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As filed with the Securities and Exchange Commission on July 19, 2024

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Tectonic Therapeutic, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2836	81-0710585
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code No.)	(I.R.S. Employer Identification Number)

490 Arsenal Way
Suite 210
Watertown, MA 02472
(339) 666-3320
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Daniel Lochner
Chief Financial Officer
490 Arsenal Way
Suite 210
Watertown, MA 02472
(339) 666-3320
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Marc A. Recht
Courtney T. Thorne
Cooley LLP
500 Boylston Street, 14th Floor
Boston, Massachusetts 02116
(617) 937-2300

Approximate Date of Commencement of Proposed Sale to the Public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

On June 20, 2024 (the "Closing Date"), Tectonic Therapeutic, Inc., a Delaware corporation (previously named AVROBIO, Inc. and our predecessor company ("AVROBIO")), consummated the previously announced merger pursuant to the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 30, 2024 (the "Merger Agreement"), by and among AVROBIO, Alpine Merger Subsidiary, Inc., a Delaware corporation and direct wholly owned subsidiary of AVROBIO ("Merger Sub"), and Tectonic Operating Company, Inc., a Delaware corporation (previously named Tectonic Therapeutic, Inc. ("Legacy Tectonic")).

Pursuant to the Merger Agreement, on the Closing Date, (i) AVROBIO effected a reverse stock split of AVROBIO's issued and outstanding common stock at a ratio of 1:12 (the "Reverse Stock Split"), (ii) AVROBIO changed its name to "Tectonic Therapeutic, Inc." and Legacy Tectonic changed its name to "Tectonic Operating Company, Inc.," and (iii) Merger Sub merged with and into Legacy Tectonic (the "Merger"), with Legacy Tectonic continuing as the surviving company in the Merger and as a wholly-owned subsidiary of Tectonic Therapeutic, Inc. (the "Company" and together with its consolidated subsidiaries, "Tectonic," "we" or "us").

In accordance with the terms and subject to the conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger, each share of Legacy Tectonic preferred stock was converted into one share of Legacy Tectonic common stock, and (ii) at the effective time of the Merger, the Company issued an aggregate of approximately 5,322,169 shares of its common stock to Legacy Tectonic stockholders, based on an exchange ratio (after giving effect to the Reverse Stock Split) of 0.53441999 shares of the Company's common stock for each share of Legacy Tectonic common stock outstanding immediately prior to the Merger, including those shares of Legacy Tectonic common stock issued upon conversion of the Legacy Tectonic preferred stock and simple agreements for future equity ("SAFEs") and those shares of Legacy Tectonic common stock issued in the Pre-Closing Financing (defined below), but excluding shares to be canceled pursuant to the Merger Agreement, resulting in approximately 14,734,323 shares of the Company's common stock being issued and outstanding immediately following the effective time of the Merger.

On January 30, 2024, Legacy Tectonic entered into a subscription agreement (the "Subscription Agreement"), with certain institutional investors named therein. Pursuant to the Subscription Agreement, immediately prior to consummation of the Merger, Legacy Tectonic issued and sold an aggregate of 7,790,889 shares of its common stock at a purchase price of approximately $12.39908 per share, for an aggregate purchase price of approximately $96.6 million (the "Pre-Closing Financing"), and the shares of Legacy Tectonic common stock issued to investors in the Pre-Closing Financing were exchanged at the closing of the Merger at the exchange ratio for an aggregate of 4,163,606 shares of the Company's common stock.

As of the open of trading on June 21, 2024, the common stock of the Company began trading on the Nasdaq Global Market under the symbol "TECX."

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The information in this preliminary prospectus is not complete and may be changed. Neither we nor the selling securityholders may sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED July 19, 2024

PRELIMINARY PROSPECTUS

Up to 2,969,583 Shares of Common Stock

This prospectus relates to the proposed offer and resale or other disposition from time to time by the selling stockholders identified in this prospectus of up to an aggregate of 2,969,583 shares of common stock, par value $0.0001 per share, of Tectonic Therapeutic, Inc.

We are registering the resale of the shares of common stock pursuant to the selling stockholders' registration rights under the Subscription Agreement between us and the selling stockholders. Our registration of the resale of the shares of common stock covered by this prospectus does not mean that the selling stockholders will offer or sell all or any of the shares of common stock. The selling stockholders may offer, sell or distribute all or a portion of their shares of common stock from time to time directly or indirectly through one or more underwriters, broker-dealers or agents, and in one or more public or private transactions, which may involve crosses or block transactions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale or at negotiated prices. See the section entitled "*Plan of Distribution*" for more information.

We will not receive any proceeds from any sale of common stock by the selling stockholders pursuant to this prospectus. We have agreed to bear the expenses in connection with the registration of the resale of the shares of common stock to be offered by this prospectus by the selling stockholders except for any underwriting discounts and commissions or transfer taxes relating to the sale of common stock, which will be borne by the selling stockholders.

Our common stock is listed on the Nasdaq Global Market ("Nasdaq") under the symbol "TECX." On July 12, 2024, the closing price for our common stock, as reported on Nasdaq, was $16.94 per share.

See the section entitled "Risk Factors" beginning on page 9 of this prospectus to read about factors you should consider before buying our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2024.

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You should rely only on the information provided in this prospectus, as well as the information incorporated by reference to exhibits to the registration statement of which this prospectus forms a part and any applicable prospectus supplement or amendment. Neither we nor the selling stockholders have authorized anyone to provide you with different information. Neither we nor the selling stockholders are making an offer of these securities in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date of the applicable document. Since the date of this prospectus and the documents filed as exhibits to the registration statement of which this prospectus forms a part, our business, financial condition, results of operations and prospects may have changed.

ABOUT THIS PROSPECTUS

This prospectus relates to the resale by the selling stockholders identified in this prospectus under the caption "Selling Stockholders," from time to time, of up to an aggregate of 2,969,583 shares of common stock. We are not selling any shares of common stock under this prospectus, and we will not receive any proceeds from the sale of shares of common stock offered hereby by the Selling Stockholders.

Neither we, nor the selling stockholders, have authorized anyone to give any information or to make any representation other than those contained or incorporated by reference in this prospectus. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where it is lawful to do so. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any shares other than the registered shares to which it relates, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy shares in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus is delivered or shares are sold on a later date. Our business, financial condition, results of operations and prospects may have changed since those dates. This prospectus incorporates by reference market data and industry statistics and forecasts that are based on independent industry publications and other publicly available information. Although we believe these sources are reliable, we do not guarantee the accuracy or completeness of this information and we have not independently verified this information. In addition, the market and industry data and forecasts that may be included or incorporated by reference in this prospectus may involve estimates, assumptions and other risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "Risk Factors" contained in this prospectus, and under similar headings in other documents that are incorporated by reference into this prospectus. Accordingly, investors should not place undue reliance on this information.

A prospectus supplement may add to, update or change the information contained in this prospectus. You should read both this prospectus and any applicable prospectus supplement together with additional information described below under the heading "Where You Can Find Additional Information" or incorporated by reference herein as described under the heading "Incorporation of Certain Information by Reference."

Unless the context otherwise indicates, references in this prospectus to "Company," "we," "our" and "us" refer, collectively to Tectonic Therapeutic, Inc., a Delaware corporation, and its consolidated subsidiaries (including Legacy Tectonic).

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains and/or incorporates by reference statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward looking statements in this prospectus may include, for example, statements about:

- our strategies, prospects, plans, expectations or objectives of management for our future operations;
- our progress, scope or timing of the development of our product candidates;
- our expectations surrounding the potential safety, efficacy, and regulatory and clinical progress of TX45 and any other product candidates, and our anticipated milestones and timing therefor;
- the benefits that may be derived from any of our future products or the commercial or market opportunity with respect to any of our future products;
- our ability to protect our intellectual property rights;
- our anticipated operations, financial position, ability to raise capital to fund our operations, revenues, costs or expenses; and
- the statements regarding our future economic conditions or performance, statements of belief and any statement of assumptions underlying any of the foregoing.

These forward-looking statements are based on information available to us at the time of this prospectus or the documents incorporated by reference herein and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties, and other factors. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements, including those set forth in this prospectus in the section entitled "Risk Factors" and in our periodic filings with the Securities and Exchange Commission (the "SEC"). Our SEC filings are available publicly on the SEC's website at www.sec.gov. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Additional cautionary statements or discussions of risks and uncertainties that could affect our results or the achievement of the expectations described in forward-looking statements may also be contained in any accompanying prospectus supplement. Should one or more of the risks or uncertainties described in this prospectus, or should underlying assumptions prove incorrect, actual results and plans could differ materially from those expressed in any forward-looking statements.

You should read this prospectus and any accompanying prospectus supplement if any, completely and with the understanding that our actual future results, levels of activity and performance as well as other events and

circumstances may be materially different from what we expect. Except as otherwise required by applicable law, we disclaim any duty to update any forward-looking statements, all of which are expressly qualified by the statements in this section, to reflect events or circumstances after the date of this prospectus. We qualify all of our forward-looking statements by these cautionary statements.

PROSPECTUS SUMMARY

Our Company

We are a biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of G-protein coupled receptors ("GPCRs"). The discovery of biologics that can modulate GPCRs has historically been quite challenging. We have developed a proprietary technology platform called GEODe™ with the aim of addressing these challenges to enable the discovery and development of GPCR-targeted biologic medicines that can modify the course of disease. We focus on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality of life or extend duration of life.

GPCRs are receptor molecules found on the surface of cells that act as sensors for various extracellular stimuli to enable communication between cells and their environment. These molecules regulate diverse aspects of human biology including blood pressure, glucose metabolism, transmission between neurons and immune surveillance. There are over 800 human genes encoding GPCRs, underscoring the extent to which nature has relied on this molecular system for physiological control. The breadth of effects controlled by GPCRs is best illustrated by the fact that greater than 30% of all approved drugs address targets in this class. The vast majority of these drugs, however, are small molecules, and their targets have been largely confined to a few GPCR subfamilies, many of which have a natural ligand that is also a small molecule. We believe there are many situations where biologics could present advantages over small molecules for this class of targets. For instance, when targeting a single member of a highly related family of GPCRs, the selectivity profile achievable with an antibody may be preferable to that of a small molecule to optimize therapeutic efficacy and safety for the patient. Conversely, when multi-modal action is needed to achieve a desired physiological effect, proteins engineered for bispecific function allow for dual target engagement, unlike small molecules that are generally optimized for action on a single target. We are focused on developing biologics to address GPCRs with the goal of capturing such opportunities.

It has been historically difficult, however, to discover therapeutic proteins and antibodies that bind to and modulate the activity of GPCRs because of the low endogenous level of expression of many GPCRs, complex biochemistry, and their inherent instability when removed from their natural environment, the cell membrane. With the goal of unlocking the potential for biologic therapeutics to broaden the clinical utility of GPCRs, we use our proprietary GEODe™ technology platform in an attempt to overcome the known challenges of GPCR-targeted drug discovery. The initial platform components, first generation yeast library design and initial yeast selection protocols, were developed in Dr. Andrew Kruse's lab at Harvard Medical School. However, over the last few years our team has made many improvements and modifications to all aspects of the platform including second and third generation library designs, optimized GPCR engineering strategies and yeast selection protocols better suited to GPCR antibody discovery. These modifications have resulted in selection campaigns that have a higher hit rate with molecules that have higher affinity and potency compared to hits identified from initial antibody selection campaigns. The GEODe™ platform includes components aimed at optimizing the expression, purification, and stabilization of GPCRs and pairs these advances with our protein engineering and structural biology capabilities. While the current libraries, receptor engineering and selection strategies are producing GPCR-targeted antibodies, our team continues to evolve and modify aspects of the platform, which we believe will lead to even better results.

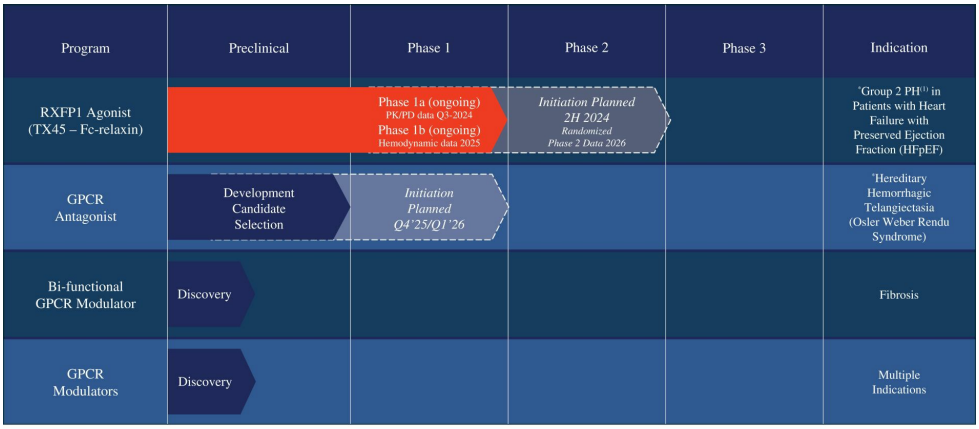
Our lead asset, TX000045 ("TX45") is an Fc-relaxin fusion molecule that activates the RXFP1 receptor, the GPCR target of the hormone relaxin. Relaxin is an endogenous protein, expressed at low levels in both men and women. In normal human physiology, relaxin is upregulated during pregnancy where it exerts vasodilative effects, reduces systemic and pulmonary vascular resistance and increases cardiac output to accommodate the increased demand for oxygen and nutrients from the developing fetus. Relaxin also exerts anti-fibrotic effects on pelvic ligaments to facilitate delivery of the baby. It has long been hypothesized that these unique dual aspects of relaxin biology may offer therapeutic potential in the treatment of cardiovascular disease. Unfortunately, the

development of a viable therapeutic has been challenging, primarily because of relaxin's very short half-life. We believe TX45's pharmacological profile, the direct result of applying our protein engineering capabilities, has the potential to overcome the limitations that have impeded previous attempts to develop relaxin as a therapeutic protein. To interrogate the therapeutic potential of relaxin, we have identified Group 2 Pulmonary Hypertension ("PH") in the setting of Heart Failure with Preserved Ejection Fraction ("HFpEF") referred to as Group 2 PH / HFpEF hereafter, as the initial disease setting. We hypothesize that in this setting, treatment with relaxin could improve hemodynamics through effects on pulmonary and systemic vasodilation, cardiac diastolic dysfunction and potential remodeling in both the pulmonary vessels and the heart which could translate into a clinically meaningful improvement in exercise capacity in these patients. Clinical trials are planned to confirm this hypothesis. Despite this belief, our business carries substantial risks, including our limited experience in therapeutic discovery and development, and the risk that that the platform may never result in the regulatory approval of a product candidate.

Our second program is aimed at the discovery and development of a GPCR targeting biotherapeutic as a potential treatment for Hereditary Hemorrhagic Telangiectasia ("HHT"), the second-most common genetic bleeding disorder. In HHT, abnormal blood vessel formations result in telangiectasias and arterio-venous malformations or "AVMs." These abnormal vessels are prone to spontaneous and severe bleeding that can be life-threatening. There are no currently approved therapies to treat HHT. In HHT patients, mutations have been identified in BMP9, BMP10, Endoglin, ALK1 and SMAD4 proteins, all of which are members of a common signaling pathway. Preclinically, knock-out or inhibition of pathway members leads to increased expression of factors that drive angiogenesis and abnormal blood vessel formation that phenocopy the clinical situation. The planned GPCR target for our HHT program is a receptor for an angiogenic factor known to be upregulated in HHT animal models. By blocking the signaling of this receptor, we anticipate the potential for decreased bleeding resulting from the abnormal angiogenesis seen in HHT, a hypothesis we plan to investigate in the clinical setting following the selection of a development candidate to evaluate its safety and efficacy.

Our Pipeline

The following table summarizes key information about our development programs and other pipeline programs:



(1) Pulmonary Hypertension

Our principal executive offices are located at 490 Arsenal Way, Suite 210, Watertown, Massachusetts 02472, and our telephone number is (339) 666-3320. Our website address is *www.tectonictx.com*.

Risks Associated with Our Business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled "Risk Factors," following this prospectus summary. These risks include the following, among others:

- We have a limited operating history, have incurred net losses in every year since our inception, and expect to continue to incur net losses in the future.
- We will need substantial additional funding in order to complete the development and commence commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, reduce or eliminate certain of our product development or research operations.
- We have limited experience in therapeutic discovery and development and our GEODe ™ platform may never result in the regulatory approval of a product candidate.
- All of our product candidates are in discovery, preclinical or early clinical development. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of TX45 or any future product candidates.
- Our clinical trials may fail to demonstrate substantial evidence of the safety, efficacy, purity and potency of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.
- If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.
- 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 depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture TX45 and any other product candidates, and we may rely on third parties to produce and process our products, if approved.
- Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Corporate Information

Our principal executive office is located at 490 Arsenal Way, Suite 210, Watertown, Massachusetts 02472, and our telephone number is (339) 666-3320. Our website address is www.tectonictx.com. We do not incorporate

the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus. Our common stock is listed on Nasdaq under the symbol “TECX.”

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of the common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of the common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

The Offering	
Issuer	Tectonic Therapeutic, Inc.
Shares of Common Stock Offered by the Selling Stockholders	Up to an aggregate of 2,969,583 shares of common stock.
Shares of Common Stock Outstanding	14,734,325 shares of common stock as of July 6, 2024
Use of Proceeds	All of the shares of common stock offered by the selling stockholders pursuant to this prospectus will be sold by the selling stockholders for their respective accounts. We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus.
Nasdaq Symbol	TECX
Offering Price	The selling stockholders will offer the shares of common stock offered by this prospectus at the prevailing market prices or at privately negotiated prices.
Risk Factors	You should read the “Risk Factors” section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

For additional information concerning the offering, see “ *Plan of Distribution* ” beginning on page 185.

RISK FACTORS

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements," you should carefully consider the specific risks set forth herein. We operate in a dynamic and rapidly changing industry that involves numerous risks and uncertainties. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto, and the other financial information concerning us included elsewhere in this prospectus. Additionally, the risks and uncertainties described in this prospectus or any prospectus supplement are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risks Related to Our Financial Position and Cash Needs

We have a limited operating history and have incurred net losses in every year since our inception. We expect to continue to incur net losses in the future.

We are a clinical-stage biotechnology company with a limited operating history. Since our inception in 2019, we have invested most of our resources in organizing and staffing our company, developing our technology and product candidates, building our intellectual property portfolio, conducting business planning, raising capital and providing general and administrative support for these operations. We also completed the Merger in June 2024 and have been operating under this structure for only a short time. Consequently, we have no meaningful 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 continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. For the three months ended March 31, 2024 and 2023, Legacy Tectonic reported a net loss of $15.2 million and $14.4 million, respectively. As of March 31, 2024, Legacy Tectonic had an accumulated deficit of $105.8 million. We expect to continue to incur significant losses for the foreseeable future, and expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our lead product candidate, TX45, along with any future product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our lead product candidate TX45;
- increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- establish 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;
- invest in or in-license other technologies; and

- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we, our collaborators and any potential future collaborators 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 preclinical studies and clinical trials, producing biologics with contract manufacturing development organizations ("CDMOs") in the United States and in other countries, 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 or large 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 the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will need substantial additional funding in order to complete the development and commence commercialization of our product candidates. Failure to obtain this necessary capital when needed may force us to delay, reduce or eliminate certain of our product development or research operations.

