, net cash provided by financing activities consisted of $13.4 million of net proceeds from the issuance of SAFEs.

For the year ended December 31, 2022, net cash provided by financing activities consisted of $13.4 million of net proceeds from the issuance of SAFEs.

For the year ended December 31, 2021, net cash used in financing activities consisted of $0.4 million of deferred financing costs.

Contractual Obligations and Commitments

Lease Obligations

Lung leases space under an operating lease agreement for administrative offices in Austin, Texas, which expires on March 31, 2024.

The following table summarizes its contractual obligations and commitments as of September 30, 2023:

	Payments Due by Period				
	Total	2023	2024	2025	Thereafter
			(in thousands)		
Operating lease obligation	$ 97	$ 49	$ 48	$—	$ —

Research and Development and Manufacturing Agreements

Lung has entered into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials and preclinical research studies and testing, clinical trials and manufacturing services. These contracts do not contain any minimum purchase commitments and are cancelable by Lung upon prior notice. Payments due upon postponement or cancellation consist of payments for services provided and expenses incurred, including non-cancelable obligations of Lung's service providers, up to the date of cancellation and penalties for postponement or cancellation for select vendors. These potential penalties were also not considered to be contractual obligations or commitments as they are uncertain as of September 30, 2023.

License and Collaboration Agreements

Lung is required to make certain payments under its license agreements, related to patent expenses, license fees, and assignment fees, as well as milestone and royalty payments upon the achievement of certain development and sales-based events. Lung's licenses agreements are described in more detail in Note 8 and Note 9, respectively, of the notes to its audited consolidated financial statements and unaudited condensed consolidated financial statements attached as Annex A and Annex B to this proxy statement, respectively.

Off-Balance Sheet Arrangements

As of September 30, 2023, Lung did not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Lung's consolidated financial statements are prepared in accordance with generally accepted accounting principles in the U.S. The preparation of Lung's consolidated financial statements and related disclosures requires it to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in its consolidated financial statements. Lung based its estimates on historical experience, known trends and events and various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Lung evaluates its estimates and assumptions on a periodic basis. Lung's actual results may differ from these estimates.

While Lung's significant accounting policies are described in more detail in Note 2 of the notes to its consolidated financial statements attached as Annex A to this proxy statement, Lung believes that the following accounting policies are those most critical to the judgments and estimates used in the preparation of its consolidated financial statements.

Revenue Recognition

In accordance with ASC 606, Lung recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which Lung expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, Lung performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as Lung satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, Lung identifies the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. Lung then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Licensing revenue

On November 12, 2020, Lung entered into the License Agreement with Taiho. Lung's license arrangements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and products, and obligations to participate on certain development committees with licensing partners.

The terms of such license arrangements generally include payment to Lung of one or more of the following:

- nonrefundable up-front fees, payments for the supply of clinical products, payment for research and development
- services, milestone payments and royalties on net sales of licensed products. Lung assessed whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to Lung's intellectual property is distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation as applicable. Judgment is required to determine SSP. Due to the early stage of Lung's licensed technology, the license of such technology is typically combined with the research and development services and committee participation as one performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development services cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. Lung utilizes judgment to assess the pattern of delivery of the performance obligation.

At the inception of each agreement that includes milestone payments, Lung evaluates whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within Lung's control or that of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation in the agreement based on relative SSP. At the end of each subsequent reporting period, Lung re-evaluates the probability of achievement of each such milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Research and Development Expenses

As part of the process of preparing Lung's consolidated financial statements, Lung is required to estimate its accrued research and development expenses. This process involves reviewing open contracts and work orders, communicating with Lung's personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when Lung has not yet been invoiced or otherwise notified of actual costs. Some of Lung's service providers invoice it in arrears for services performed, based on a pre-determined schedule or when contractual milestones are met. A significant portion of Lung's service providers require it to make advance payments and there may be instances in which these advance payments will exceed the level of services provided to it, resulting in a prepayment of the expense. Lung makes estimates of its accrued or prepaid expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to it at that time. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, Lung modifies its estimates of clinical

trial accruals or prepaids accordingly on a prospective basis. Examples of estimated accrued or prepaid research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with clinical trials and preclinical studies; and
- CMOs in connection with the production of preclinical and clinical trial materials.

Lung based its expenses related to external research and development services on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CMOs and CROs that supply, conduct and manage clinical trials and preclinical studies on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In recording accrued or prepaid service fees, Lung estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, Lung adjusts the accrual or the amount of prepaid expenses accordingly.

Although Lung does not expect its estimates to be materially different from amounts actually incurred, Lung's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. As of the date of the Lung Acquisition, there had not been any material adjustments to Lung's prior estimates of accrued research and development expenses.

Stock-Based Compensation

Lung accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments, including grants of stock options and restricted stock, to be recognized in the statements of operations and comprehensive loss based on their fair values. Lung measures stock-based awards based on their fair value on the date of grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, Lung issues stock options and restricted stock awards with only service-based vesting conditions and record the expense for these awards using the straight-line method.

Lung estimates the fair value of each stock option grant at the date of grant using the Black-Scholes option-pricing model and the fair value of each restricted common stock award is estimated on the date of grant based on the fair value of Lung's common stock on that same date. The Black-Scholes option-pricing model requires inputs based on certain subjective assumptions. Changes to these assumptions can materially affect the fair value of stock options and ultimately the amount of stock-based compensation expense recognized in Lung's consolidated financial statements. These assumptions include:

Expected Term—Lung has opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option, which is generally 10 years.

Expected Volatility—Due to Lung's limited operating history and a lack of company-specific historical and implied volatility data, Lung has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. Lung believes the group selected has sufficiently similar economic and industry characteristics, including stage of product development and life science industry focus, and includes companies that are most representative of Lung.

Risk-Free Interest Rate—The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of Lung's stock options.

Expected Dividend—As of the date of the Lung Acquisition, Lung had not issued any dividends and does not expect to issue dividends over the life of the options and therefore have estimated the dividend yield to be zero.

Lung accounted for stock option forfeitures during the period in which they occur.

Determination of the Fair Value of Common Stock

As there has been no public market for Lung's common stock as of September 30, 2023, the estimated fair value of its common stock has been determined by its board of directors as of the date of each option grant, with input from management, considering its most recently available third-party valuation of its common stock as well as its board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent third-party valuation to the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or Practice Aid. The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, Lung's board of directors considered the following methods:

- *Probability-Weighted Expected Return Method*. The probability-weighted expected return method, or PWERM is a scenario-based analysis that estimates the fair value of common stock based upon an analysis of future values for the business, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible forecasted outcomes as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk- adjusted discount rate and probability weighted to arrive at a non-marketable indication of value for the common stock.
- *Option Pricing Method*. Under the option pricing method, or OPM, shares are valued by creating a series of call options, representing the present value of the expected future returns to the stockholders, with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Hybrid Return Method*. The Hybrid Method is a blended approach using aspects of both the PWERM and OPM, in which the equity value in one of the scenarios is calculated using an OPM.

Based on Lung's stage of development and other relevant factors, Lung determined that the Hybrid Method was the most appropriate method for allocating its enterprise value to determine the estimated future fair value of its common stock. In addition to considering the third-party valuations of Lung's common stock, its board of directors considered various objective and subjective factors to determine the fair value of its common stock as of each grant date, including:

- the prices at which it sold preferred stock and the superior rights and preferences of the preferred stock relative to its common stock at the time of each grant;
- the progress of its research and development programs, including their stage of development, and its business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- its financial position, including cash on hand, and its historical and forecasted performance and operating results;

- the lack of an active public market for its common stock and the likelihood of achieving a liquidity event, such as an initial public offering or a sale of its company taking into consideration prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represent Lung's board of directors' and management's best estimates, which involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and it uses significantly different assumptions or estimates, its stock-based compensation expense could be materially different.

Investment in TFF

Pursuant to a contribution agreement executed on January 24, 2018, Lung's wholly owned subsidiary, TFF, was spun out into a separate company, whereby Lung received 4,000,000 shares of TFF's common stock in exchange for providing TFF with certain intellectual property assets licensed by Lung from the University of Texas. Lung applied the equity method of accounting to its investment in TFF as Lung determined that it continues to exercise significant influence over the operating and financial policies of TFF. Based on TFF's history of losses, Lung had previously concluded that its share of TFF's net losses under the equity method was greater than the carrying value of the investment. As a result, in 2019 management wrote down its investment in TFF to $0 and suspended further recognition of its share of losses incurred by TFF. In 2020 and 2021, Lung sold 1,765,000 shares of common stock of TFF generating proceeds of $23.4 million. In January 2022, Lung entered into a variable price forward sales contract with Jefferies LLC to sell 962,000 shares of common stock of TFF based upon the daily volume-weighted average price during the three-month period ended March 31, 2022 plus a premium applied over the term of the contract. In April 2022, the contract was consummated and as a result, Lung received total cash proceeds of $6.2 million from the sale of these shares. In April 2022, Lung sold 500,000 additional shares of common stock of TFF to Bios Special Opportunity Fund, LP, a related party, at a price of $6.43 per share, generating net proceeds of $3.2 million.

As of September 30, 2023 and December 31, 2022, Lung owned 733,000 shares of common stock of TFF, having a fair market value of $0.3 million and $0.6 million based on TFF's closing price per share of $0.35 and $0.84 on those dates, respectively.

Income Taxes

Lung accounted for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes Lung expected to pay or have refunded in the current year. Lung deferred income tax assets and liabilities are determined based on differences between financial statement reporting and tax basis accounting of assets and liabilities and net operating loss and credit carryforwards, which Lung measures using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Lung reduces deferred income tax assets, as necessary, by applying a valuation allowance to the extent that it determines it is more likely than not that some or all of its tax benefits will not be realized. In assessing the realizability of the net deferred tax assets, management considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes that it is more likely than not that Lung's deferred income tax assets will not be realized.

Lung accounted for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes.* Lung assessed all material positions reflected in its income tax returns, including all significant uncertain positions, for all tax years that are subject to assessment or challenge by relevant taxing authorities.

Upon determining the sustainability of its positions, Lung measured the largest amount of benefit possessing greater than 50% likelihood of being realized upon ultimate settlement. Lung reassessed such positions at each balance sheet date to determine whether any factors underlying the sustainability assertion have changed and whether or not the amount of the recognized tax benefit is still appropriate.

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

Lung historically recorded no current or deferred income tax expenses or benefits as it has incurred losses since its inception and accordingly, provide a full valuation allowance against its deferred tax assets.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Lung's financial position and results of operations is disclosed in the notes to its consolidated financial statements attached as Annex A to this proxy statement.

MATTERS TO BE VOTED ON

Proposal 1: To Approve the Issuance, in accordance with Nasdaq Listing Rule 5635(a), of Our Common Stock, Upon Conversion of Our Outstanding Series X Preferred Stock

Overview

As described above, we issued 19,903 shares of Series X Preferred Stock in the Lung Acquisition and 4,707 shares of Series X Preferred Stock in the Financing. The Series X Preferred Stock is intended to have rights that are generally equivalent to common stock, provided that the Series X Preferred Stock does not have the right to vote on most matters (including the election of directors). 24,610,000 shares of common stock (or 83.4% of our outstanding common stock on an as-converted basis) are issuable upon conversion of the above-described Series X Preferred Stock, assuming the approval of this Proposal 1 and without taking into account certain beneficial ownership limitations.

Subject to stockholder approval and certain beneficial ownership limitations, each share of Series X Preferred Stock is convertible into 1,000 shares of common stock. This Proposal 1 would provide the necessary approval to permit such conversion. If our stockholders have not approved the conversion of the Series X Preferred Stock into common stock by May 1, 2024 (six months after the closing of the Lung Acquisition), then a holder of 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. See *"Risk Factors—Risks Related to Common Stock*".

Shares Issuable Upon Conversion

Set forth below is a table summarizing the issued and outstanding Series X Preferred Stock, as well as the number of shares of common stock that are potentially issuable upon conversion of the Series X Preferred Stock, without taking into account certain beneficial ownership limitations. The sale into the public market of the underlying common stock could materially and adversely affect the market price of our common stock. See "*Risk Factors—Risks Related to Our Common Stock*".

	Series X Preferred Stock Issued and Outstanding	Common Stock (as converted)
Shares issued in Lung Acquisition	19,903	19,903,000
Shares issued in Financing	4,707	4,707,000
Total	24,610	24,610,000

Description of Series X Preferred Stock

Conversion. Subject to stockholder approval of this Proposal 1, (i) effective as of 5:00 p.m. (Eastern time) on the fourth business day after the date such stockholder approval is received, each share of Series X Preferred Stock then outstanding automatically converts into common stock at a rate of 1,000 shares of common stock for every one share of Series X Preferred Stock that is converted, and (ii) at any time thereafter at the option of the holder, into 1,000 shares of common stock, in the case of each of (i) and (ii) subject to certain beneficial ownership limitations, including that a holder of Series X Preferred Stock is prohibited from converting shares of Series X Preferred Stock into shares of common stock if, as a result of such conversion, such holder (together with its affiliates and any other persons acting as a group together with the holder or any of its affiliates) would beneficially own more than a specified percentage (to be initially set at 19.99% and thereafter adjusted by the holder to a number not to exceed 19.99%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

Voting Rights. Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of, or add any provision to, our restated certificate of incorporation or by-laws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing. Additionally, the approval of the holders of a majority of the Series X Preferred Stock is required for certain change of control transactions, provided that this approval right will terminate upon stockholder approval of this Proposal 1.

Dividends. Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal, on an as-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the common stock.

Liquidation and Dissolution. The Series X Preferred Stock ranks on parity with common stock upon any such liquidation, dissolution or winding-up.

Reasons for Stockholder Approval

Our common stock is listed on the Nasdaq Capital Market, and, as such, we are subject to the applicable rules of the Nasdaq Stock Market LLC, including Nasdaq Listing Rule 5635(a), which requires stockholder approval in connection with the acquisition of another company if the Nasdaq-listed company will issue 20% or more of its common stock. For purposes of Nasdaq Listing Rule 5635(a), the issuance of any common stock in the Lung Acquisition and the Financing is aggregated together. Thus, in order to permit the issuance of common stock upon conversion of the Series X Preferred Stock, we must first obtain stockholder approval of this issuance.

Beneficial Ownership Limitations

We are not seeking stockholder approval of a potential "change in control" under Nasdaq Listing Rule 5635(b), which generally prohibits Nasdaq-listed companies from issuing common stock to a stockholder in a transaction that would cause the holder to beneficially own 20% or more of the then-outstanding common stock (subject to certain exceptions). Assuming that Proposal 1 is approved, the Series X Preferred Stock will continue to have a beneficial ownership conversion limit that would prevent a stockholder from converting such stockholder's shares if, as a result of such conversion, such stockholder would beneficially own a number of shares above such stockholder's applicable conversion blocker (which cannot exceed 19.9% of our outstanding common stock).

Vote Required and Board of Directors Recommendation

Stockholder approval of this Proposal 1 requires a "FOR" vote from the stockholders representing a majority of the votes cast on the matter.

Of the shares of our common stock outstanding entitled to vote at the annual meeting, 344,345 shares of common stock were issued in the Lung Acquisition (as defined below under "*Proposal 1 – Lung Acquisition Agreement*") and any votes in favor of Proposal 1 with respect to shares will not count as votes in favor of Proposal 1 pursuant to the listing rules of the Nasdaq Stock Market. In addition, 2,502,346 shares of our common stock were reserved for issuance pursuant to options and warrants assumed in the Lung Acquisition. Any votes in favor of Proposal 1 with respect to shares issued upon exercise of such options or warrants will not count as votes in favor of Proposal 1 pursuant to the listing rules of the Nasdaq Stock Market. Such shares of common stock issued in

the Lung Acquisition and reserved for issuance pursuant to options and warrants assumed in the Lung Acquisition may be voted in favor of Proposal 1 for purposes of Delaware law. However, to comply with Nasdaq rules, we will instruct the inspector of elections to conduct a separate tabulation that subtracts the votes represented by these shares from the total number of shares voted on Proposal 1 to determine whether that proposal has been adopted in accordance with applicable Nasdaq rules.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE "*FOR*" THE APPROVAL OF THE SERIES X PREFERRED STOCK CONVERSION PROPOSAL.

Proposal 2: Election of Directors

Our restated certificate of incorporation, as amended, provides for a classified board of directors. This means our board of directors is divided into three classes, with each class having as nearly as possible an equal number of directors. The term of service of each class of directors is staggered so that the term of one class expires at each annual meeting of the stockholders.

Our board of directors currently consists of six members, divided into three classes as follows:

- Class I is comprised of Alan Musso, with a term ending at the 2024 annual meeting of stockholders;
- Class II is comprised of William C. Fairey and Nolan Sigal, M.D., Ph.D., each with a term ending at the 2025 annual meeting of stockholders; and
- Class III is comprised of Manuel C. Alves Aivado, M.D., Ph.D., Reinhard Ambros, Ph.D., and Josef H. von Rickenbach, each with a term ending at the annual meeting.

At each annual meeting of stockholders, directors are elected for a full term of three years to succeed those directors whose terms are expiring. Our board of directors, on the recommendation of our nominating and corporate governance committee, has nominated each of Manuel C. Alves-Aivado, M.D., Ph.D., Reinhard Ambros, Ph.D., and Josef H. von Rickenbach for re-election as Class III directors, with a term ending at the 2026 annual meeting of stockholders.

Unless otherwise instructed in the proxy, all proxies will be voted "FOR" the election of Dr. Aivado, Dr. Ambros and Mr. von Rickenbach to three-year terms ending at the 2026 annual meeting of stockholders, each such nominee to hold office until his successor has been duly elected and qualified. If elected, Dr. Aivado, Dr. Ambros and Mr. von Rickenbach have indicated a willingness to continue to serve as a director. In the event that Dr. Aivado, Dr. Ambros or Mr. von Rickenbach should be unable to serve, discretionary authority is reserved for the named proxy holders to vote for a substitute or to reduce the number of directors to be elected.

Each of Dr. Aivado, Dr. Ambros and Mr. von Rickenbach will be elected as a director at the annual meeting if the nominee receives a plurality of the votes cast by stockholders entitled to vote at the meeting.

Set forth below are the names of and certain information for each board member, including the nominees for election as Class III directors, as of November 30, 2023. The information presented includes each director's and nominee's principal occupation and business experience for the past five years and the names of other public companies of which he has served as a director during the past five years.

Nominees for Election as Class III Directors

Manuel C. Alves Aivado, M.D., Ph.D., has served as our chief executive officer and as a member of our board of directors since September 2018. Previously, Dr. Aivado served as our president from September 2018 to October 2023, and senior vice president, chief medical officer from September 2014 to September 2018. From March 2012 to September 2014, Dr. Aivado served as vice president of clinical development and pharmacovigilance at Taiho Oncology, Inc., a pharmaceutical company. From October 2006 to March 2012, Dr. Aivado served as senior medical director in the clinical development group at GlaxoSmithKline, Inc., a global pharmaceutical company. Dr. Aivado has also served as an instructor in medicine at Beth Israel Deaconess Medical Center/Harvard Medical School. Prior to his industry experience, Dr. Aivado practiced clinical medicine in Germany for nearly ten years. During that time, he was awarded the Dr. Mildred Scheel cancer research scholarship award in 2002. Dr. Aivado is a German board-certified physician for internal medicine, hematology, and medical oncology. He received an M.D. and Ph.D. from the Medical School of the University of Dusseldorf in Germany. We believe that Dr. Aivado is qualified to serve on our board of directors due to his service as our president and chief executive officer, previous role as our chief medical officer, extensive knowledge of our company, and significant background in pharmaceutical research and development.

Reinhard J. Ambros, Ph.D., has served as a member of our board of directors since June 2013. From 2005 until 2017, Dr. Ambros served as global head of Novartis Venture Funds, a globally acting corporate biotechnology venture fund. Prior to that, from 1999 until 2005, he served as head of group strategic planning and as global head of business development and licensing for cardiovascular and metabolic diseases at Novartis AG, a multinational pharmaceutical company. He currently serves on the boards of several biotechnology companies in Europe and the U.S. He also served as advisor to German and Swiss Government Biotechnology Funds. Dr. Ambros received an M.S. from the University of Regensburg, Germany, and a Ph.D. in medicinal chemistry and pharmacology from the University of Regensburg, Germany. We believe Dr. Ambros is qualified to serve on our board of directors due to his management experience in the biotechnology sector and his service on other boards of directors.

Josef H. von Rickenbach has served as a member of our board of directors since June 2019. Mr. von Rickenbach has served as managing director of Stet Vision LLC, a life sciences business advisory firm, since December 2018. He co-founded and served as president and chief executive officer of HelioVision, Inc., a biotechnology company, from April 2017 until its acquisition by Aldeyra Therapeutics, Inc. in February 2019. Previously, Mr. von Rickenbach was a founder of Parexel International Corporation, a global clinical research organization and biopharmaceutical services company, in 1982 and served as a director, chairman of the board, and chief executive officer of Parexel from 1983 until the company's acquisition by Pamplona Capital Management, LLP in September 2017. Mr. von Rickenbach received an M.B.A. from Harvard Business School and a B.A. in business economics from the University of Lucerne in Switzerland. We believe Mr. von Rickenbach is qualified to serve on our board of directors due to his management experience in the biotechnology sector, his decades of experience in drug development, and his service on other boards of directors.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE "*FOR*" THE ELECTION OF MANUEL C. ALVES-AIVADO, M.D., PH.D., REINHARD J. AMBROS, PH.D., AND JOSEF H. VON RICKENBACH AS CLASS III DIRECTORS.

Directors Continuing in Office Class I Directors (Term Expires at 2024 Annual Meeting)

Alan Musso has served as a member of our board of directors since October 2023. Since August 2023, Mr. Musso has served as the chief financial officer of Fulcrum Therapeutics, a public clinical-stage biopharmaceutical company focused on improving the lives of patients with genetically defined rare diseases in areas of high unmet medical need. Previously, he served as the chief financial officer of ReViral Ltd., a privately held, clinical-stage biopharmaceutical company focused on discovering, developing, and commercializing novel antiviral therapeutics that target respiratory syncytial virus (RSV), that was acquired by Pfizer Inc., in June 2022, from October 2019 until September 2022. Prior to ReViral, from September 2018 to September 2019, Mr. Musso was the chief financial officer and treasurer at Peloton Therapeutics Inc., a company focused on the development of novel small molecule therapeutic candidates for the treatment of cancer. While at Peloton, Mr. Musso helped to prepare the company for an initial public offering until the company was acquired by Merck & Co. in July 2019. Prior to Peloton, from November 2014 to August 2018, Mr. Musso served as the chief financial officer and treasurer at Bellicum Pharmaceuticals, Inc., a public biotechnology company focused on discovering and developing novel, controllable cellular immunotherapies for various forms of cancer. Prior to Bellicum, from February 2002 to November 2014, Mr. Musso served in various positions at Targacept, Inc., a public biopharmaceutical company. Mr. Musso spent the early part of his career as a senior internal auditor for Pfizer as well as a certified public accountant for KPMG International. Mr. Musso served as a member of the board of directors of Lung from April 2022 until the closing of the Lung Acquisition in October 2023. Mr. Musso holds a B.S. in accounting from Saint Mary's College of California, and a Master's Degree from the Thunderbird School of Global Management. We believe Mr. Musso is qualified to serve on our board of directors due to his extensive management and financial experience in the life sciences industry.

Class II Directors (Term Expires at 2025 Annual Meeting)

William C. Fairey has served as a member of our board of directors since October 2023. Mr. Fairey served as executive vice president and chief commercial officer of MyoKardia, Inc., a clinical-stage biopharmaceutical company discovering and developing targeted therapies for the treatment of serious cardiovascular diseases, from January 2019 to November 2020 prior to its acquisition by Bristol Myers Squibb in October 2020. Prior to MyoKardia, from January 2018 to January 2019, Mr. Fairey served as executive vice president and chief operating officer of ChemoCentryx, Inc., a public biopharmaceutical company focused on discovering, developing and commercializing orally administered therapeutics to treat autoimmune diseases, inflammatory disorders and cancer. During that time, Mr. Fairey was responsible for the sales, marketing, medical affairs and market access functions, including commercialization of late stages compounds. Prior to ChemoCentryx, Mr. Fairey served in various roles at Actelion Pharmaceuticals Ltd., a pharmaceutical company, and its subsidiaries, from January 2001 to December 2017. Actelion was acquired by Johnson & Johnson in 2017. Mr. Fairey has served on the board of directors of Mirum Pharmaceuticals, a public biopharmaceutical company focused on the identification, acquisition, development and commercialization of novel therapies for debilitating rare and orphan diseases, since August 2021 and on the board of directors of Ascendis Pharma A/S, a public biopharmaceutical company organized under the laws of the Kingdom of Denmark, since August 2022. Mr. Fairey served as a member of the board of directors of Lung from August 2021 until the closing of the Lung Acquisition in October 2023. Mr. Fairey holds a B.S. in biology from the University of Oregon and an M.B.A. from Saint Mary's College of California. We believe Mr. Fairey is qualified to serve on our board of directors due to his significant experience in the life sciences industry and his experience on corporate boards of public companies.

Nolan Sigal, M.D., Ph.D., has served as a member of our board of directors since April 2019. Dr. Sigal has served as a partner at Alerce Management Co., L.P., a private investment firm, since January 2018. From March 2008 to December 2017, Dr. Sigal was founder and chief executive officer of Tunitas Therapeutics, Inc., a biopharmaceutical company. Prior to Tunitas, Dr. Sigal's biotechnology experience included president of Trellis Bioscience, Inc., a biotechnology company, EVP of research and development, and chief scientific officer at Cytokinetics, Inc., a biopharmaceutical company, and SVP, research at Pharmacopeia, Inc., a biotechnology company, where he was one of Pharmacopeia's founders. He served at Merck & Company Inc. as executive director of the Department of Immunology Research. Prior to Merck, he was an assistant professor at the University of Toronto. Dr. Sigal graduated from Princeton University with an A.B. in chemistry, and he completed an M.D./Ph.D. program at the University of Pennsylvania. We believe Dr. Sigal is qualified to serve on our board of directors due to his significant experience as an executive of a biopharmaceutical company and his background in life sciences investing.

The information presented above regarding the specific experience, qualifications, attributes, and skills of each director and nominee led our nominating and corporate governance committee and our board of directors to conclude that he or she should serve as a director. In addition, we believe that all of our directors and nominees possess the attributes or characteristics described in "*Corporate Governance Matters—Director Nomination Process*" that the nominating and corporate governance committee expects of each director. There are no family relationships among any of our directors, nominees for director, or executive officers.

Proposal 3: Approval of an Amendment to our 2021 Stock Incentive Plan to Increase the Number of Shares of our Common Stock Available for Issuance Thereunder by 3,000,000 Shares

Why We Are Requesting Stockholder Approval of an Amendment to the 2021 Stock Incentive Plan

We are asking stockholders to approve an amendment, which we refer to as the Plan Amendment, to our 2021 Stock Incentive Plan, which we refer to as the 2021 Plan, to increase the number of shares issuable under the 2021 Plan. Our board of directors believes that the future success of the company depends, in large part, on our ability to maintain a competitive position by attracting, retaining and motivating key employees with experience and ability. We believe that our stock-based compensation programs are central to this objective. The market for qualified personnel in our industry remains highly competitive. Among the companies we compete with for talent are many early stage, private and venture-backed entities, as well as recently public and mature public companies. In each case, these companies offer equity incentives as a central and significant component of their compensation packages. The ability to grant equity awards is therefore critical to our ability to attract, retain and motivate top talent and is a key component of our compensation program. We expect the additional share authorization under the 2021 Plan to provide us with enough shares to make critical, market-based grants to our executives and other employees and non-employee directors for at least the next two years, with such timing dependent on a variety of factors, including the price of our shares and hiring activity during the next few years, forfeiture of outstanding option awards, and noting that future circumstances may require us to change our current equity grant practices. However, we cannot predict our future equity grant practices, the future price of our shares or future hiring activity with any degree of certainty at this time, and the additional shares authorized under the 2021 Plan could last for a shorter or longer time.

The 2021 Plan was adopted by our board of directors, upon the recommendation of the compensation committee and subject to stockholder approval, on April 14, 2021, and was approved by our stockholders on June 15, 2021. On January 17, 2024, upon the recommendation of the compensation committee and subject to stockholder approval, our board of directors adopted the Plan Amendment solely to increase the number of shares of common stock issuable under the 2021 Plan by 3,000,000 shares, subject to adjustment in the event of stock splits and other similar events. We refer to the 2021 Plan, as amended by the Plan Amendment, as the Amended Plan. Other than increasing the number of shares issuable under the 2021 Plan, the Plan Amendment does not make any changes to the 2021 Plan.

If stockholders approve the Plan Amendment, subject to adjustment in the event of stock splits and other similar events, awards may be made under the Amended Plan for up to the sum of (i) 3,625,000 shares of common stock (reduced by the number of shares subject to awards granted under our 2017 Stock Incentive Plan, or the 2017 Plan, between April 15, 2021 and June 15, 2021) and (ii) the number of shares of common stock (up to 429,123 shares) subject to awards granted under the 2017 Plan, our 2016 Stock Incentive Plan, or the 2016 Plan, and our 2006 Stock Incentive Plan, or the 2006 Plan, which awards expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us pursuant to a contractual repurchase right.

We and our board of directors understand that our equity compensation needs must be balanced against the dilutive effect of such programs to our stockholders. Accordingly, the share pool increase being requested for the Amended Plan is the result of careful consideration by our compensation committee of the expected impact of utilizing regular annual equity compensation grants and an assessment of the magnitude of the increase that our stockholders would likely find acceptable. We believe that the size of the proposed share pool under the Amended Plan is reasonable and, if stockholder approval of the Plan Amendment is obtained, we expect that the share pool under the Amended Plan will allow us to grant equity awards at rates sufficient to meet our future growth needs following the Lung Acquisition, which will depend on a variety of factors, including the price of our shares and hiring activity during the next few years, forfeitures of outstanding awards, and noting that future circumstances may require us to change our current equity grant practices. We cannot predict our future equity grant practices, the future price of our shares or future hiring activity with any degree of certainty at this time, and the share reserve under the Amended Plan could last for a shorter or longer time.

The following table includes information regarding (i) all of the company's outstanding equity awards as of December 31, 2023 (under all of the company's equity-based compensation plans or arrangements under which shares of the Company's common stock may be issued, but excluding the 2017 Employee Stock Purchase Plan) and including outstanding stock options granted under Lung's 2013 Long-Term Incentive Plan, as amended, or the 2013 Plan, that were assumed by us in connection with the Lung Acquisition and (ii) the number of shares available for future awards under each such equity-based compensation plan or arrangement as of December 31, 2023:

Number of shares underlying outstanding options	2,201,202
Weighted average exercise price of outstanding options	$ 7.45
Weighted average remaining contractual term of outstanding options	6.33 years
Shares available under the 2006 Plan	—
Shares available under the 2016 Plan	—
Shares available under the 2013 Plan	—
Shares available under the 2021 Plan	427,517
Shares requested for approval pursuant to the 2021 Plan	3,000,000
Estimated total number of shares available for issuance under all plans (assuming approval of the Amendment)	3,427,517
Number of shares of common stock outstanding	4,885,512

On January 19, 2024, our compensation committee approved the grant to certain employees of the company who are not executive officers of options to purchase an aggregate of 100,000 shares of our common stock pursuant to the 2021 Plan.

The shares available for issuance, if the Plan Amendment is approved, would facilitate our ability to continue to grant equity incentives which is vital to our ability to fully engage and attract and retain the highly skilled individuals required to support our retention and growth in the extremely competitive labor markets in which we compete. Our employees are some of our most valuable assets, and such awards are crucial to our ability to motivate individuals in our service to achieve our goals, particularly in light of the Lung Acquisition. We strongly believe that the approval of the Plan Amendment is instrumental to our future success.

OUR BOARD OF DIRECTORS RECOMMENDS THAT YOU VOTE TO APPROVE THE AMENDMENT OF THE 2021 PLAN BY VOTING FOR PROPOSAL 3.

The remainder of this Proposal 3 includes:

- Highlights of the Amended Plan;
- Reasons Why Stockholders Should Approve the Plan Amendment;
- Information Regarding Overhang and Dilution; and
- Description of the Amended Plan

Highlights of the Amended Plan

- *No Evergreen*. The Amended Plan does not provide for any automatic increase in the number of shares of common stock available for issuance under the Amended Plan.
- *No Liberal Share Recycling*. The Amended Plan prohibits the re-granting of (i) shares withheld or delivered to satisfy the exercise price of an award or to satisfy tax withholding obligations, (ii) shares that were subject to a stock appreciation right, or SAR, and were not issued upon the net settlement or net exercise of such award, or (iii) shares repurchased on the open market using proceeds from the exercise of an award.
- *No Repricing of Options or SARs*. The Amended Plan prohibits the direct or indirect repricing of stock options or SARs without stockholder approval.

- *No Discounted Options or SARs*. All options and SARs must have an exercise or measurement price that is at least equal to the fair market value of the underlying common stock on the date of grant.
- *No Reload Options or SARs*. No options or SARs granted under the Amended Plan may contain a provision entitling the award holder to the automatic grant of additional options or SARs in connection with any exercise of the original option or SAR.
- *No Dividend Equivalents on Options or SARs*. No options or SARs granted under the Amended Plan may provide for the payment or accrual of dividend equivalents.
- *Dividends & Dividend Equivalents on Restricted Stock, RSUs and Other-Stock Based Awards Not Paid Until Award Vests*. Any dividends or dividend equivalents granted with respect to restricted stock, restricted stock units, or RSUs, or other stock-based awards will be subject to the same restrictions on transfer and forfeitability as the award with respect to which it is granted.
- *Limit on Awards to Non-Employee Directors*. The maximum aggregate amount of cash value (calculated based on grant date fair value for financial reporting purposes) granted to any individual non-employee director in his or her capacity as a non-employee director in any calendar year may not exceed $750,000, provided, however, that such maximum aggregate amount shall not exceed $1,000,000 in any calendar year for any individual non-employee director in such non-employee director's initial year of service. Fees paid by us on behalf of any non-employee director in connection with regulatory compliance and amounts paid to a non-employee director as a reimbursement for an expense will not count against this limitation. Exceptions to this limitation may be made by our board of directors, in its discretion, in extraordinary circumstances, provided that the non-employee director receiving the additional compensation does not participate in the decision to award such compensation. This limitation on awards to non-employee directors shall not apply to cash or awards granted to a non-employee director in their capacity as a consultant or advisor to us.
- *Material Amendments Require Stockholder Approval*. Stockholder approval is required prior to an amendment to the Amended Plan that would (i) materially increase the number of shares authorized, (ii) expand the types of awards that may be granted, or (iii) materially expand the class of participants eligible to participate.
- *Administered by an Independent Committee*. The Amended Plan is administered by our compensation committee, which is made up entirely of independent directors.

Reasons Why Stockholders Should Approve the Plan Amendment

Incents, Retains and Motivates Talent. It is critical to our success that we incent, retain and motivate the best talent in what is a tremendously competitive labor market. Our equity-based compensation program has always been a key component in our ability to pay market-competitive compensation to our employees and, if the Plan Amendment is approved by stockholders, we will be able to continue to offer market-competitive compensation.

Broad-based Eligibility for Equity Awards. Our equity incentive program is broad-based, with eligible employees in good standing being eligible to receive equity awards, including individuals employed by Lung who became employees of the Company following the Lung Acquisition. Furthermore, since our board of directors typically grants awards to employees that generally vest over a period of time, employees must generally remain with us in order to realize the potential benefits of their equity awards. If the Plan Amendment is approved by stockholders, we will be able to maintain a broad-based equity compensation program.

Aligns with our Pay-for-Performance Compensation Philosophy. We believe that equity-based compensation is fundamentally performance-based. As the value of our stock appreciates, our employees receive greater compensation at the same time that our stockholders are receiving a greater return on their investment. Conversely, if the stock price does not appreciate following the grant of an equity award, then our employees

would not receive any compensation in respect of stock options and would receive reduced compensation in respect of RSUs. If the Plan Amendment is approved by stockholders, we will be able to continue to link pay-for-performance closely.

Aligns Employee and Director Interests with Stockholder Interests. Providing a significant portion of our employee and non-employee director compensation in the form of equity directly aligns the interests of those employees and directors with the interests of our stockholders. If the Plan Amendment is approved by stockholders, we will be able to grant equity-based incentives that foster this alignment between our employees and non-employee directors and our stockholders.

Consistent with Stockholder Interests and Sound Corporate Governance. As described under the heading "*—Highlights of the Amended Plan*" and more thoroughly below, the Amended Plan was purposefully designed to include features that are consistent with the interests of our stockholders and sound corporate governance. The approval by stockholders of the Plan Amendment would allow us to continue to make equity awards subject to such terms and conditions.

Information Regarding Overhang and Dilution

In developing our request to increase the number of shares of common stock under the Amended Plan and in analyzing the impact of utilizing equity as a means of compensation on our stockholders, we considered both our "overhang" and our "burn rate."

Overhang is a measure of potential dilution which we define as the sum of (i) the total number of shares underlying all equity awards outstanding and (ii) the total number of shares available for future award grants, divided by the sum of (a) the total number of shares underlying all equity awards outstanding, (b) the total number of shares available for future awards and (c) the number of shares outstanding. As of December 31, 2023, there were 2,201,202 shares underlying all option awards outstanding, 427,517 shares available for future awards and the number of shares of common stock outstanding as of December 31, 2023 was 4,885,512. Accordingly, our overhang on December 31, 2023 was 38.2%. If the 3,000,000 additional shares of common stock proposed to be authorized for issuance under the Amended Plan are included in the calculation, our overhang on December 31, 2023 would have been 55.2%.

Burn rate provides a measure of the potential dilutive impact of our equity award program which we calculate by dividing the number of shares subject to equity awards granted during the year by the basic weighted average number of shares outstanding. Set forth below is a table that reflects our burn rate for the 2023, 2022 and 2021 calendar years as well as an average over those years.

Calendar Year	Awards Granted (1)	Basic Weighted Average Number of Shares of Common Stock Outstanding	Gross Burn Rate (2)
2023	—	4,598,715	0%
2022	170,262	4,539,318	4%
2021	281,100	4,440,338	6%
Three-Year Average	150,454	4,526,124	3%

(1) "Awards granted" includes shares subject to stock options and shares subject to RSUs, in each case counted on a one-for-one basis.
(2) We define "Gross burn rate" as the number of equity awards granted in the year divided by the basic weighted average number of shares of common stock outstanding.

We expect our burn rate to increase in the year ending December 31, 2024 as compared to the year ended December 31, 2023 as a result of the Lung Acquisition.