To date, Legacy Tectonic has funded its operations primarily with proceeds from the sale of Series A convertible preferred stock, convertible promissory notes and the issuance of SAFEs. We are also planning to fund our operations with the funds we received in the Merger and pursuant to the Subscription Agreement. We expect our expenses to increase in connection with our ongoing activities, particularly as we complete the Phase 1 clinical trial of TX45, continue our Phase 1b clinical trial and initiate the planned Phase 2 clinical trial of TX45, and continue to research, develop and initiate clinical trials of any other future product candidates. In addition, if we successfully complete development through Phase 3 and obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our product development programs or any future commercialization efforts.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into mid-2027. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Future capital requirements for TX45 or our preclinical programs will depend on many factors, including:

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and pandemics or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreements with President and Fellows of Harvard College ("Harvard") and other license agreements, as applicable;
- the number of potential new product candidates we identify and decide to develop;
- the need for additional or expanded pre-clinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;

- the costs involved in growing the organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- 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;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

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 product or royalty 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.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from geopolitical and economic instability, including the conflicts between Russia and Ukraine and Israel and Hamas or other factors could also adversely impact our ability to access capital as and when needed. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

Raising additional capital will cause dilution to our stockholders, and may restrict our operations, or require us to relinquish rights to its product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity or debt financings, third-party funding, marketing, and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our current stockholders will be diluted, and the terms of these securities may include liquidation or other preferences. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances, or third-party licensing arrangements, it may have to relinquish certain valuable rights to its intellectual property, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are

unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise develop and market ourselves.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

We have limited experience in therapeutic discovery and development and our GEODe ™ platform may never result in the regulatory approval of a product candidate.

Notwithstanding the prior experience of individuals on our management team in drug discovery and development, we are still a relatively young organization that has not yet completed the full cycle of activities from discovery through regulatory approval for any of our portfolio projects. Our GEODe™ discovery platform has been the focus of technology development efforts over the last four years and is in the early stages of being applied to novel therapeutic target opportunities. There is no guarantee the platform's capabilities or its application to targets of interest will lead to therapeutic product candidates that can be successfully developed through different stages of clinical trials and registered for marketing as therapeutic drugs in the United States or any other territory.

We are very early in our development efforts. If we are unable to advance TX45 or any of our other product candidates through clinical development, obtain regulatory approval and ultimately commercialize TX45 or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have no products approved for sale and our lead product candidate, TX45, will require clinical development, regulatory review and approval in each jurisdiction in which we intend to market it, access to sufficient commercial manufacturing capacity, and significant sales and marketing efforts before we can generate any revenue from product sales.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. We are early in our product candidate development efforts, as TX45 is still in Phase 1 clinical trials.

Our ability to generate product revenues, which we do not expect will occur in the foreseeable future, if ever, will depend heavily on the successful development and eventual commercialization of TX45 and any future product candidates we develop, which may never occur. TX45 and any future product candidates we develop will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions for specific indications for use, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

- successful and timely completion of preclinical studies and clinical trials for which the FDA, or any comparable foreign regulatory authority agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or authorizations for conducting our planned clinical trials or future clinical trials;
- initiation and successful patient enrollment in, and completion of, additional clinical trials on a timely basis;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe, pure, and potent for its targeted indications;

- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishing and scaling up, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- obtaining and maintaining patent and proprietary information protection or regulatory exclusivity for our product candidates, both in the United States and internationally;
- successfully scaling a sales and marketing organization and launching commercial sales of our product candidates, if approved;
- acceptance of our product candidates' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of our product candidates following approval;
- effectively competing with companies developing and commercializing other therapies in the indications which our product candidates target;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- enforcing and defending intellectual property rights and claims.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize TX45 or any future product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for our current and future product candidates, we may not be able to continue our operations.

All of our product candidates are in discovery, preclinical or early clinical development. Clinical trials are difficult to design and implement, and they involve a lengthy and expensive process with uncertain outcomes. We may experience delays in completing, or ultimately be unable to complete, the development and commercialization of TX45 or any future product candidates.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We cannot guarantee that any of our ongoing and planned clinical trials will be conducted as planned or completed on schedule, if at all. Moreover, even if these trials are initiated or conducted on a timely basis, issues may arise that could result in the suspension or termination of such clinical trials.

To date, we have not completed any clinical trials required for the approval of any of our product candidates. Although we have completed dosing in our Phase 1a clinical trial of TX45 in healthy volunteers, and we have initiated a Phase 1b clinical trial in Group 2 PH patients with HFpEF, we may experience delays in our ongoing clinical trials or preclinical studies and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, have sufficient drug supply for our product candidates on a timely basis or be completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. We also may experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize TX45 or any future product candidates, including:

- delays in or failure to obtain regulatory authorizations to commence a trial;

- delays in reaching a consensus with regulatory agencies as to the design or implementation of our clinical trials;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to obtain institutional review board ("IRB") approval at each site;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- delays in adding new clinical trial sites;
- failure to manufacture sufficient quantities of our product candidates for use in clinical trials in a timely manner;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, such as complications with pharmacokinetic behaviors, or safety or tolerability concerns that could cause us or our collaborators, as applicable, to suspend or terminate a trial if we or our collaborators find that the participants are being exposed to unacceptable health risks;
- failure to perform clinical trials in accordance with the FDA's or any other regulatory authority's good clinical practices ("GCP") requirements, or regulatory guidelines in other countries;
- failure to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- changes in regulatory requirements, policies and guidelines;
- failure of our third-party research contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays in establishing the appropriate dosage levels in clinical trials;
- the quality or stability of our product candidates falling below acceptable standards; and
- business interruptions resulting from natural disasters, political, geopolitical and economic instability, including political unrest or unstable economic conditions in China, the war between Russia and Ukraine, the conflict in the Middle East, terrorism, political turmoil, disease outbreaks, epidemics and pandemics.

In addition, we could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or comparable foreign regulatory authorities, or recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or 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. Significant clinical trial delays also could shorten any period 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 clinical trials may fail to demonstrate substantial evidence of the safety, efficacy, purity and potency of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, including TX45 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our biologic products, including TX45, are safe and effective for use in each targeted indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Further, the process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications, patient population and regulatory agency. Prior to obtaining approval to commercialize TX45 and any future product candidates in the United States or abroad, we, our collaborators or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with its product candidates, we may be delayed in obtaining marketing approval, if at all. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses or may not provide a sufficient risk-benefit ratio, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do or find a risk-benefit ratio for a proposed indication acceptable, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, approval of TX45 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of

such approval may limit the scope and use of the specific product candidate, which may also limit our commercial potential.

The results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later-stage trials.

The results of nonclinical, preclinical and early-stage clinical trials may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for product candidates proceeding through clinical trials. Many companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. Any such setbacks in our clinical development could have a material adverse effect on our business, financial condition and results of operations.

Our product candidates may be associated with serious adverse, undesirable or unacceptable side effects or other properties or safety risks, which may delay or halt their clinical development, or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, we may suspend or abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. While our lead product candidate, TX45, has been generally well tolerated in its preclinical studies and the Phase 1a healthy volunteer trial to date, the results from future preclinical studies and clinical trials, including of our other product candidates, may identify safety concerns or other undesirable properties of our product candidates.

The results of our ongoing Phase 1 clinical trials of TX45, the planned Phase 2 clinical trials of TX45, and future clinical trials of these and other product candidates may show that our product candidates cause undesirable or unacceptable side effects or even death. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Moreover, if our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for the product candidate, if approved.

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical

trials or to change the requirements for approval of any of our product candidates. For example, immunogenicity is a concern for all protein therapeutics in human clinical trials, and immunogenic reactions in patients in our trials may lead to adverse effects and/or impact exposure, which in turn may lead to protocol amendments, clinical holds, or other actions that delay or significantly impact the prospects for our product candidates.

Additionally, if any of our product candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product and require us to take such approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy ("REMS") plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates, if approved.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent us from proceeding with, or otherwise adversely affect, clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to its success. The timely completion of our clinical trials in accordance with our protocols depends, among other things, on our ability to recruit a sufficient number of eligible patients to participate and remain in the trial until its conclusion. Patients may be unwilling to participate in our clinical trials because of negative publicity from adverse events related to novel therapeutic approaches, competitive clinical trials for similar patient populations, the existence of current treatments or for other reasons. Any delays related to patient enrollment could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of the clinical trials altogether. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with the required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment and trial completion is affected by many factors, including the:

- location of one of our expected trial sites in Moldova for the Phase 1b trial and its proximity to the conflict between Russia and the Ukraine;
- size and nature of the patient population and process for identifying patients;
- proximity and availability of clinical trial sites for prospective patients;
- eligibility and exclusion criteria for the trial;
- design of the clinical trial;

- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of our approach;
- approval of competing product candidates currently under investigation for the treatment of similar diseases or conditions, or competing clinical trials for similar product candidates or targeting patient populations meeting our patient eligibility criteria;
- severity of the disease under investigation;
- degree of progression of the patient's disease at the time of enrollment;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to adequately monitor patients during and after treatment.

Our clinical trials will 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, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

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.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, topline or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, topline and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, if any, and the company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in its disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, if any, product candidate or its business. If the preliminary and interim data that we report

differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business.

Before we can commence clinical trials for any product candidate, we must complete extensive preclinical studies that support any future Investigational New Drug ("IND") applications in the United States, or similar applications in other jurisdictions. We have completed a pre-IND consultation with the FDA for our TX45 program but we do not yet have an approved IND in the US and as of July 6, 2024, studies are only being conducted in Australia, Moldova and the Netherlands. Conducting preclinical testing is a lengthy, time-consuming and expensive process and delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. While we are currently conducting Phase 1a and Phase 1b clinical trials for TX45, and plan to initially conduct Phase 2 clinical trials for TX45, including some trials which may be outside of the United States, we cannot be certain of the timely completion or outcome of our preclinical testing and studies for our other product candidates and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and foreign clinical trials will ultimately support the further development of our other product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, laws or regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our 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, pure and potent for its proposed indication;
- the population studied may not be sufficiently broad or representative to assure safety or efficacy in the population for which we seek approval;
- the results of clinical trials may not meet the level of clinical 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 FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials beyond those that we currently anticipate;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a Biologics License Application ("BLA") as applicable, to the FDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or any comparable foreign regulatory authorities or the laws they enforce may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of its product candidates, which would significantly harm our business, financial condition and results of operations. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of its product candidates. Even if we believe the data collected from clinical trials of its product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if any, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The FDA and any comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We are presently conducting clinical development in Australia, Moldova and the Netherlands and will likely choose to conduct additional international clinical trials in the future. The acceptance of study data by the FDA or any comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice, (ii) the trials are performed by clinical investigators of recognized competence and pursuant to compliance with current GCP requirements and (iii) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in its product candidates not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive regulatory approval of a product candidate, 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 such product candidate.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, 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 United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with current Good Manufacturing Practices ("cGMPs") and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' 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 BLA, other 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, or 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. The FDA may also require a 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 may impose 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 its 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:

- 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 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. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective

advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

The holder of a BLA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of its products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for its products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

The policies of the FDA and of comparable foreign 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 United States 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.

If approved, our investigational products may face competition from biosimilars approved through an abbreviated regulatory pathway.

We are developing TX45 initially for the treatment of Group 2 Pulmonary Hypertension ("PH"), which we anticipate will be regulated as a biological product. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. 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 market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our 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.

If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of biotechnology products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us and our collaborators in clinical trials, and the potential sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients who use the product, healthcare providers, pharmaceutical companies, its collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

Although we believe we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular proprietary molecules in its library, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of its product candidates or misread trends in the biotechnology industry, in particular for our lead product candidate, TX45, our business, financial condition and results of operations could be materially adversely affected.

We may seek orphan drug designation for product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for any product candidates we develop, and we may be unsuccessful. While we have not made a determination on whether we intend to seek orphan drug designation for any of our product candidates at this time, we may do so in the future. Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act in the United States, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards certain clinical trial costs, tax advantages and user-fee waivers.

Generally, in the United States, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same indication for seven years, except in limited circumstances.

Even if we obtain orphan drug exclusivity for any of our product candidates, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Risks Related to Commercialization of Our Product Candidates

If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for TX45 or any other product candidate, our ability to generate revenues from any such products will depend on its success in:

- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating strategic collaborations with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products (i) in sufficient quantities, (ii) at acceptable quality and cost and (iii) in a presentation that is practical and compatible with the intended clinical use to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.
- To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of

technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of its product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

We compete in the segments of the biotechnology, pharmaceutical and other related industries that develop and market therapies for the treatment of Group 2 PH with HFpEF and Hereditary Hemorrhagic Telangiectasia ("HHT") disorders. Although there are no other companies who have commercialized therapies for the same therapeutic areas that our product candidates target, there are many other companies, including large biotechnology and pharmaceutical companies, that are developing therapies for the same therapeutic areas. For example, AstraZeneca for the treatment of Group 2 PH and Diagonal Therapeutics and Vaderis Therapeutics for the treatment of HHT. Also, treatments that could potentially be of use across all HFpEF patients, such as are currently being developed by Lilly and others, could also benefit the Group 2 PH subgroup of the HFpEF population and thus represent competition for us in this segment as well.

We anticipate that we will continue to face intense and increasing competition as new treatments enter the market and advanced technologies become available. There can be no assurance that our competitors are not currently developing, or will not in the future develop, products that are equally or more effective or are more economically attractive than any of our current or future product candidates. Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on its business, financial condition and results of operations.

We do not have a sales or marketing infrastructure and have no experience in the sale or marketing of biotechnology products. To achieve commercial success for any approved product, we must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into strategic collaborations.

We may decide to establish our own sales and marketing capabilities and promote our product candidates if and when regulatory approval has been obtained in the United States or in other jurisdictions. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. Even if we establish sales and marketing capabilities, we may fail to launch our products effectively or to market our products effectively since we have no experience in the sales and marketing of biotechnology products. In addition, recruiting and training a sales force is expensive and time consuming and could delay any product launch. In the event that any such launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate adequate numbers of physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- costs of marketing and promotion above those anticipated by us.

If we enter into arrangements with third parties to perform sales and marketing services, our product revenues or the profitability of these product revenues to us could be lower than if we were to market and sell any products that we develop ourselves. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we may not be successful in commercializing our products, if any, which in turn would have a material adverse effect on our business, financial condition and results of operations.

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. The revenues that we generate from our sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of its product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or comparable foreign regulatory authorities;
- the timing of market introduction of our product candidates in relation to other potentially competitive products;
- the cost of our product candidates in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;

- the availability of coverage and adequate reimbursement from third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the effectiveness of our sales and marketing efforts and distribution support; and
- the presence or perceived risk of potential product liability claims.

Healthcare reform may negatively impact our ability to profitably sell TX45 and any potential future product candidates, if approved.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of TX45 or any potential future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and/or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the “individual mandate.” On June 17, 2021, the Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Further, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition.

Additionally, on August 16, 2022, President Biden signed the Inflation Reduction Act (the “IRA”), into law, which among other things, (1) directs the Department of Health and Human Services (the “HHS”), to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA includes certain exemptions to the price negotiation program, including a limited exemption for products with orphan drug designation. This exemption applies only to products with one orphan drug designation that is (i) for a rare disease or condition and (ii) is approved for indication(s) for such rare disease or condition. By limiting price

negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for its product candidates in multiple indications. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug pricing negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for TX45 and any potential future product candidates, which would adversely affect our business.

There has also been increasing executive, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been U.S. congressional inquiries, presidential executive orders and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in an executive order, the administration of President Biden expressed its intent to pursue certain policy initiatives to reduce drug prices and, in response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to lower drug prices. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services ("CMS"), Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve the quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from TX45 and any potential future product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In many countries outside the United States, government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls,

price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government-mandated price cuts, limitations on coverage of target population and introduction of volume caps.

Many countries implement health technology assessment ("HTA"), procedures that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, Regulation (EU) 2021/2282 on Health Technology Assessment, which will become effective on January 12, 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for its products in some EU member states, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action. However, it is possible that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Inadequate funding for the FDA and other government agencies, including from government shutdowns, 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, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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 its operation.

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

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we or our partner obtains marketing approval. Our arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products for which we or our partner obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (the “FCA”) or federal civil monetary penalties;
- the FCA imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, processing and transmission 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. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in

certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal Sunshine Act, as amended, and its implementing regulations, requires 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 HHS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical 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; state and local laws requiring the registration of pharmaceutical sales representatives; 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 pricing; federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and state and foreign laws that govern the privacy and security and other processing 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental 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 our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, damages, fines, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of its operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of EU member states, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our business could be materially and adversely affected in the future by political unrest in China, as well as the effects of disease outbreaks, epidemics and pandemics.

Disease outbreaks, epidemics and pandemics in regions where we may have clinical trial sites or other business operations could adversely affect its business, including by causing significant disruptions in our operations and/or in the operations of third-party manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics have negative impacts on our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating in its clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of TX45 and

any potential future product candidates, if at all. Disease outbreaks, epidemics and pandemics also could adversely impact clinical trial results for TX45 or other future potential product candidates, such as by diminishing or eliminating their efficacy or by producing a safety concern, either through direct biological effects or through confounding of the data collection and analysis. This adverse impact could terminate further development of TX45, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TX45.

In addition, because our key manufacturer and supplier for TX45 is located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies, laws, rules and regulations of the United States or Chinese governments, as well as political unrest or unstable economic conditions in China. For example, trade tensions between the United States and China have been escalating in recent years. Most notably, several rounds of U.S. tariffs have been placed on Chinese goods being exported to the United States. Each of these U.S. tariff impositions against Chinese exports was followed by a round of retaliatory Chinese tariffs on U.S. exports to China. Our components may in the future be subject to these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs. We may otherwise experience supply disruptions or delays, and although we carefully manage our inventory and lead-times, our supplier may not continue to provide us with battery components in our required quantities, to our required specifications and quality levels or at attractive prices. In addition, certain Chinese biotechnology companies and CDMOs may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotechnology companies, and would authorize the U.S. government to name additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. Such disruption could have adverse effects on the development of our product candidates and our business operations.

General supply chain issues may be exacerbated during disease outbreaks, epidemics and pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all.

If our CMOs are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and regulatory approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials could adversely affect our ability to conduct ongoing and future clinical trials of TX45 on our anticipated development timelines. Likewise, the operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders. If any of our CMOs or raw materials or components suppliers become subject to acts or orders of U.S. or foreign government entities to allocate or prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meets its size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, the ability to gain market share and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than our expects or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Even if we obtain approval to market TX45 or other potential future product candidates, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States and abroad, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many regions, including the EU, Japan and Canada, the pricing of prescription drugs is controlled by the government and 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 regulatory approval for the product is granted. Regulatory agencies in those countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtains marketing approval.

Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, private health insurers, health maintenance organizations and other organizations, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. In the United States and markets in other countries, governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS an agency within the HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners

obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and 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 health authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs of 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 only be temporary. 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 and may be incorporated into existing payments for other services. 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 United States. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition.

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 commercial success 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, 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 its product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. 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, prosecute and maintain 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. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The strength of patents in the biotechnology 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 United States or in other foreign countries. Even if the patents are successfully issued, 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 intellectual property or prevent others from designing around its claims. If the breadth or strength of protection provided by the patent applications, we hold

with respect to our product candidates is threatened, we could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in its clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates.

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 claim, and we may be subject to a third-party preissuance submission of prior art to the USPTO. There also may be prior art of which we are aware, but which we believe does not affect 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, a competitor's technology or product would be found by a court to infringe our patents. 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 we have had issued 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 its issued patents. Under the enacted Leahy-Smith America Invents Act ("America Invents Act"), enacted in 2013, the United States 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 its 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 its competitive advantage. For example:

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of its patents;
- the active biological ingredients in our current product candidates will eventually become commercially available in biosimilar drug products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet its obligations to the U.S. government in regards 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 us or our licensors' patents, as the case may be, or parts of ours 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 its own;
- the laws of foreign countries may not protect ours or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- 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 its 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 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 depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Please see the section titled "*Our Business—Collaboration, License and Services Agreements* " located elsewhere in this prospectus for additional information regarding our license agreements.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

In addition, intellectual property license agreements 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. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which is described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

If we fail to comply with our obligations under our patent license with a third party, we could lose license rights that are important to our business.