Description of the Amended Plan

The following is a brief summary of the Amended Plan, which is qualified in its entirety by reference to the Amended Plan. A copy of the Plan Amendment is attached as *Annex D* to this proxy statement, and a full copy of the Amended Plan is attached as *Annex E* to this proxy statement. References to our board of directors in this summary will include our compensation committee or any similar committee appointed by our board of directors to administer the Amended Plan.

Types of Awards; Shares Available for Awards; Share Counting Rules

The Amended Plan provides for the grant of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, or the Code, nonstatutory stock options, SARs, restricted stock, RSUs, other stock-based awards and cash-based awards as described below, which we collectively refer to as awards.

Subject to adjustment in the event of stock splits, stock dividends or similar events, awards may be made under the Amended Plan for up to the sum of 3,625,000 shares of our common stock (reduced by the number of shares subject to awards granted under the 2017 Plan between April 15, 2021 and June 15, 2021) plus the number of shares of common stock (up to 429,123 shares) subject to awards granted under the 2017 Plan, the 2016 Plan or the 2006 Plan, which awards expire, terminate or are otherwise surrendered, cancelled or forfeited or repurchased by us pursuant to a contractual repurchase right. Any or all of the awards may be in the form of incentive stock options, subject to any limitations under the Code.

The Amended Plan provides that the maximum amount of cash and equity compensation (calculated based on grant date fair value for financial reporting purposes) granted to any individual non-employee director in his or her capacity as a non-employee director in any calendar year may not exceed $0.75 million in the case of an incumbent non-employee director or $1.0 million in the case of the first year of service of a non-employee director. Fees paid by us on behalf of any non-employee director in connection with regulatory compliance and amounts paid to a non-employee director as a reimbursement for an expense will not count against this limitation. Exceptions to this limitation may only be made by our board of directors, in its discretion, in extraordinary circumstances, provided that the non-employee director receiving the additional compensation does not participate in the decision to award such compensation. Cash and awards granted under the Amended Plan to non-employee directors in their capacity as our consultants or advisors are not subject to this limitation.

For purposes of counting the number of shares available for the grant of awards under the Amended Plan, all shares of common stock covered by SARs will be counted against the number of shares available for the grant of awards. However, SARs that may be settled only in cash will not be so counted. Similarly, to the extent that an award of RSUs may be settled only in cash, no shares will be counted against the shares available for the grant of awards under the Amended Plan. In addition, if we grant an SAR in tandem with an option for the same number of shares of our common stock and provide that only one such award may be exercised, which we refer to as a tandem SAR, only the shares covered by the option, and not the shares covered by the tandem SAR, will be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Amended Plan.

Shares covered by awards under the Amended Plan that expire or are terminated, surrendered, or cancelled without having been exercised or are forfeited in whole or in part (including as the result of shares subject to such award being repurchased by us at the original issuance price pursuant to a contractual repurchase right) or that result in any shares not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash) will again be available for the grant of awards under the Amended Plan (subject, in the case of incentive stock options, to any limitations under the Code). In the case of the exercise of an SAR, the number of shares counted against the shares available for the grant of awards under the Amended Plan will be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle the SAR upon exercise, and the shares covered by a tandem SAR will not again become available for grant upon the expiration or termination of the tandem SAR.

Shares of common stock that are delivered (by actual delivery, attestation, or net exercise) to us by a participant to purchase shares of common stock upon exercise of an award or to satisfy tax withholding obligations (including shares retained from the award creating the tax obligation) will not be added back to the number of shares available for the future grant of awards under the Amended Plan. Shares purchased by us on the open market using proceeds from the exercise of an award will not increase the number of shares available for future grant of awards.

In connection with a merger or consolidation of an entity with us or our acquisition of property or stock of an entity, our board of directors may grant awards under the Amended Plan in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof on such terms as our board of directors determines appropriate in the circumstances, notwithstanding any limitation on awards contained in the Amended Plan. Any such substitute awards will not count against the overall share limits of the Amended Plan or any sublimits contained in the plan, except as required by reason of Section 422 and related provisions of the Code.

Descriptions of Awards

Options. Optionees receive the right to purchase a specified number of shares of common stock at a specified exercise price and subject to the other terms and conditions that are specified in connection with the option grant. An option that is not intended to be an "incentive stock option" is a "nonstatutory stock option." Options may not be granted at an exercise price that is less than 100% of the fair market value of our common stock on the date of grant. If our board of directors approves the grant of an option with an exercise price to be determined on a future date, the exercise price may not be less than 100% of the fair market value of our common stock on that future date. Under present law, incentive stock options may not be granted at an exercise price less than 110% of the fair market value in the case of stock options granted to optionees holding more than 10% of the total combined voting power of all classes of our stock or any of our subsidiaries. Under the terms of the Amended Plan, options may not be granted for a term in excess of ten years (and, under present law, five years in the case of incentive stock options granted to optionees holding greater than 10% of the total combined voting power of all classes of our stock or any of our subsidiaries). The Amended Plan permits participants to pay the exercise price of options using one or more of the following manners of payment: (i) payment by cash or by check, (ii) except as may otherwise be provided in the applicable option agreement or approved by our board of directors, in connection with a "cashless exercise" through a broker, (iii) to the extent provided in the applicable option agreement or approved by our board of directors, and subject to certain conditions, by delivery of shares of common stock to us owned by the participant valued at their fair market value, (iv) to the extent provided in an applicable nonstatutory stock option agreement or approved by our board of directors, by delivery of a notice of "net exercise" as a result of which we will retain a number of shares of common stock otherwise issuable pursuant to the stock option equal to the aggregate exercise price for the portion of the option being exercised divided by the fair market value of our common stock on the date of exercise, (v) to the extent permitted by applicable law and provided for in the applicable option agreement or approved by our board of directors, by any other lawful means, or (vi) by any combination of these forms of payment. No option granted under the Amended Plan may contain a provision entitling the participant to the automatic grant of additional options in connection with any exercise of the original option. No options granted under the Amended Plan may provide for the payment or accrual of dividend equivalents.

*Stock Appreciation Right*s. An SAR is an award entitling the holder, upon exercise, to receive a number of shares of our common stock, or cash (or a combination of shares of our common stock and cash) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of our common stock over the measurement price. The Amended Plan provides that the measurement price of an SAR may not be less than the fair market value of our common stock on the date the SAR is granted (provided, however, that if our board of directors approves the grant of an SAR effective as of a future date, the measurement price will not be less than 100% of the fair market value on such future date) and that SARs may not be granted with a term in excess of 10 years. No SARs granted under the Amended Plan may contain a provision entitling the participant to the automatic grant of additional SARs in connection with any exercise of the original SAR. No SARs granted under the Amended Plan may provide for the payment or accrual of dividend equivalents.

Limitation on Repricing of Options or SARs. With respect to options and SARs, unless such action is approved by our stockholders or otherwise permitted under the terms of the Amended Plan in connection with certain changes in capitalization and reorganization events, we may not (1) amend any outstanding option or SAR granted under the Amended Plan to provide an exercise price or measurement price per share that is lower than the then-current exercise price or measurement price per share of such outstanding option or SAR, (2) cancel any outstanding option or SAR (whether or not granted under the Amended Plan) and grant in substitution therefor new awards under the Amended Plan (other than certain substitute awards issued in connection with an acquisition by us, as described above) covering the same or a different number of shares of our common stock and having an exercise price or measurement price per share lower than the then-current exercise price or measurement price per share of the canceled option or SAR, (3) cancel in exchange for a cash payment any outstanding option or SAR with an exercise price or measurement price per share above the then-current fair market value of our common stock, or (4) take any other action under the Amended Plan that constitutes a "repricing" within the meaning of the Nasdaq Listing Rules.

Restricted Stock Awards. Restricted stock awards entitle recipients to acquire shares of our common stock, subject to our right to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) in the event that the conditions specified in the applicable award are not satisfied prior to the end of the applicable restriction period established for such award. Any dividends (whether paid in cash, stock or property) declared and paid by us with respect to shares of restricted stock will be paid to the participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of unvested dividends will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. No interest will be paid on unvested dividends.

Restricted Stock Unit Awards. RSUs entitle the recipient to receive shares of our common stock, or cash equal to the fair market value of such shares, to be delivered at the time such award vests and settles pursuant to the terms and conditions established by our board of directors. Our board of directors may provide that settlement of RSUs will be deferred, on a mandatory basis or at the election of the participant in a manner that complies with Section 409A of the Code. A participant has no voting rights with respect to any RSU. Our board of directors may provide that a grant of RSUs may provide the participant with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of our common stock. Any such dividend equivalents may be paid currently or credited to an account for the participant and may be settled in cash and/or shares of our common stock to the extent provided in the applicable award agreement and will be subject to the same restrictions on transfer and forfeitability as the RSUs with respect to which such dividend equivalents are awarded. No interest will be paid on dividend equivalents.

Other Stock-Based Awards. Under the Amended Plan, our board of directors may grant other awards of shares of our common stock, and other awards that are valued in whole or in part by reference to, or are otherwise based on, shares of our common stock or other property, having such terms and conditions as our board of directors may determine. We refer to these types of awards as other stock-based awards. Other stock-based awards may be available as a form of payment in settlement of other awards granted under the Amended Plan or as payment in lieu of compensation to which a participant is otherwise entitled. Other stock-based awards may be paid in shares of our common stock or in cash, as our board of directors may determine. The award agreement of other stock-based award may provide the holder of other stock-based award with the right to receive dividend equivalents. Dividend equivalents may be paid currently or credited to an account for the participant and may be settled in cash and/or shares of our common stock and will be subject to the same restrictions on transfer and forfeitability as the other stock-based award with respect to which they are paid. No interest will be paid on dividend equivalents.

Cash-Based Awards. Under the Amended Plan, the board of directors has the right to grant cash-based awards including awards subject to performance conditions.

Performance Conditions. Awards under the Amended Plan may be subject to the achievement of performance goals. Our board of directors may specify that the degree of granting, vesting and/or payout of any award is subject to the achievement of one or more of the following objective performance measures established by the board of directors, which may be based on the relative or absolute attainment of specified levels of one or any combination of the following measures (and which may be determined in accordance with generally accepted accounting principles, or GAAP, or on a non-GAAP basis, as determined by the board of directors): (1) the entry into an arrangement or agreement with a third party for the development, commercialization, marketing or distribution of products, services or technologies, or for conducting a research program to discover and develop a product, service or technology, and/or the achievement of milestones under such arrangement or agreement, including events that trigger an obligation or payment right; (2) achievement of domestic and international regulatory milestones, including the submission of filings required to advance products, services and technologies in clinical development and the achievement of approvals by regulatory authorities relating to the commercialization of products, services and technologies; (3) the achievement of discovery, preclinical and clinical stage scientific objectives, discoveries or inventions for products, services and technologies under research and development; (4) the entry into or completion of a phase of clinical development for any product, service or technology, such as the entry into or completion of phase 1, 2 and/or 3 clinical trials; (5) the consummation of debt or equity financing transactions, or acquisitions of business, technologies and assets; (6) new product or service releases; (7) the achievement of qualitative or quantitative performance measures set forth in operating plans approved by the board of directors from time to time; (8) specified levels of product sales, net income, earnings before or after discontinued operations, interest, taxes, depreciation and/or amortization, operating profit before or after discontinued operations and/or taxes, sales, sales growth, earnings growth, cash flow or cash position, gross margins, stock price, market share, return on sales, assets, equity or investment; (9) improvement of financial ratings; (10) achievement of balance sheet or income statement objectives; (11) total stockholder return; (12) other comparable measures of financial and operational performance; and/ or (13) any other measure selected by the board of directors. Such goals may reflect absolute entity or business unit performance or a relative comparison to the performance of a peer group of entities or other external measure of the selected performance criteria and may be absolute in their terms or measured against or in relationship to other companies comparably, similarly or otherwise situated. The board of directors may specify that such performance measures will be adjusted to exclude any one or more of (i) non-recurring or unusual gains or losses, (ii) gains or losses on the dispositions of discontinued operations, (iii) the cumulative effects of changes in accounting principles, (iv) the write-down of any asset, (v) fluctuation in foreign currency exchange rates, (vi) charges for restructuring and rationalization programs and (vii) any other item or items determined by our board of directors. Such performance measures: (x) may vary by participant and may be different for different awards; (y) may be particular to a participant or the department, branch, line of business, subsidiary or other unit in which the participant works and (z) may cover such period as may be specified by our board of directors. The board of directors may, at any time, waive the achievement of the applicable performance measures, or otherwise amend performance awards in a manner permitted under the Amended Plan.

Eligibility to Receive Awards

All of our employees, officers, and directors, as well as our consultants and advisors, are eligible to receive awards under the Amended Plan. However, incentive stock options may only be granted to our employees, employees of our present or future parent or subsidiary corporations, and employees of any other entities the employees of which are eligible to receive incentive stock options under the Code.

Transferability of Awards

Awards may not be sold, assigned, transferred, pledged or otherwise encumbered by a participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an incentive stock option, pursuant to a qualified domestic relations order. During the life of the participant, awards are exercisable only by the participant. However, except with respect to awards that are subject to Section 409A of the Code, our board of directors may permit or provide in an award for the gratuitous transfer of

the award by the participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the participant and/or an immediate family member thereof if we would be eligible to use a Registration Statement on Form S-8 for the registration under the Securities Act of 1933, as amended, of common stock subject to such award to the proposed transferee. Further, we are not required to recognize any transfer until such time as the participant and the permitted transferee have, as a condition to the transfer, delivered to us a written instrument in form and substance satisfactory to us confirming that such transferee will be bound by all of the terms and conditions of the award. None of the restrictions described in this paragraph prohibit a transfer from the participant to the Company.

No Rights as a Stockholder; Clawback

No participant will have any rights as a stockholder with respect to any shares of common stock to be issued with respect to an award granted under the Amended Plan until becoming a record holder of such shares, subject to the terms of an award agreement. In accepting an award under the Amended Plan, a participant agrees to be bound by any clawback policy that we have in effect or may adopt in the future, including the clawback policy we adopted in November 2023.

Administration

The Amended Plan will be administered by our board of directors. Our board of directors has the authority to grant awards and to adopt, amend and repeal the administrative rules, guidelines and practices relating to the Amended Plan that it deems advisable and to construe and interpret the provisions of the Amended Plan and any award agreements entered into under the Amended Plan. Our board of directors may correct any defect, supply any omission or reconcile any inconsistency in the Amended Plan or any award. All actions and decisions by our board of directors with respect to the Amended Plan and any awards made under the Amended Plan will be made in our board of directors' discretion and will be final and binding on all persons having or claiming any interest in the Amended Plan or in any award.

Pursuant to the terms of the Amended Plan, our board of directors may delegate any or all of its powers under the Amended Plan to one or more committees or subcommittees of our board of directors. Our board of directors has authorized our compensation committee to administer certain aspects of the Amended Plan, including the granting of awards to executive officers. Our board of directors, or any such committee, may delegate to an officer of the Company, the authority to make grants under the Amended Plan, subject to the limitations set forth in the Amended Plan. Our board of directors delegated such authority to our chief executive officer for awards under the Amended Plan.

Subject to any applicable limitations contained in the Amended Plan, our board of directors, our compensation committee, or any other committee or officer to whom our board of directors delegates authority, as the case may be, selects the recipients of awards and determines (i) the number of shares of common stock, cash or other consideration covered by awards and the terms and conditions of such awards, including the dates upon which such awards become exercisable or otherwise vest, (ii) the exercise or measurement price of awards, if any, and (iii) the duration of awards.

Each award under the Amended Plan may be made alone or in addition or in relation to any other award. The terms of each award need not be identical, and our board of directors need not treat participants uniformly. Our board of directors will determine the effect on an award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a participant, and the extent to which, and the period during which, the participant (or the participant's legal representative, conservator, guardian or designated beneficiary) may exercise rights or receive any benefits under an award. Our board of directors may at any time provide that any award will become immediately exercisable in whole or in part, free from some or all restrictions or conditions or otherwise realizable in whole or in part, as the case may be.

In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock, other than an ordinary cash dividend, we are required to make equitable adjustments (or make substituted awards, as applicable), in the manner determined by our board of directors, to (i) the number and class of securities available under the Amended Plan, (ii) the share counting rules set forth in the Amended Plan, (iii) the number and class of securities and exercise price per share of each outstanding option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of restricted stock, and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding RSU award and each outstanding other stock-based award.

We will indemnify and hold harmless each director, officer, employee or agent to whom any duty or power relating to the administration or interpretation of the Amended Plan has been or will be delegated against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with our board of directors' approval) arising out of any act or omission to act concerning the Amended Plan unless arising out of such person's own fraud or bad faith.

Amendment of Awards. Except as otherwise provided under the Amended Plan with respect to repricing outstanding stock options or SARs, our board of directors may amend, modify or terminate any outstanding award, including but not limited to, substituting therefor another award of the same or a different type, changing the date of exercise or realization, and converting an incentive stock option to a nonstatutory stock option, provided that the participant's consent to any such action will be required unless our board of directors determines that the action, taking into account any related action, does not materially and adversely affect the participant's rights under the Amended Plan or the change is otherwise permitted under the terms of the Amended Plan in connection with a change in capitalization or reorganization event.

Documentation. Each award will be evidenced in a manner as determined by our board of directors. Each award may contain terms and conditions in addition to those set forth in the Amended Plan.

Reorganization Events

The Amended Plan contains provisions addressing the consequences of any reorganization event. A reorganization event is defined under the Amended Plan as (a) any merger or consolidation of us with or into another entity as a result of which all of our common stock is converted into or exchanged for the right to receive cash, securities or other property, or is cancelled, (b) any transfer or disposition of all of our common stock for cash, securities or other property pursuant to a share exchange or other transaction or (c) our liquidation or dissolution.

Provisions Applicable to Awards Other than Restricted Stock. Under the Amended Plan, in connection with a reorganization event, our board of directors may take any one or more of the following actions as to all or any (or any portion of) outstanding awards other than restricted stock on such terms as our board of directors determines, unless otherwise provided in an applicable agreement): (i) provide that such awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited immediately prior to the consummation of the reorganization event and/or unexercised awards will terminate immediately prior to the consummation of the reorganization event unless exercised by the participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part prior to or upon such reorganization event, (iv) in the event of a reorganization event under the terms of which holders of common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (A) the number of shares of common stock subject to the

vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (B) the excess, if any, of (I) the acquisition price over (II) the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award, (v) provide that, in connection with a liquidation or dissolution of the Company, awards will convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under the Amended Plan in regard to reorganization events, our board of directors will not be obligated to treat all awards, all awards held by a participant, or all awards of the same type, identically.

For the purposes of the previous paragraph, an award (other than restricted stock) will be considered assumed if, following the reorganization event, the award confers the right to purchase or receive pursuant to the terms of such award, for each share of common stock subject to the award immediately prior to the consummation of the reorganization event, the consideration (whether cash, securities or other property) received as a result of the reorganization event by holders of common stock for each share of common stock held immediately prior to the consummation of the reorganization event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of common stock). However, if the consideration received as a result of the reorganization event is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), we may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that our board of directors determines to be equivalent in value (as of the date of such determination or another date specified by our board of directors) to the per share consideration received by holders of outstanding shares of common stock as a result of the reorganization event.

The Amended Plan also contains certain provisions related to the treatment of RSUs that are subject to Section 409A of the Code in connection with a reorganization event.

Provisions Applicable to Restricted Stock. Upon the occurrence of a reorganization event other than our liquidation or dissolution, our repurchase and other rights with respect to outstanding restricted stock will inure to the benefit of our successor and will, unless our board of directors determines otherwise, apply to the cash, securities or other property which our common stock was converted into or exchanged for pursuant to such reorganization event in the same manner and to the same extent as they applied to such restricted stock. Our board of directors, however, may either provide for termination or deemed satisfaction of the repurchase or other rights under any applicable agreement between the participant and us, either initially or by amendment, or provide for forfeiture of such restricted stock if issued at no cost. Upon the occurrence of a reorganization event involving our liquidation or dissolution, except as otherwise provided in any applicable agreement between the participant and us, all restrictions and conditions on all restricted stock then outstanding will automatically be deemed terminated or satisfied.

Provisions for Foreign Participants

Our board of directors may establish one or more sub-plans under the Amended Plan to satisfy applicable securities, tax or other laws of various jurisdictions. Our board of directors will establish such sub-plans by adopting supplements to the Amended Plan containing any limitations on the board of directors' discretion under the Amended Plan and any additional terms and conditions not otherwise inconsistent with the Amended Plan as our board of directors deems necessary or desirable. All supplements adopted by the board of directors will be deemed to be part of the Amended Plan, but each supplement will only apply to participants within the affected jurisdiction.

Amendment or Termination

No award may be granted under the Amended Plan after June 15, 2031, but awards previously granted may extend beyond that date. Our board of directors may amend, suspend or terminate the Amended Plan or any portion of the Amended Plan at any time, except that no amendment that would require stockholder approval under the rules of the national securities exchange on which we then maintain our primary listing may be made effective unless and until such amendment has been approved by our stockholders. If the national securities exchange on which we then maintain our primary listing does not have rules regarding when stockholder approval of amendments to equity compensation plans is required (or if our common stock is not then listed on any national securities exchange), no amendment of the Amended Plan materially increasing the number of shares authorized under the Amended Plan, expanding the types of awards that may be granted under the Amended Plan or materially expanding the class of participants eligible to participate in the Amended Plan will be effective unless and until the Company's stockholders approve such amendment. If at any time the approval of our stockholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to incentive stock options, our board of directors may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Amended Plan adopted in accordance with the procedures described above will apply to, and be binding on the holders of, all awards outstanding under the Amended Plan at the time the amendment is adopted, provided that our board of directors determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of participants under the Amended Plan. No award will be made that is conditioned on stockholder approval of any amendment to the Amended Plan unless the award provides that (i) it will terminate or be forfeited if stockholder approval of such amendment is not obtained within no more than 12 months from the date the award was granted and (ii) it may not be exercised or settled (or otherwise result in the issuance of shares of our common stock) prior to the receipt of such stockholder approval.

No additional shares will become issuable under the Amended Plan if stockholders do not approve the Plan Amendment. In this event, awards may continue to be made under the 2021 Plan for so long as shares remain available thereunder, and the board of directors will consider whether to adopt additional and/or alternative arrangements based on its assessment of the needs of the Company.

Plan Benefits

As of December 31, 2023, approximately 46 persons were eligible to receive awards under the 2021 Plan, including our currently serving named executive officers, 12 employees (other than our currently serving named executive officers), five non-employee directors, and 17 consultants.

New Plan Benefits Table

The granting of awards under the Amended Plan is discretionary, and we cannot now determine the number or type of awards to be granted in the future to any particular person or group. We are obligated to grant each of our non-employee directors an option to purchase 2,725 shares in 2024 under the terms of our director compensation program. Based upon our current director compensation program, future awards to purchase shares will be made to non-employee directors in years subsequent to 2024.

Name and Position	Dollar Value	Number of Shares of Common Stock Underlying Option Awards
Manuel C. Alves Aivado, M.D., Ph.D., *Chief Executive Officer*	—	—
Brian Windsor, Ph.D., *President*	—	—
D. Allen Annis, Ph.D., *Former Senior Vice President, Research*	—	—
Vojislav Vukovic, M.D., Ph.D., *Former Senior Vice President, Chief Medical Officer*	—	—
All Current Executive Officers as a Group	—	—
All Current Directors who are not Executive Officers as a Group(1)	—	13,625
All Employees, including all Current Executive Officers who are not Executive Officers, as a Group	—	—
Each associate of any Director, Executive Officer, or Nominee for Director	—	—

(1) Represents the annual stock option award to purchase shares of common stock to be granted in 2024 to each non-employee director. Under our director compensation program, each non-employee director who has served on our board of directors for at least six months will receive an option to purchase 2,725 shares of our common stock immediately following each annual meeting of stockholders. The value of a stock option to be granted under this policy will be determined using the same method we use to calculate the grant-date fair value of stock options in our financial statements included in our 2022 annual report to stockholders. Excludes (i) options that the non-employee directors will be entitled to receive under our director compensation program for subsequent years following 2024 and (ii) any discretionary awards that any non-employee director may be awarded under the Amended Plan.

On January 18, 2024 the last reported sale price of the Company's common stock on the Nasdaq Capital Market was $4.23.

Awards Granted Under the 2021 Plan

Since the initial effectiveness of the 2021 Plan through December 31, 2023, the following number of shares underlying equity awards have been granted to the individuals and groups described in the table below.

Name and Position	Number of Shares of Common Stock Underlying Options Granted	Number of Shares of Common Stock Underlying RSU Awards Granted
Named Executive Officers:		
Manuel C. Alves Aivado, M.D., Ph.D., *Chief Executive Officer*	178,652	—
Brian Windsor, Ph.D., *President*	—	—
D. Allen Annis, Ph.D., *Former Senior Vice President, Research*	39,352	—
Vojislav Vukovic, M.D., Ph.D., *Former Senior Vice President, Chief Medical Officer*	27,502	—
All current executive officers, as a group	218,004	—
All current directors who are not executive officers, as a group	22,575	—
Each nominee for election as a director	—	—
Each associate of our directors, executive officers or nominees	—	—
Each other person who received or is to receive 5 percent of such options, warrants or rights	—	—
All employees, including all current officers who are not executive officers, as a group	98,585	—

Federal Income Tax Consequences

The following is a summary of the U.S. federal income tax consequences that generally will arise with respect to awards granted under the Amended Plan. This summary is based on the federal tax laws in effect as of the date of this proxy statement. In addition, this summary assumes that all awards are exempt from, or comply with, the rules under Section 409A of the Code regarding nonqualified deferred compensation. Changes to these laws could alter the tax consequences described below.

Incentive Stock Options. A participant will not have income upon the grant of an incentive stock option. Also, except as described below, a participant will not have income upon exercise of an incentive stock option if the participant has been employed by the Company or its corporate parent or 50% or majority-owned corporate subsidiary at all times beginning with the option grant date and ending three months before the date the participant exercises the option. If the participant has not been so employed during that time, then the participant will be taxed as described below under "Nonstatutory Stock Options." The exercise of an incentive stock option may subject the participant to the alternative minimum tax. A participant will have income upon the sale of the stock acquired under an incentive stock option at a profit (if sales proceeds exceed the exercise price). The type of income will depend on when the participant sells the stock. If a participant sells the stock more than two years after the option was granted and more than one year after the option was exercised, then all of the profit will be long-term capital gain. If a participant sells the stock prior to satisfying these waiting periods, then the participant will have engaged in a disqualifying disposition and a portion of the profit will be ordinary income and a portion may be capital gain. This capital gain will be long-term if the participant has held the stock for more than one year and otherwise will be short-term. If a participant sells the stock at a loss (sales proceeds are less than the exercise price), then the loss will be a capital loss. This capital loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

Nonstatutory Stock Options. A participant will not have income upon the grant of a nonstatutory stock option. A participant will have compensation income upon the exercise of a nonstatutory stock option equal to the value of the stock on the day the participant exercised the option less the exercise price. Upon sale of the stock, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the stock on the day the option was exercised. This capital gain or loss will be long-term if the participant has held the stock for more than one year and otherwise will be short-term.

Stock Appreciation Rights. A participant will not have income upon the grant of a stock appreciation right. A participant generally will recognize compensation income upon the exercise of an SAR equal to the amount of the cash and the fair market value of any stock received. Upon the sale of the stock, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the stock on the day the SAR was exercised. This capital gain or loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

Restricted Stock Awards. A participant will not have income upon the grant of restricted stock unless an election under Section 83(b) of the Code is made within 30 days of the date of grant. If a timely 83(b) election is made, then a participant will have compensation income equal to the value of the stock less the purchase price. When the stock is sold, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the stock on the date of grant. If the participant does not make an 83(b) election, then when the stock vests the participant will have compensation income equal to the value of the stock on the vesting date less the purchase price. When the stock is sold, the participant will have capital gain or loss equal to the sales proceeds less the value of the stock on the vesting date. Any capital gain or loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

Restricted Stock Units. A participant will not have income upon the grant of an RSU. A participant is not permitted to make a Section 83(b) election with respect to an award of RSUs. When the shares of common stock are delivered with respect to the RSUs (which may be upon vesting or may be at a later date), the participant will have income on the settlement date in an amount equal to the fair market value of the stock on such date less the purchase price, if any. When the stock is sold, the participant will have capital gain or loss equal to the sales proceeds less the value of the stock on the settlement date. Any capital gain or loss will be long-term if the participant held the stock for more than one year and otherwise will be short-term.

Other Stock-Based Awards. The tax consequences associated with any other stock-based award granted under the Amended Plan will vary depending on the specific terms of such award. Among the relevant factors are whether or not the award has a readily ascertainable fair market value, whether or not the award is subject to forfeiture provisions or restrictions on transfer, the nature of the property to be received by the participant under the award, and the participant's holding period and tax basis for the award or underlying common stock.

Tax Consequences to the Company. There will be no tax consequences to the Company except that the Company will be entitled to a deduction when a participant has compensation income, subject to the limitations of Section 162(m) of the Code.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE "*FOR*" APPROVAL OF THE AMENDMENT TO THE 2021 STOCK INCENTIVE PLAN

Proposal 4: Approval of an Amendment to our Restated Certificate of Incorporation, as Amended, to Increase the Number of Authorized Shares of our Common Stock from 45,000,000 to 100,000,000

Background

We are asking our stockholders to approve an amendment to our restated certificate of incorporation, as amended, to increase the number of authorized shares of our common stock. Our authorized capital stock presently consists of 45,000,000 shares of common stock, $0.001 par value per share ("common stock"), and 5,000,000 shares of preferred stock, $0.001 par value per share ("preferred stock"), of which 24,847 are designated as Series X Preferred Stock. On January 17, 2024, our board of directors approved, subject to stockholder approval, an amendment to our restated certificate of incorporation, as amended, to (i) increase the number of authorized shares of our capital stock from 50,000,000 shares to 105,000,000 shares and (ii) increase the number of authorized shares of our common stock from 45,000,000 shares to 100,000,000 shares. The proposed amendment to our restated certificate of incorporation, as amended, would not increase or otherwise affect our authorized preferred stock.

As of November 30, 2023, 4,885,512 shares of our common stock were issued and outstanding, no shares were held in treasury, and 24,610 shares of Series X Preferred Stock were issued and outstanding. In addition, as of November 30, 2023, there were:

- 24,847,000 shares of common stock reserved for issuance upon conversion of the Series X Preferred Stock;
- 2,205,752 shares of common stock issuable upon the exercise of options under our existing equity incentive plans;
- 427,517 and 7,500 shares of common stock reserved for issuance under our 2021 Plan and 2017 Employee Stock Purchase Plan, respectively, as well as any automatic increases in the number of shares of our common stock reserved under these plans; and
- 3,726,696 shares of common stock reserved for issuance upon exercise of outstanding warrants.

Accordingly, as of November 30, 2023, out of the 45,000,000 shares of common stock presently authorized, 36,099,977 shares are issued and outstanding or reserved for issuance and 8,900,023 shares of common stock remain available for future issuance.

In addition, if Proposal 3 is approved, we will be required to reserve 3,000,000 additional shares of common stock for future issuance under the 2021 Plan (as further described under "*Description of the Amended Plan – Types of Awards; Shares Available for Awards; Share Counting Rules*" on page 120 above).

The approval of Proposal 4 is not necessary for the conversion of the Series X Preferred Stock into our shares of common Stock pursuant to Proposal 1 as there is sufficient number of common stock authorized to permit such conversion without the approval of Proposal 4. Proposal 4 has been considered and approved independently by our board of directors.

Overview of the Proposed Amendment

A copy of the amendment to our restated certificate of incorporation, as amended, is attached as Annex F to this proxy statement. The proposed amendment provides that the third paragraph of Article Fourth of our restated certificate of incorporation, as amended, be deleted in its entirety, and replaced with the following:

"The total number of shares of all classes of stock of which the Corporation shall have the authority to issue is 105,000,000 shares, consisting of (i)100,000,000 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock")."

The proposed amendment, if approved by our stockholders, would become effective upon the filing of a certificate of amendment of our restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware. Our board of directors reserves the right, notwithstanding stockholder approval and without further action by our stockholders, to elect not to proceed with the proposed amendment if the board of directors determines that the proposed amendment is no longer in our best interests and the best interests of our stockholders.

If our stockholders approve the proposed amendment, subject to the discretion of our board of directors, we intend to file the certificate of amendment of our restated certificate of incorporation, as amended, with the Secretary of State of the State of Delaware as soon as practicable after the annual meeting.

Rationale for the Proposed Amendment

Over the past several years, we have used shares of our common stock to, among other things, engage in financings, incentivize and compensate employees and other service providers and for other general corporate purposes. Our board of directors believes that it is in the best interests of our company to increase the number of authorized shares of our common stock in order to give us greater flexibility in considering and planning for potential business needs. The increase in the number of authorized but unissued shares of common stock would enable us, without the expense and delay of seeking stockholder approval, to issue shares from time to time as may be required for proper business purposes.

We anticipate that we may issue additional shares of common stock in the future in connection with one or more of the following:

- financing transactions, such as public or private offerings of common stock or convertible securities;
- licenses, partnerships, collaborations and other similar transactions;
- our equity incentive plans;
- strategic investments and transactions; and
- other corporate purposes that have not yet been identified.

At this time, we do not have any plans, proposals or arrangements, written or oral, to issue any of the proposed additional authorized shares of our common stock for general corporate or any other purposes. However, our board of directors believes that the availability of additional authorized shares of our common stock will afford us needed flexibility in acting upon financing transactions to strengthen our financial position and/or engaging in strategic activities without using cash. Unless required by applicable law or stock exchange rules, no further vote of the holders of common stock will be required with respect to any such transaction.

Potential Effects of the Proposed Amendment

The additional shares of common stock for which authorization is sought would be identical in powers, privileges and rights to the shares of common stock that are now authorized. Holders of common stock do not have preemptive rights to subscribe to additional securities that we may issue.

The issuance of additional shares of common stock may, among other things, have a dilutive effect on earnings per share and on stockholders' equity and voting rights. Further, future sales of substantial amounts of our common stock, or the perception that these sales might occur, could adversely affect the prevailing market price of our common stock or limit our ability to raise additional capital. Stockholders should recognize that, as a result of this proposal, they will own a smaller percentage of shares relative to the total authorized shares of the company than they presently own.

Our board of directors has not proposed the increase in amount of authorized shares with the intention of discouraging tender offers or takeover attempts. However, the availability of additional authorized shares for issuance may have the effect of discouraging a merger, tender offer, proxy contest or other attempt to obtain control.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE "*FOR*" APPROVAL OF THE AMENDMENT TO OUR RESTATED CERTIFICATE OF INCORPORATION, AS AMENDED, TO INCREASE THE NUMBER OF AUTHORIZED SHARES OF OUR COMMON STOCK FROM 45,000,000 TO 100,000,000.

Proposal 5: Advisory Vote to Approve Named Executive Officer Compensation

We are providing our stockholders the opportunity to vote to approve, on an advisory, non-binding basis, the compensation of the executive officers named in the Summary Compensation Table under "Executive Compensation," who we refer to as our "named executive officers," as disclosed in this proxy statement in accordance with the SEC's rules. This proposal, which is commonly referred to as "say-on-pay," is required by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which added Section 14A to the Exchange Act. Section 14A of the Exchange Act also requires that stockholders have the opportunity to cast an advisory vote with respect to whether future executive compensation advisory votes will be held every one, two or three years, which is the subject of Proposal 6.

Our executive compensation programs are designed to attract, motivate, and retain our executive officers, who are critical to our success. Under these programs, our named executive officers are rewarded for the achievement of our near-term and longer-term financial and strategic goals and for driving corporate financial performance and stability. The programs contain elements of cash and equity-based compensation and are designed to align the interests of our executives with those of our stockholders.

The "Executive Compensation" section of this proxy statement beginning on page 146 describes in detail our executive compensation programs and the decisions made by the compensation committee and our board of directors with respect to the year ended December 31, 2022. Our executive compensation program embodies a pay-for-performance philosophy that supports our business strategy and aligns the interests of our executives with our stockholders.

Our board of directors believes the link between compensation and the achievement of our near- and long-term business goals can help drive our performance over time. At the same time, we believe our compensation programs do not encourage excessive risk-taking by management.

Our board of directors is asking stockholders to approve a non-binding advisory vote on the following resolution:

RESOLVED, that the compensation paid to the company's named executive officers, as disclosed pursuant to the compensation disclosure rules of the Securities and Exchange Commission, the compensation tables and any related material disclosed in this proxy statement, is hereby approved.

As an advisory vote, this proposal is not binding. Neither the outcome of this advisory vote nor of the advisory vote included in Proposal 6 overrules any decision by the company or our board of directors (or any committee thereof), creates or implies any change to the fiduciary duties of the company or our board of directors (or any committee thereof), or creates or implies any additional fiduciary duties for the company or our board of directors (or any committee thereof). However, our compensation committee and board of directors value the opinions expressed by our stockholders in their vote on this proposal and will consider the outcome of the vote when making future compensation decisions for named executive officers.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE "*FOR*" APPROVAL OF THE COMPENSATION OF OUR NAMED EXECUTIVE OFFICERS

Proposal 6: Advisory Vote on the Frequency of Future Advisory Votes to Approve Named Executive Officer Compensation

In Proposal 5, we are providing our stockholders the opportunity to vote to approve, on an advisory, non-binding basis, the compensation of our named executive officers. In this Proposal 6, we are asking our stockholders to cast a non-binding advisory vote regarding the frequency of future advisory votes to approve named executive officer compensation. Stockholders may vote for a frequency of every one, two, or three years, or may abstain.

Our board of directors believes that an annual executive compensation advisory vote will facilitate more direct stockholder input about named executive officer compensation and is consistent with our policy of reviewing our compensation program annually, as well as seeking frequent input from our stockholders on corporate governance and executive compensation matters. We believe an annual vote would be the best governance practice for our company at this time.

Our board of directors will take into consideration the outcome of this vote in making a determination about the frequency of future named executive officer compensation advisory votes. However, because this vote is advisory and non-binding, our board of directors may decide that it is in the best interests of our stockholders and the company to hold the advisory vote to approve executive compensation more or less frequently than the option selected by a plurality of our stockholders.

OUR BOARD OF DIRECTORS BELIEVES THAT HOLDING THE EXECUTIVE COMPENSATION ADVISORY VOTE *EVERY ONE YEAR* IS IN THE BEST INTERESTS OF THE COMPANY AND ITS STOCKHOLDERS AND RECOMMENDS VOTING FOR A FREQUENCY OF *EVERY ONE YEAR*.