We are a party to a license agreement pursuant to which we in-license key patent and patent applications for our product candidates. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by our licensor 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.

If we are unable to protect the confidentiality of its proprietary information, our business and competitive position would be harmed.

In addition to patent protection, we rely upon know-how, 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 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 proprietary information 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 proprietary information can be difficult, expensive, and time-

consuming, and the outcome is unpredictable. In addition, proprietary information may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information 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 United States are sometimes less willing to protect proprietary information. If we choose to go to court to stop a third party from using any of our proprietary information, 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 proprietary information, 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, or disclose, our technology.

Thus, we may not be able to meaningfully protect our proprietary information. 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 its 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 its premises or using its 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 information by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our proprietary information.

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 pharmaceutical 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. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to our product candidates and programs. As the biotechnology and pharmaceutical 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 its products; 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.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting clinical trials and other development activities in the United States is protected under the Safe Harbor exemption as set forth in 35 U.S.C. § 271. If and when TX45 or another one of our product candidates is approved by the FDA, that certain third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims of such patent that could otherwise materially adversely affect commercialization of its product candidates, if approved, are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in a litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates 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 patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the 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 companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block its ability to further develop and commercialize its 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 its 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. Even if such a license is available, it may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. 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.

Lastly, we may need to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our product candidates, including TX45. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical 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.

We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing its compounds and pre-existing

pharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm its business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may 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 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 its patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, 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-exam, *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 foreign patent offices. 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 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 United States may be maintained in secrecy until the patents are issued, patent applications in the United States 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 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 proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference 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 proceedings provoked by third parties or brought 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. 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 proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

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.

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 such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensing partners 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 United States, 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 United States or abroad, even outside the context of litigation. Such

mechanisms include re-examination, 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.

Moreover, the patents included in our patent portfolio may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current or future owned or licensed patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own pending patent applications covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2041 through 2042, without taking into account any possible patent term adjustments or extensions. However, we cannot be assured that the USPTO or relevant foreign patent offices will grant any of these patent applications.

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in ex-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case *Amgen Inc. v. Sanofi,* the Federal Circuit held that a well-characterized antigen is insufficient to satisfy the written description requirement of certain claims directed to a genus of antibodies that are solely defined by function; and in the case of *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the Supreme Court held that certain claims to DNA molecules are not patentable. We cannot predict how these decisions or any future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition.

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

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 United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government

agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to its business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Also, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our 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 United States. 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 patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of its 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 its efforts and attention from other aspects of its 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.

We may incur substantial costs as a result of litigation or other proceedings relating to patents, and we may be unable to protect our rights to our products and technology.

If we or our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third party's activities do not infringe our owned or in-licensed patents. In addition, the Supreme Court has recently changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third-party can request that the USPTO review the patent claims such as in an *inter partes* review, *ex parte* re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in foreign patent offices, where either our owned or in-licensed foreign patents are challenged.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of such proceedings is highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

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 United States, 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, including biosimilars. 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.

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. 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 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. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

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. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trade names or trademarks that incorporate variations of our unregistered trade names or trademarks. 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 Our Reliance on Third Parties

We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture TX45 and any other product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.

We do not currently lease or own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a contract manufacturing organization ("CMO"), WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), to manufacture TX45 our product candidate used in our Phase 1a and Phase Ib clinical trials. We currently have a sole source relationship with WuXi Biologics for our supply of TX45 (see the section titled "*Our Business–Collaboration, License and Services Agreements*" located elsewhere in this prospectus for additional information on our relationship with WuXi Biologics). If there should be any disruption in such supply arrangement, including any adverse events affecting our sole supplier, Wuxi Biologics, it could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partner for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of a product candidate. We perform periodic audits of each CMO facility that supports our supply of TX45 and reviews and approves all TX45 cGMP-related documentation. We also have a quality agreement with WuXi Biologics that documents our mutual agreement on compliance with cGMPs and expectations on quality-required communications to us. Beyond this, we have no control over the ability of its CMO to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities and the associated Quality Management System for the manufacture of a product candidate or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market such product candidate, if approved. Similarly, our failure, or the failure of our CMO, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of a product candidate or drug and harm our business and results of operations. In addition, we have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved.

Moreover, our CMO may experience manufacturing difficulties due to resource constraints, governmental restrictions or as a result of labor disputes or unstable political environments. Supply chain issues, including those resulting from the COVID-19 pandemic and the ongoing military conflict between Russia and Ukraine, may affect our third-party vendors and cause delays. Furthermore, since we have engaged WuXi Biologics, a manufacturer located in China, we are exposed to the possibility of product supply disruption and increased costs

in the event of changes in the policies of the United States or Chinese governments or political unrest or unstable economic conditions in China. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, loans, and grants to entities that use equipment or services from certain Chinese biotechnology companies and would authorize the U.S. government to name other Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. 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. For example, in the event that we need to transfer from WuXi Biologics, which is our sole manufacturing source for TX45, we anticipate that the complexity of the manufacturing process may materially impact the amount of time it would take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to supply product candidates, including TX45, in a timely manner or within budget. If any CMO on which we will rely fails to manufacture quantities of a product candidate at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, cash flows, and prospects could be materially and adversely affected. In addition, our CMO and/or distribution partners are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and our CMO may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our products.

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements, to validate our assays and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices ("GLPs"), as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving its marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our preclinical studies or clinical trials comply with applicable GLP or GCP regulations. In addition, our clinical trials must be conducted with product,

including biologic product, produced in compliance with applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat preclinical studies or clinical trials, which would delay the regulatory approval process.

Further, these laboratories, investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent laboratories, investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if we can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. If any of our relationships with these third-party laboratories, CROs or clinical investigators terminate, we may not be able to enter into arrangements with alternative laboratories, CROs or investigators or to do so in a timely manner or on commercially reasonable terms. If laboratories, CROs or clinical investigators 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 clinical data they obtain is compromised due to the failure to adhere to its preclinical or clinical protocols, regulatory requirements or for other reasons, its preclinical or clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional laboratories or CROs (or investigators) involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new laboratory or CRO commences work. As a result, delays occur, which can materially impact our ability to meet its desired clinical development timelines. Though we carefully manage our relationships with our contracted laboratories and 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 results of operations.

In addition, clinical investigators may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

Our future collaborations 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 strategically evaluate and, as deemed appropriate, enter into additional strategic collaborations in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any

capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for its programs and technology. If we fail to enter into or maintain collaborations on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our product could change and our costs of development and commercialization could increase. Furthermore, we may find that our programs require the use of intellectual property rights held by third parties, and the growth of our business may depend in part on our ability to acquire or in-license these intellectual property rights.

Any future collaborations we enter into may pose a number of risks, including, but not limited to, 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 ours 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 its 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;
- 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 collaborations do not result in the successful discovery, 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 described in this prospectus also apply to the activities of its therapeutic collaborators.

Additionally, if one of our 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 collaborative partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon an 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. These factors may include the design or results of preclinical studies or clinical trials, the likelihood of regulatory approval, 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 products, the existence of any uncertainty with respect to our ownership of technology (which can exist if there is a challenge to such ownership regardless of the merits of the challenge) and industry and market conditions generally. The 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.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization, 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 product candidates or bring them to market and generate product revenue.

Nonclinical research requires the use of Non-Human Primates ("NHP"), the supply of which could delay or prevent development of product candidates.

Consistent with various rules, regulations and cGMP requirements, our ability to advance our pre-clinical programs and successfully develop our product candidates requires access to animal research models sufficient to assess safety and in some cases to establish the rationale for therapeutic use. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfil regulatory requirements may materially adversely affect our ability to advance our pre-clinical programs and successfully develop our product candidates and this could result in significant harm to our business. During the COVID-19 pandemic, researchers and CROs experienced significant limitations in their access to animal research models, specifically including a sharp reduction in the availability of NHPs originating from breeding farms in Southeast Asia and limited access to the generation of genetically-modified rodent models used in efficacy evaluations. If we are unable to obtain NHPs in sufficient quantities and in a timely manner to meet the needs of its pre-clinical research programs, if the price of NHPs that are available increases significantly, or if our suppliers are unable to ship the NHPs in their possession that are reserved for them, our ability to advance our pre-clinical programs and successfully develop our pre-clinical candidates may be materially adversely affected or significantly delayed.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on our management team, including Alise Reicin, M.D., our President and Chief Executive Officer, Daniel Lochner, our Chief Financial Officer, Peter McNamara, Ph.D., our Chief Scientific Officer and Marcella K. Ruddy, M.D., our Chief Medical Officer. Each of them may currently terminate their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We may become exposed to costly and damaging liability claims, either when testing a product candidate in the clinical or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of a product candidate in

clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially and adversely affect the market for our products or any prospects for commercialization of our products. Although we believe we currently maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage or that in the future we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a significant disruption of our product development programs and our ability to operate our business effectively.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Cyber-attacks are increasing in their frequency, sophistication, and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

While we have not experienced any significant system failure, accident, 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 or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials by us or our CROs could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures to protect our information technology systems and infrastructure, such measures may not prevent service interruptions or security breaches that could adversely affect our business and to the extent that any disruption 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 liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any current and future collaborators may be subject to federal, state/provincial, municipal and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we violate HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees, and other individuals about whom we or our current or future collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

If our information technology systems, or the information technology systems of our CROs, our CMOs, service providers, our current and potential future partners or other third parties upon which we rely were compromised, we could experience adverse consequences, including but not limited to material disruptions to our business operations, regulatory investigations or actions, litigation, fines and penalties, reputational harm, loss of revenue or profits, or other adverse consequences.

We collect, store, receive, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, share, and transmit (collectively, process) proprietary, confidential and sensitive information, including personal information (such as health-related data of clinical trial participants and employee information), in the course of our business. Similarly, third-parties upon which we rely process certain of that information on our behalf.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are constantly evolving and growing in frequency, sophistication, and intensity. For example, these threats may include (without limitation) malware, viruses, software vulnerabilities and bugs, software or hardware failure, hacking, denial of service attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), ransomware, insider threats (such as theft of misuse by personnel), credential stuffing, telecommunications failures, loss or theft of devices, data or other information technology assets, attacks enhanced or facilitated by AI, earthquakes, fires, floods and similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe, and attackers are increasingly leveraging multiple attack methods to extort payment from victims, such as data theft and disabling systems and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Security incidents may result from the actions of a wide variety of actors with a wide range of motives and expertise, including traditional hackers, our personnel or the personnel of the third parties upon which we rely, organized criminal threat actors, hacktivists, sophisticated nation-states and nation-state-supported actors. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to its business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of its research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if its third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Certain functional areas of our workforce work remotely on a full- or part-time basis or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. We may be required to, or we may choose to, expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, particularly where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or its information technology systems, or those of the third parties upon which we rely. If our information systems or data, or that of the third parties on which we rely, are compromised, it could interrupt our operations, disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of TX45, to analyze clinical trial samples and to conduct clinical trials, and security incidents experienced by these third parties could have a material adverse effect on our business. Security incidents affecting us or the third parties we rely on or partners with could also result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations (including availability of data), financial loss and other liabilities and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stockholders, including affected individuals, customers, regulators, and investors. Such disclosures may be costly, and related requirements or the failure to comply with them could lead to adverse consequences. Even a perceived security incident or failure in compliance by us or a third-party partner may result in negative publicity, harm to our reputation, or other adverse effects.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

We are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and otherwise harm our business.

We process proprietary, confidential and sensitive information, including personal information (including health-related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of such information in connection with our business.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") and the Swiss Federal Data Protection Act (collectively, "European Data Protection Laws") impose strict requirements for processing personal information, including relating to transfer of personal information to countries like the United States. European Data Protection Laws and other relevant laws govern patient confidentiality and storage of personal health data, and may apply to our processing of personal information from clinical trial participants and other individuals located in the EEA, the United Kingdom (the "UK"), or Switzerland and, if TX45 or any potential future product candidates are approved, our possible commercialization of those products in the EEA, the UK, or Switzerland (as applicable). Companies that violate the EU or UK GDPR can face private litigation, regulatory investigations and enforcement actions, prohibitions on data processing, other administrative measures, reputational damage and fines of up to the greater of 20 million Euros /17.5 million pounds sterling or 4% of their worldwide annual revenue, in either case, whichever is greater. Certain jurisdictions have enacted data localization restrictions or laws and regulations restricting cross-border transfers of personal information, except in limited circumstances where adequate safeguards are in place. In particular, regulators and courts in the EEA, the UK, and Switzerland have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws they generally believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA, the UK, or Switzerland to the United States, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework (the "Framework") and the UK extension thereto (which allows for transfers for to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If we are unable to implement a valid compliance solution for cross-border transfers of personal information, or if the requirements for a legally-compliant transfer are too onerous, we may face increased exposure to significant adverse consequences, including substantial fines, regulatory actions, as well as injunctions against the export and processing of personal information from the EEA, UK, Switzerland, or other countries that implement cross-border data transfer restrictions. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or prohibit our clinical trial activities in those countries; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to laws restricting cross-border data transfers; require us to increase our data processing capabilities in other countries at significant expense and may otherwise negatively impact our business operations. We may also become subject to new laws in the EEA and other jurisdictions that regulate cybersecurity and non-personal data, such as data collected through the internet of things. Depending on how these laws are interpreted, we may have to make changes to our business practices and products to comply with such obligations.

Additionally, other countries have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Privacy and data security laws in the United States at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. Many states have enacted comprehensive privacy laws. For example, the California Consumer Rights Act ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA") applies to personal information data of consumers, business representatives, and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA contains an exemption for certain personal information processed in connection with clinical trials, we may process other personal information that is subject to the CCPA. Other states, such as Virginia, Colorado, Connecticut, and Utah, have also passed comprehensive privacy laws that become effective in 2023, and similar laws have been passed or are being considered in several other states, as well as at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

We are bound by contractual obligations and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security (and consumers' data privacy obligations) are quickly changing in an increasingly stringent fashion and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on its behalf. In addition, these obligations may require us to change aspects of our business model. Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could impact whether or not we are in compliance.

If we (or third parties on which we rely) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize its products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of its operations.

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

If earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

We conduct certain research and development operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development incentive payment allowed by Australian regulations, our business and results of operations could suffer.

In September 2023, we formed a wholly-owned Australian subsidiary, Tectonic Therapeutic Pty Ltd., to conduct various preclinical studies and clinical trials for its product candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor its clinical activities in Australia, including conducting preclinical studies and clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidate in Australia will be accepted by the FDA or comparable foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development incentive payment equal to 43.5% of qualified expenditures to companies with an annual turnover of less than AU$20 million. Tectonic Therapeutic Pty Ltd. may be eligible to receive incentive payments during 2025 for research expenditures made during 2024. If our subsidiary loses our ability to operate in Australia, or if we are ineligible or unable to receive the research and development incentive payment, or the Australian government significantly reduces or eliminates the incentive program, our business and results of operation may be adversely affected.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

As of March 31, 2024, we had U.S. federal net operating loss carryforwards of approximately $15.2 million. The amount of net operating loss carryforwards that we are permitted to deduct is limited to 80% of taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, our U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Code, if we have undergone or undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law.

Our ability to utilize our net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, any necessary debt or equity financing that we undertake may be more difficult, more costly and more dilutive than it would be otherwise. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy and financial performance and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Geopolitical developments, such as the Russian invasion of Ukraine, the conflict in the Middle East or deterioration in the bilateral relationship between the United States and China, may impact government spending, international trade and market stability, and cause weaker macro-economic conditions. Certain political developments may also lead to regulatory uncertainty and to rules that may adversely affect our business.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect its reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

If we or any CMOs and suppliers we engage 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 and any CMOs and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We could also incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding its resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Any third-party CMOs and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that Legacy Tectonic did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. For

example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Once we are no longer a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results and cash flows.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. We currently qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, which allows the us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and in our periodic reports and proxy statements. Once we are no longer a smaller reporting company or otherwise no longer qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of Nasdaq, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. The Sarbanes-Oxley Act requires us to, among other things, establish corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. Commencing with our fiscal year ending the year after the Merger is completed, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to the closing of the Merger, we were never required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how

well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Stockholders could file lawsuits relating to the Merger.

Prior to the Merger, three actions were filed by purported stockholders of AVROBIO in connection with the Merger. One action has been filed in the United States District Court for the Southern District of New York captioned *Garofalo v. Avrobio, Inc. et al.* , 24-cv-1493 (filed February 27, 2024), which was voluntarily dismissed without prejudice on June 13, 2024. Two actions have been filed in the Supreme Court of New York, captioned *Price v. Avrobio, Inc., et al.* , No. 652555/2024 (filed May 17, 2024) and *Keller v. Avrobio, Inc., et al.* , No. 652597/2024 (filed May 21, 2024). The foregoing actions are referred to as the "Merger Actions."

The Merger Actions generally allege that the Registration Statement (filed by AVROBIO on February 14, 2024, as amended on March 26, 2024, April 15, 2024, and April 29, 2024 (the "Registration Statement")) misrepresents and/or omits certain purportedly material information in connection with the Merger, potential conflicts of interest of AVROBIO's officers and directors, and the events that led to the signing of the Merger Agreement. The *Price* and *Keller* actions assert claims for breach of fiduciary duty against all defendants. The Merger Actions seek, among other things, an injunction enjoining the consummation of the Merger, rescission of the Merger if consummated, costs of the action, including plaintiff's attorneys' fees and experts' fees and other relief the court may deem just and proper.

AVROBIO also received demand letters from eleven purported AVROBIO stockholders (the "Demands"). The Demands generally assert that the Registration Statement misrepresents and/or omits certain purportedly material information relating to the Merger.

AVROBIO believed that the disclosures set forth in the Registration Statement complied fully with all applicable law, that no supplemental disclosures were required under applicable law, and that the allegations in the Merger Actions and Demands were without merit. However, in order to moot the claims in the Merger Actions and Demands, avoid nuisance and possible expense and business delays, and provide additional information to its stockholders, and without admitting any liability or wrongdoing, AVROBIO decided voluntarily to supplement certain disclosures in the Registration Statement (the "Supplemental Disclosures"). On June 4, 2024, AVROBIO made certain Supplemental Disclosures on Form 8-K filed with the Securities and Exchange Commission.

Additional potential plaintiffs may file lawsuits challenging the Merger. The outcome of any current or future litigation is uncertain. Such litigation, if not resolved, could result in substantial costs to us, including any costs associated with the indemnification of directors and officers. If a plaintiff were successful in obtaining an injunction obtaining a rescission of the Merger, then such injunction may rescind the Merger after its consummation. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. Regardless of the outcome, litigation can have a material and adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and is likely to continue to be volatile and fluctuate substantially.

The trading price of our common stock has been and is likely to continue to be highly volatile. Furthermore, the stock market in general and the market for biopharmaceutical and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their shares at or above the price they paid for their shares. The market price of our common stock may be influenced by many factors, including:

- results of clinical trials and preclinical studies of the our product candidates, or those of our competitors or existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us, the selling stockholders or other securityholders in the future;
- if we fail to raise an adequate amount of capital to fund its operations or continued development of its product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our product candidates; and
- period-to-period fluctuations in our financial results; and
- the other factors described in this "*Risk Factors*" section.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Sales of our Common Stock or the perception of such sales, by us or the selling stockholders pursuant to this prospectus, in the public market or otherwise, could cause the market price for our securities to decline, even though the selling stockholders would still realize a profit on sales at lower prices. Resales of the securities offered by this prospectus may cause the market price of such securities to drop significantly, even if our business is doing well.

The sale of our Common Stock in the public market or otherwise, including sales pursuant to this prospectus, or the perception that such sales could occur, could harm the prevailing market price of our Common Stock. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Resales of our Common Stock may cause the market price of our securities to drop significantly, even if our business is doing well.

Certain of the selling stockholders named in this prospectus acquired securities at prices that are significantly less than the current trading price of our Common Stock. Accordingly, certain of the selling stockholders could still realize a profit on sales at lower prices. Even if the trading price of our Common Stock falls to or significantly below the current trading price, the selling stockholders may still have an incentive to sell and profit due to the nominal purchase prices paid by such selling stockholders, which are significantly lower than the purchase prices paid by the public stockholders.

In addition, the selling stockholders named in this prospectus hold a large portion of our outstanding Common Stock. The Common Stock being offered for resale pursuant to this prospectus by the selling stockholders would represent approximately 20.2% of our outstanding Common Stock as of July 6, 2024. Given the substantial number of shares of Common Stock being registered for potential resale by selling stockholders pursuant to this prospectus, the sale of shares by the selling stockholders of a large number of shares, or the perception in the market that the selling stockholders of a large number of shares intend to sell shares, could increase the volatility of the market price of our Common Stock or result in a significant decline in the public trading price of our Common Stock. While certain of the selling stockholders may experience a positive rate of return on their investment in our Common Stock as a result, the public securityholders may not experience a similar rate of return on the securities they purchased due to differences in their purchase prices and the trading price.

The number of shares being registered for sale is significant in relation to the number of outstanding shares of our common stock. Future sales of shares by existing stockholders could cause our stock price to decline.

As of July 6, 2024, we had approximately 14,734,325 shares of common stock outstanding. This prospectus is a part of a registration statement on Form S-1 that registers 2,969,583 shares of common stock for sale into the public market by the selling stockholders. These shares represent a significant number of our outstanding common stock, and if sold in the market all at once or at about the same time, such transactions could depress the market price of our common stock during the period the registration statement remains effective. Any such transaction could also adversely affect our ability to raise equity capital.

In addition, certain of our shares are subject to lock-up agreements between AVROBIO and Legacy Tectonic. Following the expiration of these lock-up agreements, the relevant stockholders will not be restricted

from selling shares our common stock held by them, other than by applicable securities laws. Stockholders not subject to these lock-up agreements will not be restricted from selling shares of our common stock held by them, other than by applicable securities laws. In addition, shares of common stock that are subject to outstanding options or will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any legal or contractual restrictions on resale lapse, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of July 6, 2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 47.4% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect to not provide research coverage of our common stock and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We have broad discretion in the use of our cash and cash equivalents and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We have broad discretion over the use of our cash and cash equivalents. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to our cash resources.

Because we do not anticipate paying any cash dividends on our share capital in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

You should not rely on an investment in our shares to provide dividend income. We have never declared or paid cash dividends on our share capital. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements or preferred equity may preclude us from paying dividends. As a result, capital appreciation, if any, of our common shares will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our shares.

Provisions in our charter and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our charter and bylaws and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of the Company or changes in our management. Our charter and bylaws, include provisions that:

- authorize "blank check" preferred stock, which could be issued by the Board without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by the Board, the chairperson of the Board, our Chief Executive Officer or our President;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the Board;
- provide that our directors may be removed only for cause;
- provide that vacancies on the Board may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize the Board to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our charter and bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our charter, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our bylaws contain exclusive forum provisions, which may limit a stockholder's ability to bring a claim in a judicial forum it finds favorable and may discourage lawsuits with respect to such claims.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of or based on a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless AVROBIO consents in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action

arising under the Securities Act, or the Federal Forum Provision, as our principal executive offices are located in Watertown, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, these forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they 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 even though an action, if successful, might benefit our stockholders. Section 22 of the Securities Act creates a concurrent jurisdiction for state and federal courts over all suits brought concerning a duty or liability created by the securities laws, rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is unenforceable, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

USE OF PROCEEDS

All of the shares of common stock offered by the selling stockholders pursuant to this prospectus will be sold by the selling stockholders for their respective accounts. We will not receive any proceeds from any sales of shares of our common stock by the selling stockholders.

MARKET INFORMATION FOR COMMON STOCK AND DIVIDEND POLICY

Market Information

Our common stock is currently listed on the Nasdaq Global Market under the symbol “TECX.” Prior to the consummation of the Merger, the common stock was listed on the Nasdaq Global Select Market under the symbol “AVRO.”

As of July 6, 2024, we had approximately 14,734,325 shares of common stock issued and outstanding held of record by approximately 86 registered holders.

Dividends

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

On June 20, 2024, AVROBIO, Inc. ("AVROBIO"), Tectonic Therapeutic, Inc. ("Tectonic"), and Alpine Merger Subsidiary, Inc., a direct, wholly owned subsidiary of AVROBIO ("Merger Sub") consummated the previously announced merger transaction pursuant to that certain agreement and plan of merger and reorganization (the "Merger Agreement"), dated January 30, 2024. Pursuant to the terms of the Merger Agreement, Merger Sub merged with and into Tectonic, with Tectonic surviving as a wholly owned subsidiary of AVROBIO (such transaction, the "merger"). Upon completion of the merger, the business of Tectonic will continue as the business of the surviving corporation, referred to herein as the "combined company." After the completion of the merger, AVROBIO changed its corporate name to Tectonic Therapeutic, Inc.

At the closing of the merger (the "effective time" or the "Closing") and related transactions, the shares of Tectonic common stock outstanding immediately prior to the effective time, including outstanding and unvested Tectonic Restricted Stock (defined in Note 1 of the accompanying notes), were converted into 10,956,614 shares of AVROBIO common stock in the aggregate, based on an exchange ratio determined in accordance with the terms of the Merger Agreement (the "Exchange Ratio"). The shares of AVROBIO common stock received by former Tectonic stockholders include 11,448 shares that are subject to vesting conditions, based on the unvested Tectonic Restricted Stock at Closing multiplied by the Exchange Ratio. The number of shares of Tectonic common stock outstanding immediately prior to the effective time included Tectonic common stock issued upon conversion of each share of Tectonic convertible preferred stock, and shares of Tectonic common stock issued in connection with the Subscription Agreements and Company SAFEs as defined in Note 1 of the accompanying notes (together with the merger, the "Transactions"). The Exchange Ratio is approximately 0.53 shares of AVROBIO common stock for each share of Tectonic common stock, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024.

The unaudited pro forma condensed combined balance sheet combines the historical balance sheets of AVROBIO and Tectonic as of March 31, 2024, and depicts the accounting of the Transactions under U.S. generally accepted accounting principles ("pro forma balance sheet transaction accounting adjustments"). The unaudited pro forma condensed combined statement of operations for the three months ended March 31, 2024, and the year ended December 31, 2023 combine the historical results of AVROBIO and Tectonic for these periods and depict the pro forma balance sheet transaction accounting adjustments assuming that those adjustments were made as of January 1, 2023 ("pro forma statement of operations transaction accounting adjustments"). Collectively, pro forma balance sheet transaction accounting adjustments and pro forma statement of operations transaction accounting adjustments are referred to as "transaction accounting adjustments" or "pro forma adjustments."

These unaudited pro forma condensed combined financial information and related notes have been derived from and should be read in conjunction with:

- The historical unaudited condensed consolidated financial statements of Tectonic as of and for the three months ended March 31, 2024, and the related notes included elsewhere in this prospectus;
- the historical unaudited condensed consolidated financial statements of AVROBIO as of and for the three months ended March 31, 2024, and the related notes included elsewhere in this prospectus;
- the historical audited consolidated financial statements of Tectonic as of and for the years ended December 31, 2023 and 2022, and the related notes included elsewhere in this prospectus;
- the historical audited consolidated financial statements of AVROBIO as of and for the years ended December 31, 2023 and 2022, and the related notes included elsewhere in this prospectus; and
- the sections titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations* ," and other financial information relating to Tectonic and AVROBIO included elsewhere in this prospectus.

The unaudited pro forma condensed combined financial information is based on the assumptions and pro forma adjustments that are described in the accompanying notes. 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, may occur and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information.

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 the future periods or the result that actually would have been realized had AVROBIO and Tectonic 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 condensed combined pro forma 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.

UNAUDITED PRO FORMA CONDENSED COMBINED BALANCE SHEET
AS OF MARCH 31, 2024
(In thousands, except share and per share amounts)

	Historical				
	(A) AVROBIO Inc.	(B) Tectonic Therapeutic Inc.	Transaction Accounting Adjustments		Pro Forma Combined
Assets					
Current assets:					
Cash and cash equivalents	$ 90,481	$ 18,748	$ 94,600	6(e)	$ 203,421
			644	6(a)	
			41	6(b)	
			(1,776)	6(h)	
			683	6(k)	
Restricted cash	283	—	(283)	6(k)	—
Prepaid expenses and other current assets	1,074	1,810	(448)	6(i)	2,436
Total current assets	91,838	20,558	93,461		205,857
Operating right-of-use assets	110	2,375	(110)	6(j)	2,375
Finance right-of-use assets, net	—	1,323	—		1,323
Property, equipment and improvements, net	—	2,864	—		2,864
Deferred offering costs	—	3,444	(3,444)	6(g)	—
Restricted cash, net of current portion	400	587	(400)	6(k)	587
Other assets	—	4	—		4
Total assets	$ 92,348	$ 31,155	$ 89,507		$ 213,010
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)					
Current liabilities:					
Accounts payable	$ 243	$ 2,563	$ —		$ 2,806
Accrued expenses and other current liabilities	3,042	11,048	5,236	6(g)	27,063
			3,950	6(c)	
			3,380	6(h)	
			407	6(l)	
SAFE liabilities	—	32,590	1,535	6(f)	—
			(34,125)	6(f)	
Operating lease liability - current portion	224	1,388	(224)	6(j)	1,388
Finance lease liability - current portion	—	475	—		475
Total current liabilities	3,509	48,064	(19,841)		31,732
Operating lease liability - net of current portion	—	1,280	—		1,280
Finance lease liability - net of current portion	—	758	—		758
Total liabilities	3,509	50,102	(19,841)		33,770
Tectonic convertible preferred stock (Series A-1, A-2, A-3 and A-4), $0.0001 par value	—	80,627	(80,627)	6(d)	—
Stockholders' equity (deficit):					
AVROBIO common stock, $0.0001 par value	4	—	—	6(b)	1
			—	6(l)	
			(4)	6(m)	
			1	6(m)	
Tectonic common stock, $0.0001 par value	—	—	1	6(d)	—
			1	6(e)	
			—	6(f)	
			—	6(a)	
			(2)	6(m)	
Additional paid-in capital	572,918	6,304	80,626	6(d)	287,059
			94,599	6(e)	
			34,125	6(f)	
			644	6(a)	
			(8,680)	6(g)	
			41	6(b)	
			(493,518)	6(m)	
Accumulated other comprehensive loss	—	(53)	—		(53)
Accumulated deficit	(484,083)	(105,825)	(1,535)	6(f)	(107,767)
			(3,950)	6(c)	
			(5,156)	6(h)	
			(448)	6(i)	
			114	6(j)	
			(407)	6(l)	
			493,523	6(m)	
Total stockholders' equity (deficit)	88,839	(99,574)	189,975		179,240
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 92,348	$ 31,155	$ 89,507		$ 213,010

See accompanying notes to the unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE THREE MONTHS ENDED MARCH 31, 2024
(In thousands, except share and per share amounts)

	Historical				
	(A) AVROBIO Inc.	(B) Tectonic Therapeutic Inc.	Transaction Accounting Adjustments		Pro Forma Combined	
Operating expenses:						
Research and development	$ 683	$ 10,818	$ —		$ 11,501	
General and administrative	7,258	2,150	—		9,408	
Total operating expenses	7,941	12,968	—		20,909	
Loss from operations	(7,941)	(12,968)	—		(20,909)	
Other income (expense), net						
Interest income	1,146	256	—		1,402	
Interest expense	—	(31)	—		(31)	
Other expense	(13)	(403)	—		(416)	
Change in fair value of SAFE liabilities	—	(2,075)	2,075	7(d)	—	
Total other income (expense), net	1,133	(2,253)	2,075		955	
Net loss	$ (6,808)	$ (15,221)	$ 2,075		$ (19,954)	
Basic and diluted, net income (loss) for the period attributable to equity holders	$ (6,808)	$ (15,221)			$ (19,954)	
Weighted average number of common shares outstanding - basic and diluted	44,790,825*	2,608,740			14,711,544	7(f)
Net loss per common share - basic and diluted	$ (0.15)*	$ (5.83)			$ (1.36)	

* After giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024, the basic and diluted net loss per common share was $1.82 and the basic and diluted weighted average number of common shares outstanding was 3,732,568 shares.

See accompanying notes to the unaudited pro forma condensed combined financial information.

UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2023
(In thousands, except share and per share amounts)

	Historical					
	(C) AVROBIO Inc.		(D) Tectonic Therapeutic Inc.	Transaction Accounting Adjustments		Pro Forma Combined
Operating expenses:						
Research and development	$ 47,700		$ 36,966	$ 37	7(c)	$ 86,041
				1,338	7(a)	
General and administrative	23,967		7,682	5,156	7(b)	39,828
				411	7(c)	
				2,612	7(a)	
Total operating expenses	71,667		44,648	9,554		125,869
Gain on asset sale	83,736		—	—		83,736
Loss on impairment	(1,877)		—	—		(1,877)
Income (loss) from operations	10,192		(44,648)	(9,554)		(44,010)
Other income (expense), net:						
Interest income	2,420		581	—		3,001
Interest expense	—		(152)	—		(152)
Other income (expense)	(78)		396	114	7(e)	432
Loss on issuance of SAFEs	—		(255)	—		(255)
Change in fair value of SAFE liabilities	—		1,255	(1,255)	7(d)	(1,535)
				(1,535)	7(d)	
Total other income (expense), net	2,342		1,825	(2,676)		1,491
Income (loss) before income taxes	12,534		(42,823)	(12,230)		(42,519)
Provision for income taxes	377		—	—		377
Net income (loss)	$ 12,157		$ (42,823)	$ (12,230)		$ (42,896)
Basic and diluted, net income (loss) for the period attributable to equity holders	$ 12,157		$ (42,823)			$ (42,896)
Weighted average number of common shares outstanding - basic	44,327,204	*	2,373,674			14,547,285	7(f)
Net income (loss) per common share - basic	$ 0.27	*	$ (18.04)			$ (2.95)
Weighted average number of common shares outstanding - diluted	44,567,918	*	2,373,674			14,567,345	7(f)
Net income (loss) per common share - diluted	$ 0.27	*	$ (18.04)			$ (2.94)

* After giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024, the basic and diluted net income per common share was $3.29 and $3.27, respectively, and the basic and diluted weighted average number of common shares outstanding was 3,693,933 shares and 3,713,993 shares, respectively.

See accompanying notes to the unaudited pro forma condensed combined financial information.

NOTES TO UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

1. Description of the Merger

On June 20, 2024, AVROBIO, Tectonic and Merger Sub consummated the previously announced merger transaction pursuant to the terms of the Merger Agreement dated January 30, 2024, pursuant to which Merger Sub merged with and into Tectonic, with Tectonic surviving as a wholly owned subsidiary of AVROBIO. Subject to the terms and conditions of the Merger Agreement, at Closing:

a) each outstanding share of Tectonic common stock, including outstanding and unvested Tectonic Restricted Stock (defined below), after giving effect to the Transactions, converted into a number of shares of AVROBIO's common stock, based on the Exchange Ratio,

b) each outstanding and unexercised option to purchase shares of Tectonic common stock ("Tectonic options") immediately prior to Closing was assumed by AVROBIO and converted into an option to purchase shares of AVROBIO common stock, with necessary adjustments to the number of shares and exercise price to reflect the Exchange Ratio; and

c) All Tectonic restricted common stock outstanding and unvested immediately prior to Closing ("Tectonic Restricted Stock") that was assumed by AVROBIO in the merger remains unvested to the same extent and is subject to the same repurchase option, risk of forfeiture or other condition under any applicable restricted stock purchase agreement.

Under the terms of the Merger Agreement, the board of directors of AVROBIO accelerated the vesting of certain outstanding options to purchase AVROBIO common stock, after giving effect to the 1-for-12 reverse stock split that was effected on June 20, 2024, held by a current employee, director or consultant of AVROBIO as of the Closing, and accelerated the vesting and settled into shares of AVROBIO common stock each outstanding restricted stock unit ("RSU") in respect of AVROBIO common stock that vests solely on the basis of time. The acceleration of vesting of AVROBIO's options and RSUs occurs either upon a change of control as defined, pursuant to the terms of the original awards, or a modification of the awards as a result of the merger. The post-merger stock-based compensation expense, including the incremental fair value of the AVROBIO's options and RSUs associated with the modification to accelerate vesting is immaterial at Closing and is not included as an adjustment to the unaudited pro forma condensed combined financial information.

Immediately following the merger, AVROBIO stockholders as of immediately prior to the merger will own approximately 24.8% of the outstanding capital stock of the combined company on a diluted basis, former Tectonic stockholders will own approximately 38.5% of the outstanding capital stock of the combined company on a diluted basis, and investors participating in the Subscription Agreements and Company SAFEs will own approximately 27.1% and 9.6% of the outstanding capital stock of the combined company, respectively, on a diluted basis. Tectonic stockholders received approximately 10,956,614 shares of AVROBIO common stock in connection with the merger, including 11,448 shares of AVROBIO common stock subject to vesting terms, based on the number of shares of Tectonic common stock outstanding immediately prior to the merger, including Tectonic Restricted Stock, the number of shares Tectonic common stock issued to investors participating in the Subscription Agreements and Company SAFEs, and Tectonic convertible preferred stock outstanding immediately prior to the merger, which was converted into shares of Tectonic common stock on a one-for-one basis immediately prior to the closing of the merger. The number of shares of AVROBIO common stock issued to Tectonic stockholders in connection with the merger was based on certain inputs, including (i) AVROBIO's net cash at Closing of $77.3 million, (ii) the 1-for-12 reverse stock split of AVROBIO common stock effected on June 20, 2024, and (iii) aggregate proceeds from the Private Financing Transactions (as defined below) of

$130.7 million. The following table summarizes the number of shares of common stock of the combined company outstanding following the consummation of the Transactions.

Equity Capitalization Summary Upon Consummation of the Merger	Number of Shares Owned	% Ownership
Tectonic stockholders (1)	5,322,169	36.1%
AVROBIO stockholders	3,777,709	25.6%
Investors participating in the Company SAFEs	1,470,839	10.0%
Investors participating in the Subscription Agreements	4,163,606	28.3%
Total common stock of the combined company	14,734,323	100%

(1) Shares of common stock of the combined company received by former Tectonic stockholders include 11,448 shares that are subject to vesting conditions, based on 21,422 shares of unvested Tectonic Restricted Stock at Closing multiplied by the Exchange Ratio of 0.53.

The employment agreements for AVROBIO employees included entitlement to change in control payments for certain executives, and severance and retention bonus payments for certain non-executives, the aggregate of which was treated as pre-merger compensation expense of AVROBIO and reflected as an increase to accrued expenses of AVROBIO, which was assumed by the combined company at Closing. Prior to Closing, AVROBIO also discontinued its research and development activities and terminated and/or expired its leases. Additionally, AVROBIO's directors & officers (D&O) insurance policy was fully utilized at Closing.

Private Financing Transactions

Subscription Agreements

Concurrently with the execution of the Merger Agreement, certain parties have entered into certain subscription agreements (the "Subscription Agreements") with Tectonic to purchase, prior to the consummation of the merger, 7,790,889 shares of Tectonic common stock at a purchase price of approximately $12.40 per share for an aggregate purchase price of approximately $96.6 million (the "Private Placement"). The closing of the Private Placement was completed on June 20, 2024, and shares of Tectonic common stock issued pursuant to the Subscription Agreements were converted into 4,163,606 shares of AVROBIO common stock at Closing based on the Exchange Ratio, pursuant to the Merger Agreement.