Proposal 7: Ratification of the Appointment of Independent Registered Public Accounting Firm

Our audit committee has appointed the firm of Marcum LLP, or Marcum, an independent registered public accounting firm, as independent auditors for the fiscal year ended December 31, 2023 on January 10, 2024, and we formally engaged Marcum on January 9, 2024. Prior to the appointment of Marcum, PricewaterhouseCoopers LLP, or PricewaterhouseCoopers, served as our independent registered public accounting firm. On October 30, 2023, the audit committee dismissed PricewaterhouseCoopers from service as our independent registered public accounting firm, effective as of the closing of the Lung Acquisition.

The report of PricewaterhouseCoopers on our financial statements for the fiscal years ended December 31, 2022 and 2021 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, did not contain an adverse opinion or a disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principle. The report included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern.

During the years ended December 31, 2022 and 2021, and the subsequent interim period from January 1, 2023 to October 30, 2023, there were:

(i) no "disagreements" (as that term is defined in Item 303(a)(1)(iv) of Regulation S-K and the related instructions) between us and PricewaterhouseCoopers on any matter of accounting principles or practices, financial statement disclosure, or audit scope or procedures, which disagreements, if not resolved to PricewaterhouseCoopers' satisfaction, would have caused PricewaterhouseCoopers to make reference in connection with its opinion to the subject matter of the disagreement, and

(ii) no "reportable events," as that term is described in Item 304(a)(1)(v) of Regulation S-K and the related instructions.

Although stockholder approval of our audit committee's appointment of Marcum is not required by law, our board of directors believes that it is advisable to give stockholders an opportunity to ratify this appointment. If this proposal is not approved at the annual meeting, our audit committee will reconsider its appointment of Marcum. Marcum has no direct or indirect material financial interest in our company or our subsidiaries. Representatives of Marcum are expected to attend the annual meeting and will have the opportunity to make a statement, if they desire to do so, and will be available to respond to appropriate questions from our stockholders.

Audit Fees and Services

PricewaterhouseCoopers was our independent registered public accounting firm for the years ended December 31, 2022 and December 31, 2021. The following table summarizes the fees of PricewaterhouseCoopers for those two fiscal years as well as the subsequent interim period from January 1, 2023 to October 31, 2023. All such services and fees were pre-approved by our audit committee in accordance with the "Pre-Approval Policies and Procedures" described below. During the years ended December 31, 2023, December 31, 2022 and December 31, 2021, no services were provided to us by Marcum.

Fee Category	2023	2022	2021
Audit Fees (1)	$214,100	$546,200	$477,600
All Other Fees (2)	$ 2,125	$ 3,081	$ 3,000
Total Fees	$216,225	$549,281	$480,600

(1) "Audit Fees" consist of fees for the audit of our annual financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q and other professional services provided in connection with regulatory filings or engagements.
(2) "All Other Fees" consist of database subscription fees paid to PricewaterhouseCoopers.

Pre-Approval Policies and Procedures

Our audit committee has adopted procedures requiring the pre-approval of all non-audit services performed by our independent registered public accounting firm in order to assure that these services do not impair the auditor's independence. These procedures generally approve the performance of specific services subject to a cost limit for all such services. This general approval is to be reviewed, and if necessary modified, at least annually. Management must obtain the specific prior approval of the audit committee for each engagement of the independent registered public accounting firm to perform other audit-related or other non-audit services. The audit committee does not delegate its responsibility to approve services performed by the independent registered public accounting firm to any member of management. Our audit committee has delegated authority to the committee chair to pre-approve any audit or non-audit service to be provided to us by our independent registered public accounting firm provided that the fees for such services do not exceed $100,000. Any approval of services by the committee chair pursuant to this delegated authority must be reported to the audit committee at the next meeting of the committee.

The standard applied by the audit committee, or the chair of the audit committee, in determining whether to grant approval of any type of non-audit service, or of any specific engagement to perform a non-audit service, is whether the services to be performed, the compensation to be paid therefore and other related factors are consistent with the independent registered public accounting firm's independence under guidelines of the SEC and applicable professional standards. Relevant considerations include whether the work product is likely to be subject to, or implicated in, audit procedures during the audit of our financial statements, whether the independent registered public accounting firm would be functioning in the role of management or in an advocacy role, whether the independent registered public accounting firm's performance of the service would enhance our ability to manage or control risk or improve audit quality, whether such performance would increase efficiency because of the independent registered public accounting firm's familiarity with our business, personnel, culture, systems, risk profile and other factors, and whether the amount of fees involved, or the non-audit services portion of the total fees payable to the independent registered public accounting firm in the period would tend to reduce the independent registered public accounting firm's ability to exercise independent judgment in performing the audit.

OUR BOARD OF DIRECTORS RECOMMENDS THAT STOCKHOLDERS VOTE "*FOR*" THE RATIFICATION OF THE APPOINTMENT OF MARCUM LLP AS OUR INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023.

BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

Election of Directors

Our board of directors is divided into three classes, with members of each class holding office for staggered three-year terms. There is currently one Class I director (Alan Musso), whose term expires at the 2024 annual meeting of stockholders; two Class II directors (William C. Fairey and Nolan Sigal, M.D., Ph.D.), whose terms expire at the 2025 annual meeting of stockholders; and three Class III directors (Manuel C. Alves Aivado, M.D., Ph.D., Reinhard J. Ambros, Ph.D. and Josef H. von Rickenbach), whose terms expire at this annual meeting of stockholders (in all cases until his successor has been duly elected and qualified). Our board of directors, on the recommendation of our nominating and corporate governance committee, has nominated each of Dr. Aivado, Dr. Ambros and Mr. Rickenbach for re-election as Class III directors, with terms ending at the 2026 annual meeting of stockholders.

Name	Age	Position(s)
Class I Directors		
Alan Musso (1)(2)	61	Director
Class II Directors		
William C. Fairey (1)(3)	59	Director
Nolan Sigal, M.D., Ph.D. (3)	73	Director
Class III Directors		
Manuel C. Alves Aivado, M.D., Ph.D.	53	Chief Executive Officer, Director
Reinhard J. Ambros, Ph.D. (1)(2)	67	Director
Josef H. von Rickenbach (2)(3)	68	Chairman of the Board of Directors

(1) Member of compensation committee.
(2) Member of audit committee.
(3) Member of nominating and corporate governance committee.

Corporate Governance Matters

Our board of directors believes that good corporate governance is important to ensure that our company is managed for the long-term benefit of stockholders. This section describes key corporate governance guidelines and practices that our board of directors has adopted. Complete copies of our corporate governance guidelines, committee charters and code of conduct are available on the "*Investors & Media—Corporate Governance*" section of our website, which is located at *www.aileronrx.com*. Alternatively, you can request a copy of any of these documents by writing us at Aileron Therapeutics, Inc., 738 Main Street #398, Waltham, MA 02451, Attention: Interim Chief Financial Officer.

Corporate Governance Guidelines

Our board of directors has adopted corporate governance guidelines to assist in the exercise of its duties and responsibilities and to serve the best interests of our company and our stockholders. These guidelines, which provide a framework for the conduct of our board of directors' business, provide that:

- the principal responsibility of our board of directors is to oversee our management;
- a majority of the members of the board of directors must be independent directors, unless otherwise permitted by the Nasdaq Stock Market, or Nasdaq, rules;
- the independent directors meet at least twice a year in executive session;
- directors have full and free access to management and, as necessary and appropriate, independent advisors;

- our nominating and corporate governance committee will oversee an annual self-evaluation of the board to determine whether it and its committees are functioning effectively; and
- new directors participate in an orientation program and all directors are expected to participate in continuing director education on an ongoing basis.

Board Leadership Structure

Our corporate governance guidelines provide that the nominating and corporate governance committee shall periodically assess the board of directors' leadership structure, including whether the offices of chief executive officer and chair of the board of directors should be separate. Our guidelines provide the board of directors with flexibility to determine whether the two roles should be combined or separated based upon our needs and the board of directors' assessment of its leadership from time to time. We currently separate the roles of chief executive officer and chair of the board of directors. Separating the duties of the chair of the board from the duties of the chief executive officer allows our chief executive officer to focus on our day-to-day business, while allowing the chair of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Specifically, the chair of our board of directors presides over meetings of the board of directors, facilitates communications between management and the board of directors and assists with other corporate governance matters.

Our board of directors has three standing committees that currently consist of, and are chaired by, independent directors. Our board of directors delegates substantial responsibilities to the committees, which then report their activities and actions back to the full board of directors. We believe that the independent committees of our board of directors and their chairpersons promote effective independent governance. We believe this structure represents an appropriate allocation of roles and responsibilities for our company at this time because it strikes an effective balance between management and independent leadership participation in our board of director proceedings.

Our board of directors oversees our risk management processes directly and through its committees. Our management is responsible for risk management on a day-to-day basis. The role of our board of directors and its committees is to oversee the risk management activities of management. Our board of directors fulfills this duty by discussing with management the policies and practices utilized by management in assessing and managing risks and providing input on those policies and practices. In general, our board of directors oversees risk management activities relating to business strategy, acquisitions, capital allocation, organizational structure and certain operational risks; our audit committee oversees risk management activities related to financial controls and legal and compliance risks; our compensation committee oversees risk management activities relating to our compensation policies and practices; and our nominating and corporate governance committee oversees risk management activities relating to the composition of our board of directors and management succession planning. Each committee reports to the full board of directors on a regular basis, including reports with respect to the committee's risk oversight activities as appropriate. In addition, since risk issues often overlap, committees from time to time request that the full board of directors discuss particular risks.

Board Determination of Independence

Applicable Nasdaq rules require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the

responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting, advisory or other compensatory fee paid by such company to the director; and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In January 2024, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Manuel C. Alves Aivado, M.D., Ph.D., is an "independent director" as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Dr. Aivado is not an independent director under these rules because he is our chief executive officer.

Board of Director Meetings and Attendance

Our board of directors held nine meetings during the year ended December 31, 2022, or fiscal 2022, and **[●]** meetings during the year ended December 31, 2023, or fiscal 2023. During fiscal 2022 and fiscal 2023, each of the directors then in office attended at least 75% of the aggregate of the number of board of director meetings held during the period which the person has been a director and the number of meetings held by all committees of the board of directors on which such director then served (during the periods that such person served). Our corporate governance guidelines provide that directors are expected to attend the annual meeting of stockholders. All directors then serving on our board of directors attended the 2022 annual meeting of stockholders.

Communicating with our Directors

Our board of directors provides a process for stockholders to send communications to the board. Any interested party with concerns about our company may report such concerns to the board of directors, or the chair of our board of directors, or otherwise the chair of the nominating and corporate governance committee, by submitting a written communication to the attention of such director at the following address:

c/o Aileron Therapeutics, Inc.
738 Main Street #398
Waltham, MA 02451

You may submit your concern anonymously or confidentially by postal mail. You may also indicate whether you are a stockholder, customer, supplier, or other interested party.

A copy of any such written communication may also be forwarded to our legal counsel, and a copy of such communication may be retained for a reasonable period of time. The director may discuss the matter with our legal counsel, with independent advisors, with non-management directors, or with our management, or may take other action or no action as the director determines in good faith, using reasonable judgment and discretion.

Communications may be forwarded to all directors if they relate to important substantive matters and include suggestions or comments that may be important for the directors to know. In general, communications relating to corporate governance and long-term corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances, and matters as to which we tend to receive repetitive or duplicative communications.

The audit committee oversees the procedures for the receipt, retention, and treatment of complaints received by us regarding accounting, internal accounting controls, or audit matters, and the confidential, anonymous submission by employees of concerns regarding questionable accounting, internal accounting controls, or auditing matters. We have also established a toll-free telephone number for the reporting of such activity, which is 866-869-5217.

Committees of the Board of Directors

We have established an audit committee in accordance with Section 3(a)(58)(A) of the Exchange Act, a compensation committee, and a nominating and corporate governance committee. Each of these committees operates under a charter that has been approved by our board of directors. A copy of each committee's charter can be found under the "Investors & Media—Corporate Governance" section of our website, located at *www.aileronrx.com*.

Audit Committee

The current members of our audit committee are Reinhard J. Ambros, Ph.D., Alan Musso, and Josef H. von Rickenbach. Mr. Musso has served as chair of our audit committee since October 31, 2023. Dr. Ambros, Mr. Musso, and Mr. von Rickenbach were appointed as members of the audit committee on October 31, 2023 in connection with the Lung Acquisition. William T McKee served as a member and chair of our audit committee, and Jodie P. Morrison served as member of our audit committee until their resignations on October 31, 2023 in connection with the Lung Acquisition. In fiscal 2022, our audit committee met seven times, and in fiscal 2023, our audit committee met **[●]** times. Our audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from that firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls, and procedures, and code of business conduct and ethics;
- overseeing our internal audit function, if any;
- discussing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting-related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by the SEC rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Mr. Musso is an "audit committee financial expert" as defined in applicable SEC rules and that each of the members of our audit committee possesses the financial sophistication required for audit committee members under Nasdaq rules. We believe that the composition of our audit committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Compensation Committee

The current members of our compensation committee are Dr. Ambros, William C. Fairey, and Mr. Musso. Dr. Ambros has served as the chair of the compensation committee since October 31, 2023. Dr. Ambros, Mr. Fairey, and Mr. Musso were appointed as members of our compensation committee on October 31, 2023 in connection with the Lung Acquisition. Jeffrey A Bailey served as a member and chair of our compensation committee, and Nolan Sigal, M.D., Ph.D., and Mr. von Rickenbach served as members of our compensation committee, until their resignations on October 31, 2023 in connection with the Lung Acquisition. Prior to his appointment to our compensation committee on October 31, 2023, Dr. Ambros served as a member and chair of the compensation committee until June 15, 2022, and Ms. Morrision served as a member of our compensation committee until June 15, 2022. In fiscal 2022, our compensation committee met five times, and in fiscal 2023, our compensation committee met **[●]** times. Our compensation committee's responsibilities include:

- reviewing and approving or making recommendations to our board of directors concerning the compensation of our chief executive officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- reviewing and making recommendations to our board of directors concerning our incentive-compensation and equity-based compensation plans;
- overseeing and administering our equity-based plans;
- reviewing and making recommendations to our board of directors concerning director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent then required by SEC rules; and
- preparing the compensation committee report if and to the extent required by SEC rules.

Our compensation committee may delegate to one or more executive officers the power to grant options or other stock awards pursuant to our incentive plans to employees of the company who are not executive officers or senior vice presidents.

We believe that the composition of our compensation committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Nominating and Corporate Governance Committee

The current members of our nominating and corporate governance committee are Mr. Fairey, Dr. Sigal and Mr. von Rickenbach. Mr. Fairey has served as the chair of the nominating and corporate governance committee since October 31, 2023. Mr. Fairey, Dr. Sigal, and Mr. von Rickenbach were appointed as members of the nominating and corporate governance committee on October 31, 2023 in connection with the Lung Acquisition. Dr. Sigal served as chair of our nominating and corporate governance committee, and Dr. Ambros and Ms. Morrison served as members of our nominating and corporate governance committee until their resignations on October 31, 2023 in connection with the Lung Acquisition. Prior to his appointment to our nominating and corporate governance committee on October 31, 2023, Mr. von Rickenbach served as a member and chair of the nominating and corporate governance committee until June 15, 2022. In fiscal 2022, our nominating and corporate governance committee met one time, and in fiscal 2023, our nominating and corporate governance committee met [●] times. Our nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become members of our board of directors;

- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing an annual evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Director Nomination Process

The process followed by our nominating and corporate governance committee to identify and evaluate director candidates includes requests to board members and others for recommendations, meetings from time to time to evaluate biographical information and background material relating to potential candidates and interviews of selected candidates by members of the nominating and corporate governance committee and our board of directors.

Criteria and Diversity

In considering whether to recommend to our board of directors any particular candidate for inclusion in our board of directors' slate of recommended director nominees, including candidates recommended by stockholders, the nominating and corporate governance committee of our board of directors applies the criteria set forth in our corporate governance guidelines. These criteria include the candidate's integrity, business acumen, knowledge of our business and industry, the ability to act in the interests of all stockholders and lack of conflicts of interest.

The biographies of the Class III director nominees on pages 113 to 114 indicates each nominee's experience, qualifications, attributes and skills that led our nominating and corporate governance committee and our board of directors to conclude each nominee should continue to serve as a director. Our nominating and corporate governance committee and our board of directors believe that each of the nominees has the individual attributes and characteristics required of each of our directors, and that the nominees, together with our other directors as a group, possess the skill sets and specific experience desired of our board of directors as a whole.

Our nominating and corporate governance committee does not have a policy (formal or informal) with respect to diversity, but believes that our board, taken as a whole, should embody a diverse set of skills, experiences and backgrounds. In this regard, the nominating and corporate governance committee also takes into consideration the diversity (for example, with respect to gender, race and national origin) of our board members. The nominating and corporate governance committee does not make any particular weighting of diversity or any other characteristic in evaluating nominees and directors.

In connection with the Lung Acquisition discussed above under Proposal 1, we agreed that, upon closing of the Lung Acquisition, two new directors from Lung would be added to our board of directors. Accordingly, our board of directors elected Mr. Fairey and Mr. Musso to our board of directors.

Stockholder Nominations

Stockholders may recommend individuals to our nominating and corporate governance committee for consideration as potential director candidates by submitting their names, together with appropriate biographical information and background materials and a statement as to whether the stockholder or group of stockholders making the recommendation has beneficially owned more than 5% of our common stock for at least a year as of the date such recommendation is made, to Aileron Therapeutics, Inc., Attention: Nominating and Corporate Governance Committee, 738 Main Street, Unit #398, Waltham, MA 02451. Assuming that appropriate biographical and background material has been provided on or before the dates set forth in this proxy statement

under the heading "Other Matters – Stockholder Proposals for our 2024 annual meeting", the committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others. If the board of directors determines to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included in our proxy card for the next annual meeting.

Stockholders also have the right under our by-laws to directly nominate director candidates, without any action or recommendation on the part of the nominating and corporate governance committee or our board of directors, by following the procedures set forth under "Other Matters – Stockholder Proposals for our 2024 annual meeting."

Board Diversity Matrix (As of January [●], 2024)

Total Number of Directors			6	
	Female	**Male**	**Non-Binary**	**Did not Disclose Gender**
Part I: Gender Identity				
Directors	—	6	—	—
Part II: Demographic Background				
African American or Black	—	—	—	—
Alaskan Native or Native American	—	—	—	—
Asian	—	—	—	—
Hispanic or Latinx	—	1	—	—
Native Hawaiian or Pacific Islander	—	—	—	—
White	—	5	—	—
Two or More Races or Ethnicities	—	—	—	—
LGBTQ+	—	—	—	—
Did Not Disclose Demographic Background	—	—	—	—

Anti-Hedging Policy

Our insider trading policy expressly prohibits all of our employees, including our named executive officers, as well as our directors, from engaging in speculative transactions in our stock, including short sales, puts/calls, hedging transactions and margin accounts or pledges.

Clawback Policy

In November 2023, we adopted a "clawback policy" compliant with Nasdaq listing standards which provides that, in the event that we are required to prepare an accounting restatement for periods ending on or after October 2, 2023, we will attempt to recover from our current or former executive officers the pre-tax amount of incentive-based compensation in excess of what would have been paid to such executive officer after giving effect to the accounting restatement during the three completed fiscal years immediately preceding the earlier of (i) the date the board of directors, or a committee of the board of directors, or the officer or officers of the company authorized to take such action if board action is not required, concludes, or reasonably should have concluded, that the company is required to prepare an accounting restatement, or (ii) the date a court, regulator, or other legally authorized body directs the company to prepare an accounting restatement. For purposes of the policy, incentive-based compensation means any compensation that is granted, earned or vested based wholly or in part upon the attainment of any measures determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures (whether or not such measures are presented within the company's financial statements or included in a filing made with the SEC); stock price; and total stockholder return. If the incentive-based compensation is based on our stock price or total stockholder return and the amount of excess incentive-based

compensation is not calculable directly from the information in an accounting restatement, the amount recovered shall be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total stockholder return upon which the incentive-based compensation was received.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serve, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is, or ever has been, an officer or employee of our company.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer and principal financial officer. A copy of the code is available on the "Investors & Media—Corporate Governance" section of our website, which is located at *www.aileronrx.com*. Our board of directors is responsible for overseeing the code of business conduct and ethics and must approve any waivers of the code for directors, officers and employees. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

EXECUTIVE AND DIRECTOR COMPENSATION

Executive Officers

The following table sets forth the name, age as of November 30, 2023, and position of each of our executive officers.

Name	Age	Position(s)
Manuel C. Alves Aivado, M.D., Ph.D.*	53	Chief Executive Officer, Director
Susan L. Drexler**	53	Interim Chief Financial Officer
Brian Windsor, Ph.D.	57	President and Chief Operating Officer

* *Dr. Aivado is a member of our board of directors. See "Board of Directors and Corporate Governance – Election of Directors" for more information about Dr. Aivado.*

** *Ms. Drexler is not directly compensated by Aileron for her services to us as our interim chief financial officer.*

Susan L. Drexler has served as our interim chief financial officer since June 2022. Since January 2022, Ms. Drexler has served as a chief financial officer consultant at Danforth Advisors, a firm that specializes in outsourced corporate functions for life sciences companies. From October 2019 to March 2021, Ms. Drexler served as chief financial officer at Harmony Biosciences, a life sciences company. From April 2018 to June 2019, Ms. Drexler served in various roles as interim chief financial officer and vice president of business development at Ocugen, Inc., a biotechnology company. From August 2015 to November 2017, Ms. Drexler served in senior roles in business development and market intelligence at AmerisourceBergen Corporation, a company that provides distribution, logistics and technology solutions to life sciences companies. From July 2007 to June 2015, Ms. Drexler held a senior business development finance role at Shire Pharmaceuticals, a biopharmaceutical company. Earlier in her career, Ms. Drexler held roles of increasing responsibility in finance consulting at Duff & Phelps, LLC, a financial consultancy firm, and senior audit roles at PricewaterhouseCoopers. Ms. Drexler earned a B.S. in Accounting from Albright College and an M.B.A. from the Joseph M. Katz Graduate School of Business at the University of Pittsburgh. Ms. Drexler is a Certified Public Accountant in the State of Pennsylvania.

Brian Windsor, Ph.D. has served as our president and chief operating officer since October 2023. Prior to becoming president and chief operating officer, Dr. Windsor served, since July 2013, as president, chief executive officer and a director of Lung. From September 2019 to March 2022, Dr. Windsor served as a director and the chief science officer of TFF Pharmaceuticals, Inc., a public biopharmaceutical company that Lung spun out into an independent company. From January 2018 to March 2022, Dr. Windsor provided consulting services to TFF Pharmaceuticals, Inc. in the areas of science and technology. From November 2009 to March 2013, Dr. Windsor served as president of Enavail, LLC, a specialty pharmaceutical manufacturing company, where he oversaw all aspects of the company's pharmaceutical drug development. Before joining Enavail, Dr. Windsor directed portfolio company management for Emergent Technologies, Inc., an early stage technology venture creation and management company, where he served as managing director or president for ten portfolio companies. Dr. Windsor holds a B.S. and a Ph.D. in molecular biology from The University of Texas at Austin.

Executive Compensation

This section discusses the material elements of our executive compensation policies for our "named executive officers" and the most important factors relevant to an analysis of these policies. For 2022, our "named executive officers" are Manuel C. Alves Aivado, M.D., Ph.D., our current chief executive officer; our other most highly compensated executive officer serving at year end (other than our chief executive officer), D. Allen Annis, our former senior vice president, research who was serving as an executive officer as of December 31, 2022; and one additional individual who was no longer serving as an executive officer as of December 31, 2022, Vojislav Vukovic, M.D., Ph.D., our former senior vice president, chief medical officer. For 2023, our "named executive

officers" are Dr. Aivado, our current chief executive officer; our other most highly compensated executive officer serving at year end (other than our chief executive officer), Brian Windsor, Ph.D., our president and chief operating officer, who was serving as an executive officer as of December 31, 2023; and one individual who was no longer serving as an executive officer as of December 31, 2023, Dr. Annis, our former senior vice president, research. In addition, this section provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our named executive officers and is intended to place in perspective the data presented in the following tables and the corresponding narrative.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to our named executive officers during the years indicated.

Name and Principal Position	Year	Salary ($)	Bonus ($) (1)	Option Awards ($) (2)	All Other Compensation ($) (3)	Total ($)
Manuel C. Alves Aivado, M.D., Ph.D.	2023	587,336	—	—	43,399(4)	630,735
Chief Executive Officer	2022	587,336	—	543,850	113,234(4)	1,244,420
	2021	564,736	254,131	2,368,000	93,512(4)	3,280,379
Brian Windsor, Ph.D. (5)	2023	85,256	—	—	10	85,267
President and Chief Operating Officer						
D. Allen Annis, Ph.D. (6)	2023	141,176	—	—	314,843(7)	456,019
Former Senior Vice President, Research	2022	404,100	—	150,250	17,914	572,264
Vojislav Vukovic, M.D., Ph.D. (8)	2022	248,566	—	72,010	225,127(9)	545,703
Former Senior Vice President, Chief Medical Officer	2021	423,225	133,316	388,197	17,648	962,386

(1) Unless otherwise noted, the amounts reported in the "Bonus" column represent discretionary annual cash bonuses awarded to our named executive officers for service during the year referenced, although paid in the following year. Whether any bonuses will be paid to our named executive officers, and if paid, the amount of such bonuses, for the year ended December 31, 2023 has not yet been determined.

(2) The amounts reported in the "Options Awards" column reflect the aggregate grant date fair value of share-based compensation awarded during the year computed in accordance with the provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, Topic 718. See Note 10 to our financial statements included in our Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

(3) Unless otherwise noted, the amounts represent Health Savings Account, or HSA, contributions and the dollar value of group life insurance paid with respect to life insurance, and, beginning in fiscal 2021, company contributions under the 401(k) match program described below under "401(k) Retirement Plan" for the named executive officer consistent with those provided to all of our employees.

(4) In addition to the HSA contribution, 401k contribution, and the dollar value of group life insurance paid, the amounts for Dr. Aivado consist of $16,070, $49,816 and $50,070 in commuting reimbursements in fiscal 2023, 2022 and 2021, respectively, and $9,915, $45,504 and $25,794 in tax gross-ups in fiscal 2023, 2022 and 2021, respectively, for the payment of taxes associated with the reimbursement of commuting expenses.

(5) Dr. Windsor began to serve as our president, effective as of October 31, 2023. Because Dr. Windsor was not an NEO prior to 2023, compensation information is not provided for 2022 or 2021.

(6) Dr. Annis ceased to serve as our senior vice president, research, effective as of April 15, 2023. Because Dr. Annis was not an NEO prior to 2022, compensation information is not provided for 2021.

(7) In addition to the HSA contribution, 401k contribution, and the dollar value of group life insurance paid, this amount for Dr. Annis also includes $303,075 in severance paid to Dr. Annis in 2023 in connection with his separation from his position as our senior vice president, research in April 2023.

(8) Dr. Vukovic ceased to serve as our senior vice president, chief medical officer, effective as of July 8, 2022.

(9) In addition to the HSA contribution and the dollar value of group life insurance paid, this amount for Dr. Vukovic also includes $209,732 in severance paid to Dr. Vukovic in 2022 in connection with his separation from his position as our senior vice president, chief medical officer in July 2022.

Narrative Disclosure to Summary Compensation Table

We review compensation for our executive officers annually. The material terms of the elements of our executive compensation program for 2022 and 2023 are described below.

Our compensation committee sets base salaries and bonus targets, and grants bonuses and equity incentive awards to our executive officers. In setting base salaries and bonus targets and granting equity incentive awards, our compensation committee considers compensation for comparable positions in the market, the historical compensation levels of our executives, individual and corporate performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. In granting bonuses, our compensation committee considers corporate and individual performance.

As part of our annual compensation process, our president and chief executive officer prepares performance evaluations for the other executive officers and recommends annual salary increases, annual stock option awards and cash bonuses to the compensation committee. The compensation committee conducts a performance evaluation of our president and chief executive officer. The compensation committee consults with the board of directors as to the achievement of corporate objectives that drive compensation awards.

In March 2021, February 2022 and December 2022, the compensation committee engaged Radford as its independent compensation consultant to provide comparative data on executive and director compensation practices in our industry and assess our executives' and directors' compensation relative to comparable companies for 2021, 2022, and 2023, respectively.

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. None of our named executive officers is currently party to an employment agreement or other agreement or arrangement that provides for automatic or scheduled increases in base salary.

In March 2021, based upon comparative data on executive compensation provided by Radford and annual performance reviews of our named executive officers, our compensation committee increased (i) Dr. Aivado's annual base salary to $564,736 and (ii) Dr. Annis' annual base salary to $354,900, in each case retroactively effective to January 1, 2021.

In March 2022, based upon comparative data on executive compensation provided by Radford and annual performance reviews conducted by our compensation committee of our named executive officers, our compensation committee increased (i) Dr. Aivado's annual base salary to $587,336, (ii) Dr. Annis' annual base salary to $404,100, and (iii) Dr. Vukovic's annual base salary to $435,925, in each case retroactively effective to January 1, 2022.

Our compensation committee determined not to make any adjustments to our named executive officers' base salaries for 2023. Our compensation committee has not yet determined whether to make any adjustments to our named executive officers' base salaries for 2024.

Cash Incentives

The compensation committee awards annual performance-based cash bonuses to our executive officers for up to a specific percentage of his salary as a vehicle to reward achievement of value-driving milestones and recognize individual performance.

Pursuant to the terms of Dr. Aivado's September 2018 employment agreement, Dr. Aivado is eligible to receive, commencing in 2019 and for each calendar year thereafter that Dr. Aivado is employed by us, a discretionary performance target bonus of up to 50% of his annual base salary based on the achievement of performance milestones set by either our board of directors or the compensation committee of the board.

Pursuant to the terms of Dr. Windsor's employment agreement, Dr. Windsor is eligible to receive an annual bonus based on a bonus target of 45% of his annual base salary based on performance against goals and at the discretion of our board of directors.

Pursuant to the terms of Dr. Annis' November 2007 employment offer letter, Dr. Annis is eligible to receive a performance-based cash bonus of up to 20% of his annual base salary, subject to the achievement of performance milestones as determined by our board of directors in its sole discretion. Between November 2007 and November 2018, Dr. Annis' target performance-based cash bonus was subsequently increased from 20% to 30% of his annual base salary as Dr. Annis assumed additional responsibilities. In connection with Dr. Annis' promotion to senior vice president, research in November 2018, Dr. Annis' target performance-based cash bonus was increased from 30% to 35% of his annual base salary, effective for 2019 and each calendar year thereafter.

Pursuant to the terms of Dr. Vukovic's November 2018 employment offer letter, Dr. Vukovic is eligible to receive a performance-based cash bonus of up to 35% of his annual base salary, subject to the achievement of performance milestones as determined by our board of directors in its sole discretion.

In January 2022, we paid cash bonus awards of $254,131 to Dr. Aivado, $111,794 to Dr. Annis and $133,316 to Dr. Vukovic based on the compensation committee's assessment of achievement of corporate and individual goals in calendar year 2021.

The compensation committee determined not to award cash bonuses to our executive officers for their performance in 2022. In addition, the compensation committee determined not to change the target performance-based cash bonuses for our executive officers for 2023, which remained and will remain at 50% for Dr. Aivado and 45% for Dr. Windsor. Our compensation committee has not made any determinations with respect to cash bonuses for the year ended December 31, 2023.

Equity Incentives

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incents our executive officers to remain in our employment during the vesting period, and equity grants with a performance-based feature incents our executive officers to focus on what we see as key business goals. Accordingly, the compensation committee periodically reviews the equity incentive compensation of our named executive officers and from time to time may grant equity incentive awards to them in the form of stock options.

In June 2021, our board of directors granted options to purchase 120,000, 23,700 and 20,000 shares of our common stock to Dr. Aivado, Dr. Annis and Dr. Vukovic, respectively. 25% of the shares underlying each option vest on June 15, 2022 and the remaining shares underlying each option vest and become exercisable thereafter in 36 monthly installments through June 15, 2025.

In March 2022, our board of directors granted options to purchase 56,650, 15,650 and 7,500 shares of our common stock to Dr. Aivado, Dr. Annis and Dr. Vukovic, respectively. Each of the options vest in equal monthly installments over four years from March 30, 2022.

The compensation committee determined not to grant equity awards to our executive officers in 2023. Our compensation committee has not made any determinations with respect to equity awards to our executive officers for the year ended December 31, 2023.

All Other Compensation

We determined to cease providing our executive officers with commuting reimbursements, beginning May 1, 2023.

Outstanding Equity Awards at Fiscal Year End 2023

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2023:

Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($/ share)	Option Expiration Date
Manuel C. Alves Aivado, M.D., Ph.D.	6290	—	101.40	3/9/2025
	7196	—	115.40	3/1/2027
	2870	—	260.00	7/24/2027
	11646	—	67.80	9/5/2028
	25001	—	35.00	4/14/2029
	19585(1)	416	13.60	1/30/2030
	76256(2)	45745	25.80	6/14/2031
	24790(3)	31861	9.60	3/29/2032
Brian Windsor, Ph.D.	8,532	—	0.29	9/29/2025
	209,468(4)	43,183	0.70	10/9/2027
	34,736	—	0.70	3/14/2028
	304,379(5)	13,234	1.17	2/25/2030
	134,070(5)	5,829	1.17	2/25/2030
	170,646	—	3.87	10/19/2033
D. Allen Annis, Ph.D.	2789	—	101.40	3/12/2024
	403	—	101.40	3/9/2025
	1208	—	115.40	3/1/2027
	1251	—	260.00	7/24/2027
	7501	—	35.00	4/14/2029
	6121(1)	130	13.60	1/30/2030
	14819(2)	8882	25.80	6/14/2031
	6851(3)	8800	9.60	3/29/2032
Vojislav Vukovic, M.D., Ph.D.	—	—	—	—

(1) These options were granted on January 31, 2020 and vest as to 2.0833% of the shares in equal monthly installments through January 31, 2024.
(2) These options were granted on June 15, 2021 and vest as to 25% of the shares on June 15, 2022 with the remaining shares vesting in equal monthly installments of 2.0833% of the shares through June 15, 2025.
(3) These options were granted on March 30, 2022 and vest as to 2.0833% of the shares in equal monthly installments through March 30, 2026.
(4) These options were granted on October 10, 2017 and vest as to 52,267 of the shares on the date of grant, 157,101 of the shares in thirty-six equal monthly installments beginning on November 10, 2017 and 43,183 of the shares on the first to occur of (i) a change of control in which Lung is sold for a valuation per share of

greater than $1.8573 per share of common stock or (ii) the completion of an offering of Lung's equity securities at a valuation of greater than $1.2382 per share of common stock.

(5) These options were granted on February 26, 2020 and vest as to 25% of the shares on the one-year anniversary of the date of grant and the remaining shares vesting as to 2.0833% of the shares in equal monthly installments through February 26, 2024.

Employment Agreements

Manuel C. Alves Aivado, M.D., Ph.D.

In September 2018, in connection with our appointment of Dr. Aivado as our president and chief executive officer, we entered into a new employment agreement with Dr. Aivado, which superseded his July 2014 employment agreement with us. Pursuant to the terms of Dr. Aivado's September 2018 employment agreement, we agreed to pay Dr. Aivado a base salary at a rate of $41,666.67 per month, which was based on an annualized base salary of $500,000. Beginning in 2019, following the end of each calendar year that Dr. Aivado is employed by us, Dr. Aivado will be eligible to receive a discretionary performance target bonus of up to 50% of his then annual base salary based on the achievement of performance milestones set by either our board of directors or the compensation committee of the board. The employment agreement also provided that following the end of the 2018 calendar year, Dr. Aivado was eligible to receive a discretionary performance target bonus calculated on the basis of 35% of his base salary as of August 31, 2018 pro-rated for the first eight months of the fiscal year, and 50% of his current base salary under the employment agreement pro-rated for the remaining four months of the fiscal year. The amount of such bonus and the achievement of such milestones were determined by our board in its sole discretion. Dr. Aivado is also entitled to receive reimbursement of up to $4,400 per month for travel and living accommodations pursuant to the employment agreement.

Pursuant to the employment agreement, in September 2018 we granted Dr. Aivado options to purchase 11,646 shares of our common stock under our 2017 Stock Incentive Plan. The options have an exercise price of $67.80, which was the closing price of our common stock on September 6, 2018. The options vest in equal monthly installments over four years from September 6, 2018.

Brian Windsor, Ph.D.

In February 2014, Lung entered into an employment agreement with Brian Windsor, Ph.D., as amended by a letter agreement between Dr. Windsor and Lung in February 2023 and as amended by a letter agreement between Dr. Windsor and Lung in October 2023. Pursuant to the employment agreement, as amended, Dr. Windsor is entitled to an annual base salary of $500,000 and is eligible to receive an annual bonus based on a bonus target of 45% of his annual base salary based on performance against goals and at the discretion of the board of directors. In addition, pursuant to the employment agreement, in the event that Dr. Windsor is terminated without cause or resigns for good reason then, subject to the execution of a release agreement, Dr. Windsor will be eligible to receive twelve (12) months' base salary in the form of severance payments, less statutory deductions and withholdings, payable in the form of salary continuation.

D. Allen Annis, Ph.D.

In November 2007, we entered into an employment offer letter with D. Allen Annis, Ph.D. The offer letter established Dr. Annis' title, his base salary, his eligibility for an annual bonus, and his eligibility for benefits made available to employees generally. The offer letter established that Dr. Annis' employment was at will. Pursuant to the offer letter, we granted Dr. Annis options to purchase 3,750 shares of our common stock under our 2006 Plan, at a price per share equal to the fair market value of one share of our common stock on the date of the option grant as determined by our board.

On April 24, 2023, we entered into a separation and release of claims agreement with Dr. Annis, which provided for Dr. Annis' separation of employment as our senior vice president, research, effective as of April 15, 2023. In

accordance with the terms of the separation agreement, we agreed to provide Dr. Annis with (i) a lump sum payment representing an aggregate amount equal to nine months of Dr. Annis' salary as of April 15, 2023, subject to applicable taxes and withholdings, and (ii) payment on Dr. Annis' behalf of the monthly premiums for group medical insurance coverage under COBRA until the earlier of the date that is nine months after April 15, 2023 and the date on which Dr. Annis becomes eligible to receive the same or substantially similar group health insurance coverage through another employer. The separation agreement also contains a release of claims by Dr. Annis, subject to customary exceptions, and covenants not to solicit or disparage and to cooperate with us.

In April 2023, we also entered into a consulting agreement with Dr. Annis for an initial term of six months. We will pay Dr. Annis an hourly consulting fee equal to $500 per hour for his services under the consulting agreement, which may not exceed 10 hours per month without our prior written consent. The consulting agreement also provides that Dr. Annis may be eligible to receive a cash bonus award in recognition of his services under the consulting agreement, in an amount not to exceed $50,000, as determined in the sole discretion of our compensation committee. Pursuant to the terms of the consulting agreement, Dr. Annis' options to purchase shares of our common stock continue to vest and be exercisable during the term of the consulting agreement. The consulting agreement may be terminated by Dr. Annis or us for any reason upon fifteen days' advance written notice to the other party.

Vojislav Vukovic, M.D., Ph.D.

In November 2018, we entered into an employment offer letter with Vojislav Vukovic, M.D., Ph.D. pursuant to which Dr. Vukovic agreed to serve as our senior vice president, chief medical officer. The offer letter established Dr. Vukovic's title, his base salary, his eligibility for an annual bonus, and his eligibility for benefits made available to employees generally. Dr. Vukovic's employment was at will. Pursuant to his offer letter, we granted Dr. Vukovic options to purchase 150,000 shares of our common stock under our 2017 Plan, which options were subject to service-based vesting, at an exercise price equal to $2.16, which was the fair market value of one share of our common stock on the date of grant.

On July 8, 2022, we entered into a separation and release of claims agreement with Dr. Vukovic, which provided for Dr. Vukovic's separation of employment as our senior vice president, chief medical officer. In accordance with the terms of the separation agreement, we agreed to provide Dr. Vukovic with (i) nine months of semi-monthly salary continuation payments, payable in equal installments in accordance with our regular payroll practices, in an aggregate amount equal to nine (9) months of Dr. Vukovic's base salary as of July 8, 2022, subject to applicable taxes and withholdings, and (ii) payment on Dr. Vukovic's behalf of the monthly premiums for group medical insurance coverage under COBRA until the earlier of the date that is nine months after July 8, 2022 and the date on which Dr. Vukovic becomes eligible to receive the same or substantially similar group health insurance coverage through another employer. The separation agreement also contains a release of claims by Dr. Vukovic, subject to customary exceptions, and covenants not to solicit or disparage and to cooperate with us.

In July 2022, we also entered into a consulting agreement with Dr. Vukovic for an initial term of twelve months. The consulting agreement expired at the end of the initial twelve-month term. Pursuant to the terms of the consulting agreement, Dr. Vukovic's options to purchase shares of our common stock continue to vest and be exercisable during the term of the consulting agreement. Dr. Vukovic does not receive any cash compensation from us under the consulting agreement. The consulting agreement may be terminated by Dr. Vukovic or us for any reason upon thirty days' advance written notice to the other party.

Severance and Change in Control Agreements

We have entered into a severance agreement with Dr. Aivado. Under the terms of the severance agreement, if we terminate Dr. Aivado's employment other than for cause or by reason of death or disability, or if Dr. Aivado terminates his employment for good reason and, in each case, not upon or within twelve months following a change in control event, as such terms are defined in the severance agreement, Dr. Aivado will be entitled to

receive his then current base salary for twelve months following the date of Dr. Aivado's termination and (B) payments on Dr. Aivado's behalf of the monthly premiums for medical insurance coverage under COBRA until the earlier of the date that is 12 months following the date of Dr. Aivado's termination or the date on which Dr. Aivado becomes eligible to receive group health insurance coverage through another employer, which we refer to as the standard severance benefits. If we terminate Dr. Aivado's employment other than for cause or by reason of death or disability, or if Dr. Aivado terminates his employment for good reason, in each case upon or within 12 months following a change in control event, Dr. Aivado will be entitled to receive the standard severance benefits for a period of 18 months following the date of Dr. Aivado's termination and a lump sum payment equal to one and one-half times Dr. Aivado's target bonus for the year in which he is terminated, and the vesting of any unvested equity awards will accelerate in full on the date of Dr. Aivado's termination. Dr. Aivado's receipt of any post-separation benefits under the severance agreement is conditioned upon his execution of a severance and release of claims agreement in a form satisfactory to us. Upon the execution of his severance agreement, Dr. Aivado ceased to be entitled to the severance and post-employment payments and benefits provided under any preexisting agreements between us and Dr. Aivado.

The board of directors determined that the Lung Acquisition constituted a change in control event for purposes of Dr. Aivado's severance agreement, such that subject to Dr. Aivado's satisfaction of the certain conditions set forth in the severance agreement, if, upon, or within the 12-month period following the consummation of the Lung Acquisition, Dr. Aivado's employment is terminated by us without cause or by Dr. Aivado for good reason, then Dr. Aivado shall be entitled to receive the change in control severance benefits in addition to any other payments and benefits Dr. Aivado is otherwise entitled to receive under the terms of the severance agreement.

Other Agreements

We have also entered into employee confidentiality, inventions, non-solicitation and non-competition agreements with each of our named executive officers. Under the employee confidentiality, inventions, non-solicitation and

non-competition agreements, each named executive officer has agreed (1) not to compete with us during his employment and for a period of one year after the termination of his employment, (2) not to solicit our employees during his employment and for a period of two years after the termination of his employment, (3) to protect our confidential and proprietary information and (4) to assign to us related intellectual property developed during the course of his employment.

401(k) Retirement Plan

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of our employees are eligible to participate, beginning on the first day of the month following commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, equal to $19,500 in 2021 and $20,500 in 2022 and have the amount of the reduction contributed to the 401(k) plan. Participants over the age of 50 are entitled to an additional catch-up contribution up to the statutorily prescribed limit, equal to $6,500 in 2021 and 2022.

Prior to the 2021 calendar year, we did not match employee contributions.

In March 2021, our compensation committee adopted a 100% match on the first 4% of eligible compensation, retroactively effective to January 1, 2021, which remained applicable in 2022 and 2023. This was a non-voluntary contribution by the Company for 2021 and 2022 and 2023 and will be a non-voluntary contribution by the Company for 2024.

Limitations on Liability and Indemnification

As permitted by Delaware law, we adopted provisions in our restated certificate of incorporation, as amended, that limit or eliminate the personal liability of our directors. Our restated certificate of incorporation, as amended,

limits the personal liability of directors for breach of fiduciary duty to the maximum extent permitted by the General Corporation Law of the State of Delaware and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the General Corporation Law of the State of Delaware is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the General Corporation Law of the State of Delaware.

In addition, our restated certificate of incorporation, as amended, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we entered into indemnification agreements with each of our officers and directors. These indemnification agreements require us, among other things, to indemnify each such director or officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts, incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or officers.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Director Compensation

Our non-employee directors receive compensation under our director compensation program. We intend to review our director compensation program in 2024.

Cash Retainer

Under this program, we pay our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chair of each committee and the chair of the board of directors receive higher retainers for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, subject to proration for any portion of such quarter that the director is not serving on our board of directors, on such committee or in such position. The fees paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

	Base	Incremental — Chair	Incremental — Non-Chair
Board of Directors	$35,000	$ 50,000	—
Audit Committee	—	$ 22,500	$ 15,000
Compensation Committee	—	$ 15,000	$ 10,000
Nominating and Corporate Governance Committee	—	$ 11,250	$ 7,500

Equity Grants

In June 2021, based upon comparative data on board compensation provided by Radford and following the recommendation of our compensation committee, our board granted each current non-employee director an option award in the amount of 4,800 shares of our common stock, contingent upon the approval of our 2021 Stock Incentive Plan, or the 2021 Plan, by our stockholders at the 2021 annual meeting of our stockholders. The June 2021 options vested in full on the earlier of the 1-year anniversary of the date of grant or the date of the 2022 annual meeting of stockholders, subject to continued service, with full acceleration upon a change in control of our company. In June 2021, our board also revised our director compensation program to provide that, commencing with the 2022 annual meeting of stockholders, each non-employee director who has served on our board of directors for at least six months will receive an option to purchase 2,400 shares of our common stock immediately following each annual meeting of our stockholders. Such annual option grants vest in full on the earlier of the first anniversary of the date of grant and the date of the next annual meeting of stockholders, subject to continued service, with full acceleration upon a change in control of our company. The board also revised the director compensation program to provide that each new member of the board will receive an initial grant of 4,800 shares of our common stock, which shall vest over 48 equal monthly installments, subject to continued service, with full acceleration upon a change in control of our company. In all cases, options granted pursuant to our director compensation program have an exercise price equivalent to fair market value of a share of common stock at the time of grant and have a term of 10 years.

In March 2022, based upon comparative data on board compensation provided by Radford, the board of directors further revised the director compensation program to increase the annual stock option grants, such that each non-employee director who has served on our board of directors for at least six months will receive an option to purchase will receive an option to purchase 2,725 shares of our common stock immediately following each annual meeting of our stockholders. In addition, the compensation committee revised the director compensation program to increase the initial grant, such that each new member of the board will receive an option to purchase 5,450 shares of our common stock upon election to the board. All other provisions of the director compensation program, including the vesting terms for such grants, remain unchanged.

We also reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending our board of directors and committee meetings.

We do not pay any compensation to our president and chief executive officer in connection with his service on our board of directors. The compensation that we pay to our president and chief executive officer is discussed earlier in this “Executive Compensation” section.

The following table sets forth information regarding compensation earned by our non-employee directors for service during fiscal 2023. Jeffrey A. Bailey, William T. McKee and Jodie P. Morrison resigned from the board as of October 31, 2023. Mr Fairey and Mr. Musso joined the board as of October 31, 2023 in connection with the Lung Acquisition.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Josef H. von Rickenbach	67,968	—	67,968
Reinhard J. Ambros, Ph.D.	46,250	—	46,250
William C. Fairey	9,375	—	9,375
Alan Musso	11,250	—	11,250
Nolan Sigal, M.D., Ph.D.	55,464	—	55,464
Jeffrey A. Bailey	83,333	—	83,333
William T. McKee	47,917	—	47,917
Jodie P. Morrison	47,917	—	47,917

(1) The amounts reported in the “Option Awards” column reflect the aggregate grant date fair value of stock-based compensation awarded during the year computed in accordance with the provisions of ASC Topic 718. See Note 10 to our financial statements included in our Annual Report on Form 10-K regarding assumptions underlying the valuation of equity awards.

As of December 31, 2023, our non-employee directors that served in such capacity during fiscal 2023 held the following stock options, including stock options assumed by us in the Lung Acquisition, all of which were granted under (a) our 2017 Stock Incentive Plan, or 2017 Plan, (b) our 2021 Plan and (c) Lung’s 2013 Plan:

Name	Option Awards
Josef H. von Rickenbach	9,400
Reinhard J. Ambros, Ph.D.	12,150
William C. Fairey	17,064
Alan Musso	17,064
Nolan Sigal, M.D., Ph.D.	9,400
Jeffrey A. Bailey	12,150
William T.McKee	9,400
Jodie P. Morrison	10,900

SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table contains information about our equity compensation plans as of December 31, 2023. As of December 31, 2023, we had five equity compensation plans, each of which was approved by our stockholders: our 2006 Equity Incentive Plan, as amended, or the 2006 Plan, our 2016 Stock Incentive Plan, or the 2016 Plan, our 2017 Plan, our 2021 Plan, and our 2017 Employee Stock Purchase Plan, or 2017 ESPP.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights ($/share) (1) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	425,293(2)	31.89	756,658(3)(4)
Equity compensation plans not approved by security holders(5)	—	—	—
Total	425,293	31.89	756,658

(1) Represents the weighted average exercise price of the 425,293 stock options that were outstanding as of December 31, 2023.

(2) Consists of (i) 9,482 shares to be issued upon exercise of outstanding options under our 2006 Plan as of December 31, 2023, (ii) 8,404 shares to be issued upon exercise of outstanding options under our 2016 Plan as of December 31, 2023, (iii) 130,903 shares to be issued upon exercise of outstanding options under our 2017 Plan as of December 31, 2023, and (iv) 276,504 shares to be issued upon exercise of outstanding options under our 2021 Plan as of December 31, 2023.

(3) Consists of (i) 427,517 shares that remained available for future issuance under our 2021 Plan as of December 31, 2023, and (ii) 7,500 shares that remained available for future issuance under our 2017 ESPP as of December 31, 2023. No shares remained available for future issuance under the 2006 Plan, the 2016 Plan, or the 2017 Plan as of December 31, 2023.

(4) Our 2017 ESPP has an evergreen provision that allows for an annual increase in the number of shares available for issuance under the 2017 ESPP to be added on the first day of each fiscal year through the fiscal year ending December 31, 2027, in an amount equal to the least of 31,120 shares of our common stock, 1% of the total number of shares of our common stock outstanding on the first day of the applicable fiscal year and an amount determined by our board of directors. On January 1, 2023 and January 1, 2024, no additional shares were reserved for issuance under the 2017 ESPP pursuant to this provision.

(5) The table does not include 1,775,909 shares to be issued upon exercise of options outstanding under Lung's 2013 Plan, with a weighted average exercise price of $1.60, as of December 31, 2023, and 726,437 shares to be issued upon exercise of outstanding warrants under Lung's 2013 Plan, with a weighted average exercise price of $5.66, as of December 31, 2023, which options and warrants were assumed by us in connection with the Lung Acquisition. The 2013 Plan was not approved by our stockholders. Following the closing of the Lung Acquisition, no further awards can be granted under the 2013 Plan.

PAY VERSUS PERFORMANCE

The following tables and related disclosures provide information about (i) the "total compensation" of our principal executive officer, or the PEO, and our other named executive officers, or the Other NEOs, as presented in the Summary Compensation Table on page 147, or the SCT Amounts, (ii) the "compensation actually paid" to our PEO and our Other NEOs, as calculated pursuant to the SEC's pay-versus-performance rules, or the CAP Amounts, (iii) certain financial performance measures, and (iv) the relationship of the CAP Amounts to those financial performance measures.

This disclosure has been prepared in accordance with Item 402(v) of Regulation S-K under the Exchange Act and does not necessarily reflect value actually realized by the executives or how our compensation committee evaluates compensation decisions in light of company or individual performance. For discussion of how our compensation committee seeks to align pay with performance when making compensation decisions, please review the "Executive Compensation" section beginning on page 146.

Year (a)	Summary Compensation Table Total for PEO (b) (1)	Compensation Actually Paid to PEO (c) (1)(2)	Average Summary Compensation Table Total for Non-PEO Named Executive Officers (d) (1)	Average Compensation Actually Paid to Non-PEO Named Executive Officers (e) (1)(2)	Value of Initial Fixed $100 Investment Based on Total Shareholder Return (f)	Net Income (Loss) (in millions) (g)
2023	$ 630,735	$ 640,513	$ 270,642.50	$ 285,970	$ (85.34)	(27.3)[3]
2022	$ 3,280,379	$ 242,961	$ 558,982,98	$ 357,304	$ (88.61)	(27.3)
2021	$ 1,244,420	$ 871,515	$1,079,708.06	$ 599,056	$ (45.87)	(26.2)

(1) For 2023, our PEO was Manuel C. Alves-Aivado, M.D., Ph.D., and our Other NEOs were Brian Windsor, Ph.D., and Dr. Allan Annis, Ph.D. For 2022, our PEO was Dr. Aivado, and our Other NEOs were Dr. Annis and Vojislav Vukovic M.D., Ph.D. For 2021, our PEO was Dr. Aivado and our Other NEOs were Richard J. Wanstall and Dr. Vukovic.

(2) The following table describes the adjustments, each of which is required by SEC rule, to calculate the CAP Amounts from the SCT Amounts of our PEO (column (b)) and our Other NEOs (column (d)). The SCT Amounts and the CAP Amounts do not reflect the actual amount of compensation earned by or paid to our executives during the applicable years, but rather are amounts determined in accordance with Item 402 of Regulation S-K under the Exchange Act.

(3) With respect to net income (loss) for the year ended December 31, 2023, we have prepared the disclosure based on our net income (loss) for the year ended December 31, 2022 because as of the date of this proxy statement, we have not yet complete our financial closing procedures or an audit of the year ended December 31, 2023. We believe that the presentation of net income (loss) for the year ended December 31, 2022 does not materially change the information presented herein and that the net income (loss) for the year ended December 31, 2023 will not be substantially different than the year ended December 31, 2022.

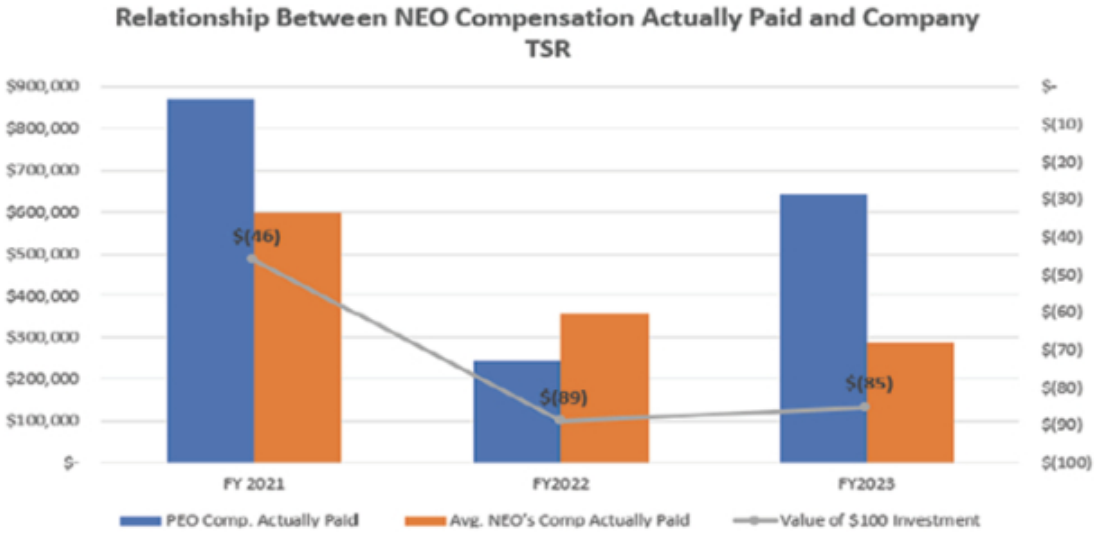
Adjustments	2023 PEO	2023 OTHER NEOs*	2022 PEO	2022 Other NEOs*	2021 PEO	2021 Other NEOs*
SCT Amounts	$ 630,735	$ 541,285	$ 1,244,420	$ 1,117,966	$ 3,280,379	$ 2,159,416
Adjustments for stock and option awards						
(Subtract): Aggregate value for stock awards and option awards included in SCT for the covered fiscal year	—	—	$ (543,850)	$ (222,259)	$ (3,147,626)	$ (1,290,052)
Add: Fair value at year end of awards granted during the covered fiscal year that were outstanding and unvested at the covered fiscal year end	—	—	$ 344,537	$ 140,728	$ 2,368,021	$ 970,531
[Add (Subtract)]: Year-over-year change in fair value at covered fiscal year end of awards granted in any prior fiscal year that were outstanding and unvested at the covered fiscal year end	$ 31,246	$ 35,409	$ (532,926)	$ (209,532)	$ (196,735)	$ (133,745)
Add: Vesting date fair value of awards granted and vested during the covered fiscal year	—	—	$ (273,513)	$ (111,718)	$ (1,441,299)	$ (516,288)
[Add (Subtract)]: Change as of the vesting date (from the end of the prior fiscal year) in fair value of awards granted in any prior fiscal year for which vesting conditions were satisfied during the covered fiscal year	$ (21,468)	$ (4,754)	$ 4,293	$ (577)	$ 8,774	$ 8,250
CAP Amounts (as calculated)	$ 640,513	$ 571,940	$ 242,961	$ 714,608	$ 871,515	$ 1,198,112

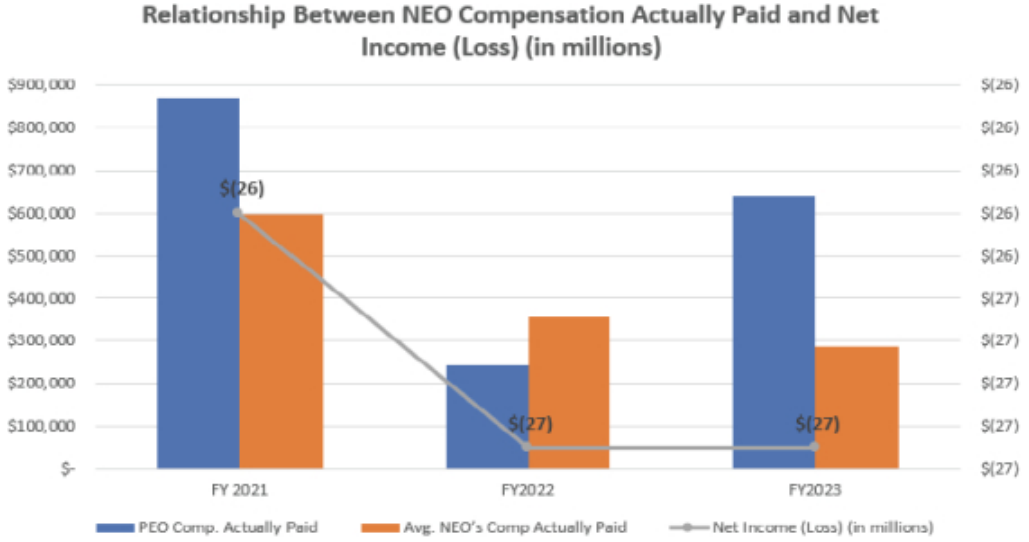
* Amounts presented are averages for the entire group of Other NEOs in each respective year.

Valuation assumptions used to calculate fair values did not materially differ from those used to calculate fair values at the time of grant as reflected in the SCT Amounts.

RELATIONSHIP BETWEEN CAP AMOUNTS AND PERFORMANCE MEASURES

The following charts show graphically the relationships over the past three years of the CAP Amounts for our PEO and Other NEOs as compared to our (i) cumulative total shareholder return and (ii) net income (loss).


Relationship Between NEO Compensation Actually Paid and Company TSR
$900,000
$800,000
$700,000
$600,000
$500,000
$400,000
$300,000
$200,000
$100,000
$-
$-
$(10)
$(20)
$(30)
$(40)
$(50)
$(60)
$(70)
$(80)
$(90)
$(100)
$(46)
$(89)
$(85)
FY 2021
FY2022
FY2023
PEO Comp. Actually Paid
Avg. NEO's Comp Actually Paid
Value of $100 Investment


Relationship Between NEO Compensation Actually Paid and Net Income (Loss) (in millions)
$900,000
$800,000
$700,000
$600,000
$500,000
$400,000
$300,000
$200,000
$100,000
$-
$(26)
$(26)
$(26)
$(26)
$(26)
$(27)
$(27)
$(27)
$(27)
$(27)
$(26)
$(27)
$(27)
FY 2021
FY2022
FY2023
PEO Comp. Actually Paid
Avg. NEO's Comp Actually Paid
Net Income (Loss) (in millions)

DESCRIPTION OF CAPITAL STOCK

The following description summarizes certain information regarding our securities that are registered under Section 12 of the Exchange Act, and is qualified by reference to our restated certificate of incorporation and amended and restated bylaws.

Authorized Capital Stock

Our authorized capital stock consists of 45,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share. As of December 31, 2023, 4,885,512 shares of our common stock were outstanding and 24,610 shares of our Series X Preferred Stock were outstanding.

Common Stock

Voting Rights. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Any matter other than the election of directors to be voted upon by the stockholders at such meeting will be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter, except when a different vote is required by law, our certificate of incorporation or our bylaws.

Dividends. Holders of our common stock are entitled to receive proportionately any dividends as may be declared and paid on the common stock from funds lawfully available therefor as and when determined by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

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

Other Rights. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. Outstanding shares of our common stock are non-assessable. Holders of our common stock are not, and will not be, subject to any liability as stockholders.

Preferred Stock

Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. The issuance of preferred stock could impede the completion of a merger, tender offer or other takeover attempt.

A description of the rights, preferences and privileges of the Series X Preferred Stock is set forth above under the caption, “Description of Series X Preferred Stock.”

Common Stock Issuable Upon Exercise of Warrants

As of December 31, 2023, we had:

- warrants to purchase 646,759 shares of our common stock, with an exercise price of $40.00 per share, which we issued in our April 2019 private placement, which expire on April 2, 2024;

- warrants to purchase 726,437 shares of our common stock, with an exercise price of $5.66, which expire on May 20, 2029, which were assumed in connection with the Lung Acquisition, as set forth above under the caption, "Description of the Transaction"; and
- warrants to purchase 2,353,500 shares of our common stock, which warrants were issued and sold in the Financing, as set forth above under the caption, "Description of the Transaction."

Provisions of Our Certificate of Incorporation and By-laws and the DGCL That May Have Anti-Takeover Effects

The Delaware General Corporation Law, or the DGCL, contains, and our certificate of incorporation and by-laws contain, provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Staggered Board; Removal of Directors. Our certificate of incorporation and by-laws divide our board of directors into three classes with staggered three-year terms. In addition, a director may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in an annual election of directors. Any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office. The classification of our board of directors and the limitations on the removal of directors and filling of vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder Action by Written Consent; Special Meetings. Our certificate of incorporation provides that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of such holders and may not be effected by any consent in writing by such holders. Our certificate of incorporation and by-laws also provide that, except as otherwise required by law, special meetings of our stockholders can only be called by the chairman of our board of directors, our chief executive officer or our board of directors.

Advance Notice Requirements for Stockholder Proposals. Our by-laws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting may consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities.

Delaware Business Combination Statute. We are subject to Section 203 of the DGCL which prohibits a Delaware corporation from engaging in business combinations with an interested stockholder. An interested stockholder is generally defined as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person. Section 203 provides that an interested stockholder may not engage in business combinations with the corporation for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the

time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (1) by persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combinations to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, transfer, pledge or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

Amendment of Certificate of Incorporation and By-laws. The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless a corporation's certificate of incorporation or by-laws, as the case may be, requires a greater percentage. Our by-laws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least 75% of the votes that all of our stockholders would be entitled to cast in any annual election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above under "—Staggered Board; Removal of Directors" and "—Stockholder Action by Written Consent; Special Meetings."

Exclusive Forum Selection. 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) shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL or our certificate of incorporation or by-laws, or (4) 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 of 1933, as amended, the Exchange Act of 1934, as amended, or any other claim for which federal courts have exclusive jurisdiction. Although our certificate of incorporation contains the choice of forum provision described above, it is possible that a court could rule that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

STOCK OWNERSHIP AND REPORTING

Security Ownership of Certain Beneficial Owners and Management

Unless otherwise provided below, the following table sets forth information regarding beneficial ownership of our common stock as of November 30, 2023, by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of 5% or more of the outstanding shares of our common stock;
  - each of our current directors;
  - our named executive officers; and
- all of our current executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Percentage of beneficial ownership is based on 4,885,512 shares of our common stock outstanding as of November 30, 2023. In addition, shares of common stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of November 30, 2023, are deemed outstanding and beneficially owned for the purpose of computing the percentage beneficially owned by (i) the person or entity holding such options, warrants or other rights (but not any other person or entity) and (ii) the directors and executive officers as a group. Due to certain limitations on the conversion of Series X Preferred Stock and the exercise of Warrants, shares of common stock issuable upon conversion of the Series X Preferred Stock or exercise of the Warrants have been excluded from beneficial ownership set forth below. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o Aileron Therapeutics, Inc., 738 Main Street #398, Waltham, Massachusetts 02451.

	Total Beneficial Ownership	
Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
Muneer Satter(1)	976,614	19.99%
Named Executive Officers and Directors		
Manuel C. Aivado, M.D., Ph.D. (2)	169,546	3.35%
Brian Windsor, Ph.D. (3)	46	*
D. Allen Annis, Ph.D. (4)	40,370	*
Vojislav Vukovic, M.D., Ph.D. (5)	3,750	*
Josef H. von Rickenbach (6)	34,160	*
Reinhard J. Ambros, Ph.D. (7)	12,440	*
William C. Fairey (8)	11,376	*
Alan Musso (9)	5,688	*
Nolan Sigal, M.D., Ph.D. (10)	9,400	*
All Executive Officers and Directors as a Group (9 persons)	286,776	5.57%

* Represents beneficial ownership of less than 1% of our outstanding stock.

(1) Based on information provided in a Schedule 13D/A filed on January 8, 2021, Muneer A. Satter's beneficial ownership consists of (i) 51,254 shares of common stock that are held by Muneer A. Satter Revocable Trust for which Mr. Satter serves as trustee and, in such capacity, has sole voting and dispositive power over all such shares; (ii) 61,552 shares of common stock that are held by various other trusts and other entities for which Mr. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and

dispositive power over all such shares; (iii) 717,666 shares of common stock that are held by Satter Medical Technology Partners, L.P., or SMTP, for which Mr. Satter has sole voting and dispositive power over all such shares and (iv) 146,142 shares of common stock which may be acquired upon the exercise of warrants held by SMTP for which Mr. Satter has sole voting and dispositive power. As a result of the application of a beneficial ownership cap in the warrants, the table above does not include 40,425 shares of common stock issuable upon exercise of warrants to purchase common stock held by SMTP. Under the terms of the warrants issued to SMTP, SMTP is not permitted to exercise such warrants to purchase common stock to the extent that such exercise would result in SMTP and its affiliates beneficially owning more than 19.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants to purchase common stock. The address for Mr. Satter is c/o Alerce Management Co., L.P., 676 N. Michigan Avenue, Suite 4000, Chicago, IL 60611.

(2) Consists of (ii) 50 shares of common stock held directly and (ii) 169,496 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

(3) Consists of 46 shares of common stock held directly. The table above does not include 871,362 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023. Under the terms of Dr. Windsor's option agreements for such options, which agreements were amended in connection with the closing of the Lung Acquisition, Dr. Windsor is not permitted to exercise such options until our stockholders approve Proposal 1.

(4) Consists of (i) 377 shares of common stock held directly and (ii) 39,993 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

(5) Consists of 3,750 shares of common stock held directly.

(6) Consists of (i) 22,273 shares of common stock held directly, (ii) 2,487 shares of common stock issuable upon the exercise of warrants to purchase common stock exercisable within 60 days after November 30, 2023, and (iii) 9,400 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

(7) Consists of (i) 290 shares of common stock held directly and (ii) 12,150 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

(8) Consists of 11,376 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

(9) Consists of 5,688 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

(10) Consists of 9,400 shares of common stock issuable upon the exercise of options exercisable within 60 days after November 30, 2023.

TRANSACTIONS WITH RELATED PERSONS

Since January 1, 2022, we have engaged in the following transactions in which the amount involved exceeded the lesser of $120,000 or one percent of our total assets at year end for fiscal years 2023 and 2022, and any of our executive officers, directors, director nominees, or beneficial holders of more than 5% of any class of voting securities, or any of their affiliates, had a direct or indirect material interest. We believe that all of these transactions were on terms comparable to terms that could have been obtained from unrelated third parties.

Lung Acquisition and Financing

Upon the closing of the Lung Acquisition, entities associated with Bios Partners became beneficial owners of more than 5% of our voting securities. Immediately following the closing of the Lung Acquisition, Bios Clinical Opportunity Fund, LP, Bio Fund III NT, LP, Bios Fund III QP, LP and Bio Fund III, LP entered into a stock and warrant purchase agreement relating to the Financing. Upon the closing of the Financing, (i) Bios Clinical Opportunity Fund, LP purchased 1,136 shares of Series X Preferred Stock and a warrant to purchase 568,000 shares of common stock for a purchase price of approximately $4.4 million, (ii) Bios Fund III NT, LP purchased 125 shares of Series X Preferred Stock and a warrant to purchase 62,500 shares of common stock for a purchase price of approximately $0.5 million, (iii) Bios Fund III QP, LP purchased 777 shares of Series X Preferred Stock and a warrant to purchase 388,500 shares of common stock for a purchase price of approximately $3.0 million, and (iv) Bios Fund III, LP purchased 119 shares of Series X Preferred Stock and a warrant to purchase 59,500 shares of common stock for a purchase price of approximately $0.5 million. In addition, certain convertible promissory notes issued by Lung to Bios Clinical Opportunity Fund, LP in an amount of approximately $1.6 million were converted, at a 10% discount to the per share price of the Series X Preferred Stock, into 444 shares of Series X Preferred Stock and a warrant to purchase 222,000 shares of common stock.

Lock-up Agreements

Concurrently and in connection with the execution of the Lung Acquisition Agreement, we entered into lock-up agreements with entities associated with Bios Partners, pursuant to which each entity 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 such entity 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 such entity at the closing of the Lung Acquisition and hereafter owned by such entity, including those shares issued in the Lung Acquisition, subject to certain customary exceptions.

Registration Rights Agreement

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

Indemnification Agreements

Our restated certificate of incorporation, as amended, provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with each of our officers and directors that may be broader in scope than the specific indemnification provisions contained in the Delaware General Corporation Law. See "Executive Compensation—Limitations on Liability and Indemnification" for additional information regarding these agreements.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy to set forth policies and procedures for the review of any transaction, arrangement, or relationship in which we are a participant, the amount involved exceeds $120,000, and one of our executive officers, directors, director nominees or 5% stockholders, or their immediate family members, each of whom we refer to as a "related person," has a direct or indirect material interest.

If a related person proposes to enter into such a transaction, arrangement, or relationship, which we refer to as a "related person transaction," the related person must report the proposed related person transaction to our chief executive officer or our chief financial officer. The policy calls for the proposed related person transaction to be reviewed and approved by our audit committee. Whenever practicable, the reporting, review, and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the committee will review and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between committee meetings, subject to ratification by the committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person's interest in the transaction. As appropriate for the circumstances, the committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

The audit committee may approve or ratify the transaction only if the committee determines that, under all of the circumstances, the transaction is in our best interests. The committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC's related-person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related-person transactions for purposes of this policy:

- interests arising solely from the related person's position as an executive officer of another entity, whether or not the person is also a director of such entity, that is a participant in the transaction, where (a) the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity; (b) the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction; (c) the amount involved in the transaction equals less than the greater of $1.0 million or 2% of the annual gross revenues of the other entity that is a party to the transaction; and (d) the amount involved in the transaction equals less than 2% of our annual gross revenues; and
- a transaction that is specifically contemplated by provisions of our charter or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by the compensation committee in the manner specified in its charter.

REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

Our audit committee has reviewed our audited consolidated financial statements for the fiscal year ended December 31, 2022 and discussed them with our management and our independent registered public accounting firm for the year ended December 31, 2022, PricewaterhouseCoopers.

Our audit committee has also received from, and discussed with, PricewaterhouseCoopers various communications that PricewaterhouseCoopers is required to provide to our audit committee, including the matters required to be discussed by Public Company Accounting Oversight Board (PCAOB) Auditing Standard No. 16, *Communications with Audit Committees* (AS 16).

In addition, PricewaterhouseCoopers provided our audit committee with the written disclosures and the letter required by applicable requirements of the PCAOB regarding the independent registered public accounting firm's communications with the audit committee concerning independence and has discussed with the Company's independent registered public accounting firm their independence.

Based on the review and discussions referred to above, our audit committee recommended to our board of directors that the audited consolidated financial statements be included in our Annual Report on Form 10-K for the year ended December 31, 2022.

By the audit committee of the board of directors of Aileron Therapeutics, Inc. *

William T. McKee, Chair
Jodie P. Morrison
Josef H. von Rickenbach

*William T. McKee and Jodie P. Morrison resigned from the board of directors on October 31, 2023 in connection with the Lung Acquisition, and each of Alan Musso, Josef H. von Rickenbach and Reinhard H. Ambros, Ph.D. were appointed to the audit committee on October 31, 2023 in connection with the Lung Acquisition.

OTHER MATTERS

As of the date of this proxy statement, we know of no matter not specifically referred to above as to which any action is expected to be taken at the annual meeting. The persons named as proxies will vote the proxies, insofar as they are not otherwise instructed, regarding such other matters and the transaction of such other business as may be properly brought before the meeting, as seems to them to be in the best interest of our company and our stockholders.

Stockholder Proposals for our 2024 Annual Meeting

Stockholder Proposals Included in Proxy Statement

In order to be considered for inclusion in our proxy statement and proxy card relating to our 2024 annual meeting of stockholders, stockholder proposals must be submitted in accordance with the procedures in Rule 14a-18 of the Exchange Act. Since the date of the 2024 annual meeting of stockholders will change by more than 30 days from the anniversary of our 2023 annual meeting, such proposals must be received by us no later than [●], 2024, which is a reasonable time before we begin to print and send our proxy materials. Upon receipt of any such proposal, we will determine whether or not to include such proposal in the proxy statement and proxy card in accordance with regulations governing the solicitation of proxies.

Stockholder Proposals Not Included in Proxy Statement

In addition, our by-laws establish an advance notice procedure for nominations for election to our board of directors and other matters that stockholders wish to present for action at an annual meeting other than those to be included in our proxy statement. Since the date of the 2024 annual meeting is more than 30 days before or more than 60 days after the anniversary date of the immediately preceding annual meeting, we must receive other proposals of stockholders (including director nominations) intended to be presented at the 2024 annual meeting of stockholders but not included in the proxy statement no earlier than the close of business 120 calendar days prior to such annual meeting and no later than the close of business on the later of 90 days prior to such annual meeting and 10 days following the day on which notice of the date of such annual meeting was mailed or public announcement of the date of such annual meeting was first made. Stockholders are advised to review our by-laws which also specify requirements as to the form and content of a stockholder's notice.

In addition to satisfying the advance notice procedure in our by-laws relating to nominations of director candidates, including the earlier notice deadlines set out above, to comply with the SEC's universal proxy rule, stockholders who intend to solicit proxies in support of director nominees other than the company's nominees in compliance with Rule 14a-19 under the Exchange Act must also provide notice that sets forth the information required by Rule 14a-19. Since the date of the 2024 annual meeting of stockholder will change by more than 30 calendar days from the date of the annual meeting, the notice required under Rule 14a-19 under the Exchange Act must be provided by the later of 60 calendar days prior to the date of the 2024 annual meeting of stockholders or the 10th calendar day following public announcement by the company of the date of the 2024 annual meeting of stockholders.

Any proposals, notices, or information about proposed director candidates should be sent to Aileron Therapeutics, Inc., Attention: Nominating and Corporate Governance Committee, 738 Main Street #398, Waltham, MA 02451.

Householding of Annual Meeting Materials

Some brokers and other nominee record holders may be "householding" our proxy materials. This means single copy of the proxy materials will be delivered to multiple stockholders sharing an address unless we receive contrary instructions. We will promptly deliver a separate copy of the proxy materials and our 2022 annual report

to stockholders, which consists of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and our Annual Report on Form 10-K/A, to you if you write to us at Aileron Therapeutics, Inc., 738 Main Street #398, Waltham, MA 02451, Attention: Interim Chief Financial Officer, or call us at (617) 995-0900. If you would like to receive separate copies of our proxy materials and annual reports in the future, or if you are receiving multiple copies and would like to receive only one copy for your household, you should contact your bank, broker, or other nominee record holder, or you may contact us at the above address and telephone number.

ANNEX A

AUDITED CONSOLIDATED FINANCIAL STATEMENTS AND ACCOMPANYING NOTES OF LUNG THERAPEUTICS, INC.