Company SAFEs

From October to December 2023, Tectonic entered into various simple agreements for future equity (the "Company SAFEs") with existing investors, who are also related parties of Tectonic and received $34.1 million representing the aggregate purchase amount. Tectonic accounts for the Company SAFEs as a liability pursuant to Accounting Standards Codification 480, *Distinguishing Liabilities from Equity.* The Company SAFEs were initially measured at their fair value upon issuance. In addition, until redemption, the Company SAFEs are measured at fair value on a recurring basis with subsequent changes in fair value recorded in the Tectonic's statement of operations and comprehensive loss. Under the terms of the Company SAFEs, in the event of a public listing transaction such as an initial public offering or a reverse merger with a public company, the Company SAFEs will be redeemed through delivery of a variable number of shares of Tectonic common stock determined by dividing the Company SAFEs purchase amount by the offering or conversion price in the respective transaction. In connection with the merger, the principal balance of the Company SAFEs was automatically redeemed into 2,752,216 shares of Tectonic common stock at the conversion price of approximately $12.40 per share immediately prior to the Closing. At Closing, shares of Tectonic common stock issued pursuant to the redemption of the Company SAFEs were converted into 1,470,839 shares of AVROBIO common stock based on the Exchange Ratio, pursuant to the Merger Agreement.

The aggregate proceeds from the Private Financing Transactions (the Subscription Agreements and the Company SAFEs) was approximately $130.7 million.

Contingent Value Rights Agreement

In connection with the merger, AVROBIO and its designated rights agent entered into a Contingent Value Rights Agreement (the "CVR Agreement"). Pursuant to the CVR Agreement, each holder of AVROBIO common stock immediately prior to the effective time, is entitled to receive a contractual contingent value right ("CVR") subject to and in accordance with the terms and conditions of the CVR Agreement, representing the contractual right to receive a pro rata portion of 80% of the net proceeds, if any, as a result of an AVROBIO disposition (including a license of AVROBIO's pre-closing assets as defined in the CVR Agreement) after the Closing and prior to the 18-month anniversary of the Closing, received within a 10-year period following the Closing; provided that no contingent payment will be payable to any holder of the CVRs until such time as the then-outstanding and undistributed proceeds exceeds $0.4 million in the aggregate. The CVRs represent contingent consideration in the merger, however the unaudited pro forma condensed combined financial information does not include the fair value of contingent consideration related to the CVRs as the fair value of the CVRs was determined to be nominal at Closing.

2. Basis of Presentation

The unaudited pro forma condensed combined financial information is prepared in accordance with Article 11 of SEC Regulation S-X. The adjustments presented in the unaudited pro forma condensed combined financial information have been identified and presented to provide relevant information necessary for an understanding of the combined company upon consummation of the merger.

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 following the completion of the merger, and have been made solely for the purpose of providing unaudited pro forma condensed combined financial information. Differences between these preliminary accounting conclusions and estimates and the final accounting conclusions and amounts may occur as a result of, among other reasons: (i) changes in initial assumptions in the determination of the accounting acquirer and related accounting, (ii) changes in the amount of cash used in AVROBIO's operations, and (iii) other changes in AVROBIO's assets and liabilities, which will be completed after the Closing, and these differences could have a material impact on the accompanying unaudited pro forma condensed combined financial information and the combined company's future results of operations and financial position.

3. Accounting Policies

During the preparation of the accompanying unaudited pro forma combined financial information, Management was not aware of any material differences between Tectonic's accounting policies and the accounting policies of AVROBIO. Following the consummation of the merger, Tectonic will conduct a more detailed review of AVROBIO's accounting policies. As a result, Tectonic may identify differences between the accounting policies of the two companies that, when conformed, could have had a material impact on the accompanying unaudited pro forma combined financial information.

4. Accounting for the Merger

The unaudited pro forma condensed combined financial information gives effect to the merger, which is accounted for under U.S. generally accepted accounting principles ("GAAP") as an in-substance reverse recapitalization of AVROBIO by Tectonic. Under this method of accounting, Tectonic is considered the accounting acquirer for financial reporting purposes. This determination is based on an evaluation of the following facts and circumstances immediately following the merger:

- Tectonic stockholders will own a substantial majority of the voting rights in the combined company;
- Tectonic's largest stockholder will retain the largest interest in the combined company;
- Tectonic will designate a majority of the initial members of the board of directors of the combined company;
- Tectonic's executive management team will become the management of the combined company; and
- The combined company will be renamed Tectonic Therapeutic, Inc. and will be headquartered in Massachusetts.

As a result of Tectonic being treated as the accounting acquirer, Tectonic's assets and liabilities are recorded at their pre-combination carrying amounts. AVROBIO's assets and liabilities are measured and recognized at their fair values as of the effective time, which approximates the carrying value of the acquired cash and other non-operating assets, with no goodwill or other intangible assets recorded. The difference between the consideration transferred and the fair value of the net assets of AVROBIO following the determination of the actual consideration transferred for AVROBIO is reflected as an adjustment to additional paid-in capital. For periods prior to Closing, the historical financial statements of Tectonic become the historical financial statements of the combined company.

Preliminary Estimated Consideration Transferred (Purchase Price)

The estimated preliminary purchase price, which represents the consideration transferred to AVROBIO stockholders in the merger, is calculated based on the fair value of the common stock of the combined company that AVROBIO stockholders own as of the Closing of the Transactions because, with no active trading market for shares of Tectonic, the fair value of the AVROBIO common stock represents a more reliable measure of the fair value of consideration transferred in the merger. Accordingly, the accompanying unaudited pro forma combined financial information reflects an estimated preliminary purchase price of approximately $68.4 million. The following summarizes the preliminary estimate of the purchase price to be paid in the merger, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024 (in thousands, except share and per share amounts):

Common shares of the combined company owned by AVROBIO stockholders (1)	3,769,005
Multiplied by the fair value per share of AVROBIO common stock (2)	$ 17.88
Total	$ 67,390
Estimated fair value of assumed AVROBIO stock-based awards based on pre-merger service (3)	1,052
Total estimated purchase price	$ 68,442

(1) The final purchase price was determined based on the number of shares of AVROBIO common stock that AVROBIO stockholders owned immediately prior to Closing. For purposes of this unaudited pro forma condensed combined financial information, the estimated number of shares, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024, represents 3,740,186 shares of AVROBIO common stock outstanding as of March 31, 2024, 3,787 shares of AVROBIO common stock issued subsequent to March 31, 2024 and 25,032 unvested RSUs outstanding as of the Closing which vested in full upon Closing in accordance with the terms of the original awards.

(2) The final purchase price was based on the closing price of AVROBIO common stock on the Nasdaq Global Select Market on June 11, 2024, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024.

(3) Reflects the estimated acquisition-date fair value of the assumed AVROBIO equity awards attributable to pre-merger service that were outstanding as of the effective time. This is included as an adjustment to the unaudited pro forma condensed combined balance sheet by crediting and debiting additional paid-in capital, resulting in no impact to the unaudited pro forma condensed combined financial information.

5. Shares of AVROBIO Common Stock Issued to Tectonic Stockholders upon Closing of the Merger

At Closing, all outstanding shares of Tectonic common stock (including shares of Tectonic common stock issued upon conversion of Tectonic convertible preferred stock and shares of Tectonic common stock issued in connection with the Subscription Agreements and Company SAFEs) were exchanged for shares of AVROBIO common stock based on the Exchange Ratio of 0.53, determined in accordance with the terms of the Merger Agreement and after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024. The number of shares of AVROBIO common stock that AVROBIO expects to issue to Tectonic's stockholders is based on AVROBIO's net cash at Closing of $77.3 million and is determined as follows:

Shares of Tectonic common stock outstanding as of March 31, 2024 (1)	2,637,120
Tectonic stock option exercises subsequent to March 31, 2024	496,182
Shares of Tectonic common stock issued upon conversion of Tectonic convertible preferred stock, see Note 6(d)	6,825,483
Shares of Tectonic common stock issued in connection with the Subscription Agreements, see Note 6(e)	7,790,889
Shares of Tectonic common stock issued upon redemption of the Company SAFEs, see Note 6(f)	2,752,216
Total Tectonic common shares outstanding prior to the closing of the merger	20,501,890
Exchange Ratio	0.53
Shares of AVROBIO common stock issued to Tectonic stockholders upon closing of the merger (2)	10,956,614

(1) Shares of Tectonic common stock outstanding include 21,565 shares of unvested Tectonic Restricted Stock as of March 31, 2024.
(2) Represents the total shares of AVROBIO common stock issued to Tectonic stockholders at Closing, including 11,448 shares of AVROBIO common stock subject to vesting conditions, based on 21,422 shares of unvested Tectonic Restricted Stock at Closing multiplied by the Exchange Ratio of 0.53.

In addition, in connection with the merger, AVROBIO assumes all of the outstanding options to acquire Tectonic common stock and such stock options will become exercisable for shares of AVROBIO common stock following the merger.

6. Adjustments to Unaudited Pro Forma Condensed Combined Balance Sheet as of December 31, 2023

The pro forma notes and adjustments, based on preliminary estimates that could change materially as additional information is obtained, are as follows:

Pro forma notes:

6(A) Derived from the unaudited condensed consolidated balance sheet of AVROBIO as of March 31, 2024.

6(B) Derived from the unaudited condensed consolidated balance sheet of Tectonic as of March 31, 2024.

Pro forma Balance Sheet Transaction Accounting Adjustments:

6(a) To reflect the exercise of 496,182 Tectonic stock options subsequent to March 31, 2024.

6(b) To reflect the exercise of 3,787 AVROBIO stock options subsequent to March 31, 2024, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024.

6(c) To reflect preliminary estimated incremental compensation expense of $3.9 million related to severance, retention bonuses and change in control payments resulting from pre-existing employment agreements or from approval from AVROBIO's board of directors in connection with the merger that had not yet been paid or fully accrued for as of March 31, 2024. As such, the $3.9 million is recorded as an increase in accrued expenses and accumulated deficit in the unaudited pro forma condensed combined balance sheet as of March 31, 2024.

6(d) To reflect the automatic conversion, on a one-to-one basis, of all outstanding shares of Tectonic convertible preferred stock, with a carrying amount of $80.6 million, into 6,825,483 shares of Tectonic common stock immediately prior to the merger. Tectonic convertible preferred stock outstanding immediately prior to the Closing was comprised of the following:

Tectonic Convertible Preferred Stock	
Series A-1	4,118,120
Series A-2	1,649,188
Series A-3	696,516
Series A-4	361,659
Total shares of Tectonic convertible preferred stock converted to shares of Tectonic common stock immediately prior to the merger	6,825,483

6(e) To reflect the issuance of 7,790,889 shares of Tectonic common stock pursuant to the Subscription Agreements entered into concurrently with the execution of the Merger Agreement, for an aggregate purchase price of $96.6 million. The proceeds received in connection with the Subscription Agreements are recorded net of transaction costs deemed to be direct and incremental costs of the equity financing in the amount of approximately $2.0 million. The issuance of shares in connection with the Subscription Agreements are recorded as the issuance of Tectonic common stock at par value, with the remaining amount recorded to additional paid-in-capital.

6(f) To reflect, pursuant to the terms of the Company SAFEs, the automatic redemption of the principal balance of the Company SAFEs of $34.1 million, in the event of a public listing transaction, into 2,752,216 shares of Tectonic common stock at the conversion price of approximately $12.40 per share immediately prior to the closing of the merger, and the change in fair value of the SAFE liabilities of $1.5 million immediately prior to the redemption, which represents the difference between principal balance and the fair value of the Company SAFEs as of March 31, 2024, as an increase to accumulated deficit. The redemption is recorded as the issuance of Tectonic common stock at par value, with the remaining amount recorded to additional paid-in-capital.

6(g) To reflect preliminary estimated transaction costs of $8.7 million incurred by Tectonic in connection with the merger, such as advisory, legal and auditor fees, as an increase in accrued expenses of $5.2 million for transaction costs not yet reflected in the historical financial statements, the derecognition of the deferred offering costs of $3.4 million included in the historical financial statements, and a reduction to additional paid-in capital of $8.7 million in the unaudited pro forma condensed combined balance sheet. As the merger is accounted for as a reverse recapitalization equivalent to the issuance of equity for the net assets, primarily cash, of AVROBIO, these direct and incremental costs are treated as a reduction of the net proceeds received within additional paid-in capital.

6(h) To reflect preliminary estimated transaction costs of $5.2 million, not yet reflected in the historical financial statements, which were incurred by AVROBIO in connection with the merger, such as advisory,

legal and auditor fees and including the estimated $1.8 million cost of a D&O tail policy. The adjustment is reflected in the unaudited pro forma condensed combined balance sheet as a decrease in cash of $1.8 million to reflect payments made subsequent to March 31, 2024, an increase in accrued expenses of $3.4 million and an increase in accumulated deficit of $5.2 million.

6(i) To derecognize $0.5 million of AVROBIO's prepaid expenses consisting of $0.1 million of prepaid research and development expenses related to discontinued research and development activities and $0.4 million of prepaid insurance primarily related to the current AVROBIO's D&O policy that was fully utilized at Closing.

6(j) To reflect the derecognition of AVROBIO's operating leases that were terminated or expired prior to the closing of the merger. The operating lease right-of-use assets of $0.1 million and related operating lease liabilities of $0.2 million, were derecognized, resulting in a $0.1 million gain on termination of lease.

6(k) To reflect the release of $0.7 million of AVROBIO's restricted cash, consisting of cash used to secure letters of credit in connection with AVROBIO's lease agreements and corporate credit card program that was terminated prior to the closing of the merger, to cash and cash equivalents.

6(l) To reflect the acceleration of vesting and net settlement of AVROBIO's RSUs at Closing as the release of 33,736 shares of AVROBIO common stock after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024, at par value, an increase in accrued expenses of $0.4 million representing the number of shares withheld to satisfy tax withholding and remittance obligations for the vested AVROBIO's RSUs based on the closing price of AVROBIO common stock on the Nasdaq Global Select Market on June 11, 2024, and a decrease in additional paid-in capital of $0.4 million.

6(m) To reflect the recapitalization of Tectonic, pursuant to the Merger Agreement, through the contribution of 20,501,890 shares of Tectonic common stock (see Note 5), and the issuance of 10,956,614 shares of AVROBIO common stock, reflecting the Exchange Ratio of 0.53 after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock effected on June 20, 2024, and to reflect the derecognition of the accumulated deficit of AVROBIO which is reversed to additional paid-in capital.

The derecognition of accumulated deficit of AVROBIO of $493.5 million is determined as follows (in thousands):

Accumulated deficit of AVROBIO as of March 31, 2024	$484,083
Compensation expense related to severance, retention bonuses and change in control payments, see Note 6(c)	3,950
Transaction costs of AVROBIO, see Note 6(h)	5,156
Derecognition of prepaid research and development and prepaid insurance, see Note 6(i)	448
Gain on termination of operating leases, see Note 6(j)	(114)
Total adjustment to derecognize the accumulated deficit of AVROBIO	$493,523

7. Adjustments to Unaudited Pro Forma Condensed Combined Statement of Operations

The pro forma notes and adjustments, based on preliminary estimates that could change materially as additional information is obtained, are as follows:

Pro forma notes:

7(A) Derived from the unaudited condensed consolidated statement of operations and comprehensive income (loss) of AVROBIO for the three months ended March 31, 2024.

7(B) Derived from the unaudited condensed consolidated statement of operations and comprehensive loss of Tectonic for the three months ended March 31, 2024.

7(C) Derived from the audited consolidated statement of operations and comprehensive loss of AVROBIO for the year ended December 31, 2023.

7(D) Derived from the audited consolidated statement of operations and comprehensive loss of Tectonic for the year ended December 31, 2023.

Given Tectonic's history of net losses and valuation allowance, management assumed an effective tax rate of 0%. Therefore, the pro forma adjustments to the unaudited pro forma condensed combined statement of operations resulted in no additional income tax adjustment to the unaudited pro forma condensed combined financial information.

Pro forma Statement of Operations Transaction Accounting Adjustments:

7(a) To reflect preliminary estimated incremental compensation expense related to severance, retention bonuses and change in control payments recorded in research and development expenses of $1.3 million and general and administrative expenses of $2.6 million, resulting from pre-existing employment agreements or from approval from AVROBIO's board of directors in connection with the merger that had not yet been paid or fully accrued for as of March 31, 2024 assuming that the adjustment described in Note 6(c) was made on January 1, 2023.

7(b) To reflect AVROBIO's estimated advisory, legal, audit and other costs related to the merger, including the estimated cost of a D&O tail policy, that were not recorded in its historical financial statements as an increase to general and administrative expenses in the unaudited pro forma condensed combined statement of operations for the year ended December 31, 2023 assuming that the adjustment described in Note 6(h) was made on January 1, 2023.

7(c) To reflect the derecognition of AVROBIO's prepaid research and development expenses of $0.1 million related to discontinued research and development activities, and prepaid insurance of $0.4 million primarily related to AVROBIO's D&O policy that was fully utilized at Closing, assuming the adjustment made in Note 6(i) was made on January 1, 2023.

7(d) To eliminate the change in fair value of SAFE liabilities that was included in the historical financial statements, assuming that the principal balance of the Company SAFEs was redeemed for shares of Tectonic common stock on January 1, 2023.

The pro forma adjustment also reflects the change in fair value of SAFE liabilities of $1.5 million immediately prior to the redemption of the Company SAFEs, assuming that the adjustment described in Note 6(f) was made on January 1, 2023.

7(e) To reflect the gain on termination of AVROBIO's operating leases of $0.1 million, relating to AVROBIO's operating leases that were terminated or expired prior to the closing of the merger assuming that the adjustment described in Note 6(j) was made on January 1, 2023.

7(f) The pro forma combined basic and diluted net income (loss) per share have been adjusted to reflect the pro forma net losses for the three months ended March 31, 2024, and the year ended December 31, 2023. 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 at the Closing of the merger, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024. For the three months ended March 31, 2024 and the year ended December 31, 2023, the pro forma weighted average shares outstanding, after giving effect to the aforementioned reverse stock split, has been calculated as follows:

	March 31, 2024	December 31, 2023	
	Basic and Diluted	Basic	Diluted
Historical weighted-average number of Tectonic common shares outstanding	2,608,740	2,373,674	2,373,674
Tectonic stock option exercises subsequent to March 31, 2024, assuming consummation of the merger as of January 1, 2023, see Note 6(a)	496,182	496,182	496,182
Impact of Tectonic convertible preferred stock assuming conversion as of January 1, 2023, see Note 6(d)	6,825,483	6,825,483	6,825,483
Impact of Tectonic private financing transactions assuming consummation of the merger as of January 1, 2023, see Note 6(e) and 6(f)	10,543,105	10,543,105	10,543,105
Total	20,473,510	20,238,444	20,238,444
Application of exchange ratio to historical Tectonic weighted-average shares outstanding	0.53	0.53	0.53
Adjusted Tectonic weighted-average number of common shares outstanding	10,941,453	10,815,829	10,815,829
Historical weighted-average number of AVROBIO common shares outstanding, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock	3,732,568	3,693,933	3,713,993
Shares of AVROBIO common stock issued subsequent to March 31, 2024, assuming consummation of the merger as of January 1, 2023, see Note 6(b)	3,787	3,787	3,787
Equity awards subject to outstanding AVROBIO RSUs that fully vest upon consummation of the merger (1)	33,736	33,736	33,736
Pro forma combined weighted average number of common shares outstanding	14,711,544	14,547,285	14,567,345

(1) Represents the total AVROBIO RSUs outstanding as of the Closing, net of the number of shares withheld to satisfy tax withholding and remittance obligations and after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024, including 25,032 RSUs that vested in full immediately prior to the Closing in accordance with the terms of the original awards and 8,704 RSUs that vested in full as a result of the merger.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited interim consolidated financial statements and the related notes thereto as of March 31, 2024, and for the three months ended March 31, 2024 and 2023, included elsewhere in this prospectus and our audited consolidated financial statements as of and for the fiscal year ended December 31, 2024 and the related notes appearing elsewhere or incorporated by reference in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those described in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this prospectus.