(Years ended December 31, 2022 and 2021)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

INDEPENDENT AUDITOR'S REPORT

To the stockholders and Board of Directors of Lung Therapeutics, Inc.

Opinion

We have audited the consolidated financial statements of Lung Therapeutics, Inc. and subsidiaries (the "Company"), which comprise the consolidated balance sheets as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholder's deficit, and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively referred to as the "financial statements").

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations that raise substantial doubt exists about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Responsibilities of Management for the Financial Statements

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

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

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not absolute assurance and therefore is not a guarantee that an audit conducted in accordance with GAAS will always detect a material misstatement when it exists. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as

fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control. Misstatements are considered material if there is a substantial likelihood that, individually or in the aggregate, they would influence the judgment made by a reasonable user based on the financial statements.

In performing an audit in accordance with GAAS, we:

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

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

/s/ Deloitte & Touche LLP

Morristown, New Jersey
May 25, 2023

LUNG THERAPEUTICS, INC.

Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	As of December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 11,881	$ 11,483
Prepaid expenses and other current assets	2,714	8,073
Total current assets	14,595	19,556
Property and equipment, net	5	10
Operating lease right-of-use assets	221	—
Deferred financing costs	—	1,032
Other assets	27	27
Total assets	$ 14,848	$ 20,625
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Simple agreements for future equity	$ 13,435	$ —
Accounts payable	860	428
Deferred revenue	352	1,591
Operating lease liabilities, current	184	—
Accrued expenses and other current liabilities	1,753	2,306
Total current liabilities	16,584	4,325
Deferred revenue, net of current portion	2,515	1,964
Operating lease liabilities, net of current portion	48	—
Total liabilities	19,147	6,289
Commitments and contingencies (Note 10)		
Series A convertible preferred stock, par value $0.0001 per share; 10,888,283 shares authorized, issued and outstanding as of December 31, 2022 and 2021, respectively	2,874	2,874
Series B convertible preferred stock, par value $0.0001 per share; 23,152,737 shares authorized, issued and outstanding as of December 31, 2022 and 2021, respectively	14,293	14,293
Series C convertible preferred stock, par value $0.0001 per share; 41,076,061 and 44,162,774 shares authorized as of December 31, 2022 and 2021, respectively; 41,076,061 shares issued and outstanding as of December 31, 2022 and 2021, respectively	39,858	39,858
Stockholders' deficit:		
Common stock, par value $0.0001 per share; 106,000,000 shares authorized as of December 31, 2022 and 2021, respectively; 9,245,103 and 9,150,208 shares issued and outstanding as of December 31, 2022 and 2021, respectively	1	1
Additional paid-in capital	2,119	1,713
Accumulated deficit	(63,444)	(44,403)
Total stockholders' deficit	(61,324)	(42,689)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 14,848	$ 20,625

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

LUNG THERAPEUTICS, INC.

Consolidated Statements of Operations and Comprehensive Loss
(in thousands)

	For the Year Ended December 31,	
	2022	2021
Licensing revenue	$ 688	$ 556
Operating expenses:		
Research and development	(22,465)	(15,397)
General and administrative	(6,763)	(4,720)
Total operating expenses	(29,228)	(20,117)
Loss from operations before gains from affiliate	(28,540)	(19,561)
Gain from sale of equity securities in TFF	9,400	9,373
Loss from operations	(19,140)	(10,188)
Other income, net:		
Interest income	99	30
Gain on extinguishment of PPP loan	—	253
Other income, net	—	2
Total other income, net	99	285
Net loss and comprehensive loss	$(19,041)	$ (9,903)

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

LUNG THERAPEUTICS, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)

	Convertible preferred stock										
	$0.0001 Par Value Series A		$0.0001 Par Value Series B		$0.0001 Par Value Series C		Common stock $0.0001 Par Value		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, January 1, 2021	10,888,283	$ 2,874	23,152,737	$ 14,293	41,076,061	$ 39,858	9,150,208	$ 1	$ 1,461	$ (34,500)	$ (33,038)
Stock-based compensation	—	—	—	—	—	—	—	—	252	—	252
Net loss	—	—	—	—	—	—	—	—	—	(9,903)	(9,903)
Balance, December 31, 2021	10,888,283	$ 2,874	23,152,737	$ 14,293	41,076,061	$ 39,858	9,150,208	$ 1	$ 1,713	$ (44,403)	$ (42,689)
Stock-based compensation	—	—	—	—	—	—	—	—	393	—	393
Exercise of common stock warrants	—	—	—	—	—	—	75,000	—	9	—	9
Exercise of common stock options	—	—	—	—	—	—	19,895	—	4	—	4
Net loss	—	—	—	—	—	—	—	—	—	(19,041)	(19,041)
Balance, December 31, 2022	10,888,283	$ 2,874	23,152,737	$ 14,293	41,076,061	$ 39,858	9,245,103	$ 1	$ 2,119	$ (63,444)	$ (61,324)

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

LUNG THERAPEUTICS, INC.

Consolidated Statements of Cash Flows
(in thousands)

	For the Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	$(19,041)	$ (9,903)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	5	6
Amortization of operating lease right-of-use assets	163	—
Deferred financing costs written off	1,032	—
Gain from sale of equity securities in TFF	(9,400)	(9,373)
Stock-based compensation expense	393	252
Gain on extinguishment of PPP loan	—	(253)
Changes in operating assets and liabilities:		
Due from licensing partner	—	5,000
Prepaid expenses and other current assets	5,359	(6,414)
Other assets	—	(15)
Accounts payable	1,113	(296)
Deferred revenue	(688)	(556)
Operating lease liability	(152)	—
Accrued expenses and other current liabilities	(553)	877
Net cash flows used in operating activities	(21,769)	(20,675)
Cash flows from investing activities		
Proceeds from sale of equity securities in TFF, net of commissions and other transaction costs of $0 and $637, respectively	9,400	9,373
Purchase of property and equipment	—	(5)
Net cash flows provided by investing activities	9,400	9,368
Cash flows from financing activities		
Proceeds from issuance of simple agreements for future equity, net of issuance costs	13,435	—
Proceeds from exercise of common stock options and warrants	13	—
Deferred financing costs	(681)	(351)
Net cash flows provided by (used in) financing activities	12,767	(351)
Net increase (decrease) in cash and cash equivalents	398	(11,658)
Cash and cash equivalents, beginning of year	11,483	23,141
Cash and cash equivalents, end of year	$ 11,881	$ 11,483
Non-cash financing activities:		
Recognition of right-of-use asset and operating lease liability	$ 384	$ —
Deferred financing costs included in accounts payable and accrued expenses	$ —	$ 681

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

LUNG THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

Note 1. Description of Business

Lung Therapeutics, Inc. ("Lung Therapeutics" or the "Company"), was incorporated in November 2012 under the laws of the state of Texas. Its principal offices are in Austin, Texas. The Company's focus is developing novel therapeutics for orphan pulmonary and fibrosis indications with the potential to greatly improve patient outcomes over currently available treatments.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned, non-operating subsidiaries, Lung Therapeutics Australia Pty Ltd ("Lung Therapeutics Australia") and Lung Therapeutics Limited, which is an Irish entity.

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to the risk that the Company never achieves profitability, the need for substantial additional financing, the risk of relying on third parties, risks of clinical trial failures, dependence on key personnel, protection of proprietary technology, and compliance with government regulations. The Company's lead product candidate, LTI-03, is being developed for the treatment of Idiopathic Pulmonary Fibrosis ("IPF") and has completed a healthy volunteer Phase 1a clinical trial. LTI-03 is currently in a Phase 1b clinical trial in IPF patients. The Company's second product candidate, LTI-01, is in development for loculated pleural effusion ("LPE"). The Company has completed Phase 1 and Phase 2 clinical trials in LPE patients.

Liquidity and Going Concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to its research and development efforts relating to its product candidates, including activities to manufacture product candidates, conduct clinical studies of its product candidates and perform preclinical research to identify new product candidates. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future. To date, the Company has financed its operations primarily through private placements of convertible preferred stock, an upfront payment received from a licensing agreement, and sales of marketable equity securities in TFF Pharmaceuticals, Inc. ("TFF").

As of December 31, 2022, the Company had $11.9 million of cash and cash equivalents to fund its operations. Notwithstanding the amounts on hand, the Company anticipates it will need to secure additional funding through public or private convertible preferred financings, debt financings, and/or collaboration agreements or government grants over the next twelve months in order to continue to fund the Company's operations. Given the lack of a finalized plan to secure additional funding that would be considered probable of occurrence under ASC 205-40 as of the date of issuance of the accompanying consolidated financial statements, the Company can provide no assurance that additional funding will be obtained on acceptable terms, or at all. If the Company is unable to secure additional funding to continue to fund its operations over the next twelve months, the Company would need to pursue other alternatives, such as a scale back in its operating plan by deferring or limiting some or all of its research, development or clinical projects, further reductions to its workforce, and/or seek other strategic investment alternatives. Management has concluded the uncertainty surrounding the Company's ability to secure additional funding over the next twelve months raises substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Note 2. Summary of Significant Accounting Policies

Basis of presentation

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

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual for research and development expenses, the valuation of simple agreements for future equity ("SAFEs"), the valuation of warrants, and the valuation of common stock. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Foreign Currency Transactions

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

Revenue Recognition

In accordance with ASC *Topic 606, Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company identifies the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. The Company then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

Licensing revenue

On November 12, 2020, the Company entered into a license agreement (the "License Agreement") with Taiho Pharmaceutical Co., Ltd ("Taiho"). This agreement is discussed further in Note 8 of Notes to Consolidated Financial Statements. The Company's license arrangements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and products, and obligations to participate on certain development committees with licensing partners.

The terms of such license arrangements generally include payment to the Company of one or more of the following: nonrefundable upfront fees, payments for the supply of clinical products, payment for research and development services, payments related to milestone payments and royalties on net sales of licensed products. The Company assesses whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation as applicable. Judgment is required to determine SSP. Due to the early stage of the Company's licensed technology, the license of such technology is typically combined with the research and development services and committee participation as one performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development services cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. The Company utilizes judgment to assess the pattern of delivery of the performance obligation.

At the inception of each agreement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation in the agreement based on relative SSP. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash and cash equivalents. Periodically, the Company maintains balances in operating accounts above federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Investment in TFF

The Company applies the equity method of accounting to investments when it has significant influence, but not controlling interest in the investee. In assessing whether it can exercise significant influence, the Company considers key factors such as ownership interest, representation on the board of directors, participation in policy-making decisions and material intercompany transactions. Under the equity method of accounting, the Company records in its consolidated statements of operations and comprehensive loss its share of income or loss of the other company. If its share of losses exceeds the carrying value of its investment, the Company will suspend the recognition of additional losses. Pursuant to a contribution agreement executed on January 24, 2018, the Company's wholly-owned subsidiary, TFF, was spun out into a separate company, whereby the Company received 4,000,000 shares of TFF's common stock in exchange for providing TFF with certain intellectual property assets licensed by the Company from the University of Texas. The Company had previously concluded that it had the ability to exercise significant influence over the operating and financial policies of TFF.

Consequently, during 2019 the Company had concluded that its share of TFF's net losses under the equity method was greater than the carrying value of its investment and as a result, had written down the investment in TFF to $0 and suspended the recognition of any additional losses by TFF.

In January 2022, the Company entered into a variable price forward sales contract with Jefferies LLC to sell 962,000 shares of TFF common stock based upon the daily volume-weighted average price during the three-month period ended March 31, 2022 plus a premium applied over the term of the contract. On April 1, 2022, the contract was consummated and as a result, the Company received total cash proceeds of $6.2 million from the sale of these shares. In April 2022, the Company sold 500,000 additional shares of TFF common stock to Bios Special Opportunity Fund, LP at a price of $6.43 per share, generating net proceeds of $3.2 million. Aaron G.L. Fletcher, a Board member of the Company and Managing Partner of Bios Partners, a shareholder of the Company, is the General Partner of Bios Special Opportunity Fund, LP.

In March 2021, the Company sold 715,000 shares of common stock of TFF at an average price of $14.00 per share, generating proceeds of $9.4 million, net of commissions and other direct selling expenses.

The Company recorded gains from the sale of these shares of $9.4 million and $9.4 million that are reflected under Gain from sale of equity securities in TFF on its consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, the Company's remaining ownership of TFF common stock amounted to 773,000 shares.

Fair Value Measurements

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

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

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

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

Simple Agreement for Future Equity - SAFE

The Company accounts for SAFEs at fair value in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). The SAFEs are subject to revaluation at the end of each reporting period, with changes in fair value recognized in the Company's consolidated statements of operations and comprehensive loss.

Cash and Cash Equivalents

Cash and cash equivalents consist of standard checking accounts and money market funds. The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents. The Company's cash equivalents are comprised of funds held in money market accounts and are measured at fair value on a recurring basis. As of December 31, 2022 and 2021, the fair value of cash equivalents was $11.8 million and $11.2 million, respectively.

Deferred Financing Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred financing costs until such financings are consummated. The deferred financing costs are initially recorded as a long-term asset on the balance sheet. After consummation of the equity financing, these costs are reclassified and recorded as a reduction to the carrying value of convertible preferred stock or of stockholders' deficit through a reduction of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be aborted, the deferred financing costs will be expensed immediately as a charge to general and administrative expenses in the consolidated statements of operations and comprehensive loss.

As of December 31, 2022 and 2021, deferred financing costs amounted to $0 and $1.03 million, respectively. The deferred financing costs of $1.03 million as of December 31, 2021 were written off as a charge to general and administrative expenses during 2022, following the Company's decision to abort its plan to pursue an initial public offering.

Convertible Preferred Stock

The Company has classified convertible preferred stock, referred to as preferred stock, as temporary equity in the accompanying consolidated balance sheets due to terms that allow for redemption of the shares in cash upon certain change in control events that are outside of the Company's control, including sale or transfer of control of the Company as holders of the preferred stock could cause redemption of the shares in these situations. The Company did not accrete the carrying values of the preferred stock to the redemption values since a liquidation event was not considered probable as of December 31, 2022. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur**.**

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or the Company's tax returns. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities using the enacted statutory tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Recognition of deferred tax assets is limited to amounts for which, in the opinion of management, realization is considered more likely than not in future periods.

Research and Development Expenses

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

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

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

Upfront payments, milestone payments and annual maintenance fees under license agreements are expensed in the period in which they are incurred.

Patent Costs

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

Leases

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or financing leases. Operating leases are included in Operating lease right-of-use assets and Operating lease liabilities in the Company's consolidated balance sheets.

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

Stock-Based Compensation

The Company's stock-based compensation expense stems from granted awards that may include stock options, restricted stock awards, restricted stock units, and other stock-based awards. The fair values of stock option

grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the awards are expensed over the requisite service period, which is generally the vesting period of the award. The Company accounts for forfeitures as they occur. For performance-based awards, the Company does not recognize expense until the underlying vesting conditions are deemed to be probable of occurrence.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company has utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (the "Practice Aid"), to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The Company historically has been a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time that it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees was determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employee consultants is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Comprehensive Income or Loss

Comprehensive income or loss consists of net income or loss and changes in equity during a period from transactions and other equity and circumstances generated from non-owner sources. For the years ended December 31, 2022 and 2021, the Company's net loss equals comprehensive loss.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which requires lessees to recognize ROU assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842, Leases* and ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which offered a practical expedient for transitioning at the adoption date. ASU No. 2018-11 provides registrants with an option to not restate comparative periods presented in the financial statements.

The Company adopted the new standard on January 1, 2022 using the effective date as the date of initial application. Consequently, prior period amounts were not adjusted and will continue to be reported in accordance with historical accounting policies under ASC 840*, Leases (Topic 840)*. The Company elected the package of

practical expedients under which the Company did not reassess prior conclusions about lease identification, lease classification and initial direct costs. Additionally, the Company made a policy election to not recognize ROU assets and lease liabilities related to short-term leases that have a term of twelve months or less.

The largest impact upon adoption of this new standard was the recognition of ROU assets and lease liabilities on the consolidated balance sheet, as the Company's lease portfolio primarily consists of an operating lease for its corporate headquarters in Austin, Texas. The Company recognized ROU assets and corresponding lease liabilities of $384,000 at the date of adoption, determined based on the present value of the remaining minimum rental payments under current leasing standards for the existing operating lease. The Company's results of operations and cash flows were not materially impacted by the adoption of this new standard.

Note 3. Fair Value Measurements

The following tables present information about the Company's assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
As of December 31, 2022				
Assets:				
Money market funds	$11,763	$11,763	$ —	$ —
SAFEs	13,435	—	—	13,435
Total	$25,198	$11,763	$ —	$ 13,435
As of December 31, 2021				
Assets:				
Money market funds	$11,204	$11,204	$ —	$ —
Total	$11,204	$11,204	$ —	$ —

The fair value of the SAFEs is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

There were no transfers between fair value levels during the years ended December 31, 2022 and 2021. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Simple Agreement for Future Equity - SAFE

In March and April 2022, the Company executed a series of SAFE arrangements primarily with new investors, pursuant to which the Company received net proceeds in an aggregate amount equal to $13.4 million. The fair value of the SAFEs on the date of issuance was determined to equal the proceeds received by the Company. The SAFE arrangements provide investors with future equity by conversion of the SAFE amounts into preferred stock at the Company's subsequent equity financing event, to the extent that the Company receives aggregate gross proceeds of at least $20,000,000 and provided that such equity financing event occurs prior to December 31, 2022, the date of maturity of the SAFE. The initial discount for the SAFE was 90%, but if, prior to the subsequent equity financing event, the Company has supplied to any potential third-party investor the results of its Phase II data with respect to its drug candidate LTI-01, the discount is reduced to 80%. If there is no equity financing prior to December 31, 2022 that yields aggregate gross proceeds of at least $20,000,000, or if a liquidity or dissolution event of the Company does not occur, each SAFE will automatically convert into the Company's Series C Preferred Stock at the original issuance price of such Series C shares.

The SAFEs are not mandatorily redeemable, nor do they require the Company to repurchase a fixed number of shares. The Company determined that the SAFEs contain a liquidity event provision that embodies an obligation indexed to the fair value of the Company's preferred shares and could require the Company to settle the SAFE obligation by transferring assets or cash. For this reason, the Company records the SAFEs as a liability under ASC 480 and re-measures the fair value at the end of each reporting period, with changes in fair value reported in earnings. As of December 31, 2022, the fair value of the SAFEs was determined to be $0.98, the price at which they will convert into shares of Series C Preferred Stock. Accordingly, the Company did not record any fair value changes associated with the SAFEs during the year ended December 31, 2022.

The following table sets forth a summary of the activities of the SAFE arrangements which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	Amount
Balance as of December 31, 2021	$ —
Issuance of SAFEs	13,435
Change in fair value	—
Balance as of December 31, 2022	$ 13,435

Non-Recurring Fair Value Measurements

The Company issued warrants to purchase common stock in 2014, 2015, 2018, and 2019, pursuant to its convertible preferred stock issuances (See Note 11 of Notes to Consolidated Financial Statements) and its license agreement with Vivarta Therapeutics LLC (See Note 9 of Notes to Consolidated Financial Statements). All warrants were determined to be equity-classified and recorded as part of additional paid in capital at fair value using the Black-Scholes option pricing model. The warrants are not subsequently remeasured.

Preferred Stock Warrants

Prior to 2020, the Company had issued to its preferred shareholders a total of 7,096,828 warrants to purchase shares of common stock. Of these warrants, 3,043,184 were granted in connection with Series A and Series B convertible preferred stock ("Series A" and "Series B") issuances and 4,053,644 were granted in conjunction with the issuance of the Company's convertible Series C preferred stock ("Series C") (See Note 11 of Notes to Consolidated Financial Statements). In November 2021, the Company issued an additional 122,045 warrants to purchase shares of common stock. No additional warrants to purchase shares were issued in 2022. The Company had determined the fair value of these warrants using the following inputs: fair value of common stock at the time of issuance, exercise price, the contractual period, risk free rate, volatility, and dividend yield. These warrants to purchase a total of 7,218,873 shares of the Company's common stock remained outstanding as of December 31, 2022 and 2021, and none have been exercised to date.

Vivarta Therapeutics LLC Warrants

In March 2018, the Company had issued warrants to purchase 75,000 shares of common stock to Vivarta Therapeutics LLC ("Vivarta"). The Company determined the fair value of the warrants using the fair value of the common stock at the time of issuance, the exercise price, contractual period, volatility, and dividend yield. These warrants to purchase 75,000 shares of common stock were wholly exercised by Vivarta during the year ended December 31, 2022 at a price of $0.12 per share.

Note 4. Prepaid Expenses and Other Current Assets

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

	As of December 31,	
	2022	2021
Prepaid research and development	$2,544	$7,946
Other	170	127
Total prepaid and other current assets	$2,714	$8,073

Note 5. Property and Equipment, net

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

	As of December 31,	
	2022	2021
Property and equipment:		
Furniture and equipment	$ 53	$ 53
Total property and equipment	53	53
Less: accumulated depreciation	(48)	(43)
Property and equipment, net	$ 5	$ 10

Depreciation expense was $5,000 and $6,000 for the years ended December 31, 2022 and 2021, respectively.

Note 6. Accrued Expenses and Other Current Liabilities

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

	As of December 31,	
	2022	2021
Accrued compensation and benefits	$ 904	$ 847
Clinical and development costs	657	628
Deferred financing costs	—	626
Other	192	205
Total accrued expenses and other current liabilities	$1,753	$2,306

Note 7. Notes Payable

On April 15, 2020, the Company obtained a loan from Ciera Bank in the aggregate amount of $251,000 (the “PPP Loan”) pursuant to the Small Business Administration Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”).

The PPP Loan, which was in the form of a promissory note dated April 15, 2020, had a maturity date of April 15, 2022 and bore interest at a rate of 1% per annum. No payments had been made under the loan, although interest continued to accrue during the deferment period. Under the terms of the CARES Act, PPP Loan participants could apply for and be granted forgiveness for all or a portion of loans if proceeds were used for qualifying expenses, including payroll, benefits, rent and utilities, and provided that participants maintain their payroll levels.

The Company applied for forgiveness of the loan and was notified by the lender in May 2021 that an aggregate amount of $253,000, including accrued interest on the loan, had been approved for forgiveness in accordance with PPP guidelines. The forgiveness of the loan was recorded as a gain on extinguishment of debt in the Company's consolidated financial statements during the second quarter of 2021.

Note 8. Licensing Arrangement with Taiho

On November 12, 2020, the Company entered into a License Agreement with Taiho pursuant to which the Company is collaborating with Taiho regarding the development and potential commercialization of the Company's lead product candidate, LTI-01. Under the License Agreement, the Company granted Taiho an exclusive, royalty-bearing license to develop, seek regulatory approval for, and commercialize LTI-01 in Japan. The Company is obligated to conduct all development activities for LTI-01 through regulatory approval in the United States or other markets worldwide, except Japan. The Company will retain the right to commercialize LTI-01 in all markets worldwide except Japan. Under the terms of the License Agreement, the Company, in part through its 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 License Agreement, Taiho agreed to make a non-refundable, non-creditable payment to the Company of $5.0 million. This up-front payment, deemed a partial reimbursement of past and future development costs for LTI-01, was received by the Company in February 2021. The License Agreement also provides that the Company is eligible to receive an additional milestone payment of $10.0 million.

In addition, the Company will 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 the later of: (a) ten years from the date of first commercial sale of LTI-01 in Japan; and (b) expiration of the last-to-expire valid claim of the Company's patents covering the manufacture, use or sale or exploitation of LTI-01 in Japan.

The Company evaluated the License Agreement under ASC 606 and determined that there is one combined performance obligation that consists of the license and data transfer, the research and development services in which the Company will use commercially reasonable efforts to further the development of LTI-01, including execution of the necessary clinical trials, and supply of all clinical products during the term of the Agreement. These deliverables are non-contingent in nature.

The Company's assessment of the transaction price included an analysis of amounts it expected to receive, which at contract inception consisted of the non-refundable, upfront payment of $5.0 million that was received by the Company in February 2021. The Company considered this non-refundable fee of $5.0 million to be the initial transaction price.

The Company determined that the combined performance obligation is satisfied over time. The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company transfers its performance obligation to Taiho. In applying the cost-based input method of revenue recognition, the Company uses actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of third-party contract costs relative to the level of patient enrollment in the studies. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be

reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Company also determined that the milestone payment of $10.0 million under the License Agreement is variable consideration under Topic 606 which needs to be added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of milestones, such as the regulatory approvals which are generally not within the Company's control, the Company will not consider achievement of this milestone to be probable until the uncertainty associated with such milestone has been resolved. When it is probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which the Company recognizes revenue. As of December 31, 2022 and 2021, no milestones had been achieved under the License Agreement.

The Company will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). As of December 31, 2022 and 2021, no royalty revenue has been recognized.

For the years ended December 31, 2022 and 2021, the Company recognized revenue totaling $688,000 and $556,000, respectively, from its agreement with Taiho. As of December 31, 2022 and 2021, the Company recorded current deferred revenue of $0.35 million and $1.59 million, and noncurrent deferred revenue of $2.52 million and $1.96 million, respectively, on its consolidated balance sheets.

Note 9. License Agreements

Agreements with the Board of Regents of the University of Texas System ("UT System")

In June 2013, May 2014 and May 2015, the Company entered into three license agreements with affiliates of the Board of Regents of the University of Texas (collectively, the "UT Agreements"). These three affiliated entities (collectively, the "UT entities") are as follows: University of Texas Health Science Center at Tyler ("UTHSCT"), University of Texas Horizon Fund ("UT Horizon Fund") and University of Texas at Austin ("UT Austin"). The UT Agreements were accounted for as asset acquisitions and do not meet the definition of a business under ASU 2017-01, *Business Combinations—Clarifying the definition of a business* ("ASC 805").

Pursuant to the UT Agreements, the Company acquired licenses and underlying technology rights to certain intellectual property within defined fields to develop its product candidates. The Company received an exclusive, royalty-bearing license to certain patent rights and know-how, as well as a non-exclusive license to the UT intellectual property, which includes future rights to royalties on licensed products. The UT Agreements also provide for sublicensing rights, whereby the Company may grant sublicenses to third parties to use the licensed technology, subject to certain terms within the UT Agreements. The UT Agreements can be terminated at-will by the Company with 90 days' notice, or by the UT entities in the event of a material breach of terms. Under the UT Agreements, the Company is responsible for the following payments, which are made to the indicated parties:

- *License Fees* – The Company is required to make annual payments of $10,000 for license fees under the UT Austin agreement until the agreement is terminated. Under the UT Austin agreement, the Company made a license fee payment of $10,000 during each of the years ended December 31, 2022 and 2021.
- *Sublicensing fees* – The Company will pay a percentage of non-royalty sublicensing consideration for the UT Agreements, with varying rates that will depend on when the sublicensing agreement is executed.
- *Assignment fee* – The Company will pay the greater of 10% of the consideration received or $100,000, if any of the UT Agreements are assigned to a third party.
- *Royalties* – The Company will pay tiered royalties that are in the low-to-mid single-digit percentages, based on net sales of all products licensed under the UT Agreements.

- *Milestones* – The Company will make milestone payments to UT Austin of up to $395,000 if specified regulatory and clinical development milestone events occur. There were no milestone payments made during each of the years ended December 31, 2022 and 2021.

The Company's expense associated with annual license fees and milestone payments under the UT Agreements was $10,000 for each of the years ended December 31, 2022 and 2021, respectively. All license fee and milestone payments are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

In addition to the UT Agreements, the Company previously conducted sponsored research programs with and retained the UT entities to provide certain research-related services. The Company's expense associated with these sponsored research and other services was $34,000 for the year ended December 31, 2021. No such expense was incurred during the year ended December 31, 2022. Payments for these sponsored research and other services were recorded as research and development expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2022 and 2021, no amounts were payable to the UT entities for sponsored research and other services rendered to the Company.

Agreement with Medical University of South Carolina ("MUSC")

In March 2016, the Company entered into a license agreement with MUSC (the "MUSC Agreement"), pursuant to which the Company acquired licenses and underlying technology rights to certain intellectual property within defined fields to develop its product candidates. The MUSC Agreement was accounted for as an asset acquisition and does not meet the definition of a business under ASC 805.

The Company received an exclusive, royalty-bearing license to certain patent rights and know-how, as well as a non-exclusive license to the MUSC intellectual property, which includes future rights to royalties on licensed products. The MUSC Agreement also provided for sublicensing rights, whereby the Company may grant sublicenses to third parties to use the licensed technology, subject to certain terms in the MUSC Agreement. The MUSC Agreement can be terminated at-will by the Company with 90 days' notice, or by MUSC only in the event of a material breach of terms. Under the MUSC Agreement, the Company is responsible for the following payments:

- *License Fee* – The Company was obligated to and paid a one-time, nonrefundable license fee of $10,000 at the execution of the MUSC Agreement.
- *Sublicensing fees* – The Company will pay sublicensing fees, which vary from 15-30% of total consideration based on the Company's progression through each phase of development.
- *Transaction fee* – The Company will pay the lesser of $2.5 million or 1% of total consideration in the event of a liquidation.
- *Royalties* – The Company will pay a running royalty rate in the low single digits on all net sales and is also required to pay annual minimum royalties of $10,000 on the third, fourth, and fifth anniversaries of the execution date and $25,000 on the sixth anniversary of the execution date and all years thereafter. Under this agreement, the Company made minimum royalty payments of $25,000 and $10,000 for each of the years ended December 31, 2022 and 2021, respectively.
- *Milestones* – The Company will make milestone payments to MUSC of up to $300,000 if specified regulatory and clinical development milestone events occur. There were no milestone payments made during the years ended December 31, 2022 and 2021.

The Company's expense associated with minimum royalty and milestone payments under the MUSC Agreement was $25,000 and $10,000 for the years ended December 31, 2022 and 2021, respectively. All minimum royalty and milestone payments are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Agreement with Vivarta Therapeutics LLC ("Vivarta")

In March 2018, the Company entered into a license agreement with Vivarta (the "Vivarta Agreement"), pursuant to which the Company acquired licenses and underlying technology rights to certain intellectual property within defined fields to develop its product candidates. The Vivarta Agreement was accounted for as an asset acquisition and does not meet the definition of a business under ASC 805.

The Company received an exclusive, royalty-bearing license to certain patent rights and know-how, as well as a non-exclusive license to the Vivarta intellectual property, which includes future rights to royalties on licensed products. The Vivarta Agreement also provided for sublicensing rights, whereby the Company may grant sublicenses to third parties to use the licensed technology, subject to certain terms in the Vivarta Agreement. The Vivarta Agreement can be terminated at-will by the Company with 90 days' notice, or by Vivarta only in the event of a material breach of terms. Under the Vivarta Agreement, the Company is responsible for the following payments:

- *License Fee* – The Company was obligated to and paid one-time, nonrefundable license fees of $10,000 due upon the execution of the Vivarta Agreement and $40,000 due upon receipt by the Company of a positive freedom to operate analysis.
- *Sublicensing fees* – The Company will pay sublicensing fees, which vary from 5-40% of total consideration based on the Company's progression through each phase of development.
- *Royalties* – The Company will pay a running royalty rate in the low single digits on all net sales.
- *Milestones* – The Company will make milestone payments to Vivarta of up to $6.83 million if specified research, regulatory and clinical development milestone events occur. A milestone payment in the amount of $50,000 was made to Vivarta during the year ended December 31, 2022 following the attainment of a research and development milestone. No milestone payments were made to Vivarta during the year ended December 31, 2021.

Pursuant to the Vivarta Agreement, the Company issued warrants to Vivarta to purchase 75,000 shares of common stock at an exercise price of $0.12 per share in 2018 (See Note 3 of Notes to Consolidated Financial Statements). These warrants were wholly exercised by Vivarta during the year ended December 31, 2022.

The Company's expense associated with license fees and milestones under the Vivarta Agreement amounted to $50,000 and $0 in each of the years ended December 31, 2022 and 2021, respectively. Any license fee and milestone payments are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Note 10. Commitments and Contingencies

Lease Agreements

On August 16, 2021, the Company entered into an operating lease agreement to rent approximately 6,455 square feet of office space for its corporate headquarters in Austin, Texas, beginning on October 1, 2021. The lease agreement is for a 30-month term that ends on March 31, 2024 and includes a rent escalation clause and a rent holiday. Rent expense during the year ended December 31, 2021 for this lease agreement was recognized on a straight-line basis over the lease term. In addition to the base rent, the Company was also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the lease agreement.

In May 2019, the Company entered into an operating lease agreement to rent approximately 2,560 square feet of office space for its corporate headquarters in Austin, Texas. The lease agreement was for a 28-month term that ended on October 31, 2021 and had included a rent escalation clause which resulted in average cash rental payments of $51,000 per year. Rent expense during the year ended December 31, 2021 for this lease agreement was recognized on a straight-line basis over the lease term. In addition to the base rent, the Company was also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the lease agreement.

Amounts reported in the Company's consolidated balance sheet as of December 31, 2022 for the existing operating lease were as follows, in thousands:

Assets	
Operating lease right-of-use assets	$221
Total operating lease right-of-use assets	$221
Liabilities	
Current	
Operating lease liabilities	$184
Noncurrent	
Operating lease liabilities, net of current	48
Total operating lease liabilities	$232

Operating lease costs for the year ended December 31, 2022 amounted to $184,000. Rent expense was $88,000 for the year ended December 31, 2021.

The maturities of the operating lease liabilities and minimum lease payments as of December 31, 2022 were as follows, in thousands:

For the Years Ending December 31,	Operating Lease
2023	$ 193
2024	48
Total undiscounted lease payments	241
Less: Imputed interest	(9)
Present value of operating lease liabilities	$ 232

The following table summarizes the lease term and discount rate as of December 31, 2022:

	As of December 31, 2022
Remaining lease term (years)	
Operating lease	1.25
Discount rate	
Operating lease	6.6%

Operating cash flows used for the operating lease during the year ended December 31, 2022 amounted to $172,000.

License Agreements

The Company is required to make certain payments under its license agreements, related to patent expenses, license fees, and assignment fees, as well as milestone and royalty payments upon the achievement of certain development and sales-based events (See Note 9 of Notes to Consolidated Financial Statements).

Legal Proceedings

The Company may from time to time be party to litigation arising in the ordinary course of business. As of December 31, 2022 and 2021, the Company was not party to any legal proceedings and no material legal proceedings are currently pending or, to the best of the Company's knowledge, threatened.

Note 11. Convertible Preferred Stock

The Company has issued Series A convertible preferred stock ("Series A"), Series B convertible preferred stock ("Series B") and Series C convertible preferred stock ("Series C"), collectively referred to as Preferred Stock.

As of December 31, 2022 and 2021, the authorized shares of Preferred Stock consisted of the following:

	As of December 31, 2022	As of December 31, 2021
Series A	10,888,283	10,888,283
Series B	23,152,737	23,152,737
Series C	41,076,061	44,162,774
	75,117,081	78,203,794

As of December 31, 2022 and 2021, the issued and outstanding shares of Preferred Stock consisted of the following (in thousands, except amounts):

	Preferred stock issued and outstanding	Carrying value	Liquidation value	Common stock issuable upon conversion
Series A	10,888,283	$ 2,874	$ 2,931	10,888,283
Series B	23,152,737	14,293	14,307	23,152,737
Series C	41,076,061	39,858	39,911	41,076,061
	75,117,081	$ 57,025	$ 57,149	75,117,081

The Company recorded all issued shares of Preferred Stock at fair value on the date of issuance, net of issuance costs. All Preferred Stock has a par value of $0.0001 per share. The rights, privileges, and preferences of the Preferred Stock are discussed below.

Voting

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Company's articles of incorporation, holders of Preferred Stock shall vote together with the holders of common stock as a single class.

The holders of outstanding shares of Preferred Stock shall be entitled to elect one member of the Board of Directors (the "Board").

Dividends

The holders of Preferred Stock are entitled to an 8% non-cumulative dividend. Dividends are payable only when and if declared by the Board. No dividends are payable to the common stockholders unless a dividend is also paid to preferred stockholders equal to at least the amount that would be received if the shares of Preferred Stock were converted into common stock. To date, the Company has not declared or paid any dividends.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of shares of Preferred Stock then outstanding shall be entitled to receive an amount per share equal to the Preferred Stock original issue price, plus any dividends declared but unpaid thereon, prior to any distribution to the common shareholders.

Note that in relation to the above, no series of the Preferred Stock has a higher liquidation preference than another, but the Preferred Stock as a whole has a higher liquidation preference than the common stock.

Redemption

The Company's certificate of incorporation, as amended and restated, does not provide redemption rights to the holders of Preferred Stock.

Conversion

Each share of Preferred Stock shall be convertible into shares of common stock on a one-for-one basis at the option of the stockholder, at any time, and without the payment of additional consideration by dividing the Preferred Stock original issue price by the conversion price. The conversion price may be adjusted for issuance of additional shares of Common Stock, for stock splits, for stock combinations, for certain dividends and distributions, and for mergers and reorganizations.

Note 12. Stockholders' Deficit

Common Stock

As of December 31, 2022, the Company had 106,000,000 shares of common stock authorized, of which 9,245,103 were issued and outstanding.

The holders of the Company's common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written action in lieu of meetings; there is no cumulative voting. The holders of outstanding shares of common stock shall be entitled to elect one member of the Board.

After payment to the holders of shares of Preferred Stock of their liquidation preferences, the remaining assets of the Company are distributed to the holders of the Company's common stock.

Shares of common stock reserved for future issuance were as follows:

	As of December 31,	
	2022	2021
Preferred Stock issued and outstanding	75,117,081	75,117,081
Warrants to issue shares of common stock	7,218,873	7,293,873
Stock options outstanding	11,611,674	11,261,257
Shares available for future grants under the Plan	2,407,145	2,777,457
	96,354,773	96,449,668

Warrants

As of December 31, 2022, a total of 7,218,873 warrants to purchase the Company's common stock were outstanding. All of the Company's outstanding warrants are non-tradeable and equity-classified because they meet the derivative scope exception under ASC Topic 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* ("ASC 815-40").

Note 13. Stock-Based Compensation

In October 2013, the Company's board of directors approved the 2013 Long-Term Incentive Plan (the "Plan") to provide long-term incentives for its employees, non-employee directors and certain consultants. As of December 31, 2022, the Company was authorized to issue a total of 14,188,922 shares of common stock under the Plan and as of that date, a total of 2,407,145 shares remained available for future issuance.

The Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The vesting periods for equity awards are determined by the Board, but generally are four years. The contractual term for stock option awards is ten years.