Unless otherwise indicated or the context otherwise requires, references in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" section to "the Company," "we," "us," and "our" refer to the business and operations of Tectonic Operating Company, Inc. (previously Tectonic Therapeutic, Inc., referred to as "Legacy Tectonic") and its consolidated subsidiaries prior to the Merger, and the business and operations of Tectonic Therapeutic, Inc. (previously AVROBIO, Inc., referred to as "AVROBIO") and its consolidated subsidiaries following the Merger.

Overview

We are a biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of GPCRs. The discovery of biologics that can modulate GPCRs has historically been quite challenging. We have developed a proprietary technology platform called GEODe™, with the aim of addressing these challenges to enable the discovery and development of GPCR-targeted biologic medicines that can modify the course of disease. We focus on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality or extend duration of life.

GPCRs are receptor molecules found on the surface of cells that act as sensors for various extracellular stimuli to enable communication between cells and their environment. These molecules regulate diverse aspects of human biology including blood pressure, glucose metabolism, transmission between neurons and immune surveillance. There are over 800 human genes encoding GPCRs, underscoring the extent to which nature has relied on this molecular system for physiological control. The breadth of effects controlled by GPCRs is best illustrated by the fact that greater than 30% of all approved drugs address targets in this class. The vast majority of these drugs, however, are small molecules, and their targets have been largely confined to a few GPCR subfamilies, many of which have a natural ligand that is also a small molecule. We believe there are many situations where biologics could present advantages over small molecules for this class of targets. For instance, when targeting a single member of a highly related family of GPCRs, the selectivity profile achievable with an antibody may be preferable to that of a small molecule to optimize therapeutic efficacy and safety for the patient. Conversely, when multi-modal action is needed to achieve a desired physiological effect, proteins engineered for bispecific function allow for dual target engagement, unlike small molecules that are generally optimized for action on a single target. We are focused on developing biologics to address GPCRs with the goal of capturing such opportunities.

It has been historically difficult, however, to discover therapeutic proteins and antibodies that bind to and modulate the activity of GPCRs because of the low endogenous level of expression of many GPCRs, complex biochemistry and their inherent instability when removed from their natural environment, the cell membrane. With the goal of unlocking the potential for biologic therapeutics to broaden the clinical utility of GPCRs, we use our proprietary GEODe™ technology platform in an attempt to overcome the known challenges of GPCR-targeted drug discovery.

Our lead asset, TX45, is an Fc-relaxin fusion molecule that activates the RXFP1 receptor, the GPCR target of the hormone, relaxin. Relaxin is an endogenous protein, expressed at low levels in both men and women. In normal human physiology, relaxin is upregulated during pregnancy where it exerts vasodilative effects, reduces systemic and pulmonary vascular resistance and increases cardiac output to accommodate the increased demand for oxygen and nutrients from the developing fetus. Relaxin also exerts anti-fibrotic effects on pelvic ligaments to facilitate delivery of the baby. It has long been hypothesized that these unique dual aspects of relaxin biology may offer therapeutic potential in the treatment of cardiovascular disease. Unfortunately, the development of a viable therapeutic has been challenging, primarily because of relaxin's very short half-life. We believe TX45's pharmacological profile, the direct result of applying our protein engineering capabilities, has the potential to overcome the limitations that have impeded previous attempts to develop relaxin as a therapeutic protein. To interrogate the therapeutic potential of relaxin, we have identified: Group 2 Pulmonary Hypertension ("PH") in the setting of Heart Failure with Preserved Ejection Fraction ("HFpEF"), referred to as Group 2 PH / HFpEF hereafter, as the initial disease setting. We hypothesize that in this setting, treatment with relaxin could improve hemodynamics through effects on pulmonary and systemic vasodilation, cardiac diastolic remodeling and potential remodeling in both the pulmonary vessels and the heart which could translate into a clinically meaningful improvement in exercise capacity in these patients. Clinical trials are planned to confirm this hypothesis. Despite this belief, our business carries substantial risks, including our limited experience in therapeutic discovery and development, and the risk that the platform may never result in the regulatory approval of a product candidate.

Since our inception in 2019, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. Our operations have been funded primarily with proceeds from sales of Legacy Tectonic's Series A-1, A-2, A-3, and A-4 convertible preferred stock (collectively, the "Preferred Stock"), proceeds from the issuance of common stock, proceeds from issuance of convertible promissory notes, which were all converted to convertible preferred stock in March 2021 and proceeds from issuance of Simple Agreements for Future Equity ("SAFEs") in October and December 2023. From our inception through March 31, 2024, we received $114.7 million in capital contributions from sales of Preferred Stock, issuance of convertible promissory notes, and proceeds from issuance of SAFEs. As of March 31, 2024, we had $18.7 million in cash and cash equivalents. Upon the consummation of the transactions contemplated by that certain Agreement and Plan of Merger and Reorganization (the "Merger Agreement") dated January 30, 2024 by and among AVROBIO, Inc. ("AVROBIO"), Alpine Merger Subsidiary, Inc. and Tectonic Operating Company, Inc. on June 20, 2024 (the "Merger"), we received $77.3 million in cash proceeds from AVROBIO, and $96.6 million in proceeds related to the sale of shares to investors pursuant to that certain subscription agreement dated January 30, 2024 among Legacy Tectonic and certain investors (the "Subscription Agreement").

We do not have any product candidates approved for sale and have not generated any revenue from product sales. Since our inception, we have incurred significant operating losses. Our net losses were $15.2 million and $14.4 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $105.8 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue our ongoing and planned research and development of our lead product candidate TX45 and our other product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and eventual potential commercialization;

- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other product candidates and technologies;
- hire additional clinical, quality control and manufacturing personnel;
- add discovery, clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our internal commercialization capability to support product sales, marketing and distribution. Further, we will continue to incur additional costs associated with operating as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings, debt financings or other capital sources, which may include collaborations with other companies, marketing, distribution or licensing arrangements with third parties, or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate our product discovery and development programs or commercialization efforts.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or is unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Recent Developments

Merger with AVROBIO

On January 30, 2024, Legacy Tectonic entered into the Merger Agreement with AVROBIO and Merger Sub. Pursuant to the Merger Agreement, on June 20, 2024, Merger Sub merged with and into Legacy Tectonic, with Legacy Tectonic surviving as a wholly owned subsidiary of AVROBIO.

Subject to the terms and conditions of the Merger Agreement, at the effective time, (a) each outstanding share of Legacy Tectonic common stock (including shares of Legacy Tectonic common stock issued upon conversion of its preferred stock and the shares issued pursuant to the Subscription Agreement and conversion of the SAFEs) was converted into the right to receive a number of shares of AVROBIO common stock equal to the exchange ratio; and (b) each then outstanding Legacy Tectonic stock option that was outstanding and unexercised immediately prior to the effective time was assumed by AVROBIO, subject to the exchange ratio.

Immediately after the Merger, AVROBIO securityholders as of immediately prior to the Merger owned approximately 24.8% of the outstanding shares of capital stock of the Company on a diluted basis. Immediately

after the Merger, Legacy Tectonic securityholders owned approximately 38.5% of the outstanding shares of capital stock of the Company on a diluted basis. Investors participating in the Subscription Agreement and the SAFEs owned approximately 27.1% and 9.6% of the outstanding shares of capital stock of the Company, respectively, on a diluted basis.

Legacy Tectonic stockholders received approximately 10,956,614 shares of AVROBIO common stock in connection with the Merger, including 11,448 shares of AVROBIO common stock subject to vesting terms, based on the number of shares of Legacy Tectonic common stock outstanding immediately prior to the Merger, including Legacy Tectonic restricted stock, the number of shares of Legacy Tectonic common stock issued to investors participating in the Subscription Agreement and SAFEs, and Legacy Tectonic convertible preferred stock outstanding immediately prior to the Merger, which was converted into shares of Legacy Tectonic common stock on a one-for-one basis immediately prior to the closing of the Merger.

Concurrently with the closing of the Merger, on June 20, 2024, certain investors completed the purchase of shares of Legacy Tectonic common stock pursuant to the Subscription Agreement at a price of approximately $12.40 per share, for an aggregate purchase price of approximately $96.6 million. The shares of Legacy Tectonic common stock that were issued pursuant to the Subscription Agreement were converted into 4,163,606 shares of the Company's common stock upon the closing of the Merger based on the exchange ratio, pursuant to the Merger Agreement.

Following the closing of the Merger, Legacy Tectonic was considered the accounting acquirer for financial reporting purposes and we are accounting for the Merger as an in-substance reverse recapitalization of AVROBIO by Tectonic. See " *Unaudited Pro Forma Condensed Combined Financial Information*" included elsewhere in this prospectus.

Macroeconomic Considerations

Uncertainty in the global economy presents significant risks to our business. We are subject to continuing risks and uncertainties in connection with the current macroeconomic environment, including rising interest rates, recent bank failures and geopolitical factors, such as tensions involving China and the United States, the war between Russia and Ukraine and the conflict in the Middle East and the responses thereto. While we are closely monitoring the impact of the current macroeconomic conditions on all aspects of its business, including the impacts on our participants in our clinical trials, employees, suppliers, vendors and collaboration partners, the ultimate extent of the impact on our business remains highly uncertain and will depend on future developments and factors that continue to evolve. Most of these developments and factors are outside our control and could exist for an extended period of time. We will continue to evaluate the nature and extent of the potential impacts to our business, results of operations, liquidity and capital resources.

Revenue

We have not generated any revenue since our inception and we do not expect to generate any revenue from the sale of products in the foreseeable future, if at all. If our development efforts for our product candidates are successful and result in regulatory approval, or in collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements that we may enter into with third parties, or any combination thereof. We cannot predict if, when or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of its product candidates.

Operating Expenses

Research and Development

Research and development expenses consist of costs incurred for our research activities, including our discovery efforts and the development of its programs and platform. These expenses include:

- employee-related expenses, including salaries, related benefits and share-based compensation expense, for employees engaged in research and development functions;
- expenses incurred in connection with research and the preclinical and clinical development of our programs and our product candidates, including under agreements with third parties;
- laboratory supplies, consumables and other research materials;
- facilities, depreciation and other expenses related to research and development activities, which include direct or allocated expenses for rent and maintenance of facilities, and utilities;
- costs related to compliance with regulatory requirements; and
- payments made under third-party licensing agreements.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on our evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers. 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 amounts are recognized as an expense when the goods have been delivered or the services have been performed, or when it is no longer expected that the goods will be delivered or the services rendered. Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license or collaboration agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Our direct research and development expenses related to the development of our lead product candidate, TX45, as well as the nonclinical safety pharmacology and toxicology testing of our product candidates. Our external services expenses consist of the external costs and fees paid to consultants and other research laboratories in connection with our preclinical development and clinical development activities.

Costs that are deployed across multiple of our programs, including the HHT program and programs aimed at the discovery and development of potential therapies for fibrotic disease, and our platform technology and are not directly attributable to any single program are not allocated to any single program and, as such, are not separately classified. These costs include multi-program employee costs, cross-program payments made under third-party licensing agreements, costs of laboratory supplies and facilities expenses, including rent, depreciation and other indirect costs, the costs of our discovery efforts and projects are included in unallocated employee-related expenses, laboratory supplies and other expenses.

General and Administrative

General and administrative expenses consist primarily of salaries and personnel-related costs, including share-based compensation, for our personnel in executive, legal, finance and accounting, human resources and other administrative functions. General and administrative expenses also include legal fees relating to patents and corporate matters, professional fees paid for accounting, auditing, consulting and tax service, insurance costs, travel expenses, office and information technology costs and facilities, depreciation and other expenses related to general and administrative activities, which include direct or allocated expenses for rent and maintenance of facilities and utilities.

We anticipate that our general and administrative expenses will increase in the future as the we are expected to incur significantly increased accounting, audit, legal, regulatory, compliance, director and officer insurance, and investor and public relations expenses associated with operating as a public company. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense), Net

Loss on Issuance of SAFEs and Change in Fair Value of SAFE Liabilities

In October and December 2023, Legacy Tectonic issued SAFEs for proceeds of $34.1 million. The SAFEs were recorded as liabilities in the consolidated balance sheet at their fair value on the issuance dates. Until redemption, the SAFEs were measured at a fair value on a recurring basis, with subsequent changes in fair value recorded in other income and expenses on the consolidated statement of operations and comprehensive loss. Legacy Tectonic recorded a loss of $2.1 million resulting from the remeasurement of the SAFEs to fair value from December 31, 2023 to March 31, 2024.

Immediately prior to the closing of the Merger, the principal balance of the SAFEs was automatically redeemed into 2,752,216 shares of Legacy Tectonic's common stock at the conversion price of approximately $12.40 per share. At the closing of the Merger, shares of Legacy Tectonic common stock issued pursuant to the redemption of the SAFEs were converted into 1,470,839 shares of the Company's common stock based on the exchange ratio, pursuant to the Merger Agreement.

Interest Income

Interest income primarily consists of interest earned on our invested cash balances, which consist of deposit accounts and a sweep account.

Interest Expense

Interest expense primarily consists of interest expense on finance lease liabilities.

Other Income (Expense), net

Other income (expense), net primarily consists of the difference between transactional currency and functional currency.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses incurred or for the research and development tax credits earned in each year by our operations in the United States, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credit carryforwards will not be realized.

Components of Results of Operations

Comparison of the Three Months Ended March 31, 2024 and 2023

The following table summarizes our results of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,			
	2024	2023	Change	%
	(in thousands)			
Operating expenses:				
Research and development	$ 10,818	$ 12,985	$(2,167)	(17)%
General and administrative	2,150	1,546	604	39
Total operating expenses	12,968	14,531	(1,563)	(11)
Loss from operations	(12,968)	(14,531)	1,563	(11)
Other income (expense), net:				
Change in fair value of the SAFE liabilities	(2,075)	—	(2,075)	100
Interest income	256	128	128	100
Interest expense	(31)	(42)	11	(26)
Other expense	(403)	—	(403)	— %
Total other (expense) income, net	(2,253)	86	(2,339)	(2,720)
Net loss	$(15,221)	$(14,445)	$ (776)	5

Operating Expenses

Research and Development Expenses

Direct research and development expenses by program:

	Three Months Ended March 31,			
	2024	2023	Change	%
	(in thousands)			
Direct research and development expenses by program:				
TX45	$ 5,710	$ 8,655	(2,945)	(34)%
Platform development, early-stage research and unallocated expenses:				
Personnel related (including share-based compensation)	3,203	2,853	350	12
External services	784	273	511	187
Facility, supplies and other	1,121	1,204	(83)	(7)
Total research and development expenses	$10,818	$12,985	$(2,167)	(17)%

Research and development expenses were $10.8 million for the three months ended March 31, 2024, as compared to $13.0 million for the three months ended March 31, 2023. The decrease of $2.2 million was primarily due to a decrease of $2.9 million in direct research and development expenses which were specifically attributed to our lead product candidate, TX45. This decrease resulted from a reduction of $5.2 million in direct research and development expenses which were specifically attributed to the end of a development and manufacturing services contract term with a major customer, partially offset by an increase of $2.3 million in clinical trial CRO costs. The increase of $0.4 million in personnel related costs was primarily due to severance and related costs incurred as a result of a reduction in force that occurred during the three months ended March 31, 2024. The increase of $0.5 million in external services was primarily due to an increase in consulting and

professional services to support the ongoing development activities. The decrease of less than $0.1 million in facility, supplies and other expenses was primarily due to decreased travel costs and laboratory service and equipment purchases.

General and Administrative Expenses

	Three Months Ended March 31,			
	2024	2023	Change	%
	(in thousands)			
Personnel related (including share-based compensation)	$1,246	$1,015	$ 231	23%
Professional and consultant fees	582	375	207	55
Facility related and other	322	156	166	106
Total general and administrative expenses	$2,150	$1,546	$ 604	39%

General and administrative expenses were $2.2 million for the three months ended March 31, 2024 as compared to $1.5 million for the three months ended March 31, 2023. The increase of $0.6 million resulted from an increase of $0.2 million in personnel related costs and was primarily due to severance and costs incurred as a result of a reduction in force that occurred during the three months ended March 31, 2024. The increase of $0.2 million in professional and consultant fees was related to an increase in consulting and professional services fees to support Merger related activities during the three months ended March 31, 2024. The increase of $0.2 million in facility related costs and other expenses was due to increased office and insurance costs.

Other Income (Expense), Net

Change in Fair Value of SAFE Liabilities

The SAFE liabilities loss of $2.1 million resulted from the remeasurement of the SAFE liabilities to fair value from December 31, 2023 to March 31, 2024.

Interest Income

Interest income increased by $0.1 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 due to an increase in interest rates in 2023.

Interest Expense

Interest expense was consistent for the three months ended March 31, 2024 and 2023.

Other Expense

Other expense increased by $0.4 million for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 due to the reversal of an Australian research and development tax credit claim during the three months ended March 31, 2024.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our

research programs and product candidates. We expect that our research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials for our current and future research programs and product candidates, contracting with CMOs to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and we have never generated any revenue from product sales. Historically, we have funded our operations primarily through proceeds from sales of Preferred Stock and common stock, proceeds from issuance of convertible promissory notes, and proceeds from issuance of SAFEs. From inception through March 31, 2024, we had received $114.7 million in capital contributions from sales of Preferred Stock and convertible promissory notes and proceeds from issuance of SAFEs. As of March 31, 2024, we had $18.7 million in cash and cash equivalents and an accumulated deficit of $105.8 million.

Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (9,273)	$(10,815)
Net cash used in investing activities	(4)	(136)
Net cash used in financing activities	(668)	(143)
Effect of exchange rate changes on cash and cash equivalents	(76)	—
Net decrease in cash, cash equivalents and restricted cash	$ (10,021)	$(11,094)

Operating Activities

During the three months ended March 31, 2024, operating activities used $9.3 million of cash, primarily resulting from a net loss of $15.2 million, offset by changes in our operating assets and liabilities of $2.9 million and non-cash charges of $3.1 million. Non-cash charges primarily consisted of $2.1 million change in fair value of the SAFE liabilities, $0.4 million in depreciation and amortization expense, $0.3 million in stock-based compensation expense, and $0.3 million in non-cash lease expense. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $1.5 million increase in accounts payable, a $1.4 million increase in accrued expenses and other current liabilities, and a $0.3 million decrease in prepaid expenses and other current assets, partially offset by a $0.3 million decrease in operating lease liabilities. The increase in accrued expenses and other current liabilities and accounts payable was primarily due to the timing of vendor and research partner payments and invoicing. The decrease in prepaid and other current assets was due to a reassessment of the tax benefit amount related to Australia. The decrease in operating lease liabilities was primarily due to the lease payments made during the three months ended March 31, 2024.

During the three months ended March 31, 2023, operating activities used $10.8 million of cash, primarily resulting from a net loss of $14.4 million, offset by non-cash charges of $1.0 million and changes in our operating assets and liabilities of $2.7 million. Non-cash charges primarily consisted of $0.4 million in depreciation and amortization expense, $0.3 million in stock-based compensation expense, and $0.3 million in non-cash lease expense. Net cash provided by changes in our operating assets and liabilities consisted primarily

of a $2.3 million increase in accrued expenses and other current liabilities and a $1.0 million increase in accounts payable, partially offset by a $0.3 million increase in prepaid expenses and other current assets and a $0.3 million decrease in operating lease liabilities. The increase in accrued expenses and other current liabilities and increase in accounts payable were primarily due to the timing of vendor and research partner payments and invoicing. The increase in prepaid expenses and other current assets is due to prepayments of material costs and insurance and license fees. The decrease in operating lease liabilities was primarily due to the lease payments made during the three months ended March 31, 2023.

Investing Activities

During the three months ended March 31, 2024 and 2023, net cash used in investing activities was less than $0.1 million and $0.1 million, respectively. The change in net cash used in investing activities during the three months ended March 31, 2024 and 2023 was due to purchases of property, equipment, and improvements.

Financing Activities

During the three months ended March 31, 2024 and 2023, net cash used in financing activities was $0.7 million and $0.1 million, respectively. Net cash used in financing activities during the three months ended March 31, 2024 was primarily due to our payments of deferred offering costs of $0.6 million and $0.1 million of repayment of finance lease obligations. Net cash used in financing activities during the three months ended March 31, 2023 was primarily due to $0.1 million of repayment of finance lease obligations.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates including our lead product candidate TX45. In addition, if we obtain marketing approval for TX45 or any of our other product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with its continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents, together with the net proceeds from the Merger and the sale of securities pursuant to the Subscription Agreement, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidate;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under the license agreements and any other collaboration agreements we enter into;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of operating as a publicly traded company; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- the macroeconomic environment, including inflation and interest rates.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve its business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue st+reams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market itself.

We expect to incur additional costs associated with operating as a public company. In addition, we anticipate that we will need substantial additional funding in connection with our continuing operations. Our projections of operating capital requirements are based on our current operating plan, which includes several assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our lease obligations.

Going Concern

Legacy Tectonic evaluated certain adverse conditions and events that raised substantial doubt about its ability to continue as a going concern within twelve months after the date that the accompanying unaudited condensed consolidated financial statements were issued. Legacy Tectonic funded its operations primarily with proceeds from the sale of common stock, preferred stock, issuance of convertible promissory notes, issuance of SAFEs. Legacy Tectonic also incurred significant recurring losses, including net losses of $15.2 million and $14.4 million for the three months ended March 31, 2024 and 2023, respectively. In addition, Legacy Tectonic used $9.3 million and $10.8 million in operations for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, Legacy Tectonic had an accumulated deficit of $105.8 million. In June 2024, the Merger was completed and we received $77.3 million of cash from AVROBIO and $96.6 million from the issuance of common stock pursuant to the Subscription Agreement. Our management believes that our current cash on hand, along with the cash received in connection with the closing of the Merger, is sufficient to fund our planned operations for at least one year from the date of issuance of the unaudited condensed consolidated financial statements included elsewhere in this prospectus.

Contractual Obligations & Commitments

Leases

The following presents our lease commitments as of March 31, 2024:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Finance Leases	$ 434	$ 915	$ 44	$ —	$1,393
Operating Leases	1,154	1,712	—	—	2,866
Total	$ 1,588	$ 2,627	$ 44	$ —	$4,259

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. The table does not include obligations under agreements that we can cancel without a significant penalty.

Harvard Agreement

In July 2020, Legacy Tectonic entered into an option agreement with the President and Fellows of Harvard College ("Harvard") and obtained an option to negotiate a license under Harvard's interest in certain patent rights (the "Patent Rights") in exchange for an option fee in the low five digits. In October 2021, Legacy Tectonic exercised the option and in February 2022 it entered into a license agreement with Harvard (the "Harvard License Agreement") to conduct research and development activities using certain materials, technology and patent rights owned by Harvard, with the intent to develop, obtain regulatory approval for, and commercialize products. The Harvard License Agreement expires upon the later of: (i) the expiry of the last valid claim within the licensed patent rights, expected to be not earlier than May 2041; and (ii) the earlier of (a) ten years after the first commercial sale of the first know-how enabled product or (b) twelve years after the first commercial sale of the first licensed product.

As partial consideration for the Harvard License Agreement, Legacy Tectonic agreed to pay Harvard a one-time license fee of $170,000, with such fee to be paid in equal installments over three years. In July 2022, Legacy Tectonic paid Harvard $56,666 and in July 2023 Tectonic paid Harvard $56,667. The final installment of $56,667 under the Harvard License Agreement is due in July 2024. As partial consideration for the Harvard License Agreement, Legacy Tectonic entered into a subscription agreement with Harvard in July 2022, pursuant to which Harvard was granted 227,486 shares of common stock of the Company with a fair market value in the mid six digits.

We are required to pay an annual maintenance fee ranging from the low five digits to the low six digits until the first commercial sale of a royalty-bearing product, following which the annual maintenance fee will increase to a low six digits for the remainder of the term of the Harvard License Agreement. We are required to pay a one-time milestone payment of $100,000 for each discovered product granted FDA marketing authorization as well as for the first licensed product or know-how enabled product to reach certain clinical developmental milestones, up to $8.5 million and for the first licensed product or know-how enabled product to reach certain commercial milestones, up to $2.0 million. We are also obligated to pay tiered royalties as a percentage in the low single digits on net sales of licensed products, as a percentage in the low single digits on the net sales of know-how enabled products and a single royalty as a percentage in the low single digits on the net sales of discovered products, subject to a reduction for third-party licenses, as well as a percentage between 10-20% of non-royalty income we receive in connection with a sublicense, strategic partnership or know-how enabled license. With respect to any net sales of licensed products and know-how enabled products sold in certain countries outside of the United States and Europe, we and Harvard will negotiate a royalty percentage on a country-by-country basis.

For a more detailed description of this agreement, see Note 6 to the interim condensed consolidated Tectonic financial statements included elsewhere in this prospectus.

Alloy Therapeutics License Agreement

On November 29, 2021, Legacy Tectonic executed a license agreement with Alloy Therapeutics, LLC ("ATX"), whereby Legacy Tectonic would use ATX technology for the purpose of preclinical development, clinical development and commercialization of potential product candidates, for an initial period of three years, with the option to extend the term for an additional two years. We will pay ATX a non-refundable and non-creditable annual fee of $0.1 million on each anniversary of the agreement. On November 7, 2022, Legacy Tectonic and ATX amended the agreement and extended the period of payment for the first fee due in May 2023. Additionally, we will be responsible for annual partnering fees if we decide to pursue clinical development of a product candidate using the ATX technology. The partnering fees may be creditable against future milestone development fees paid by us. We will also be responsible to pay ATX development milestone payments for the movement of certain product candidates thought clinical trials, which range from the low six digits to the low seven digits upon completion of each milestone and amount to $4.8 million in total milestone payments under the license agreement. Provided we are able to commercialize a product using ATX technology, we will be responsible to pay ATX commercial payments in the low seven digits per year during the first six years of commercial sales, amounting to an amount in the high eight digits in total commercial payments under the license agreement.

During the three months ended March 31, 2024 and 2023, Legacy Tectonic paid $0.1 million and $0 to ATX, respectively.

Adimab Agreement

On May 1, 2023, Legacy Tectonic entered into a discovery agreement with Adimab, LLC ("Adimab"), an antibody discovery company, whereby we and Adimab are collaborating on human antibody discovery in accordance with an agreed upon research program. Legacy Tectonic paid an upfront technology access fee totaling $20,000 upon execution of the agreement during the year ended December 31, 2023. We also will be responsible for payment of: (1) quarterly funding equal to 100% of the actual full-time employee ("FTE") expended by Adimab in the performance of its obligations in accordance with the agreed upon research program at an annual rate of $0.4 million per FTE (subject to annual consumer price index increases) per the agreement, (2) delivery fees equal to $0.1 million upon both Adimab's initial delivery of sequences or physical materials and completion pursuant to the research program (initial and completion fees payable once per target for a total of up to $0.4 million), (3) the option, with a non-creditable, non-refundable option exercise fee of $0.5 million, to obtain the licenses and assignments for information discovered during the research program (4) development milestone payments for the movement of certain product candidates thought clinical trials, which range in the low seven digits and (5) royalty payments based on the annual net sales that we generate from products that utilize Adimab technology. We have the right to terminate the agreement if certain criteria are met. During the three months ended March 31, 2024 and 2023, Legacy Tectonic paid $0.1 million and $0 to Adimab, respectively.

Critical Accounting Estimates

Our management's discussion and analysis of its financial condition and results of operations is based on Legacy Tectonic's interim condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these interim condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities at the date of the interim condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. We base our estimates on historical experience, known trends and events, and various other assumptions

that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities recorded expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates.

While our significant accounting policies are described in greater detail in Note 2 to our audited annual consolidated financial statements, we believe that the following accounting policies are those most critical to the judgements and estimates used in the preparation of our interim condensed consolidated financial statements.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our interim condensed consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our prepaid and accrued research and development expenses as of each balance sheet date in the interim condensed consolidated financial statements based on facts and circumstances known to us at that time, which includes corroboration of these estimates with the service providers. Estimated research and development expenses include those related to fees paid to vendors in connection with clinical, discovery and preclinical development activities and any research organizations in connection with clinical and preclinical studies and testing. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in changes in estimates reported in the current period. To date, there have not been any material adjustments to our prior estimates of prepaid and accrued research and development expenses.

Valuation of SAFE Liabilities

We account for the SAFEs as liabilities at fair value and adjusts the liabilities to fair value at each period end date until a triggering event occurs that results in the settlement of the liabilities. Triggering events include an equity financing, public listing transaction, change of control and dissolution. Changes in the liabilities' fair values are recognized in the Company's statement of operations and comprehensive loss in change in fair value of SAFE liabilities. The fair value of the SAFEs has been estimated using probability-weighted scenario analyses and discount rates derived by application of the build-up method to reflect the cost of equity.

The valuations of the SAFE liabilities as of March 31, 2024 and December 31, 2023 were determined based on a probability-weighted scenario analysis that assumed the probabilities of the occurrence of an equity financing, public listing transaction and dissolution to be 10.0%, 87.5% and 2.5% respectively. The estimated time to redemption used in the March 31, 2024 valuation was two months for an equity financing and dissolution and one month for a public listing transaction. The estimated time to redemption used in the December 31, 2023 valuation was five months for an equity financing and dissolution and four months for a public listing transaction. The valuations used a discount rate of 30.2% to approximate the cost of equity, which was derived from application of a build-up method that incorporated the risk-free rate at the valuation date, and adjustments to reflect market risk, a small stock premium, and a selected company-specific risk premium.

Share-Based Compensation

We measure stock options granted to employees and non-employees based on their fair value on the date of the grant using the Black-Scholes-Merton ("BSM") option pricing model. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award for employees. Compensation expense for awards to non-employee with service-based vesting conditions

is recognized in the same manner as if Tectonic had paid cash in exchange for the goods or services, which is generally the over the vesting period of the award. We use the straight-line method to recognize the expense of awards with service-based vesting conditions. We account for forfeitures of stock options as they occur.

The BSM requires the use of assumptions to determine the fair value of the stock options. The determination of fair value of our common stock is described below. Other assumptions used in the BSM, the volatility of our common stock, the expected term of our common stock, the risk-free interest rate for a period that approximates the expected term of our common stock and our expected dividend yield, are determined by our management.

Determination of Fair Value of Common Stock

As there was no public market for Legacy Tectonic common stock prior to the closing of the Merger, the estimated fair value of Legacy Tectonic common stock was historically determined by the Legacy Tectonic Board as of the date of grant of each stock options, with input from management, considering its most recently available third-party valuations of its common stock and the Legacy Tectonic Board's assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through 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 and were prepared using the option pricing model ("OPM"). OPM uses option theory to value the various classes of Legacy Tectonic's securities in light of their respective claims to the enterprise value. Total shareholders' deficit value is allocated to the various share classes based upon their respective claims on a series of call options with strike prices at various value levels depending upon the rights and preferences of each class. A BSM is typically employed in this analysis, with an option term assumption that is consistent with our expected time to a liquidity event and a volatility assumption based on the estimated stock price volatility of a peer group of comparable public companies over a similar term. In addition to considering the results of these third-party valuations, the Legacy Tectonic Board considered various objective and subjective factors to determine the fair value of Legacy Tectonic's common stock as of each grant date.

The assumptions underlying these valuations represented our management's best estimates, which involved inherent uncertainties and the application of our management's judgment. As a result, if we had used significantly different assumptions or estimates, our share-based compensation expense could have been materially different. Now that the Merger is completed and there is a public trading market for our common stock, it is not necessary for the Board to estimate the fair value of our common stock in connection with accounting for granted stock options or other such awards we may grant, as the fair value of our common stock and stock options will be determined based on the quoted market price of our common stock.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our interim condensed consolidated financial statements included elsewhere in this prospectus.

Qualitative and Quantitative Disclosures about Market Risk

Interest Rate Risk

Our primary exposure to market risk is to market risk related to interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of March 31, 2024, we had cash and cash equivalents of $18.7 million, which consisted of cash and money market funds. As of March 31, 2024, we had a finance lease liability and an operating lease liability of $1.2 million and $2.7 million, respectively. In October 2023 and December 2023, we issued SAFEs to certain of our investors, and we received proceeds of $10.1 million from

the October issuance and $24.0 million from the December issuance. Interest income and expenses are sensitive to changes in the general level of interest rates. However, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of our investment portfolio.

Inflation Risk

Our results of operations and financial condition are presented based on historical cost. While it is difficult to accurately measure the impact of inflation due to the imprecise nature of the estimates required, we believe the effects of inflation, if any, on our results of operations and financial condition have been immaterial. We cannot assure you our business will not be affected in the future by inflation.

BUSINESS

On June 20, 2024, we completed the previously announced business combination with Legacy Tectonic in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Legacy Tectonic, with Legacy Tectonic surviving as our wholly owned subsidiary (such business combination, the Merger). In connection with the completion of the Merger, we changed our name from "AVROBIO, Inc." to "Tectonic Therapeutic, Inc.," and our business became primarily the business conducted by Legacy Tectonic. We are now a clinical stage biotechnology company focused on developing novel GPCR-targeted biologics to effectively and safely treat patients with serious medical conditions where there are currently limited or no medical options. 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, or the Code.

As used in this Business Section, the words "Company," "we," "our," "us" and "Tectonic" refer, collectively to Tectonic Therapeutic, Inc. and its consolidated subsidiaries following completion of the Merger.

Overview

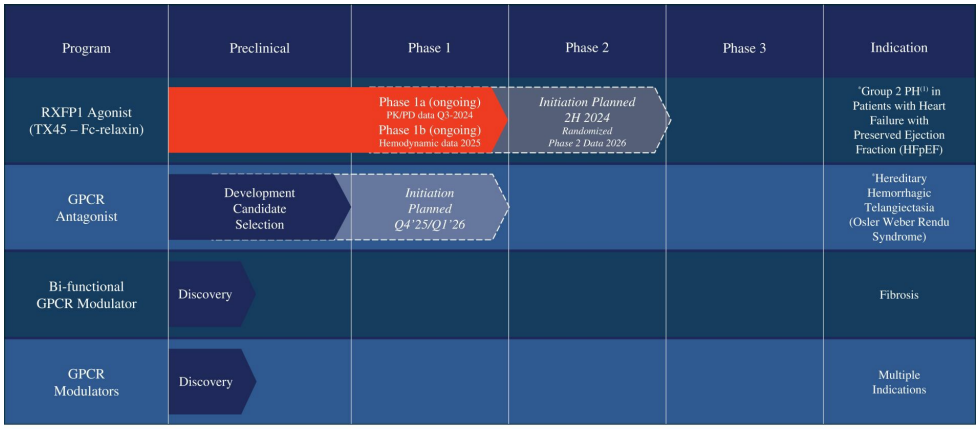
We are a biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of GPCRs. The discovery of biologics that can modulate GPCRs has historically been quite challenging. We have developed a proprietary technology platform called GEODe™, with the aim of addressing these challenges to enable the discovery and development of GPCR-targeted biologic medicines that can modify the course of disease. We focus on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality of life or extend duration of life.

GPCRs are receptor molecules found on the surface of cells that act as sensors for various extracellular stimuli to enable communication between cells and their environment. These molecules regulate diverse aspects of human biology including blood pressure, glucose metabolism, transmission between neurons and immune surveillance. There are over 800 human genes encoding GPCRs, underscoring the extent to which nature has relied on this molecular system for physiological control. The breadth of effects controlled by GPCRs is best illustrated by the fact that greater than 30% of all approved drugs address targets in this class. The vast majority of these drugs, however, are small molecules, and their targets have been largely confined to a few GPCR subfamilies, many of which have a natural ligand that is also a small molecule. We believe there are many situations where biologics could present advantages over small molecules for this class of targets. For instance, when targeting a single member of a highly related family of GPCRs, the selectivity profile achievable with an antibody may be preferable to that of a small molecule to optimize therapeutic efficacy and safety for the patient. Conversely, when multi-modal action is needed to achieve a desired physiological effect, proteins engineered for bispecific function allow for dual target engagement, unlike small molecules that are generally optimized for action on a single target. We are focused on developing biologics to address GPCRs with the goal of capturing such opportunities.

It has been historically difficult, however, to discover therapeutic proteins and antibodies that bind to and modulate the activity of GPCRs because of the low endogenous level of expression of many GPCRs, complex biochemistry and their inherent instability when removed from their natural environment, the cell membrane. To unlock the potential for biologic therapeutics to broaden the clinical utility of GPCRs, we use our proprietary GEODe™ technology platform in an attempt to overcome the known challenges of GPCR-targeted drug discovery. The initial platform components, first generation yeast library design and initial yeast selection protocols, were developed in Andrew Kruse's laboratory at Harvard Medical School. However, over the last few years we have made many improvements and modifications to all aspect of the platform including second and third generation library designs, optimized GPCR engineering strategies and yeast selection protocols better suited to GPCR antibody discovery. These modifications have resulted in selection campaigns that have a higher

hit rate with molecules that have higher affinity and potency compared to hits identified from initial antibody selection campaigns. The GEODe™ platform includes components aimed at optimizing the expression, purification, and stabilization of GPCRs and pairs these advances with our protein engineering and structural biology capabilities. While the current libraries, receptor engineering and selection strategies are producing GPCR-targeted antibodies, we continue to evolve and modify aspects of the platform, which we believe will lead to even better results.

The following table summarizes key information about our development programs and other pipeline programs:



(1) Pulmonary Hypertension

Our lead asset, TX000045 (hereafter called TX45), is an Fc-relaxin fusion molecule that activates the RXFP1 receptor, the GPCR target of the hormone, relaxin. Relaxin is an endogenous protein, expressed at low levels in both men and women. In normal human physiology, relaxin is upregulated during pregnancy where it exerts vasodilatory effects, reduces systemic and pulmonary vascular resistance and increases cardiac output to accommodate the increased demand for oxygen and nutrients from the developing fetus. Relaxin also exerts anti-fibrotic effects on pelvic ligaments to facilitate delivery of the baby. It has long been hypothesized that these unique dual aspects of relaxin biology may offer therapeutic potential in the treatment of cardiovascular disease. Unfortunately, the development of a viable therapeutic has been challenging, primarily because of relaxin's very short half-life.

We believe TX45's pharmacological profile, the direct result of applying our protein engineering capabilities, has the potential to overcome the limitations that have impeded previous attempts to develop relaxin as a therapeutic protein. We have identified Group 2 Pulmonary Hypertension ("PH") in the setting of Heart Failure with Preserved Ejection Fraction ("HFpEF") referred to as Group 2 PH / HFpEF hereafter, as the initial disease in which to interrogate the therapeutic potential of relaxin. We hypothesize that in this setting, treatment with relaxin could improve hemodynamics through effects on pulmonary and systemic vasodilation, cardiac diastolic dysfunction and potential remodeling in both the pulmonary vessels and the heart which could translate into a clinically meaningful improvement in exercise capacity in these patients. Clinical trials are planned to confirm this hypothesis. Despite this belief, our business carries substantial risks, including our limited experience in therapeutic discovery and development, and the risk that the platform may never result in the regulatory approval of a product candidate. See "*Risk Factors – Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates – We have limited experience in therapeutic discovery and development and our GEODe™ platform may never result in the regulatory approval of a product candidate.*"

Group 2 PH is a subtype of PH which develops secondary to left heart disease ("LHD"). This is a common, chronic, life-threatening condition of complex disease causes, or etiology, for which there are presently no FDA-approved medications. Group 2 PH / HFpEF is characterized by declining cardiac function, fibrotic tissue remodeling in the heart, and in some patients, fibrotic remodeling in the pulmonary vasculature as well. We have elected to prioritize development of TX45 in Group 2 PH / HFpEF because of the high unmet medical need in this population and because of the specific physiological actions of relaxin described above that suggest that it could address the key pathophysiology of the disease which involves both impairment of left ventricular function and high pressures in the pulmonary arteries, and in some patients, high resistance in the pulmonary vasculature. There are no FDA approved therapies in Group 2 PH. Furthermore, prior clinical data in patients with acute and chronic heart failure treated with a continuous infusion of a short half-life relaxin is supportive of the potential utility of relaxin administration in these patients. Clinical trials are planned to evaluate the hypothesis that relaxin could provide efficacy in patients with Group 2 PH / HFpEF. Beyond Group 2 PH / HFpEF, we believe there are additional areas where TX45 could potentially provide benefit to patients with diseases that result in the chronic deterioration of cardiac, lung and/or kidney function due to vasoconstriction and fibrotic remodeling.