A summary of the stock option activity for the year ended December 31, 2022 is as follows:

	Year Ended December 31, 2022	
	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	11,261,257	$ 0.16
Granted	430,000	0.79
Exercised	(19,895)	0.24
Cancelled or forfeited	(59,688)	0.31
Expired	—	—
Outstanding, end of year	11,611,674	$ 0.21
Vested and expected to vest, end of year	11,611,674	$ 0.21
Exercisable, end of year	7,986,566	
Weighted-average fair value of options granted during the year	$ 0.62	

As of December 31, 2022, the aggregate intrinsic value of all outstanding stock options was $6.7 million and for exercisable stock options was $4.8 million. A total of 19,895 stock options were exercised during the fiscal year ended December 31, 2022 at a weighted average exercise price of $0.24. The intrinsic value per option at December 31, 2022 is calculated as the difference between the exercise price of the underlying option and the estimated fair value of the Company's common stock on that date, which was $0.79 per share. The total fair value of options that vested during the fiscal year ended December 31, 2022 was $372,000.

Unrecognized compensation expense related to non-vested employee stock options amounted to $554,000 as of December 31, 2022. Such compensation expense is expected to be recognized over a weighted-average period of 1.76 years.

Stock-based compensation expense amounted to $393,000 and $252,000 for the years ended December 31, 2022 and 2021, respectively. The table below shows the allocation of this stock-based compensation expense (in thousands):

	Year Ended December 31	
	2022	2021
General and administrative	$ 307	$ 211
Research and development	86	41
Total	$ 393	$ 252

Stock-based compensation expense recognized in the statement of operations and comprehensive loss for the years ended December 31, 2022 and 2021 does not reflect tax related effects on stock-based compensation given the Company's historical and anticipated operating losses.

The fair value of each option granted by the Company is estimated on the grant date using the Black-Scholes stock option pricing model. For the options granted during the years ended December 31, 2022 and 2021, the following assumptions were made in estimating fair value:

	Year Ended December 31	
	2022	2021
Dividend yield	— %	— %
Expected term (in years)	5.00 - 6.08	5.50 - 6.08
Risk-free interest rate	1.6% to 3.0%	0.4% to 1.2%
Expected volatility	96.1% - 99.0%	84.3% - 95.3%

Note 14. Income Taxes

For each of the years ended December 31, 2022 and 2021, the Company did not record a current or deferred income tax expense or benefit. The components of the current and deferred income tax expense or benefit consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Current income tax expense:		
Federal	$ —	$ —
State	—	—
Total income tax expense	$ —	$ —
Deferred income tax (benefit) expense:		
Federal	$ (5,876)	$ (4,161)
State	(24)	(32)
Foreign	17	54
Change in valuation allowance	5,883	4,139
Total income tax expense	$ —	$ —

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate was as follows:

	Year Ended December 31,	
	2022	2021
Federal income tax (benefit) at statutory rate	21%	21%
Permanent differences	—	—
Research and development credits	10	21
State income tax, net of federal benefit	—	—
Change in valuation allowance	(31)	(42)
Effective tax rate	— %	— %

Coronavirus Aid, Relief and Economic Security Act

In response to the COVID-19 pandemic, the CARES Act was signed into law in the U.S. in March 2020. The CARES Act adjusted a number of provisions of the tax code, including the calculation and eligibility of certain

deductions and the treatment of net operating losses and tax credits. The enactment of the CARES Act did not result in any material adjustments to the Company's income tax provision for the years ended December 31, 2022 and 2021 or to its net deferred tax assets as of December 31, 2022 and 2021.

Tax Cuts and Jobs Act

Enacted in 2017, the Tax Cuts and Jobs Act ("TCJA") included significant changes in tax law including a change to Internal Revenue Code section 174 ("Section 174") regarding the deductibility of research and experimentation expenses ("R&E expenses"). The section 174 tax law change had a delayed effective date and became effective for the Company in 2022. The new Section 174 requires that companies capitalize and amortize R&E expenses performed in the U.S. over five years and further provides for a fifteen-year amortization period for R&E expenses incurred outside the U.S. The Company has factored any impact of section 174 in its consolidated financial statements and related disclosures.

Net deferred tax assets as of December 31, 2022 and 2021 consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss	$ 8,759	$ 9,906
Research and development credits	6,850	4,992
Section 174 costs	4,512	—
Deferred revenue	610	—
Other	130	69
Total deferred tax assets	20,861	14,967
Deferred tax liabilities:		
Prepaid assets	(33)	(22)
Property and equipment	(1)	(2)
Other	(2)	—
Total deferred tax liabilities	(36)	(24)
Deferred tax asset valuation allowance	(20,825)	(14,943)
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2022, the Company had U.S. federal and state net operating losses ("NOLs"), research and development ("R&D) tax credit, and capitalized R&D expense carryforwards of $37.2 million, $6.9 million and $4.5 million, respectively. The NOLs begin to expire in 2024.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of NOLs, R&D credits, and R&E expenses capitalized per Section 174. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a full valuation allowance was maintained as of December 31, 2022. An increase in the Company's valuation allowance in the amount of $5.9 million was recorded in 2022, due primarily to the increase in net deferred tax assets.

The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations for both federal taxes and the many states in which it operates or does business in. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits.

The Company records tax positions as liabilities and adjusts these liabilities when its judgement changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the Company's current estimate of the recognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. As of December 31, 2022, the Company has not recorded any uncertain tax positions in its consolidated financial statements.

The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. As of December 31, 2022, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's consolidated statements of operations and comprehensive loss for either of the years ended December 31, 2022 and 2021.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. All of the Company's tax years from inception are still open as the Company has tax attribute carryforwards. Accordingly, the tax years in which these tax attributes were generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period. There are currently no pending income tax examinations.

Note 15. Related Party Transactions

The Company analyzed its transactions with related parties for the years ended December 31, 2022 and 2021 and determined that other than the sponsored research and other services provided by the UT entities (See Note 9 of Notes to Consolidated Financial Statements) and the sale of 500,000 shares of TFF common stock to Bios Special Opportunity Fund, LP (See Note 2 of Notes to Consolidated Financial Statements), all other transactions related to compensation-based consulting arrangements with certain investors. As such, the Company did not have any material related party transactions in 2022 and 2021 other than the sponsored research and other services provided by the UT entities and the sale of TFF common stock to Bios Special Opportunity Fund, LP as noted above.

Note 16. Subsequent Events

For its consolidated financial statements as of December 31, 2022 and for the year then ended, the Company evaluated subsequent events through May 25, 2023, the date on which these financial statements are issued. No subsequent events have been identified for disclosure.

ANNEX B

UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS AND ACCOMPANYING NOTES OF LUNG THERAPEUTICS, INC

(Nine Months Ended September 30, 2023 and 2022)

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INDEX TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS OF LUNG THERAPEUTICS, INC.

LUNG THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 20	$ 11,881
Prepaid expenses and other current assets	2,147	2,714
Total current assets	2,167	14,595
Property and equipment, net	3	5
Operating lease right-of-use assets	91	221
Other assets	27	27
Total assets	$ 2,288	$ 14,848
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Simple agreements for future equity	$ —	$ 13,435
Loan from related party	720	—
Accounts payable	2,436	860
Deferred revenue	—	352
Operating lease liabilities, current	96	184
Accrued expenses and other current liabilities	2,110	1,753
Total current liabilities	5,362	16,584
Deferred revenue, net of current portion	2,714	2,515
Operating lease liabilities, net of current portion	—	48
Total liabilities	8,076	19,147
Commitments and contingencies (Note 9)		
Series A convertible preferred stock, par value $0.0001 per share; 10,888,283 shares authorized, issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	2,874	2,874
Series B convertible preferred stock, par value $0.0001 per share; 23,152,737 shares authorized, issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	14,293	14,293
Series C convertible preferred stock, par value $0.0001 per share; 56,176,061 and 41,076,061 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 56,139,878 and 41,076,061 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	53,293	39,858
Stockholders' deficit:		
Common stock, par value $0.0001 per share; 121,000,000 and 106,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively; 9,245,103 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	1	1
Additional paid-in capital	2,352	2,119
Accumulated deficit	(78,601)	(63,444)
Total stockholders' deficit	(76,248)	(61,324)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 2,288	$ 14,848

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

LUNG THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands)
(unaudited)

	For the Nine Months Ended September 30,	
	2023	2022
Licensing revenue	$ 153	$ 766
Operating expenses:		
Research and development	(10,861)	(16,105)
General and administrative	(4,525)	(5,287)
Total operating expenses	(15,386)	(21,392)
Loss from operations before gains from affiliate	(15,233)	(20,626)
Gain from sale of equity securities in TFF	—	9,400
Loss from operations	(15,233)	(11,226)
Other income, net:		
Interest income	76	42
Total other income, net	76	42
Net loss and comprehensive loss	$ (15,157)	$ (11,184)

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

LUNG THERAPEUTICS, INC.

Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Convertible preferred stock						Common stock $0.0001 Par Value		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	$0.0001 Par Value Series A		$0.0001 Par Value Series B		$0.0001 Par Value Series C						
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, January 1, 2023	10,888,283	$ 2,874	23,152,737	$ 14,293	41,076,061	$ 39,858	9,245,103	$ 1	$ 2,119	$ (63,444)	$ (61,324)
Stock-based compensation	—	—	—	—	—	—	—	—	233	—	233
Conversion of SAFEs into Series C convertible preferred stock	—	—	—	—	15,063,817	13,435	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(15,157)	(15,157)
Balance, September 30, 2023	10,888,283	$ 2,874	23,152,737	$ 14,293	56,139,878	$ 53,293	9,245,103	$ 1	$ 2,352	$ (78,601)	$ (76,248)

	Convertible preferred stock						Common stock $0.0001 Par Value		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	$0.0001 Par Value Series A		$0.0001 Par Value Series B		$0.0001 Par Value Series C						
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, January 1, 2022	10,888,283	$ 2,874	23,152,737	$ 14,293	41,076,061	$ 39,858	9,150,208	$ 1	$ 1,713	$ (44,403)	$ (42,689)
Stock-based compensation	—	—	—	—	—	—	—	—	304	—	304
Exercise of common stock options	—	—	—	—	—	—	17,812	—	4	—	4
Net loss	—	—	—	—	—	—	—	—	—	(11,184)	(11,184)
Balance, September 30, 2022	10,888,283	$ 2,874	23,152,737	$ 14,293	41,076,061	$ 39,858	9,168,020	$ 1	$ 2,021	$ (55,587)	$ (53,565)

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

LUNG THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	For the Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (15,157)	$ (11,184)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	132	124
Gain from sale of equity securities in TFF	—	(9,400)
Stock-based compensation expense	233	304
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	567	4,224
Accounts payable	1,576	657
Deferred revenue	(153)	(767)
Accrued expenses and other current liabilities	221	(1,313)
Net cash flows used in operating activities	(12,581)	(17,355)
Cash flows from investing activities		
Proceeds from sale of equity securities in TFF, net	—	9,400
Net cash flows provided by investing activities	—	9,400
Cash flows from financing activities		
Proceeds from issuance of simple agreements for future equity, net of issuance costs	—	13,435
Proceeds from exercise of common stock options	—	4
Proceeds from a related party loan	720	—
Net cash flows provided by (used in) financing activities	720	13,439
Net increase (decrease) in cash and cash equivalents	(11,861)	5,484
Cash and cash equivalents, beginning of year	11,881	11,483
Cash and cash equivalents, end of year	$ 20	$ 16,967
Non-cash financing activities:		
Recognition of right-of-use asset and operating lease liability	$ —	$ 384

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

LUNG THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements

Note 1. Description of Business

These unaudited condensed consolidated financial statements have not been audited or reviewed by an independent accountant.

Lung Therapeutics, Inc. ("Lung Therapeutics" or the "Company"), was incorporated in November 2012 under the laws of the state of Texas. Its principal offices are in Austin, Texas. The Company's focus is developing novel therapeutics for orphan pulmonary and fibrosis indications with the potential to greatly improve patient outcomes over currently available treatments.

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly owned, non-operating subsidiaries, Lung Therapeutics Australia Pty Ltd ("Lung Therapeutics Australia") and Lung Therapeutics Limited, which is an Irish entity.

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to the risk that the Company never achieves profitability, the need for substantial additional financing, the risk of relying on third parties, risks of clinical trial failures, dependence on key personnel, protection of proprietary technology, and compliance with government regulations. The Company's lead product candidate, LTI-03, is being developed for the treatment of idiopathic pulmonary fibrosis ("IPF") and has completed a healthy volunteer Phase 1a clinical trial. LTI-03 is currently in a Phase 1b clinical trial in IPF patients. The Company's second product candidate, LTI-01, is in development for loculated pleural effusion ("LPE"). The Company has completed Phase 1b and Phase 2a clinical trials of LTI-01 in LPE patients.

On October 31, 2023, Aileron Therapeutics, Inc., a publicly traded Delaware corporation ("Aileron") listed on The Nasdaq Capital Market, acquired the Company pursuant to an Agreement and Plan of Merger (the "Merger Agreement"), by and among Aileron, AT Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of Aileron ("First Merger Sub"), AT Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Aileron ("Second Merger Sub), and the Company. Pursuant to the Merger Agreement, among other matters, First Merger Sub merged with and into the Company, with the Company surviving as a wholly owned subsidiary of Aileron (the "First Merger"), and, immediately following the First Merger, the Company merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity (together with the First Merger, the "Merger"). Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Aileron, which is developing novel therapies for the treatment of orphan pulmonary and fibrosis indications that have no approved or limited effective treatments. The Merger was intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provision of Sections 368(a) of the Internal Revenue Code (the "Code"). (See Note 14 of Notes to unaudited condensed consolidated financial statements).

Liquidity and Going Concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern* ("ASC 205-40"), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the accompanying consolidated financial statements were issued.

As an emerging growth entity, the Company has devoted substantially all of its resources since inception to its research and development efforts relating to its product candidates, including activities to manufacture product candidates, conduct clinical studies of its product candidates and perform preclinical research to identify new

product candidates. As a result, the Company has incurred significant operating losses and negative cash flows from operations since its inception and anticipates such losses and negative cash flows will continue for the foreseeable future. To date, the Company has financed its operations primarily through private placements of convertible preferred stock, an upfront payment received from a license agreement, and sales of marketable equity securities in TFF Pharmaceuticals, Inc. ("TFF").

During the nine months ended September 30, 2023 and 2022, the Company incurred net losses of $15.2 million and $11.2 million, respectively. As of September 30, 2023, the Company had an accumulated deficit of $78.6 million and expects to continue incurring losses for the foreseeable future. Recently, the Company has been highly dependent on financing from its controlling shareholder, for which it has a convertible promissory note payable in the principal amount of $0.7 million as of September 30, 2023 (See Note 13 of Notes to unaudited condensed consolidated financial statements). The Company does not expect to generate any revenue in the near future and accordingly, will need to secure additional funding through public or private convertible preferred financings, debt financings, and/or collaboration agreements or government grants over the next twelve months in order to continue to fund the Company's operations. Given the lack of a finalized plan to secure additional funding that would be considered probable of occurrence under ASC 205-40, the Company can provide no assurance that additional funding will be obtained on acceptable terms, or at all. If the Company is unable to secure additional funding to continue to fund its operations over the next twelve months, the Company would need to pursue other alternatives, such as a scale back in its operating plan by deferring or limiting some or all of its research, development or clinical projects, further reductions to its workforce, and/or seek other strategic investment alternatives. Management has concluded the uncertainty surrounding the Company's ability to secure additional funding over the next twelve months raises substantial doubt about the Company's ability to continue as a going concern. The accompanying unaudited condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Note 2. Summary of Significant Accounting Policies

Basis of presentation

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

Unaudited Condensed Financial Statements

The condensed consolidated balance sheet as of September 30, 2023, and the condensed consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of the Company's financial position as of September 30, 2023 and its results of operations and cash flows for the nine months ended September 30, 2023 and 2022. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the nine-month periods are also unaudited. The results of operations for the nine months ended September 30, 2023 are not necessarily indicative of the results to be expected for the year ended December 31, 2023, or for any other future annual or interim period. The consolidated balance sheet as of December 31, 2022, included herein was derived from the audited financial statements as of that date, but does not contain all of the footnote disclosures from those audited annual financial statements.

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Lung Therapeutics Australia and Lung Therapeutics Limited. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed financial statements include, but are not limited to, the accrual for research and development expenses, the valuation of simple agreements for future equity ("SAFEs"), the valuation of warrants, and the valuation of common stock. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Foreign Currency Transactions

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

Revenue Recognition

In accordance with ASC *Topic 606, Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when the Company's customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company identifies the performance obligations in the contract by assessing whether the goods or services promised within each contract are distinct. The Company then recognizes revenue for the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

Licensing revenue

On November 12, 2020, the Company entered into a license agreement (the "License Agreement") with Taiho Pharmaceutical Co., Ltd ("Taiho"). The License Agreement is discussed further in Note 7 of Notes to unaudited condensed consolidated financial statements. The Company's license arrangements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and products, and obligations to participate on certain development committees with licensing partners.

The terms of such license arrangements generally include payment to the Company of one or more of the following: nonrefundable upfront fees, payments for the supply of clinical products, payment for research and development services, payments related to milestone payments and royalties on net sales of licensed products. The Company assesses whether the promises in these agreements are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation on development committees.

The transaction price in each agreement is allocated to the identified performance obligations based on the standalone selling price ("SSP") of each distinct performance obligation as applicable. Judgment is required to determine SSP. Due to the early stage of the Company's licensed technology, the license of such technology is typically combined with the research and development services and committee participation as one performance obligation.

Revenue associated with nonrefundable upfront license fees where the license fees and research and development services cannot be accounted for as separate performance obligations is deferred and recognized as revenue over the expected period of performance using a cost-based input methodology. The Company utilizes judgment to assess the pattern of delivery of the performance obligation.

At the inception of each agreement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant reversal of cumulative revenue would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the underlying activity has been completed. The transaction price is then allocated to each performance obligation in the agreement based on relative SSP. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash and cash equivalents. Periodically, the Company maintains balances in operating accounts above federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality. The Company has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash and cash equivalents.

Investment in TFF

Pursuant to a contribution agreement executed on January 24, 2018, the Company's wholly owned subsidiary, TFF, was spun out into a separate company, whereby the Company received 4,000,000 shares of TFF's common stock in exchange for providing TFF with certain intellectual property assets licensed by the Company from the University of Texas. The Company applies the equity method of accounting to its investment in TFF as the Company determined that it continues to exercise significant influence over the operating and financial policies of TFF. Based on TFF's history of losses, the Company had previously concluded that its share of TFF's net losses under the equity method was greater than the carrying value of the investment. As a result, in 2019 the Company wrote down its investment in TFF to $0 and suspended further recognition of its share of losses incurred by TFF. In 2020 and 2021, the Company sold 1,765,000 shares of common stock of TFF generating proceeds of $23.4 million. In January 2022, the Company entered into a variable price forward sales contract with Jefferies LLC to sell 962,000 shares of common stock of TFF based upon the daily volume-weighted average price during the three-month period ended March 31, 2022 plus a premium applied over the term of the contract. In April 2022, the contract was consummated and as a result, the Company received total cash proceeds of $6.2 million from the sale of these shares. In April 2022, the Company sold 500,000 additional shares of common stock of TFF to Bios Special Opportunity Fund, LP, a related party, at a price of $6.43 per share, generating net proceeds of $3.2 million.

The Company recorded gains from the sale of these shares of $9.4 million that are reflected under Gain from sale of equity securities in TFF on its condensed consolidated statements of operations and comprehensive loss for the

nine months ended September 30, 2022. As of September 30, 2023, the Company's remaining ownership of TFF common stock amounted to 773,000 shares of common stock of TFF.

Fair Value Measurements

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

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

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

An entity may choose to measure many financial instruments and certain other items at fair value at specified election dates. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings.

Simple Agreement for Future Equity - SAFE

The Company accounts for SAFEs at fair value in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). The SAFEs are subject to revaluation at the end of each reporting period, with changes in fair value recognized in the Company's consolidated statements of operations and comprehensive loss.

Cash and Cash Equivalents

Cash and cash equivalents consist of standard checking accounts and money market funds. The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents. The Company's cash equivalents are comprised of funds held in money market accounts and are measured at fair value on a recurring basis.

Convertible Preferred Stock

The Company has classified convertible preferred stock, referred to as preferred stock, as temporary equity in the accompanying condensed consolidated balance sheets due to terms that allow for redemption of the shares in cash upon certain change in control events that are outside of the Company's control, including sale or transfer of control of the Company as holders of the preferred stock could cause redemption of the shares in these situations. The Company did not accrete the carrying values of the preferred stock to the redemption values since a

liquidation event was not considered probable as of September 30, 2023. Subsequent adjustments of the carrying values to the ultimate redemption values will be made only when it becomes probable that such a liquidation event will occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or the Company's tax returns. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities using the enacted statutory tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Recognition of deferred tax assets is limited to amounts for which, in the opinion of management, realization is considered more likely than not in future periods.

For the nine months ended September 30, 2023 and 2022, the Company recorded no current or deferred income tax expenses or benefits as it has incurred losses since inception and has historically provided a full valuation allowance against its deferred tax assets.

In assessing the realizability of the net deferred tax assets, management considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes that it is more likely than not that the Company's deferred income tax assets will not be realized.

The Company has not recorded any liabilities for unrecognized tax benefits as of September 30, 2023, and 2022. The Company will recognize interest and penalties related to uncertain tax positions, if any, in income tax expense. As of September 30, 2023 and 2022, the Company had no accrued interest or penalties related to uncertain tax positions.

Research and Development Expenses

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

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

The Company has entered into various research and development and other agreements with commercial firms, researchers, universities, and others for provisions of goods and services. These agreements are generally cancelable, and the related costs are recorded as research and development expenses as incurred. Research and development expenses include costs for salaries, employee benefits, subcontractors, facility-related expenses, depreciation and amortization, stock-based compensation, laboratory supplies, and external costs of outside vendors engaged to conduct discovery, preclinical and clinical development activities, and clinical trials as well as to manufacture clinical trial materials, and other costs. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ materially from the Company's estimates. Nonrefundable

advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered, or the services rendered.

Upfront payments, milestone payments and annual maintenance fees under license agreements are expensed in the period in which they are incurred.

Patent Costs

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

Leases

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or financing leases. Operating leases are included in Operating lease right-of-use assets and Operating lease liabilities in the Company's condensed consolidated balance sheets.

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

Stock-Based Compensation

The Company's stock-based compensation expense stems from granted awards that may include stock options, restricted stock awards, restricted stock units, and other stock-based awards. The fair values of stock option grants are estimated as of the date of grant using a Black-Scholes option valuation model. The estimated fair values of the awards are expensed over the requisite service period, which is generally the vesting period of the award. The Company accounts for forfeitures as they occur. For performance-based awards, the Company does not recognize expense until the underlying vesting conditions are deemed to be probable of occurrence.

In determining the fair value of its common stock, the Company utilizes significant estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the superior rights and preferences of securities senior to the Company's common stock at the time of, and the likelihood of, achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The Company historically has been a private company and lacks company-specific historical and implied volatility information for its stock. Therefore, it estimates its expected stock price volatility based on the

historical volatility of publicly traded peer companies and expects to continue to do so until such time that it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees was determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employee consultants is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Comprehensive Income or Loss

Comprehensive income or loss consists of net income or loss and changes in equity during a period from transactions and other equity and circumstances generated from non-owner sources. For each of the nine-month periods ended September 30, 2023 and 2022, the Company's net loss equals comprehensive loss.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

Note 3. Fair Value Measurements

The following tables present information about the Company's assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
As of September 30, 2023				
Assets:				
Money market funds	$ 11	$ 11	$ —	$ —
SAFEs	—	—	—	—
Total	$ 11	$ 11	$ —	$ —
As of December 31, 2022				
Assets:				
Money market funds	$11,763	$11,763	$ —	$ —
SAFEs	13,435	—	—	13,435
Total	$25,198	$11,763	$ —	$ 13,435

The fair value of the SAFEs is based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

There were no transfers between fair value levels during the nine-month periods ended September 30, 2023 and 2022. The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Simple Agreement for Future Equity - SAFE

In March and April 2022, the Company executed a series of SAFEs primarily with new investors, pursuant to which the Company received net proceeds in an aggregate amount equal to $13.4 million. The fair value of the SAFEs on the date of issuance was determined to equal the proceeds received by the Company. The SAFEs provided investors with potential future equity by conversion of the SAFEs into preferred stock at the Company's subsequent equity financing event, to the extent that the Company received aggregate gross proceeds of at least $20.0 million and provided that such equity financing event occurs prior to December 31, 2022, the date of maturity of the SAFEs. The initial discount for the SAFEs was 90%, but if, prior to the subsequent equity financing event, the Company has supplied to any potential third-party investor the results of its Phase 2a clinical trial with respect to its drug candidate LTI-01, the discount is reduced to 80%. If there is no equity financing prior to December 31, 2022 that yields aggregate gross proceeds of at least $20.0 million or if a liquidity or dissolution event of the Company does not occur, each SAFE will automatically convert into the Company's Series C convertible preferred stock at the original issuance price of such Series C convertible preferred stock.

The SAFEs were not mandatorily redeemable, nor did they require the Company to repurchase a fixed number of shares. The Company determined that the SAFEs contained a liquidity event provision that embodies an obligation indexed to the fair value of the Company's preferred shares and could require the Company to settle the SAFE obligation by transferring assets or cash. For this reason, the Company recorded the SAFEs as a liability under ASC 480 and re-measured the fair value at the end of each reporting period, with changes in fair value reported in earnings. As of December 31, 2022, the fair value of the SAFEs was determined to be $0.98, the price at which they will convert into shares of Series C convertible preferred stock.

As the Company did not have an equity financing, liquidity or dissolution event prior to December 31, 2022, the SAFEs were converted into Series C convertible preferred stock during the three-month period ended June 30, 2023 at their fair value price of $0.98 each, resulting in the issuance by the Company of a total of 15,063,817 shares of Series C convertible preferred stock.

The following table sets forth a summary of the activities of the SAFEs which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy wherein fair value is estimated using significant unobservable inputs (in thousands):

	Amount
Balance as of December 31, 2022	$ 13,435
Change in fair value	—
Conversion of SAFEs into Series C convertible preferred stock	(13,435)
Balance as of September 30, 2023	$ —

Non-Recurring Fair Value Measurements

The Company issued warrants to purchase shares of its common stock in 2014, 2015, 2018, and 2019, pursuant to its convertible preferred stock issuances (See Note 10 of Notes to unaudited condensed consolidated financial statements) and its license agreement with Vivarta Therapeutics LLC (See Note 8 of Notes to unaudited condensed consolidated financial statements). All warrants were determined to be equity-classified and recorded as part of additional paid in capital at fair value using the Black-Scholes option pricing model. The warrants are not subsequently remeasured.

Preferred Stock Warrants

Prior to 2020, the Company had issued to its preferred stockholders a total of 7,096,828 warrants to purchase shares of common stock. Of these warrants, 3,043,184 were granted in connection with Series A and Series B

convertible preferred stock ("Series A" and "Series B") issuances and 4,053,644 were granted in conjunction with the issuance of the Company's Series C convertible preferred stock ("Series C") (See Note 10 of Notes to unaudited condensed consolidated financial statements). In November 2021, the Company issued an additional 122,045 warrants to purchase shares of common stock. No additional warrants to purchase shares of common stock have been issued since 2021. The Company had determined the fair value of these warrants using the following inputs: fair value of common stock at the time of issuance, exercise price, the contractual period, risk free rate, volatility, and dividend yield. These warrants to purchase a total of 7,218,873 shares of the Company's common stock remained outstanding as of September 30, 2023 and December 31, 2022 and none have been exercised as of September 30, 2023.

Vivarta Therapeutics LLC Warrants

In March 2018, the Company had issued warrants to purchase 75,000 shares of common stock to Vivarta Therapeutics LLC ("Vivarta"). The Company determined the fair value of the warrants using the fair value of the common stock at the time of issuance, the exercise price, contractual period, volatility, and dividend yield. These warrants to purchase 75,000 shares of common stock were wholly exercised by Vivarta during the year ended December 31, 2022 at a price of $0.12 per share.

Note 4. Prepaid Expenses and Other Current Assets

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

	As of September 30, 2023	As of December 31, 2022
Prepaid research and development	$ 1,996	$ 2,544
Other	151	170
Total prepaid and other current assets	$ 2,147	$ 2,714

Note 5. Property and Equipment, net

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

	As of September 30, 2023	As of December 31, 2022
Property and equipment:		
Furniture and equipment	$ 53	$ 53
Total property and equipment	53	53
Less: accumulated depreciation	(50)	(48)
Property and equipment, net	$ 3	$ 5

Depreciation expense was $2,000 and $3,000 for the nine months ended September 30, 2023 and 2022, respectively.

Note 6. Accrued Expenses and Other Current Liabilities

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

	As of September 30, 2023	As of December 31, 2022
Accrued compensation and benefits	$ 736	$ 904
Clinical and development costs	1,125	657
Deferred financing costs	—	—
Other	249	192
Total accrued expenses and other current liabilities	$ 2,110	$ 1,753

Note 7. Licensing Arrangement with Taiho

On November 12, 2020, the Company entered into the License Agreement with Taiho pursuant to which the Company is collaborating with Taiho regarding the development and potential commercialization of the Company's product candidate, LTI-01. Under the License Agreement, the Company granted Taiho an exclusive, royalty-bearing license to develop, seek regulatory approval for, and commercialize LTI-01 in Japan. The Company is obligated to conduct all development activities for LTI-01 through regulatory approval in the United States or other markets worldwide, except Japan. The Company retained the right to commercialize LTI-01 in all markets worldwide except Japan. Under the terms of the License Agreement, the Company, in part through its participation in a joint development committee with Taiho, may 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 License Agreement, Taiho agreed to make a non-refundable, non-creditable payment to the Company of $5.0 million. This up-front payment, deemed a partial reimbursement of past and future development costs for LTI-01, was received by the Company in February 2021. The License Agreement also provides that the Company is eligible to receive an additional milestone payment of $10.0 million.

In addition, the Company is eligible to receive royalties on net sales of LTI-01 in Japan. Royalties are payable during the period commencing on the first commercial sale of LTI-01 in Japan and ending upon the later of: (a) ten years from the date of first commercial sale of LTI-01 in Japan; and (b) expiration of the last-to-expire valid claim of the Company's patents covering the manufacture, use or sale or exploitation of LTI-01 in Japan.

The Company evaluated the License Agreement under ASC 606 and determined that there is one combined performance obligation that consists of the license and data transfer, the research and development services in which the Company is required to use commercially reasonable efforts to further the development of LTI-01, including execution of the necessary clinical trials, and supply of all clinical products during the term of the License Agreement. These deliverables are non-contingent in nature.

The Company's assessment of the transaction price included an analysis of amounts it expected to receive, which at contract inception consisted of the non-refundable, upfront payment of $5.0 million that was received by the Company in 2021. The Company considered this non-refundable fee of $5.0 million to be the initial transaction price.

The Company determined that the combined performance obligation is satisfied over time. The Company concluded that it will utilize a cost-based input method to measure its progress toward completion of its performance obligation and to calculate the corresponding amount of revenue to recognize each period. The Company believes this is the best measure of progress because other measures do not reflect how the Company

transfers its performance obligation to Taiho. In applying the cost-based input method of revenue recognition, the Company uses actual clinical study enrollment figures as well as actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of third-party contract costs relative to the level of patient enrollment in the studies. Revenue will be recognized based on the level of costs incurred relative to the total budgeted costs for the performance obligations. A cost-based input method of revenue recognition requires management to make estimates of costs to complete the Company's performance obligation. In making such estimates, significant judgment is required to evaluate assumptions related to cost estimates. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

The Company also determined that the milestone payment of $10.0 million under the License Agreement is variable consideration under Topic 606 is added to the transaction price when it is probable that a significant revenue reversal will not occur. Based on the nature of milestones, such as the regulatory approvals which are generally not within the Company's control, the Company will not consider achievement of this milestone to be probable until the uncertainty associated with such milestone has been resolved. When it is probable that a significant reversal of revenue will not occur, the milestone payment will be added to the transaction price for which the Company recognizes revenue. As of September 30, 2023 and December 31, 2022, no milestones had been achieved under the License Agreement.

The Company will recognize royalty revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). As of September 30, 2023 and December 31, 2022, no royalty revenue has been recognized.

For the nine months ended September 30, 2023 and 2022, the Company recognized revenue totaling $153,000 and $766,000, respectively, from the License Agreement with Taiho. As of September 30, 2023 and December 31, 2022, the Company recorded current deferred revenue of $0 and $0.35 million, and noncurrent deferred revenue of $2.71 million and $2.52 million, respectively, on its condensed consolidated balance sheets.

Note 8. License Agreements

Agreements with the Board of Regents of the University of Texas System ("UT System")

In June 2013, May 2014 and May 2015, the Company entered into three license agreements with affiliates of the Board of Regents of the University of Texas (collectively, the "UT Agreements"). These three affiliated entities (collectively, the "UT entities") are as follows: University of Texas Health Science Center at Tyler ("UTHSCT"), University of Texas Horizon Fund ("UT Horizon Fund") and University of Texas at Austin ("UT Austin"). The UT Agreements were accounted for as asset acquisitions and do not meet the definition of a business under ASU 2017-01, *Business Combinations—Clarifying the definition of a business* ("ASC 805").

Pursuant to the UT Agreements, the Company acquired licenses and underlying technology rights to certain intellectual property within defined fields to develop its product candidates. The Company received an exclusive, royalty-bearing license to certain patent rights and know-how, as well as a non-exclusive license to the UT intellectual property, which includes future rights to royalties on licensed products. The UT Agreements also provide for sublicensing rights, whereby the Company may grant sublicenses to third parties to use the licensed technology, subject to certain terms within the UT Agreements. The UT Agreements can be terminated at-will by the Company with 90 days' notice, or by the UT entities in the event of a material breach of terms. Under the UT Agreements, the Company is responsible for the following payments, which are made to the indicated parties:

- *License Fees* – The Company is required to make annual payments of $10,000 for license fees under the license agreement with UT Austin until the agreement is terminated.

- *Sublicensing fees* – The Company will pay a percentage of non-royalty sublicensing consideration for the UT Agreements, with varying rates that will depend on when the sublicensing agreement is executed.
- *Assignment fee* – The Company will pay the greater of 10% of the consideration received or $100,000, if any of the UT Agreements are assigned to a third party.
- *Royalties* – The Company will pay tiered royalties that are in the low-to-mid single-digit percentages, based on net sales of all products licensed under the UT Agreements.
- *Milestones* – The Company will make milestone payments to UT Austin of up to $395,000 if specified regulatory and clinical development milestone events occur. All license fee and milestone payments are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

The Company's expense associated with annual license fees and milestone payments under the UT Agreements was $0 for each of the nine-month periods ended September 30, 2023 and 2022, respectively. All license fee and milestone payments are generally incurred during the Company's fourth quarter ending December 31 of each year and are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Agreement with Medical University of South Carolina ("MUSC")

In March 2016, the Company entered into a license agreement with MUSC (the "MUSC Agreement"), pursuant to which the Company acquired licenses and underlying technology rights to certain intellectual property within defined fields to develop its product candidates. The MUSC Agreement was accounted for as an asset acquisition and does not meet the definition of a business under ASC 805.

The Company received an exclusive, royalty-bearing license to certain patent rights and know-how, as well as a non-exclusive license to the MUSC intellectual property, which includes future rights to royalties on licensed products. The MUSC Agreement also provided for sublicensing rights, whereby the Company may grant sublicenses to third parties to use the licensed technology, subject to certain terms in the MUSC Agreement. The MUSC Agreement can be terminated at-will by the Company with 90 days' notice, or by MUSC only in the event of a material breach of terms. Under the MUSC Agreement, the Company is responsible for the following payments:

- *License Fee* – The Company was obligated to and paid a one-time, nonrefundable license fee of $10,000 at the execution of the MUSC Agreement.
- *Sublicensing fees* – The Company will pay sublicensing fees, which vary from 15-30% of total consideration based on the Company's progression through each phase of development.
- *Transaction fee* – The Company will pay the lesser of $2.5 million or 1% of total consideration in the event of a liquidation.
- *Royalties* – The Company will pay a running royalty rate in the low single digits on all net sales and is also required to pay annual minimum royalties of $10,000 on the third, fourth, and fifth anniversaries of the execution date of the MUSC Agreement and $25,000 on the sixth anniversary of the execution date of the MUSC Agreement and all years thereafter.
- *Milestones* – The Company will make milestone payments to MUSC of up to $300,000 if specified regulatory and clinical development milestone events occur.

The Company's expense associated with minimum royalty and milestone payments under the MUSC Agreement was $25,000 for each of the nine-month periods ended September 30, 2023 and 2022, respectively. All minimum royalty and milestone payments under the MUSC Agreement are recorded as general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

Agreement with Vivarta Therapeutics LLC ("Vivarta")

In March 2018, the Company entered into a license agreement with Vivarta (the "Vivarta Agreement"), pursuant to which the Company acquired licenses and underlying technology rights to certain intellectual property within defined fields to develop its product candidates. The Vivarta Agreement was accounted for as an asset acquisition and does not meet the definition of a business under ASC 805.

The Company received an exclusive, royalty-bearing license to certain patent rights and know-how, as well as a non-exclusive license to the Vivarta intellectual property, which includes future rights to royalties on licensed products. The Vivarta Agreement also provided for sublicensing rights, whereby the Company may grant sublicenses to third parties to use the licensed technology, subject to certain terms in the Vivarta Agreement. The Vivarta Agreement can be terminated at-will by the Company with 90 days' notice, or by Vivarta only in the event of a material breach of terms. Under the Vivarta Agreement, the Company is responsible for the following payments:

- *License Fee* – The Company was obligated to and paid one-time, nonrefundable license fees of $10,000 due upon the execution of the Vivarta Agreement and $40,000 due upon receipt by the Company of a positive freedom to operate analysis.
- *Sublicensing fees* – The Company will pay sublicensing fees, which vary from 5-40% of total consideration based on the Company's progression through each phase of development.
- *Royalties* – The Company will pay a running royalty rate in the low single digits on all net sales.
- *Milestones* – The Company will make milestone payments to Vivarta of up to $6.83 million if specified research, regulatory and clinical development milestone events occur. Milestone payments in the amount of $0 and $50,000 were made to Vivarta during the nine months ended September 30, 2023 and 2022, respectively, following the attainment of a research and development milestone.

Pursuant to the Vivarta Agreement, the Company issued warrants to Vivarta to purchase 75,000 shares of common stock at an exercise price of $0.12 per share in 2018 (See Note 3 of Notes to unaudited condensed consolidated financial statements). These warrants were wholly exercised by Vivarta during the three months ended December 31, 2022.

The Company's expense associated with license fees and milestones under the Vivarta Agreement amounted to $0 and $50,000 in each of the nine-month periods ended September 30, 2023 and 2022, respectively. The expense incurred in 2022 was associated with the milestone payment mentioned above. Any license fee and milestone payments are recorded as general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

Note 9. Commitments and Contingencies

Lease Agreements

On August 16, 2021, the Company entered into an operating lease agreement to rent approximately 6,455 square feet of office space for its corporate headquarters in Austin, Texas, beginning on October 1, 2021. The lease agreement is for a 30-month term that ends on March 31, 2024 and includes a rent escalation clause and a rent holiday. In addition to the base rent, the Company is also responsible for its share of operating expenses, electricity and real estate taxes, in accordance with the terms of the lease agreement.

Amounts reported in the condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022 for the Company's operating lease were as follows, in thousands:

	As of September 30, 2023	As of December 31, 2022
Assets		
Operating lease right-of-use assets	$ 91	$ 221
Total operating lease right-of-use assets	$ 91	$ 221
Liabilities		
Current		
Operating lease liabilities	$ 96	$ 184
Noncurrent		
Operating lease liabilities, net of current	—	48
Total operating lease liabilities	$ 96	$ 232

Operating lease costs for each of the nine-month periods ended September 30, 2023 and 2022 amounted to $138,000, respectively.

The maturities of the operating lease liabilities and minimum lease payments as of September 30, 2023 were as follows, in thousands:

For the Periods Ending December 31,	Operating Lease
2023	$ 49
2024	48
Total undiscounted lease payments	97
Less: Imputed interest	(1)
Present value of operating lease liabilities	$ 96

The following table summarizes the lease term and discount rate as of September 30, 2023:

	As of December 31, 2022
Remaining lease term (years)	
Operating lease	0.5
Discount rate	
Operating lease	6.6%

Operating cash flows used for the operating lease during the nine months ended September 30, 2023 and 2022 amounted to $144,000 and $125,000, respectively.

License Agreements

The Company is required to make certain payments under its license agreements, related to patent expenses, license fees, and assignment fees, as well as milestone and royalty payments upon the achievement of certain development and sales-based events (See Note 8 of Notes to unaudited condensed consolidated financial statements).

Legal Proceedings

The Company may from time to time be party to litigation arising in the ordinary course of business. As of September 30, 2023 and December 31, 2022, the Company was not party to any legal proceedings and no material legal proceedings are currently pending or, to the best of the Company's knowledge, threatened.

Note 10. Convertible Preferred Stock

The Company has issued Series A, Series B and Series C preferred stock (collectively, the "Preferred Stock").

As of September 30, 2023 and December 31, 2022, the authorized shares of Preferred Stock consisted of the following:

	As of September 30, 2023	As of December 31, 2022
Series A	10,888,283	10,888,283
Series B	23,152,737	23,152,737
Series C	56,176,061	41,076,061
	90,217,081	75,117,081

As of September 30, 2023, the issued and outstanding shares of Preferred Stock consisted of the following (in thousands, except amounts):

	Preferred stock issued and outstanding	Carrying value	Liquidation value	Common stock issuable upon conversion
Series A	10,888,283	$ 2,874	$ 2,931	10,888,283
Series B	23,152,737	14,293	14,307	23,152,737
Series C	56,139,878	53,293	54,711	56,139,878
	90,180,898	$ 70,460	$ 70,584	90,180,898

As of December 31, 2022, the issued and outstanding shares of Preferred Stock consisted of the following (in thousands, except amounts):

	Preferred stock issued and outstanding	Carrying value	Liquidation value	Common stock issuable upon conversion
Series A	10,888,283	$ 2,874	$ 2,931	10,888,283
Series B	23,152,737	14,293	14,307	23,152,737
Series C	41,076,061	39,858	39,911	41,076,061
	75,117,081	$ 57,025	$ 57,149	75,117,081

The Company recorded all issued shares of Preferred Stock at fair value on the date of issuance, net of issuance costs. All Preferred Stock has a par value of $0.0001 per share. The rights, privileges, and preferences of the Preferred Stock are discussed below.

Voting

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of

outstanding shares of Preferred Stock shall be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Company's articles of incorporation, holders of Preferred Stock shall vote together with the holders of common stock as a single class.

The holders of outstanding shares of Preferred Stock shall be entitled to elect one member of the Board of Directors (the "Board").

Dividends

The holders of Preferred Stock are entitled to an 8% non-cumulative dividend. Dividends are payable only when and if declared by the Board. No dividends are payable to the common stockholders unless a dividend is also paid to preferred stockholders equal to at least the amount that would be received if the shares of Preferred Stock were converted into common stock. To date, the Company has not declared or paid any dividends.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, holders of shares of Preferred Stock then outstanding shall be entitled to receive an amount per share equal to the Preferred Stock original issue price, plus any dividends declared but unpaid thereon, prior to any distribution to the common stockholders.

Note that in relation to the above, no series of the Preferred Stock has a higher liquidation preference than another, but the Preferred Stock as a whole has a higher liquidation preference than the common stock.

Redemption

The Company's certificate of incorporation, as amended and restated, does not provide redemption rights to the holders of Preferred Stock.

Conversion

Each share of Preferred Stock shall be convertible into shares of common stock on a one-for-one basis at the option of the stockholder, at any time, and without the payment of additional consideration by dividing the Preferred Stock original issue price by the conversion price. The conversion price may be adjusted for issuance of additional shares of common stock, for stock splits, for stock combinations, for certain dividends and distributions, and for mergers and reorganizations.

Note 11. Stockholders' Deficit

Common Stock

As of September 30, 2023, the Company had 121,000,000 shares of common stock authorized, of which 9,245,103 were issued and outstanding.

The holders of the Company's common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written action in lieu of meetings; there is no cumulative voting. The holders of outstanding shares of common stock shall be entitled to elect one member of the Board.

After payment to the holders of shares of Preferred Stock of their liquidation preferences, the remaining assets of the Company are distributed to the holders of the Company's common stock.

Shares of common stock reserved for future issuance were as follows:

	As of September 30, 2023	As of December 31, 2022
Preferred Stock issued and outstanding	90,180,898	75,117,081
Warrants to issue shares of common stock	7,218,873	7,218,873
Stock options outstanding	11,780,824	11,611,674
Shares available for future grants under the Plan	2,237,995	2,407,145
	111,418,590	96,354,773

Warrants

As of September 30, 2023, a total of 7,218,873 warrants to purchase shares of the Company's common stock were outstanding. All of the Company's outstanding warrants are non-tradeable and equity-classified because they meet the derivative scope exception under ASC Topic 815-40, *Derivatives and Hedging—Contracts in Entity's Own Equity* ("ASC 815-40").

Note 12. Stock-Based Compensation

In October 2013, the Board approved the 2013 Long-Term Incentive Plan (the "Plan") to provide long-term incentives for its employees, non-employee directors and certain consultants. As of September 30, 2023, the Company was authorized to issue a total of 14,188,922 shares of common stock under the Plan and as of that date, a total of 2,237,995 shares remained available for future issuance.

The Plan is administered by the Board or, at the discretion of the Board, by a committee of the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The vesting periods for equity awards are determined by the Board, but generally are four years. The contractual term for stock option awards is ten years.

A summary of the stock option activity for the nine months ended September 30, 2023 is as follows:

	Nine Months Ended September 30, 2023	
	Shares	Weighted Average Exercise Price
Outstanding, beginning of period	11,611,674	$ 0.21
Granted	574,000	0.40
Cancelled or forfeited	(279,538)	0.63
Expired	(125,312)	0.20
Outstanding, end of period	11,780,824	$ 0.21
Vested and expected to vest, end of period	11,780,824	$ 0.21
Exercisable, end of period	8,915,290	
Weighted-average fair value of options granted during the period	$ 0.35	

Stock-based compensation expense amounted to $233,000 and $304,000 for the nine months ended September 30, 2023 and 2022, respectively. The table below shows the allocation of this stock-based compensation expense (in thousands):

	Nine Months Ended September 30	
	2023	2022
General and administrative	$ 169	$ 239
Research and development	64	65
Total	$ 233	$ 304

Stock-based compensation expense recognized in the condensed consolidated statement of operations and comprehensive loss for the nine months ended September 30, 2023 and 2022 does not reflect tax related effects on stock-based compensation given the Company's historical and anticipated operating losses.

The fair value of each option granted by the Company is estimated on the grant date using the Black-Scholes stock option pricing model. For the options granted during the nine months ended September 30, 2023 and 2022, the following assumptions were made in estimating fair value:

	Nine Months Ended September 30	
	2023	2022
Dividend yield	— %	— %
Expected term (in years)	6.03 - 6.08	5.00 - 6.08
Risk-free interest rate	3.9% to 3.9%	1.6% to 3.0%
Expected volatility	120.6% - 120.8%	96.1% - 99.0%

Note 13. Related Party Transactions

Loan from Related Party

On September 14, 2023, the Company entered into a short-term unsecured loan arrangement (Convertible Promissory Note) with Bios Clinical Opportunities Fund, LP ("Bios Clinical"), an entity controlled by the Company's majority shareholder, pursuant to which the Company would receive an advance of up to $720,000 from Bios Clinical. Interest on the Convertible Promissory Note is based on a rate of 10% per annum and the note was due and payable on October 20, 2023, its maturity date. If the Company does not execute a financing transaction by the note's maturity date, the principal amount of $720,000 and any accrued interest thereon, are convertible into shares of Preferred Stock based on the current price of shares of Series C of $0.98. However, if the Company executes a financing transaction prior to the maturity date, at the date of such closing the principal amount and any accrued interest would automatically convert into a number of shares equal to 90% of the per share price of such financing event, including an equivalent number of warrants to purchase capital stock of the Company or any successor entity that would be issuable to investors that participate in the financing event. As of September 30, 2023, accrued interest on the note amounted to $3,000 and is included in Accrued expenses and other current liabilities on the accompanying condensed consolidated balance sheet.

On October 31, 2023, Aileron acquired the Company pursuant to the Merger Agreement by and among First Merger Sub, Second Merger Sub and the Company. Pursuant to the Merger Agreement, among other matters, First Merger Sub merged with and into the Company, with the Company surviving as a wholly owned subsidiary of Aileron, and, immediately following the First Merger, the Company merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity. Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Aileron, which is developing novel therapies for the treatment of orphan pulmonary and fibrosis indications that have no approved

or limited effective treatments. The Merger was intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provision of Sections 368(a) of the Code (See Note 14 of Notes to unaudited condensed consolidated financial statements).

Sale of TFF common stock

In April 2022, the Company sold 500,000 shares of common stock of TFF to Bios Special Opportunity Fund, LP, an entity controlled by the Company's majority shareholder, at a price of $6.43 per share, generating net proceeds of $3.2 million. The Company recorded a gain from the sale of these shares of $3.2 million that are reflected within Gain from sale of equity securities in TFF on its condensed consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2022.

The Company did not have any other material related party transactions during the nine months ended September 30, 2023 and 2022 other than the Convertible Promissory Note from Bios Clinical and the sale of TFF common stock to Bios Special Opportunity Fund, LP as noted above.

Note 14. Subsequent Events

For its condensed consolidated financial statements as of September 30, 2023 and for the nine months then ended, the Company evaluated subsequent events through December 31, 2023, the date on which these condensed consolidated financial statements were issued, to ensure that the condensed consolidated financial statements include appropriate disclosure of events both recognized in the condensed consolidated financial statements as of September 30, 2023 and events which occurred subsequently but were not recognized in the condensed consolidated financial statements.

Bios Convertible Promissory Note

On October 12, 2023, the Company executed another Convertible Promissory Note with Bios Clinical, an entity controlled by the Company's majority shareholder, pursuant to which the Company would receive an additional advance of up to $833,000. Similar to the initial arrangement (See Note 13 of the Notes to unaudited condensed consolidated financial statements), interest on the Convertible Promissory Note is based on a rate of 10% per annum and the note was due and payable on November 10, 2023, its maturity date. The maturity date of the initial $720,000 loan was amended to November 10, 2023. If the Company does not execute a financing transaction by the notes' maturity date, the principal amount of $720,000 and $833,000 and any accrued interest thereon, are convertible into shares of Preferred Stock based on the current price of a share of Series C of $0.98. However, if the Company executes a financing transaction prior to the maturity date, at the date of such closing the principal amount and any accrued interest would automatically convert into a number of shares equal to 90% of the per share price of such financing event, including an equivalent number of warrants to purchase capital stock of the Company or any successor entity that would be issuable to investors that participate in the financing event.

Bios Warrant Exercises

In October 2023, Bios Partners, the Company's majority shareholder, and related affiliates exercised warrants to convert warrants into 923,167 shares of common stock of the Company. No proceeds were received by the Company as net settlement was utilized to exercise the warrants.

Acquisition and Financing

On October 31, 2023, the Company entered into the Merger Agreement with Aileron, First Merger Sub and Second Merger Sub. On that same day, the Company was acquired by Aileron in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, First Merger Sub merged with and into the

Company, with the Company surviving as a wholly owned subsidiary of Aileron, and, immediately following the First Merger, the Company merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity. Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Aileron, which is developing novel therapies for the treatment of orphan pulmonary and fibrosis indications that have no approved or limited effective treatments. The Merger was intended to qualify for U.S. federal income tax purposes as a tax-free reorganization under the provision of Sections 368(a) of the Code.

Under the terms of the Merger Agreement, at the closing of the Merger, Aileron issued to the stockholders of the Company 344,345 shares of common stock, $0.001 par value per share, of Aileron (the "Aileron Common Stock") and 19,903 shares of Series X non-voting convertible preferred stock, $0.001 par value per share, of Aileron (the "Aileron Series X Preferred Stock"). In addition, Aileron assumed (i) all Company stock options immediately outstanding prior to the First Merger, each becoming an option for Aileron Common Stock subject to adjustment pursuant to the terms of the Merger Agreement, and (ii) all warrants exercisable for the Company's common stock, subject to adjustment pursuant to the terms of the Merger Agreement.

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

ANNEX C

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION AS OF SEPTEMBER 30, 2023 AND FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 AND FOR THE YEAR ENDED DECEMBER 31, 2022

SELECTED HISTORICAL FINANCIAL DATA AND UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

Selected Historical Condensed Financial Data of Aileron

The following tables summarize financial data of Aileron Therapeutics, Inc., a Delaware corporation ("Aileron" or the "Company"). The statement of operations data for the nine months ended September 30, 2023, and 2022 and the balance sheet data as of September 30, 2023, have been derived from the unaudited condensed financial statements included in Aileron's Quarterly Report on Form 10-Q as of and for the fiscal quarter ended September 30, 2023, filed with the Securities and Exchange Commission (the "SEC") on October 13, 2023. The statement of operations data for the years ended December 31, 2022, and 2021 and the balance sheet data as of December 31, 2022, and 2021 have been derived from the audited financial statements included in Aileron's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 20, 2023. You should read the following selected condensed financial data together with "*Aileron's Management's Discussion and Analysis of Financial Condition and Results of Operations*" and Aileron's financial statements and the related notes included in Aileron's Quarterly Report on Form 10-Q as of and for the fiscal quarter ended September 30, 2023, filed with the SEC on October 13, 2023 and included in Aileron's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 20, 2023. Aileron's historical results are not necessarily indicative of results that should be expected in any future period and Aileron's results for the interim period are not necessarily indicative of the results that should be expected for the full year ended December 31, 2023.

Selected Condensed Statement of Operations Data:

	Nine Months Ended September 30,		Year Ended December 31,	
	2023	2022	2022	2021
	(in thousands, except share and per share data)			
Operating expenses				
Research and development	$ 2,019	$ 15,565	$ 17,967	$ 17,008
General and administrative	6,027	7,379	9,680	9,597
Restructuring and other charges	940	—	—	—
Total operating expenses	8,986	22,944	27,647	26,605
Loss from operations	(8,986)	(22,944)	(27,647)	(26,605)
Interest income	322	180	—	—
Other income (expense), net	271	(18)	318	441
Net Loss	(8,393)	(22,782)	(27,329)	(26,164)
Net loss per share, basic and diluted	$ (1.85)	$ (5.02)	$ (6.02)	$ (5.89)
Weighted average common shares outstanding, basic and diluted	4,541,167	4,538,707	4,539,318	4,440,338
Comprehensive loss:				
Net loss	$ (8,393)	$ (22,782)	$ (27,329)	$ (26,164)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net of tax of $0	48	(85)	(35)	(11)
Total other comprehensive gain (loss)	48	(85)	(35)	(11)
Total comprehensive loss	$ (8,345)	$ (22,867)	$ (27,364)	$ (26,175)

Selected Condensed Balance Sheet Data:

	As of September 30, 2023	As of December 31, 2022	As of December 31, 2021
		(in thousands)	
Cash and cash equivalents	$ 12,069	$ 5,194	$ 3,600
Investments	—	16,048	42,333
Working capital (1)	11,169	18,489	43,669
Total assets	12,822	22,007	48,481
Total liabilities	1,624	3,384	4,577
Accumulated deficit	(281,178)	(272,785)	(245,456)
Total stockholders' equity	11,198	18,623	43,904

(1) Working capital is defined as current assets less current liabilities.

Selected Historical Consolidated Financial Data of Lung

The following tables summarize consolidated financial data of Lung Therapeutics, Inc., a Texas corporation ("Lung"). The consolidated statement of operations data for the nine months ended September 30, 2023, and 2022, and the consolidated balance sheet data as of September 30, 2023, have been derived from Lung unaudited condensed consolidated financial statements included as Annex B to Aileron's Definitive Proxy Statement for the 2023 Annual Meeting of Stockholders of which this Annex C is a part. The unaudited condensed consolidated financial statements have not been audited or reviewed by an independent accountant. The consolidated statement of operations data for the years ended December 31, 2022, and 2021, and the consolidated balance sheet data as of December 31, 2022, and 2021, have been derived from Lung audited consolidated financial statements included as Annex A to Aileron's Definitive Proxy Statement for the 2023 Annual Meeting of Stockholders of which this Annex C is a part. You should read the following selected financial data together with Lung consolidated financial statements and related notes included as Annex A and Annex B to Aileron's Definitive Proxy Statement for the 2023 Annual Meeting of which this Annex C is a part. Lung historical results are not necessarily indicative of results that should be expected in any future period and Lung results for the interim period are not necessarily indicative of the results that should be expected for the full year ended December 31, 2023.

Selected Consolidated Condensed Statement of Operations Data:

	Nine Months Ended September 30,		Year Ended December 31,	
	2023	2022	2022	2021
	(in thousands)			
Revenues:				
Licensing revenue	$ 153	$ 766	$ 688	$ 556
Operating expenses:				
Research and development	(10,861)	(16,105)	(22,465)	(15,397)
General and administrative	(4,525)	(5,287)	(6,763)	(4,720)
Total operating expenses	(15,386)	(21,392)	(29,228)	(20,117)
Loss from operations before gains from affiliate	(15,233)	(20,626)	(28,540)	(19,561)
Gain from sale of equity securities in TFF	—	9,400	9,400	9,373
Loss from operations	(15,233)	(11,226)	(19,140)	(10,188)
Other income				
Interest income	76	42	99	30
Gain on extinguishment of PPP loan	—	—	—	253
Other income, net	—	—	—	2
Total other income, net	76	42	99	285
Net loss	$(15,157)	$(11,184)	$(19,041)	$ (9,903)

Selected Consolidated Condensed Balance Sheet Data:

	As of September 30,	As of December 31,	
	2023	2022	2021
		(in thousands)	
Cash and cash equivalents	$ 20	$ 11,881	$ 11,483
Working capital (1)	(3,541)	(1,989)	15,231
Total assets	2,288	14,848	20,625
Total liabilities	8,076	19,147	6,289
Convertible preferred stock	70,460	57,025	57,025
Accumulated deficit	(78,601)	(63,444)	(44,403)
Total stockholders' deficit	(76,248)	(61,324)	(42,689)

(1) Working capital is defined as current assets less current liabilities.

Selected Unaudited Pro Forma Condensed Combined Financial Data of Aileron and Lung

The following unaudited pro forma condensed combined financial information was prepared in accordance with Article 11 of Regulation S-X under the Securities Act of 1933, as amended (the "Securities Act") and is based on the expectation that the Merger (as defined below) will be treated as a business acquisition using the acquisition method of accounting in accordance with U.S. Generally Accepted Accounting Principles ("US GAAP"). For accounting purposes, Aileron is considered to be the acquirer in the Merger. This determination is primarily based on the expectation that, immediately following the Merger: (i) Aileron's equity holders will own a substantial majority of the voting rights in the combined company; (ii) Aileron's largest stockholder will retain the largest interest in the combined company; (iii) Aileron will designate a majority (4 out of 6) of the initial members of the board of directors of the combined company; and (iv) Aileron's executive management team will become the management of the combined company.

Aileron will finalize the acquisition accounting (including the necessary valuation and other studies) as soon as practicable within the required measurement period, but in no event later than one year following completion of the Merger.

Accordingly, for accounting purposes: (i) the Merger will be treated as the equivalent of Aileron issuing stock to acquire the net assets of Lung, (ii) the net assets of Lung will be recorded based on their fair value in the combined financial statements at the time of closing and (iii) the reported historical operating results of the combined company prior to the Merger will be those of Aileron.

The unaudited pro forma condensed combined balance sheet assumes that the Merger and the Financing (as defined below) were consummated as of September 30, 2023, and combines the historical balance sheets of Aileron and Lung as of such date. The unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2023, and for the year ended December 31, 2022, assumes that the Merger and the Financing were consummated as of January 1, 2022, and combines the historical results of Aileron and Lung for the respective periods presented.

The selected unaudited pro forma condensed combined financial data are presented for illustrative purposes only and are not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods. The selected unaudited pro forma condensed combined financial data as of and for the nine months ended September 30, 2023, and as of December 31, 2022, are derived from the unaudited pro forma condensed combined financial information and should be read in conjunction with that information. For more information, please see the section titled "*Unaudited Pro Forma Condensed Combined Financial Information*" below.

Selected Unaudited Pro Forma Condensed Combined Statement of Operations:

	Nine Months Ended September 30, 2023	Year Ended December 31, 2022
	(in thousands, except share and per share data)	
Revenues		
Licensing revenue	$ 153	$ 688
Operating expenses		
Research and development	12,880	40,432
General and administrative	10,552	21,194
Restructuring and other costs	940	—
Total operating expenses	24,372	61,626
Loss from operations before gains from affiliate	(24,219)	(60,938)
Gain from sale of equity securities in TFF	—	9,400
Loss from operations	(24,219)	(51,538)
Other income		
Interest and other income, net	398	417
Other income	271	—
Total other income, net	669	417
Net loss	$ (23,550)	$ (51,121)
Net loss per share, basic and diluted	$ (0.80)	$ (1.73)
Weighted average common shares outstanding, basic and diluted	29,495,512	29,493,663

Selected Unaudited Pro Forma Condensed Combined Balance Sheet Data:

	September 30, 2023 (in thousands)
Cash and cash equivalents	$ 28,877
Working capital(1)	20,295
Total assets	153,487
Total liabilities	37,503
Accumulated deficit	(285,929)
Total stockholders' equity	$ 115,984

(1) Working capital is defined as current assets less current liabilities.

Unaudited Pro Forma Condensed Combined Financial Information

The following unaudited pro forma condensed combined financial information are based on Aileron historical financial statements and Lung historical consolidated financial statements as adjusted to give effect to the Merger, accounted for as a business acquisition, and to the issuance of shares of Series X Preferred Stock (as defined below) and Warrants (as defined below) in the Financing.

The Merger

On October 31, 2023, Aileron acquired Lung, pursuant to that certain Agreement and Plan of Merger, dated October 31, 2023 (the "Merger Agreement"), by and among Aileron, AT Merger Sub I, Inc., a Delaware corporation, and a wholly owned subsidiary of Aileron ("First Merger Sub"), AT Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of Aileron ("Second Merger Sub"), and Lung. Pursuant to the Merger Agreement, First Merger Sub merged with and into Lung, pursuant to which Lung was the surviving entity and became a wholly owned subsidiary of Aileron (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 (the "Second Merger," together with the First Merger, the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended (the "Code"). The business of Lung will continue as the business of the combined company.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each share of Lung common stock outstanding immediately prior to the effective time, including those shares of Lung common stock issued upon conversion of Lung preferred stock, which conversion occurred immediately prior to the effective time of the Merger, were converted into the right to receive a number of shares of common stock, par value $0.001 per share, of Aileron and shares of Series X Non-Voting Convertible Preferred Stock, par value $0.001 per share, of Aileron (the "Series X Preferred Stock") based on the exchange ratio calculated in accordance with the Merger Agreement ("Exchange Ratio"). Accordingly, the Merger is expected to be treated as a business acquisition accounted in accordance with US GAAP.

The Financing

Immediately following the closing of the Merger, on October 31, 2023, Aileron entered into a Stock and Warrant Purchase Agreement (the "Purchase Agreement") with a group of accredited investors, pursuant to which Aileron issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants (the "Warrants") to purchase up to an aggregate of 2,353,500 shares of Aileron common stock (the "Warrant Shares"), for an aggregate purchase price of approximately $18.4 million, which included the conversion of certain convertible promissory notes in the aggregate principal amount of $1.6 million issued by Lung to Bios Partners, the majority stockholder of Lung prior to the closing of the Merger, prior to the closing of the Merger at a 10% discount to the

per share price of the Series X Preferred Stock (the "Financing"). The Financing closed on November 2, 2023. Subject to stockholder approval for the conversion rights of the Series X Preferred Stock, each share of Series X Preferred Stock is convertible into 1,000 shares of common stock.

The unaudited pro forma condensed combined balance sheet assumes that the Merger and the Financing were consummated as of September 30, 2023, and combines the historical balance sheets of Aileron and Lung as of such date. The unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2023, and year ended December 31, 2022, assumes that the Merger and the Financing were consummated as of January 1, 2022, and combines the historical results of Aileron and Lung for the periods presented.

The unaudited pro forma condensed combined financial information is presented for illustrative purposes only and is not necessarily indicative of the combined financial position or results of operations of future periods or the results that actually would have been realized had the entities been a single entity during these periods.

The unaudited pro forma condensed combined financial information is based on the assumptions and adjustments that are described in the accompanying notes. Accordingly, the pro forma adjustments are preliminary, subject to further revision as additional information becomes available and additional analyses are performed and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary estimates and the final accounting, expected to be completed after the closing of the Merger, will occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined organization's future results of operations and financial position.

The unaudited pro forma condensed combined financial information does not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the integration of the two companies. The unaudited pro forma condensed combined financial information is not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Aileron and Lung been a combined organization during the specified periods. The actual results reported in periods following the Merger may differ significantly from those reflected in the unaudited pro forma condensed combined financial information presented herein for a number of reasons, including, but not limited to, differences in the assumptions used to prepare this unaudited pro forma condensed combined financial information.

The unaudited pro forma condensed combined financial information, including the notes thereto, should be read in conjunction with the separate historical financial statements of Aileron and Lung, and "*Aileron's Management's Discussion and Analysis of Financial Condition and Results of Operations*" included in its Quarterly Report on Form 10-Q as of and for the fiscal quarter ended September 30, 2023, filed with the SEC on October 13, 2023.

Accounting rules require evaluation of certain assumptions, estimates, or determination of financial statement classifications. The accounting policies of Aileron may materially vary from those of Lung. During preparation of the unaudited pro forma condensed combined financial information, management has performed a preliminary analysis and is not aware of any material differences, and accordingly, this unaudited pro forma condensed combined financial information assumes no material differences in accounting policies. Following the Merger, management will conduct a final review of Lung accounting policies in order to determine if differences in accounting policies require adjustment or reclassification of Lung results of operations or reclassification of assets or liabilities to conform to Aileron's accounting policies and classifications. As a result of this review, management may identify differences that, when conformed, could have a material impact on this unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
AS OF SEPTEMBER 30, 2023
(in thousands)

	Historical				
	Aileron	Lung	Transaction Accounting Adjustments		Pro Forma Combined Total
Assets					
Current assets:					
Cash and cash equivalents	$ 12,069	$ 20	$ 16,788	(a)(b)(d)	$ 28,877
Prepaid expense and other current assets	699	2,147	—		2,846
Restricted cash	25	—	—		25
Total current assets	12,793	2,167	16,788		31,748
Property and equipment, net	29	3	—		32
Right-of-use lease assets	—	91	(15)	(f)	76
Intangible assets	—	—	104,200	(f)	104,200
Goodwill	—	—	17,404	(f)	17,404
Other assets and restricted cash	—	27	—		27
Total assets	$ 12,822	$ 2,288	$ 138,377		$ 153,487
Liabilities, convertible preferred stock and stockholders' equity (deficit)					
Current liabilities:					
Convertible promissory notes	$ —	$ 720	$ (720)	(a)	$ —
Accounts payable	484	2,436	893	(a)	3,813
Accrued expense and other current liabilities	1,140	2,110	4,310	(d)(g)	7,560
Deferred revenue	—	346	(346)	(f)	—
Operating lease liabilities, current	—	96	(16)	(f)	80
Total current liabilities	1,624	5,708	4,121		11,453
Deferred revenue	—	2,368	(2,368)	(f)	—
Deferred tax liability	—	—	26,050	(f)	26,050
Total liabilities	1,624	8,076	27,803		37,503
Convertible preferred stock	—	70,460	(70,460)	(a)(c)	—
Stockholders' equity (deficit):					
Common stock	91	1	(1)	(c)(e)	91
Series X convertible preferred stock	—	—	—		—
Additional paid-in capital	292,285	2,352	107,185	(a)(b)(c)(e)(f)	401,822
Accumulated deficit	(281,178)	(78,601)	73,850	(d)(e)(g)	(285,929)
Total stockholders' equity (deficit)	11,198	(76,248)	181,034		115,984
Total liabilities, convertible preferred stock and stockholders' equity	$ 12,822	$ 2,288	$ 138,377		$ 153,487

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023
(in thousands, except share and per share data)

	Historical		Transaction Accounting Adjustments		Pro Forma Combined Total
	Aileron	Lung			
Revenues					
Licensing revenue	$ —	$ 153	$ —		$ 153
Operating expenses					
Research and development	2,019	10,861	—		12,880
General and administrative	6,027	4,525	—		10,552
Restructuring and other costs	940	—			940
Total operating expenses	8,986	15,386	—		24,372
Loss from operations	(8,986)	(15,233)	—		(24,219)
Interest income	322	76	—		398
Other income	271	—	—		271
Total other income, net	593	76	—		669
Net loss	(8,393)	(15,157)	—		(23,550)
Net loss per share, basic and diluted	(1.85)				$ (0.80)
Weighted average common shares outstanding, basic and diluted	4,541,167	—		(h)	29,495,512

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2022
(in thousands, except share and per share data)

	Historical		Transaction Accounting Adjustments		Pro Forma Combined Total
	Aileron	Lung			
Revenues					
Licensing revenue	$ —	$ 688	$ —		$ 688
Operating expenses					
Research and development	17,967	22,465	—		40,432
General and administrative	9,680	6,763	4,751	(d)(g)	21,194
Total operating expenses	27,647	29,228	4,751		61,626
Loss from operations before gains from affiliate	(27,647)	(28,540)	(4,751)		(60,938)
Gain from sale of equity securities in TFF	—	9,400	—		9,400
Loss from operations	(27,647)	(19,140)	(4,751)		(51,538)
Interest and other income, net	318	99	—		417
Total other income, net	318	99	—		417
Net loss	(27,329)	(19,041)	(4,751)		(51,121)
Net loss per share, basic and diluted	$ (6.02)	—			$ (1.73)
Weighted average common shares outstanding, basic and diluted	4,539,318	—		(h)	29,493,663

NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Transaction

Description of the Merger

On October 31, 2023, Aileron acquired Lung, pursuant to the Merger Agreement, by and among Aileron, First Merger Sub, Second Merger Sub and Lung. Pursuant to the Merger Agreement, First Merger Sub merged with and into Lung, pursuant to which Lung was the surviving entity and became a wholly owned subsidiary of Aileron. Immediately following the First Merger, Lung merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity. The Merger is intended to qualify as a tax-free reorganization under the provisions of Section 368(a) of the Code.

Under the terms of the Merger Agreement, at the closing of the Merger, Aileron issued to the stockholders of Lung 344,345 shares of Aileron's common stock, and 19,903 shares of Series X Preferred Stock. In addition, Aileron assumed (i) all Lung stock options immediately outstanding prior to the First Merger, each becoming an option for Aileron's common stock subject to adjustment pursuant to the terms of the Merger Agreement, and (ii) all warrants exercisable for Lung common stock immediately outstanding prior to the First Merger, each becoming a warrant to purchase Aileron's common stock, subject to adjustment pursuant to the terms of the Merger Agreement. Immediately following the closing of the Merger, Aileron had 4,885,512 shares of common stock issued and outstanding. The Exchange Ratio is estimated to be approximately 0.1706 shares of Aileron's common stock for each share of Lung common stock.

Subject to stockholder approval for the conversion rights of the Series X Preferred Stock, each share of Series X Preferred Stock will convert into 1,000 shares of Aileron's common stock, subject to certain beneficial ownership limitations.

Pursuant to the Merger Agreement, Aileron has agreed to hold a stockholders' meeting no later than 120 days after the date on which the closing of the Merger occurs to submit certain matters to its stockholders for their consideration, including: (i) the approval of the conversion of the Series X Preferred Stock issued pursuant to the Merger Agreement and the Purchase Agreement into shares of Aileron's common stock in accordance with Nasdaq Listing Rule 5635(a) and (ii) if deemed necessary or appropriate by Aileron or as otherwise required by law or contract, the approval of an amendment to the certificate of incorporation of Aileron to authorize sufficient shares of Aileron common stock for the conversion of the Series X Preferred Stock issued pursuant to the Merger Agreement and the Purchase Agreement and/or to effectuate a reverse stock split.

The Board of Directors of Aileron (the "Board") approved the Merger Agreement and the related transactions, and the consummation of the Merger was not subject to approval of the Aileron stockholders.

Each stock option granted under Lung's 2013 Long-Term Incentive Plan (the "Plan") that was outstanding immediately prior to the First Merger was assumed by Aileron and became an option to acquire, on the same terms and conditions as were applicable to such Lung stock option immediately prior to the First Merger, a number of shares of Aileron's common stock equal to the number of shares of Lung common stock subject to the unexercised portion of the Lung stock option immediately prior to the First Merger, multiplied by the Exchange Ratio (rounded down to the nearest whole share number) with an exercise price per share for the options equal to the exercise price per share of such Lung stock option immediately prior to the First Merger divided by the Exchange Ratio (rounded up to the nearest whole cent). Such assumed options will continue to be governed by the terms and conditions of the Plan.

Each warrant granted by Lung that was outstanding immediately prior to the First Merger was converted into a warrant to purchase shares of Aileron common stock on the same terms and conditions as were applicable to such Lung warrant immediately prior to the First Merger, a number of shares of Aileron's common stock equal to the

number of shares of Lung common stock subject to the warrant immediately prior to the First Merger, multiplied by the Exchange Ratio (rounded down to the nearest whole share number) with an exercise price per share for the warrant equal to the exercise price per share of such Lung warrant immediately prior to the First Merger divided by the Exchange Ratio (rounded up to the nearest whole cent).

Description of the Financing

Immediately following closing of the Merger, Aileron entered into the Purchase Agreement with a group of accredited investors, pursuant to which Aileron issued and sold (i) an aggregate of 4,707 shares of Series X Preferred Stock, and (ii) warrants to purchase up to an aggregate of 2,353,500 shares of Aileron's common stock, 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, the majority stockholder of Lung prior to the closing of the Merger, prior to the closing of the Merger at a 10% discount to the per share price of the Series X Preferred Stock (see Note 5). The Financing closed on November 2, 2023.

2. Basis of Pro Forma Presentation

The unaudited pro forma condensed combined financial information was prepared in accordance with Article 11 of Regulation S-X under the Securities Act and in accordance with U.S. GAAP. The unaudited pro forma condensed combined balance sheet as of September 30, 2023, was prepared using the historical balance sheets of Aileron and Lung as of September 30, 2023. The unaudited pro forma condensed combined statement of operations for the nine months ended September 30, 2023, and for the year ended December 31, 2022, were prepared using the historical statements of operations and comprehensive loss of Aileron and Lung for the nine months ended September 30, 2023, and for the year ended December 31, 2022, respectively, and gives effect to the Merger and the Financing as if they occurred on January 1, 2022.

For legal and accounting purposes, Aileron is considered to be the acquirer, and the Merger is expected to be accounted for as a business acquisition using the acquisition method of accounting. The acquisition method of accounting is based on Accounting Standards Codification ("ASC") 805 "Business Combinations" ("ASC 805"), with Aileron as the accounting acquirer, and uses the fair value concepts defined in ASC 820 "Fair Value Measurement" ("ASC 820").

ASC 805 requires, among other things, that most assets acquired and liabilities assumed be recognized at their fair values as of the acquisition date. In addition, ASC 805 requires that the consideration transferred be measured at the date the acquisition is completed at the then-current market price.

ASC 820 defines the term "fair value," sets forth the valuation requirements for any asset or liability measured at fair value, expands related disclosure requirements and specifies a hierarchy of valuation techniques based on the nature of the inputs used to develop the fair value measures. Fair value is defined in ASC 820 as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." This is an exit price concept for the valuation of the asset or liability. In addition, market participants are assumed to be buyers and sellers in the principal (or the most advantageous) market for the asset or liability. Fair value measurements for an asset assume the highest and best use by these market participants. As a result of these standards, Aileron may be required to record the fair value of assets which are not intended to be used or sold and/or to value assets at fair value measures that do not reflect Aileron's intended use of those assets. Many of these fair value measurements can be highly subjective, and it is possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range of alternative estimated amounts.

Under the acquisition method of accounting, the assets acquired and liabilities assumed are recorded, as of the completion of the Merger, primarily at their respective fair values, with the excess of the purchase consideration

over the fair value of Lung net assets, allocated to goodwill, if any, and added to those of Aileron. Financial statements and reported results of operations of Aileron issued after completion of the Merger will reflect these values but will not be retroactively restated to reflect the historical financial position or results of operations of Lung. The pro forma allocation of the purchase price reflected in the unaudited pro forma condensed combined financial information is preliminary and thus subject to adjustment and may vary materially from the final purchase price allocation that will be completed within the measurement period, but in no event later than one year following the closing date since, among other reasons, prior to the closing of the Merger, both companies were limited in their ability to share information.

Under ASC 805, acquisition-related transaction costs (e.g., advisory, legal, and other professional fees) are not included as a component of consideration transferred but are accounted for as expenses in the periods in which such costs are incurred. Total acquisition-related transaction costs incurred by Aileron and Lung are estimated to be $4.1 million, out of which $0.9 million were recorded in the historical financial statements for the nine months ended September 30, 2023. The remaining acquisition related transaction costs in the amount of $3.2 million are reflected as a pro forma adjustment to the unaudited pro forma combined statements of operations for those same periods as a reduction in acquisition-related costs because those net costs are not expected to have a continuing impact on the combined company's results. In addition, Aileron incurred $1.5 million in severance related costs in connection with the acquisition and have been reflected as a pro forma adjustment. See Note 5 below.

Lung and Aileron may incur significant costs associated with integrating their operations following closing of the Merger. The unaudited pro forma condensed combined financial information does not reflect the costs of any integration activities or benefits that may result from realization of future cost savings from operating efficiencies which may result from the Merger.

To the extent that there are significant changes to the business following closing of the Merger, the assumptions and estimates set forth in the unaudited pro forma condensed financial information could change significantly. Accordingly, the pro forma adjustments are subject to further adjustments as additional information becomes available and as additional analyses are conducted following the closing of the Merger. There can be no assurances that these additional analyses will not result in material changes to the estimates of fair value.

3. Purchase Price

For purposes of this unaudited pro forma condensed combined financial information, the total estimated purchase price is summarized as follows (in thousands, except share and per share amounts):

Estimated number of common shares of the combined company issued to Lung stockholders (1)	344,345
Multiplied by the fair value per share of Aileron common stock (2)	$ 1.17
Estimated fair value of Aileron common stock issued to Lung stockholders	$ 403
Fair value of Aileron Series X Preferred Stock issued to Lung stockholders	$ 16,795
Estimated fair value of stock options attributable to pre-combination services (3)	$ 1,050
Estimated purchase price	$ 18,248

(1) The number of shares is based on the Merger Agreement.
(2) The estimated purchase price was based on the closing price of Aileron's common stock as reported on the Nasdaq Capital Market on October 31, 2023.
(3) The acquisition date fair value of these stock options attributable to the pre-combination services is included in the estimated purchase price. The acquisition date fair value of these stock options is calculated based on the number of such stock options expected to vest assuming that the Merger closed on October 31, 2023.

The following table presents the assumptions used in the Black-Scholes option-pricing model to determine the estimated acquisition-date fair value of the assumed Lung stock options:

Risk-free interest rate	4.82-5.58%
Expected term (in years)	0.42-6.28
Expected volatility	75-91%
Expected dividend yield	0%

4. Preliminary Allocation of the Purchase Price

The following summarizes a preliminary estimate of the assets acquired and the liabilities assumed by Aileron as of the Merger date, and includes a reconciliation to the total consideration transferred:

Assets acquired:	
Cash, cash equivalents and restricted cash	$ 194
Property and equipment, net	3
Right of use asset	76
Prepaid expenses and other assets	2,131
Intangible assets	104,200
Other assets	27
Goodwill	17,404
	124,035
Liabilities assumed:	
Accounts payable	4,453
Accrued expenses and other current liabilities	1,899
Operating lease liabilities	80
Deferred tax liability	26,050
	32,482
Net assets acquired	$ 91,553

As of the completion of the acquisition, identifiable intangible assets are required to be measured at fair value, and these acquired assets could include assets that are not intended to be used or sold or that are intended to be used in a manner other than their highest and best use. For purposes of these unaudited pro forma combined financial statements and consistent with the ASC 820 requirements for fair value measurements, it is assumed that all acquired assets will be used, and that all acquired assets will be used in a manner that represents the highest and best use of those acquired assets.

The fair value of IPR&D was capitalized as of the Merger date and accounted for as indefinite-lived intangible assets until completion or disposition of the assets or abandonment of the associated research and development efforts. Upon successful completion of the development efforts, the useful lives of the IPR&D assets will be determined based on the anticipated period of regulatory exclusivity and will be amortized within operating expenses. Until that time, the IPR&D assets will be subject to impairment testing and will not be amortized. The goodwill recorded related to the acquisition is the excess of the fair value of the consideration transferred by the acquirer over the fair value of the net identifiable assets acquired and liabilities assumed at the date of acquisition. The goodwill recorded is not deductible for tax purposes. Goodwill is not amortized.

5. Transaction Accounting Adjustments

Adjustments included in the column under the heading "Transaction Accounting Adjustments" are primarily based on information contained within the Merger Agreement and the Purchase Agreement.

Based on Aileron's management's review of Lung summary of significant accounting policies, the nature and amount of any adjustments to the historical consolidated financial statements of Lung to conform to the accounting policies of Aileron are not expected to be significant.

Both Aileron and Lung have a history of generating net operating losses and maintain a full valuation allowance against their net deferred tax assets. As a result, both entities have not previously reflected an income tax benefit or expense within the financial statement period presented. Management has not identified any changes to the income tax positions due to the Merger that would result in an incremental tax expense or benefit. Accordingly, no tax-related adjustments have been reflected for the pro forma adjustments.

The pro forma adjustments, based on preliminary estimates that may change significantly as additional information is obtained, are as follows:

(a) To reflect $18.4 million in proceeds, less issuance costs of $0.9 million, in connection with the Financing, in which Aileron issued and sold 4,707 shares of its Series X Preferred Stock and warrants to purchase an aggregate of 2,353,500 shares of its common stock. Bios Partners, the majority stockholder of Lung prior to the closing of the Merger, received certain of its shares of Series X Preferred Stock and Warrants by exchanging its convertible promissory notes issued by Lung on September 14, 2023 and October 12, 2023, in aggregate amount of $1.6 million. Based on an assessment of the Warrants' specific terms in the Purchase Agreement and applicable authoritative guidance in ASC 480 and ASC 815, the combined company will account for the Warrants as equity-classified instruments. The Series X Preferred Stock was also classified as an equity instrument.

(b) To reflect the payment in the amount of $0.3 million in lieu of fractional shares upon conversion of Lung common and preferred stock into shares of Aileron common stock and Series X Preferred Stock.

(c) To reflect the conversion of Lung convertible preferred stock into shares of Aileron's common stock at the closing of the Merger.

(d) To reflect transaction costs of $3.2 million in connection with the Merger, such as advisor fees, legal fees, printer fees, and accounting expenses that were incurred by Lung and Aileron. As $0.4 million of transaction costs had been already paid by the date of this Definitive Proxy Statement to which this Annex C is a part, the adjustment was recorded as a decrease in cash of $0.4 million, an increase in accrued liabilities of $2.8 million, an increase in general and administrative expenses of $3.2 million and an increase in accumulated deficit of $3.2 million.

(e) To reflect the elimination of Lung historical equity.

(f) To reflect application of purchase accounting under the acquisition method.

(g) To reflect Aileron compensation expense of $1.5 million related to severance payments resulting from pre-existing employment agreements that were payable in cash in connection with the Merger. The adjustment was recorded as an increase in accrued liabilities of $1.5 million, an increase in general and administrative expenses of $1.5 million and an increase in accumulated deficit of $1.5 million.

(h) The pro forma combined basic and diluted earnings per share have been adjusted to reflect the pro forma net loss for the nine months ended September 30, 2023, and the year ended December 31, 2022. In addition, the number of shares used in calculating the pro forma combined basic and diluted net loss per share has been adjusted to reflect the estimated total number of shares of common stock of the combined company that would be outstanding as of the Merger closing date, including the shares issued in the Financing. For the

nine months ended September 30, 2023, and the year ended December 31, 2022, the pro forma weighted average shares outstanding has been calculated as follows, after the Exchange Ratio has been applied:

	September 30, 2023	December 31, 2022
Weighted-average Aileron common shares outstanding—basic and diluted	4,541,167	4,539,318
Impact of the Financing assuming consummation and conversion as of January 1, 2022	4,707,000	4,707,000
Impact of Aileron Series X Preferred Stock issued at Merger assuming conversion as of January 1, 2022	19,903,000	19,903,000
Adjusted weighted-average Aileron common shares outstanding—basic and diluted	29,151,167	29,149,318
Impact of Aileron common stock issued to Lung shareholders	344,345	344,345
Pro forma combined weighted average number of shares of common stock—basic and diluted	29,495,512	29,493,663

(i) The total impact to equity for the above adjustments as reflected in the table below:

	Series X preferred stock		Common Stock						
			Aileron		Lung				
(in thousands, except share data)	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in-Capital	Accumulated Deficit	Stockholders' equity
Conversion of outstanding Lung convertible preferred stock into common stock (c)	—	$ —	344,345	$ —	90,217,081	$ 9	$ 70,451	$ —	$ 70,460
The Financing (a)	4,707	—	—	—	—	—	17,347	—	17,347
Elimination of Lung historical equity carrying value (e)	—	—	—	—	(99,462,184)	(10)	(78,591)	78,601	—
Purchase price allocation (f)	19,903	—	—	—	—	—	98,269	—	98,269
Payment for partial shares in the exchange (b)	—	—	—	—	—	—	(291)	—	(291)
Retention and severance payments to Aileron employees (g)	—	—	—	—	—	—	—	(1,526)	(1,526)
Transaction costs associated with the Merger (d)	—	—	—	—	—	—	—	(3,225)	(3,225)
Total adjustment	24,610	$ —	344,345	$ —	(9,245,103)	$ (1)	$ 107,185	$ 73,850	$ 181,034

ANNEX D

AMENDMENT TO 2021 STOCK INCENTIVE PLAN

AILERON THERAPEUTICS, INC.

AMENDMENT NO. 1 TO 2021 STOCK INCENTIVE PLAN

WHEREAS, Aileron Therapeutics, Inc. (the "Company") maintains the 2021 Stock Incentive Plan (the "Plan");

WHEREAS, the Board of Directors of the Company has determined that it is in the best interest of the Company and its stockholders to amend the Plan, pursuant to Section 12(d) thereof, to increase the number of shares of Company common stock, $0.001 par value per share, of the Company that may be granted under the Plan;

NOW, THEREFORE, in consideration of the foregoing, the Plan is amended, pursuant to Section 12(d) thereof, as follows:

1. The number set forth in Section 4(a)(1)(A) of the Plan is increased by 3,000,000 shares of Common Stock to 3,625,000 shares of Common Stock.

Except as set forth above, all other terms of the Plan shall remain unchanged and in full force and effect.

ANNEX E

2021 STOCK INCENTIVE PLAN, AS AMENDED

AILERON THERAPEUTICS, INC.

2021 STOCK INCENTIVE PLAN

1. Purpose

The purpose of this 2021 Stock Incentive Plan (the "***Plan***") of Aileron Therapeutics, Inc., a Delaware corporation (the "***Company***"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to better align the interests of such persons with those of the Company's stockholders. Except where the context otherwise requires, the term "***Company***" shall include any of the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations thereunder (the "***Code***") and any other business venture (including, without limitation, joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "***Board***").

2. Eligibility

All of the Company's employees, officers and directors, as well as consultants and advisors to the Company (as the terms consultants and advisors are defined and interpreted for purposes of Form S-8 under the Securities Act of 1933, as amended (the "***Securities Act***"), or any successor form) are eligible to be granted Awards (as defined below) under the Plan. Each person who is granted an Award under the Plan is deemed a "***Participant***." The Plan provides for the following types of awards, each of which is referred to as an "***Award***": Options (as defined in Section 5), SARs (as defined in Section 6), Restricted Stock (as defined in Section 7), RSUs (as defined in Section 7), Other Stock-Based Awards (as defined in Section 8) and Cash-Based Awards (as defined in Section 8). Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan will be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may construe and interpret the terms of the Plan and any Award agreements entered into under the Plan. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award. All actions and decisions by the Board with respect to the Plan and any Awards shall be made in the Board's discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "***Committee***"). All references in the Plan to the "***Board***" shall mean the Board or a Committee of the Board or the officers referred to in Section 3(c) to the extent that the Board's powers or authority under the Plan have been delegated to such Committee or officers.

(c) Delegation to Officers. Subject to any requirements of applicable law (including as applicable Sections 152 and 157(c) of the General Corporation Law of the State of Delaware), the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to employees or officers of the Company and to exercise such other powers under the Plan as the Board may determine, provided that the Board shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which such Awards may be granted; and

provided further, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) or to any "officer" of the Company (as defined by Rule 16a-1(f) under the Exchange Act).

4. Stock Available for Awards

(a) Number of Shares; Share Counting.

(1) Authorized Number of Shares. Subject to adjustment under Section 10, Awards may be made under the Plan (any or all of which Awards may be in the form of Incentive Stock Options (as defined in Section 5(b)) for up to such number of shares of common stock, $0.001 par value per share, of the Company (the "**Common Stock**") as is equal to the sum of:

(A) 3,625,000 shares of Common Stock (reduced by the number of shares subject to awards granted under the Company's 2017 Stock Incentive Plan between April 15, 2021 and June 15, 2021); plus

(B) such additional number of shares of Common Stock (up to 6,280,135 shares) as is equal to the number of shares of Common Stock subject to awards granted under the Company's 2017 Stock Incentive Plan, the Company's 2016 Stock Incentive Plan and the Company's 2006 Stock Incentive Plan which awards expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right (subject, however, in the case of Incentive Stock Options to any limitations of the Code).

Shares of Common Stock issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(2) Share Counting. For purposes of counting the number of shares available for the grant of Awards under the Plan under Section 4(a)(1):

(A) all shares of Common Stock covered by SARs shall be counted against the number of shares available for the grant of Awards under the Plan; *provided, however*, that (i) SARs that may be settled only in cash shall not be so counted and (ii) if the Company grants an SAR in tandem with an Option for the same number of shares of Common Stock and provides that only one such Award may be exercised (a "***Tandem SAR***"), only the shares covered by the Option, and not the shares covered by the Tandem SAR, shall be so counted, and the expiration of one in connection with the other's exercise will not restore shares to the Plan;

(B) if any Award (i) expires or is terminated, surrendered or cancelled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or (ii) results in any Common Stock not being issued (including as a result of an SAR that was settleable either in cash or in stock actually being settled in cash), the unused Common Stock covered by such Award shall again be available for the grant of Awards; *provided, however*, that (1) in the case of Incentive Stock Options, the foregoing shall be subject to any limitations under the Code, (2) in the case of the exercise of an SAR, the number of shares counted against the shares available under the Plan shall be the full number of shares subject to the SAR multiplied by the percentage of the SAR actually exercised, regardless of the number of shares actually used to settle such SAR upon exercise and (3) the shares covered by a Tandem SAR shall not again become available for grant upon the expiration or termination of such Tandem SAR;

(C) to the extent that an RSU may be settled solely in cash, no shares shall be counted against the limit on the shares available for grant of Awards under the Plan;

(D) shares of Common Stock delivered (by actual delivery, attestation, or net exercise) to the Company by a Participant to (i) purchase shares of Common Stock upon the exercise of an Award or (ii) satisfy tax withholding

obligations with respect to Awards (including shares retained from the Award creating the tax obligation) shall not be added back to the number of shares available for the future grant of Awards; and

(E) shares of Common Stock repurchased by the Company on the open market using the proceeds from the exercise of an Award shall not increase the number of shares available for future grant of Awards.

(b) Limit on Awards to Non-Employee Directors. The maximum aggregate amount of cash and equity value (calculated based on grant date fair value for financial reporting purposes) of Awards granted in any calendar year to any individual non-employee director in his or her capacity as a non-employee director shall not exceed $750,000; provided, however, that such maximum aggregate amount shall not exceed $1,000,000 in any calendar year for any individual non-employee director in such non-employee director's initial year of service; and provided, further, however, that fees paid by the Company on behalf of any non-employee director in connection with regulatory compliance and any amounts paid to a non-employee director as reimbursement of an expense shall not count against the foregoing limit. The Board may make additional exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the Board may determine in its discretion, provided that the non- employee director receiving such additional compensation may not participate in the decision to award such compensation. For the avoidance of doubt, this limitation shall not apply to cash or Awards granted to the non-employee director in his or her capacity as an advisor or consultant to the Company.

(c) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan or any sublimits contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a)(1), except as may be required by reason of Section 422 and related provisions of the Code.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "***Option***") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as the Board considers necessary or advisable.

(b) Incentive Stock Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "***Incentive Stock Option***") shall only be granted to employees of Aileron Therapeutics, Inc., any of Aileron Therapeutics, Inc.'s present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Code, and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. An Option that is not intended to be an Incentive Stock Option shall be designated a "***Nonstatutory Stock Option***." The Company shall have no liability to a Participant, or any other person, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or if the Company converts an Incentive Stock Option to a Nonstatutory Stock Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option or the formula by which such exercise price will be determined. The exercise price shall be specified in the applicable Option agreement. The exercise price shall be not less than 100% of the Grant Date Fair Market Value (as defined below) of the Common Stock on the date the Option is granted; *provided* that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Grant

Date Fair Market Value on such future date. "***Grant Date Fair Market Value***" of a share of Common Stock for purposes of the Plan will be determined as follows:

(1) if the Common Stock trades on a national securities exchange, the closing sale price (for the primary trading session) on the date of grant; or

(2) if the Common Stock does not trade on any such exchange, the average of the closing bid and asked prices on the date of grant as reported by an over-the-counter marketplace designated by the Board; or

(3) if the Common Stock is not publicly traded, the Board will determine the Grant Date Fair Market Value for purposes of the Plan using any measure of value it determines to be appropriate (including, as it considers appropriate, relying on appraisals) in a manner consistent with the valuation principles under Code Section 409A, except as the Board may expressly determine otherwise.

For any date that is not a trading day, the Grant Date Fair Market Value of a share of Common Stock for such date will be determined by using the closing sale price or average of the bid and asked prices, as appropriate, for the immediately preceding trading day and with the timing in the formulas above adjusted accordingly. The Board can substitute a particular time of day or other measure of "closing sale price" or "bid and asked prices" if appropriate because of exchange or market procedures or can, in its sole discretion, use weighted averages either on a daily basis or such longer period as complies with Code Section 409A.

The Board has sole discretion to determine the Grant Date Fair Market Value for purposes of the Plan, and all Awards are conditioned on the Participant's agreement that the Board's determination is conclusive and binding even though others might make a different determination.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable Option agreement; *provided, however*, that no Option will be granted with a term in excess of 10 years.

(e) Exercise of Options. Options may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with payment in full (in the manner specified in Section 5(f)) of the exercise price for the number of shares for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company as soon as practicable following exercise.

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable Option agreement or approved by the Board, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) to the extent provided for in the applicable Option agreement or approved by the Board, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Board), provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company,

was owned by the Participant for such minimum period of time, if any, as may be established by the Board and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent provided for in the applicable Nonstatutory Stock Option agreement or approved by the Board, by delivery of a notice of "net exercise" to the Company, as a result of which the Participant would receive (i) the number of shares underlying the portion of the Option being exercised, less (ii) such number of shares as is equal to (A) the aggregate exercise price for the portion of the Option being exercised divided by (B) the fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board) on the date of exercise;

(5) to the extent permitted by applicable law and provided for in the applicable Option agreement or approved by the Board, by payment of such other lawful consideration as the Board may determine; or

(6) by any combination of the above permitted forms of payment.

(g) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding Option granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Option, (2) cancel any outstanding option (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(c)) covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled option, (3) cancel in exchange for a cash payment any outstanding Option with an exercise price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of the Nasdaq Stock Market ("***Nasdaq***").

(h) No Reload Options. No Option granted under the Plan shall contain any provision entitling the Participant to the automatic grant of additional Options in connection with any exercise of the original Option.

(i) No Dividend Equivalents. No Option shall provide for the payment or accrual of dividend equivalents.

6. Stock Appreciation Rights

(a) General. The Board may grant Awards consisting of stock appreciation rights ("***SARs***") entitling the holder, upon exercise, to receive an amount of Common Stock or cash or a combination thereof (such form to be determined by the Board) determined by reference to appreciation, from and after the date of grant, in the fair market value of a share of Common Stock (valued in the manner determined by (or in a manner approved by) the Board) over the measurement price established pursuant to Section 6(b). The date as of which such appreciation is determined shall be the exercise date.

(b) Measurement Price. The Board shall establish the measurement price of each SAR and specify it in the applicable SAR agreement. The measurement price shall not be less than 100% of the Grant Date Fair Market Value of the Common Stock on the date the SAR is granted; *provided* that if the Board approves the grant of an SAR effective as of a future date, the measurement price shall be not less than 100% of the Grant Date Fair Market Value on such future date.

(c) Duration of SARs. Each SAR shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable SAR agreement; *provided, however*, that no SAR will be granted with a term in excess of 10 years.

(d) Exercise of SARs. SARs may be exercised by delivery to the Company of a notice of exercise in a form (which may be electronic) approved by the Company, together with any other documents required by the Board.

(e) Limitation on Repricing. Unless such action is approved by the Company's stockholders, the Company may not (except as provided for under Section 10): (1) amend any outstanding SAR granted under the Plan to provide a measurement price per share that is lower than the then-current measurement price per share of such outstanding SAR, (2) cancel any outstanding SAR (whether or not granted under the Plan) and grant in substitution therefor new Awards under the Plan (other than Awards granted pursuant to Section 4(c)) covering the same or a different number of shares of Common Stock and having a measurement price per share lower than the then-current measurement price per share of the cancelled SAR, (3) cancel in exchange for a cash payment any outstanding SAR with a measurement price per share above the then-current fair market value of the Common Stock (valued in the manner determined by (or in a manner approved by) the Board), or (4) take any other action under the Plan that constitutes a "repricing" within the meaning of the rules of Nadsaq.

(f) No Reload SARs. No SAR granted under the Plan shall contain any provision entitling the Participant to the automatic grant of additional SARs in connection with any exercise of the original SAR.

(g) No Dividend Equivalents. No SAR shall provide for the payment or accrual of dividend equivalents.

7. Restricted Stock; RSUs

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("***Restricted Stock***"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. The Board may also grant Awards entitling the recipient to receive shares of Common Stock or cash to be delivered at the time such Award vests ("***RSUs***").

(b) Terms and Conditions for Restricted Stock and RSUs. The Board shall determine the terms and conditions of Restricted Stock and RSUs, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(1) Dividends. Any dividends (whether paid in cash, stock or property) declared and paid by the Company with respect to shares of Restricted Stock ("***Unvested Dividends***") shall be paid to the Participant only if and when such shares become free from the restrictions on transferability and forfeitability that apply to such shares. Each payment of Unvested Dividends, once payable, will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the lapsing of the restrictions on transferability and the forfeitability provisions applicable to the underlying shares of Restricted Stock. No interest will be paid on Unvested Dividends.

(2) Stock Certificates. The Company may require that any stock certificates issued in respect of shares of Restricted Stock, as well as dividends or distributions paid on such Restricted Stock, shall be deposited in escrow by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). At the expiration of the applicable restriction periods, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to his or her Designated Beneficiary. "***Designated Beneficiary***" means (i) the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death or (ii) in the absence of an effective designation by a Participant, the Participant's estate.

(d) Additional Provisions Relating to RSUs.

(1) Settlement. Upon the vesting of and/or lapsing of any other restrictions (i.e., settlement) with respect to each RSU, the Participant shall be entitled to receive from the Company the number of shares of Common Stock

specified in the Award agreement or (if so provided in the applicable Award agreement or otherwise determined by the Board) an amount of cash equal to the fair market value (valued in the manner determined by (or in a manner approved by) the Board) of such number of shares or a combination thereof. The Board may provide that settlement of RSUs shall be deferred, on a mandatory basis or at the election of the Participant, in a manner that complies with Section 409A of the Code or any successor provision thereto, and the regulations thereunder ("***Section 409A***").

(2) Voting Rights. A Participant shall have no voting rights with respect to any RSUs.

(3) Dividend Equivalents. The Award agreement for RSUs may provide Participants with the right to receive an amount equal to any dividends or other distributions declared and paid on an equal number of outstanding shares of Common Stock ("***Dividend Equivalents***"). Dividend Equivalents may be paid currently or credited to an account for the Participant and may be settled in cash and/or shares of Common Stock, in each case to the extent provided in the Award agreement, and shall be subject to the same restrictions on transfer and forfeitability as the RSUs with respect to which such Dividend Equivalents are paid. No interest will be paid on Dividend Equivalents.

8. Other Stock-Based and Cash-Based Awards

(a) General. The Board may grant other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property ("***Other Stock-Based Awards***"). Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine. The Company may also grant Awards denominated in cash rather than shares of Common Stock ("***Cash-Based Awards***").

(b) Terms and Conditions. Subject to the provisions of the Plan, the Board shall determine the terms and conditions of each Other Stock-Based Award or Cash-Based Awards, including any purchase price applicable thereto.

(c) Dividend Equivalents. The Award agreement for an Other Stock-Based Award may provide Participants with the right to receive Dividend Equivalents. Dividend Equivalents may be paid currently or credited to an account for the Participant and may be settled in cash and/or shares of Common Stock, in each case to the extent provided in the Award Agreement, and shall be subject to the same restrictions on transfer and forfeitability as the Other Stock-Based Award with respect to which such Dividend Equivalents are paid. No interest will be paid on Dividend Equivalents.

9. Performance Awards.

(a) Grants. Awards under the Plan may be made subject to the achievement of performance goals pursuant to this Section 9 ("***Performance Awards***").

(b) Performance Measures. The Board may specify that the degree of granting, vesting and/or payout shall be subject to the achievement of one or more objective performance measures established by the Board, which may be based on the relative or absolute attainment of specified levels of one or any combination of the following, which may be determined in accordance with generally accepted accounting principles ("***GAAP***") or on a non-GAAP basis, as determined by the Board: (i) the entry into an arrangement or agreement with a third party for the development, commercialization, marketing or distribution of products, services or technologies, or for conducting a research program to discover and develop a product, service or technology, and/or the achievement of milestones under such arrangement or agreement, including events that trigger an obligation or payment right;
(ii) achievement of domestic and international regulatory milestones, including the submission of filings required

to advance products, services and technologies in clinical development and the achievement of approvals by regulatory authorities relating to the commercialization of products, services and technologies; (iii) the achievement of discovery, preclinical and clinical stage scientific objectives, discoveries or inventions for products, services and technologies under research and development; (iv) the entry into or completion of a phase of clinical development for any product, service or technology, such as the entry into or completion of phase 1, 2 and/or 3 clinical trials; (v) the consummation of debt or equity financing transactions, or acquisitions of business, technologies and assets; (vi) new product or service releases; (vii) the achievement of qualitative or quantitative performance measures set forth in operating plans approved by the Board from time to time; (viii) specified levels of product sales, net income, earnings before or after discontinued operations, interest, taxes, depreciation and/or amortization, operating profit before or after discontinued operations and/or taxes, sales, sales growth, earnings growth, cash flow or cash position, gross margins, stock price, market share, return on sales, assets, equity or investment; (ix) improvement of financial ratings; (x) achievement of balance sheet or income statement objectives; (xi) total stockholder return; (xii) other comparable measures of financial and operational performance; and/ or (xiii) any other measure selected by the Board. Such goals may reflect absolute entity or business unit performance or a relative comparison to the performance of a peer group of entities or other external measure of the selected performance criteria and may be absolute in their terms or measured against or in relationship to other companies comparably, similarly or otherwise situated. The Board may specify that such performance measures shall be adjusted to exclude any one or more of (i) non-recurring or unusual gains or losses, (ii) gains or losses on the dispositions of discontinued operations, (iii) the cumulative effects of changes in accounting principles, (iv) the writedown of any asset, (v) fluctuation in foreign currency exchange rates, (vi) charges for restructuring and rationalization programs and (vii) any other item or items determined by the Board. Such performance measures: (x) may vary by Participant and may be different for different Awards; and (y) may be particular to a Participant or the department, branch, line of business, subsidiary or other unit in which the Participant works and may cover such period as may be specified by the Board.

(c) Adjustments. Notwithstanding any provision of the Plan, with respect to any Performance Award, the Board may waive the achievement of the applicable performance measures or otherwise amend Performance Awards in a manner permitted under the Plan.

10. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under the Plan, (ii) the share counting rules set forth in Section 4(a), (iii) the number and class of securities and exercise price per share of each outstanding Option, (iv) the share and per-share provisions and the measurement price of each outstanding SAR, (v) the number of shares subject to and the repurchase price per share subject to each outstanding award of Restricted Stock and (vi) the share and per-share-related provisions and the purchase price, if any, of each outstanding RSU and each Other Stock-Based Award, shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Reorganization Events.

(1) Definition. A "***Reorganization Event***" shall mean: (a) any merger or consolidation of the Company with or into another entity as a result of which all of the Common Stock of the Company is converted into or exchanged

for the right to receive cash, securities or other property or is cancelled, (b) any transfer or disposition of all of the Common Stock of the Company for cash, securities or other property pursuant to a share exchange or other transaction or (c) any liquidation or dissolution of the Company.

(2) Consequences of a Reorganization Event on Awards Other than Restricted Stock.

(A) In connection with a Reorganization Event, the Board may take any one or more of the following actions as to all or any (or any portion of) outstanding Awards other than Restricted Stock on such terms as the Board determines (except to the extent specifically provided otherwise in an applicable Award agreement or another agreement between the Company and the Participant): (i) provide that such Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof), (ii) upon written notice to a Participant, provide that all of the Participant's unvested Awards will be forfeited immediately prior to the consummation of such Reorganization Event and/ or that all of the Participant's unexercised Awards will terminate immediately prior to the consummation of such Reorganization Event unless exercised by the Participant (to the extent then exercisable) within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Reorganization Event, (iv) in the event of a Reorganization Event under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Reorganization Event (the "***Acquisition Price***"), make or provide for a cash payment to Participants with respect to each Award held by a Participant equal to (A) the number of shares of Common Stock subject to the vested portion of the Award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such Reorganization Event) multiplied by (B) the excess, if any, of (I) the Acquisition Price over (II) the exercise, measurement or purchase price of such Award and any applicable tax withholdings, in exchange for the termination of such Award, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 10(b)(2)(A), the Board shall not be obligated by the Plan to treat all Awards, all Awards held by a Participant, or all Awards of the same type, identically.

(B) Notwithstanding the terms of Section 10(b)(2)(A)(i), in the case of outstanding RSUs that are subject to Section 409A: (i) if the applicable RSU agreement provides that the RSUs shall be settled upon a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i), and the Reorganization Event constitutes such a "change in control event", then no assumption or substitution shall be permitted pursuant to Section 10(b)(2)(A)(i) and the RSUs shall instead be settled in accordance with the terms of the applicable RSU agreement; and (ii) the Board may only undertake the actions set forth in clauses (iii), (iv) or (v) of Section 10(b)(2)(A) if the Reorganization Event constitutes a "change in control event" as defined under Treasury Regulation Section 1.409A-3(i)(5)(i) and such action is permitted or required by Section 409A; if the Reorganization Event is not a "change in control event" as so defined or such action is not permitted or required by Section 409A, and the acquiring or succeeding corporation does not assume or substitute the RSUs pursuant to clause (i) of Section 10(b)(2)(A), then the unvested RSUs shall terminate immediately prior to the consummation of the Reorganization Event without any payment in exchange therefor.

(C) For purposes of Section 10(b)(2)(A)(i), an Award (other than Restricted Stock) shall be considered assumed if, following consummation of the Reorganization Event, such Award confers the right to purchase or receive pursuant to the terms of such Award, for each share of Common Stock subject to the Award immediately prior to the consummation of the Reorganization Event, the consideration (whether cash, securities or other property) received as a result of the Reorganization Event by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Reorganization Event (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); *provided, however*, that if the consideration received as a result of the Reorganization Event is not solely

common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise or settlement of the Award to consist solely of such number of shares of common stock of the acquiring or succeeding corporation (or an affiliate thereof) that the Board determined to be equivalent in value (as of the date of such determination or another date specified by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Reorganization Event.

(3) Consequences of a Reorganization Event on Restricted Stock. Upon the occurrence of a Reorganization Event other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company with respect to outstanding Restricted Stock shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Reorganization Event in the same manner and to the same extent as they applied to such Restricted Stock; *provided, however*, that the Board may either provide for termination or deemed satisfaction of such repurchase or other rights under the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, either initially or by amendment, or provide for forfeiture of such Restricted Stock if issued at no cost. Upon the occurrence of a Reorganization Event involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock then outstanding shall automatically be deemed terminated or satisfied.

11. General Provisions Applicable to Awards

(a) Transferability of Awards. Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by a Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant; *provided, however*, that, except with respect to Awards subject to Section 409A, the Board may permit or provide in an Award for the gratuitous transfer of the Award by the Participant to or for the benefit of any immediate family member, family trust or other entity established for the benefit of the Participant and/or an immediate family member thereof if the Company would be eligible to use a Form S-8 under the Securities Act for the registration of the sale of the Common Stock subject to such Award to such proposed transferee; *provided further*, that the Company shall not be required to recognize any such permitted transfer until such time as such permitted transferee shall, as a condition to such transfer, deliver to the Company a written instrument in form and substance satisfactory to the Company confirming that such transferee shall be bound by all of the terms and conditions of the Award. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees. For the avoidance of doubt, nothing contained in this Section 11(a) shall be deemed to restrict a transfer to the Company.

(b) Documentation. Each Award shall be evidenced in such form (written, electronic or otherwise) as the Board shall determine. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination or other cessation of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights, or receive any benefits, under an Award.

(d) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may elect to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold

from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise, vesting or release from forfeiture of an Award or at the same time as payment of the exercise or purchase price, unless the Company determines otherwise. If provided for in an Award or approved by the Board, a Participant may satisfy the tax obligations in whole or in part by delivery (either by actual delivery or attestation) of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their fair market value (valued in the manner determined by (or in a manner approved by) the Company); *provided, however*, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income), except that, to the extent that the Company is able to retain shares of Common Stock having a fair market value (determined by, or in a manner approved by, the Company) that exceeds the statutory minimum applicable withholding tax without financial accounting implications or the Company is withholding in a jurisdiction that does not have a statutory minimum withholding tax, the Company may retain such number of shares of Common Stock (up to the number of shares having a fair market value equal to the maximum individual statutory rate of tax (determined by, or in a manner approved by, the Company)) as the Company shall determine in its sole discretion to satisfy the tax liability associated with any Award. Shares used to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(e) Amendment of Award. Except as otherwise provided in Sections 5(g) and 6(e) with respect to repricings and Section 12(d) with respect to actions requiring stockholder approval, the Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option. The Participant's consent to such action shall be required unless (i) the Board determines that the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Plan or (ii) the change is permitted under Section 10.

(f) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously issued or delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and regulations and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules or regulations.

(g) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in whole or in part, free from some or all restrictions or conditions or otherwise realizable in whole or in part, as the case may be.

12. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award by virtue of the adoption of the Plan, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder; Clawback. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be

issued with respect to an Award until becoming the record holder of such shares. In accepting an Award under the Plan, the Participant agrees to be bound by any clawback policy that the Company has in effect or may adopt in the future.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date the Plan is approved by the Company's stockholders (the "***Effective Date***"). No Awards shall be granted under the Plan after the expiration of 10 years from the Effective Date, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time provided that (i) no amendment that would require stockholder approval under the rules of the national securities exchange on which the Company then maintains its primary listing may be made effective unless and until the Company's stockholders approve such amendment; and (ii) if the national securities exchange on which the Company then maintains its primary listing does not have rules regarding when stockholder approval of amendments to equity compensation plans is required (or if the Company's Common Stock is not then listed on any national securities exchange), then no amendment to the Plan (A) materially increasing the number of shares authorized under the Plan (other than pursuant to Section 4(c) or 10), (B) expanding the types of Awards that may be granted under the Plan, or (C) materially expanding the class of participants eligible to participate in the Plan shall be effective unless and until the Company's stockholders approve such amendment. In addition, if at any time the approval of the Company's stockholders is required as to any other modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 12(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment, taking into account any related action, does not materially and adversely affect the rights of Participants under the Plan. No Award shall be made that is conditioned upon stockholder approval of any amendment to the Plan unless the Award provides that (i) it will terminate or be forfeited if stockholder approval of such amendment is not obtained within no more than 12 months from the date of grant and (2) it may not be exercised or settled (or otherwise result in the issuance of Common Stock) prior to such stockholder approval.

(e) Authorization of Sub-Plans (including for Grants to non-U.S. Employees). The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable securities, tax or other laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to the Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Compliance with Section 409A of the Code. If and to the extent (i) any portion of any payment, compensation or other benefit provided to a Participant pursuant to the Plan in connection with his or her employment termination constitutes "nonqualified deferred compensation" within the meaning of Section 409A and (ii) the Participant is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, in each case as determined by the Company in accordance with its procedures, by which determinations the Participant (through accepting the Award) agrees that he or she is bound, such portion of the payment, compensation or other benefit shall not be paid before the day that is six months plus one day after the date of "separation from service" (as determined under Section 409A) (the "***New Payment Date***"), except as Section 409A may then permit. The aggregate of any payments that otherwise would have been paid to the Participant during the period between the date of separation from service and the New Payment Date shall be paid to the Participant in a lump sum on such New Payment Date, and any remaining payments will be paid on their original schedule.

The Company makes no representations or warranty and shall have no liability to the Participant or any other person if any provisions of or payments, compensation or other benefits under the Plan are determined to constitute nonqualified deferred compensation subject to Section 409A but do not to satisfy the conditions of that section.

(g) Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer, employee or agent of the Company will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan, nor will such individual be personally liable with respect to the Plan because of any contract or other instrument he or she executes in his or her capacity as a director, officer, employee or agent of the Company. The Company will indemnify and hold harmless each director, officer, employee or agent of the Company to whom any duty or power relating to the administration or interpretation of the Plan has been or will be delegated, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Board's approval) arising out of any act or omission to act concerning the Plan unless arising out of such person's own fraud or bad faith.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and interpreted in accordance with the laws of the State of Delaware, excluding choice-of-law principles of the law of such state that would require the application of the laws of a jurisdiction other than the State of Delaware.

ANNEX F

AMENDMENT TO RESTATED CERTIFICATE OF INCORPORATION

CERTIFICATE OF AMENDMENT

TO

RESTATED CERTIFICATE OF INCORPORATION

OF

AILERON THERAPEUTICS, INC.

Pursuant to Section 242 of the
General Corporation Law of the State of Delaware

Aileron Therapeutics, Inc. (hereinafter call the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware, does hereby certify as follows:

FIRST: A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law of the State of Delaware setting forth an amendment to the Restated Certificate of Incorporation of the Corporation, as amended, and declaring said amendment to be advisable. The stockholders of the Corporation duly approved and adopted said proposed amendment in accordance with Section 242 of the General Corporation Law of the State of Delaware. The resolution setting forth the amendment is as follows:

RESOLVED: That the third paragraph of Article FOURTH of the Restated Certificate of Incorporation of the Corporation, as amended, be and hereby is deleted in its entirety and the following is inserted in lieu thereof:

"The total number of shares of all classes of stock which the Corporation shall have authority to issue is 105,000,000 shares, consisting of (i) 100,000,000 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock")."

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IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation on this day of , 2024.

AILERON THERAPEUTICS, INC.

By: _____
Name: Manuel C. Alves-Aivado
Title: Chief Executive Officer