As of July 6, 2024, we have completed all cohorts of our Phase 1a study, and TX45 has been generally well tolerated. Modeling of data available as of mid-January 2024 from these cohorts suggests that a single 1-2 mL injection of TX45 given once monthly (corresponding to a 150 mg and/or 300 mg dose) could be the target dose regimen. Decisions on dose and dosing frequency for the Phase 2 study will be based on a more complete Phase 1a dataset which is expected to be available in the third quarter of 2024.

Our second program is aimed at the discovery and development of a GPCR targeting biotherapeutic as a potential treatment for HHT, the second-most common genetic bleeding disorder. In HHT, abnormal blood vessel formations result in telangiectasias and arterio-venous malformations or "AVMs." These abnormal vessels are prone to spontaneous and severe bleeding that can be life-threatening. There are no currently approved therapies to treat HHT.

In HHT patients, mutations have been identified in BMP9, BMP10, Endoglin, ALK1 and SMAD4 proteins, all of which are members of a common signaling pathway. Preclinically, knock-out or inhibition of pathway members leads to increased expression of factors that drive angiogenesis and abnormal blood vessel formation that phenocopy the clinical situation. The planned GPCR target for our HHT program is a receptor for an angiogenic factor known to be upregulated in HHT animal models. By blocking the signaling of this receptor, we anticipate the potential for decreased bleeding resulting from the abnormal angiogenesis seen in HHT.

Our third program is aimed at the discovery and development of potential therapies for fibrotic diseases and employs a bi-specific format for the construction of a molecule with a differentiated mechanism of action. The strategy leverages two targets, one with previous human proof of concept and one novel target. Both targets are expressed on overlapping cell types with complementary and nonoverlapping modes of action that when inhibited simultaneously could enhance the therapeutic potential over inhibition of either target on its own.

We have strategically prioritized the selection of development indications for product candidates in our pipeline that we believe will offer an efficient path to Phase 2 clinical proof of concept, with outcomes measurable with 50-200 patients per indication, and which require treatment over a period of three-six months. Over the next three years, we anticipate that several significant milestones could be achieved for our lead asset TX45, including completion of the ongoing Phase 1a dose escalation trial in the third quarter of 2024, proof of concept hemodynamic data in patients with Group 2 PH / HFpEF in 2025, and data from a randomized trial in patients with Group 2 PH / HFpEF in 2026. During this time, a development candidate from our HHT program may also advance into clinical studies in the fourth quarter of 2025 or the first quarter of 2026 and could progress into efficacy studies in patients in late 2026 or early 2027.

Our GEODeTM platform has been optimized over the last three years and is in the early stages of being used to discover biologic drugs targeting GPCRs. We plan to deploy our GEODeTM platform to generate

additional pipeline assets by identifying and optimizing new GPCR targeted biologics that have the potential to address areas of substantial unmet need.

Our Founders and Management Team

We were co-founded in June 2019 by Timothy A. Springer, Latham Family Professor, Harvard Medical School and Professor of Medicine, Children's Hospital Boston, and Andrew Kruse, Professor of Biological Chemistry and Molecular Pharmacology, Harvard Medical School. These individuals are world-renowned scientists in their respective fields. Professor Springer has also been a founder of and/or founding investor in several successful biotechnology companies, including LeukoSite, Moderna, Seismic Therapeutic, Morphic Therapeutic and Scholar Rock and remains highly active in the biotechnology sector.

We have assembled a highly qualified management team with broad experience in corporate strategy, drug discovery, clinical development, business development and finance to execute on its mission to develop GPCR-targeted biologic medicines. They are industry veterans who have worked at many of the largest, global Pharmaceutical Companies. Our team and our scientific co-founders have played key roles in drug discovery or development programs that have resulted in over 20 initial drug approvals, including Keytruda® and Dupixent®. Other drugs that the founders and management team have played key roles in the discovery or development of include: Abecma®, Amevive®, Arcoxia®, Bavencio®, Braftovi®, Breyanzi®, Campath®, Camzyos®, Claritin®, Emend®, Entresto®, Entyvio®, Grastek®, Inrebic®, Mavenclad®, Mayzent®, Nasonex®, Odomzo®, Praluent®, Raptiva®, Reblozyl®, Remicade®, Simponi®, Singulair®, Tepmetko®, Velcade®, Zeposia®, and Zykadia®.

Background on GPCRs

GPCRs are a family of over 800 proteins found on the surface of cells throughout the body that mediate the body's response to extracellular stimuli by initiating a series of enzymatic reactions on the inside of cells which result in changes to cellular physiology. The diversity, functional specificity and localization to particular cell or tissue types makes GPCRs an especially compelling class of drug targets. Over 30% of approved drugs spanning a wide range of therapeutic areas, including metabolic diseases, inflammation, respiratory diseases, neurology and cancer, exert their action by modulating GPCRs. The targets for these medicines, however, represent only approximately 12% of known GPCRs, leaving at least as many GPCRs that are considered druggable still unexploited. GPCRs have a complex topology which has made both the protein production and purification of GPCRs outside of their natural environment in the cellular lipid membrane, as well as the identification of viable drug candidates to target them, challenging.

The structure of the RXFP1 GPCR activated by relaxin (also called relaxin-2) is shown below (**Figure 1**).

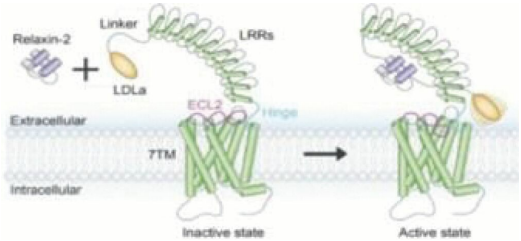


Figure 1 – Model of RXFP1 activation by Relaxin-2

Background on Relaxin / RXFP1 Biology

Relaxin is a naturally occurring peptide hormone that was first identified in 1926 in the setting of pregnancy where it is upregulated to allow for hemodynamic adaptation and increased cardiac output in response to the increased demands to the developing fetus and to allow for loosening of the pelvic ligaments prior to delivery.

Relaxin is a member of the insulin superfamily of peptide hormones, and it consists of two peptide chains linked by disulfide bonds. A representation of its structure is shown in Figure 2. Notably, activation of the RXFP1 receptor by relaxin does not result in internalization of the receptor, as is observed with many other GPCRs, which suggests there would be no receptor desensitization with chronic therapy using a relaxin-based agent.

Figure 2 – Ribbon Diagram Representation of Relaxin-2

Relaxin has long been of interest as a therapeutic agent for the treatment of cardiovascular disease because of its natural effects on hemodynamic function. The development of relaxin-based therapeutics, however, has been limited by the short half-life of the native peptide hormone, which has necessitated continuous intravenous or subcutaneous administration to establish and maintain target therapeutic levels of the compound in circulation.

Previous efforts to develop recombinant native human relaxin (serelaxin) to treat acute heart failure (AHF) have shown many signs of clinical benefit. For example, a meta-analysis published by Teerlink et al. in the European Journal of Heart Failure in 2019 assessed the results of six randomized, double-blind, placebo- controlled studies with greater than 11,000 patients enrolled to evaluate serelaxin in AHF. This analysis showed a highly statistically significant benefit in five-day worsening of heart failure and improved renal function (Table 1). Despite these intriguing signals, no relaxin-based therapeutic has been approved by the FDA. One of two pivotal studies, RELAX-AHF2, included a co-primary six-month cardiovascular mortality endpoint and failed. We believe it was ambitious to expect that a two-day infusion of the compound, with its short half-life and mechanism of action, would demonstrate clinical benefit at day 5, let alone six months after the infusion as required for the six-month cardiovascular mortality endpoint. We believe these attempts have fallen short due to the short half-life of relaxin precluding its development in chronic settings where the full benefit of its impact on both vasodilation and fibrosis can be felt over longer time periods.

	Relative Risk [95% CI]	N(drug)	N(placebo)
Pre-RELAX AHF	0.56 [0.22 – 1.45]	42	61
RELAX-AHF	0.54 [0.37 – 0.78]	581	580
RELAX-AHF-2	0.90 [0.76 – 1.07]	3274	3271
RELAX-AHF-EU	0.71 [0.52 – 0.98]	1756	894
RELAX-AHF-ASIA	0.42 [0.21 – 0.84]	437	433
RELAX Japan	0.33 [0.04 – 2.85]	15	15
Meta-Analysis	**0.77 [0.67 – 0.89]**		
	p = 0.0002	**6090***	**5239**

Table 1 – Effects of serelaxin on worsening heart failure (WHF) – fixed-effect (FE) meta-analysis; serelaxin 30 mg/kg/day vs. placebo; CI, confidence interval

To address the pharmacological limitations of the native relaxin hormone and enable its development beyond AHF, we have engineered a single-chain relaxin-Fc fusion protein, TX45, that features differentiated pharmacokinetic and biophysical properties to enhance key pharmacodynamic properties. TX45 was developed in a subcutaneous formulation with the goal of chronic administration via intermittent subcutaneous injection. As noted above, to interrogate the therapeutic potential of relaxin, we have identified Group 2 PH / HFpEF as the initial indication. We believe that in this setting, treatment with relaxin could improve hemodynamics and result

in beneficial remodeling in both the pulmonary vessels and the heart, making it potentially ideally suited for this indication. Clinical trials are needed to confirm this hypothesis.

Background on Group 2 PH

PH is a serious, life-threatening condition that affects hundreds of thousands of patients in the United States. In PH, the blood pressure in the pulmonary arteries is increased, exerting severe strain on the right side of the heart, which adapts poorly to the increased pressure. PH gradually causes worsening exercise capacity, shortness of breath and right-sided heart failure which can lead to death.

The World Health Organization has specified 5 different groups of PH (Table 2). Group 1 PH is also known as pulmonary arterial hypertension (PAH) and is caused by spontaneous thickening and fibrosis of the pulmonary arteries and arterioles without underlying significant cardiac, lung parenchymal, or chronic thromboembolic disease. Group 2 PH is due to left-sided heart disease (PH-LHD). Although several Group 1 PH medications have been explored in Group 2 PH, no medications have yet been approved by the FDA for its treatment.

Table 2 – WHO Classification of Pulmonary Hypertension

Consists of 5 Distinct Diseases; Group 2 PH is of Greatest Interest for Fc-relaxin First Indication

Group 1(PAH)	Group 2 (PH-LHD)	Group 3 (PH-LD)	Group 4 (CTEPH)	Group 5 (Misc.)
• Idiopathic • Hereditary • Connective tissue disease-associated • Congenital heart disease-associated • Drug-induced	• Due to left heart disease (HFpEF, HFrEF) or valvular heart disease • Two Subtypes: CpcPH / IpcPH • CAD, HTN, T2DM, high cholesterol are risk factors	• Due to lung disease or hypoxia • May be due to COPD, interstitial lung disease (i.e., IPF) or obstructive sleep apnea	• Due to chronic thromboembolic disease (i.e., as a consequence of blood clots)	• Miscellaneous group with causes unclear or multiple underlying factors

Group 2 PH Pathophysiology and Epidemiology

Group 2 PH is caused by left-sided heart disease, including heart failure with preserved ejection fraction (HFpEF), heart failure with reduced ejection fraction (HFrEF), and valvular heart disease (VHD). Group 2 PH itself consists of 2 disease subtypes, isolated post capillary PH (IpcPH) or combined pre- and post- capillary PH (CpcPH).

In patients with left-sided heart disease, the development of pulmonary hypertension is associated with a much worse prognosis. In various forms of heart failure, the heart fails to pump sufficient blood throughout the body to meet the metabolic demands of the individual. To compensate for inadequate cardiac output, the kidneys retain excess fluid to help increase the filling of the heart (“priming the pump”) during the relaxation phase of the cardiac cycle. This attempt to increase the filling of the heart leads to increased pressure during the relaxation phase. Pulmonary hypertension can develop in this setting when the pressure is transmitted backwards from the left atrium of the heart into the pulmonary veins and pulmonary arteries. This passive backflow of high pressure leads initially to post-capillary hypertension. These patients have a subtype of Group 2 PH called Isolated post- capillary Pulmonary Hypertension (IpcPH). Over time this increased pressure can lead to the thickening and fibrosis of the pulmonary arteries and arterioles resulting in disease of the precapillary vasculature of the lung and this is demonstrated by increased pulmonary vascular resistance (PVR). When Group 2 PH results in both increased pulmonary artery pressures from the passive backflow of pressure from the left atrium along with

intrinsic changes, such as thickening, fibrosis, and narrowing of the lumen of the pulmonary arteries, it is called Combined pre-and post-capillary Pulmonary Hypertension (CpcPH). To differentiate patients with IpcPH and CpcPH, a right heart catheterization is performed. Patients with elevated PVR, elevated pulmonary artery pressure (PAP) and an elevated Pulmonary Capillary Wedge Pressure (PCWP) have CpcPH, while those with just elevated PAP and PCWP and normal PVR have IpcPH. Pulmonary hypertension places a great strain on the right ventricle which is unable to compensate for this increased workload. Eventually, pulmonary hypertension causes the right ventricle to dilate and fail, ultimately leading to death.

There are an estimated 6 million patients with heart failure in the United States, with HFpEF representing up to ~50%, of heart failure cases. We estimate the combined Group 2 PH population with HFpEF at more than 600,000 and the respective prevalences of IpcPH and CpcPH in the HFpEF population are believed to be approximately 20% and 4%.

Testing of Group 1 PH (PAH) Drugs as Treatments for Group 2 PH – Implications of PDE5i Results

Patients suffering from CpcPH typically face worse outcomes than those with IpcPH (23% survival at five years vs. 40%-50%, respectively). Optimal treatment of heart failure may improve IpcPH to some extent. However, because of the specific pulmonary vascular pathology in CpcPH, treatment of heart failure alone is often insufficient to have a meaningful impact on this form of the disease. PDE5 inhibitors which activate the nitric oxide (NO) pathway were evaluated in three separate studies in CpcPH patients with HFpEF. In those studies, PDE5 inhibitors demonstrated improvements in hemodynamics, exercise tolerance, and a reduction in hospitalizations for heart failure. These improvements were not seen in a study with the broader group of Group 2 PH/HFpEF patients which were mainly composed of patients with IpcPH. Despite these findings, PDE5 inhibitors are not FDA approved for use in Group2 PH.

Several of the drugs used to treat Pulmonary Arterial Hypertension (Group 1 PH) have failed to demonstrate benefits in Group 2 PH/HFpEF. Most of these agents act as vasodilators in the lung, thereby increasing blood flow to the left side of the heart. However, pulmonary vasodilators have limited effect on left sided heart function or systemic circulation, and therefore, do not increase the ability of the left side of the heart to pump blood. This could worsen heart failure without improving exercise function. In contrast, PDE5 inhibitors also have a small effect on cardiac function, which may explain why they have shown the improvement in hemodynamics, exercise tolerance and hospitalizations in CpcPH as noted above.

PDE5 inhibitors activate the nitric oxide pathway which results in its hemodynamic effects including pulmonary vasodilation. Relaxin's hemodynamic effects are mediated both by inhibition of endothelin-1 as well as activation of the same nitric oxide signaling pathway by which PDE5 inhibitors exert their action. In addition, relaxin exerts anti-fibrotic and anti-inflammatory effects via the mechanisms shown in Figure 3. Therefore, although unproven at this time, based on its multimodal mechanism of action, we believe that TX45 has the potential to demonstrate statistically and clinically meaningful benefits in both CpcPH and IpcPH.

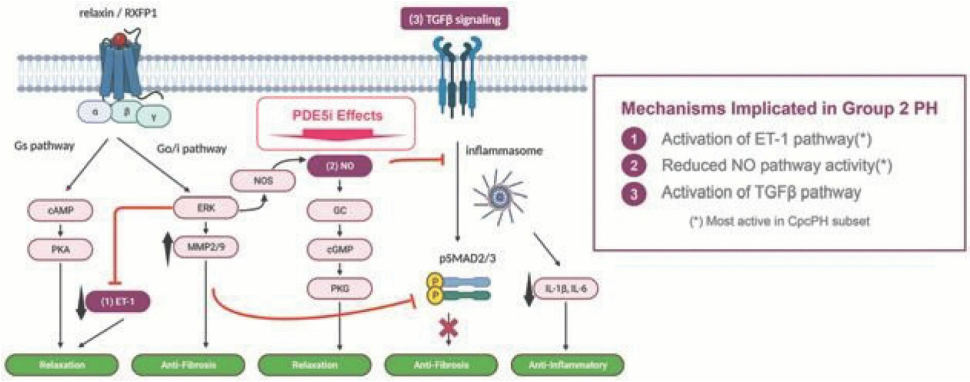


Figure 3 – PDE5 Inhibitors Affect Only One of Several Pathways Implicated in Relaxin Signaling

Our support of TX45 is based upon our hypothesis that relaxin's activities, through its remodeling and anti-fibrotic effects, may reverse the deleterious changes in the pulmonary vasculature present in CpcPH. Furthermore, relaxin's pulmonary and systemic vasodilatory activity could unload the left ventricle, while relaxin's anti-fibrotic and anti-inflammatory activities could promote reverse remodeling of the left ventricle in HFpEF. Last, relaxin's ability to relax the heart muscle could improve diastolic filling in HFpEF where cardiac hypertrophy and fibrosis lead to diastolic dysfunction and heart failure. These benefits could also extend to IpcPH patients and thus to the entire Group 2 PH / HFpEF population.

In summary, depicted in Table 3 below, we hypothesize that the inherent vasodilatory, anti-fibrotic, and anti-inflammatory activities of relaxin could be suited to address both the pulmonary and cardiac pathologies of Group 2 PH / HFpEF.

Table 3

Characteristics of Group 2 PH	IpcPH	CpcPH	Anticipated Relaxin Effects
Pulmonary artery narrowing, thickening, stiffening, fibrotic remodeling		✓	Pulmonary vasodilation anti-inflammatory, anti-fibrotic
Right ventricular dysfunction	✓	✓	Right ventricular remodeling
Thickening and stiffening of left ventricle	✓	✓	Peripheral vasodilation, cardiac relaxation, left ventricular remodeling
Compromised kidney function	✓	✓	Improvement in kidney function

Relaxin's numerous physiologic activities promote vasodilation in both the systemic and pulmonary vasculature, increasing cardiac output and decreasing pulmonary vascular wedge pressure (PCWP, a measure of heart failure) have previously been demonstrated with serelaxin (recombinant native human relaxin-2). As reported by Ponikowski P. et al in *European Heart Journal* in 2014, patients with acute heart failure who had a right heart catheterization exhibited improved hemodynamics with relaxin treatment. These observations included a reduction of mean pulmonary artery pressure (mPAP), pulmonary vascular resistance (PVR), systemic vascular resistance (SVR) and pulmonary capillary wedge pressure (PCWP). The ability of the relaxin mechanism to reduce the right ventricular strain by reducing PVR along with improving left ventricular function, as demonstrated by lowering PCWP, is fundamental to the potential of relaxin to treat PH-HFpEF. In a similar study of patients with chronic CHF reported by Dschietzig T. et al. in the *Annals of the New York Academy of Sciences* in 2009, a reduction in PCWP and an increase in cardiac output was demonstrated in response to relaxin treatment.

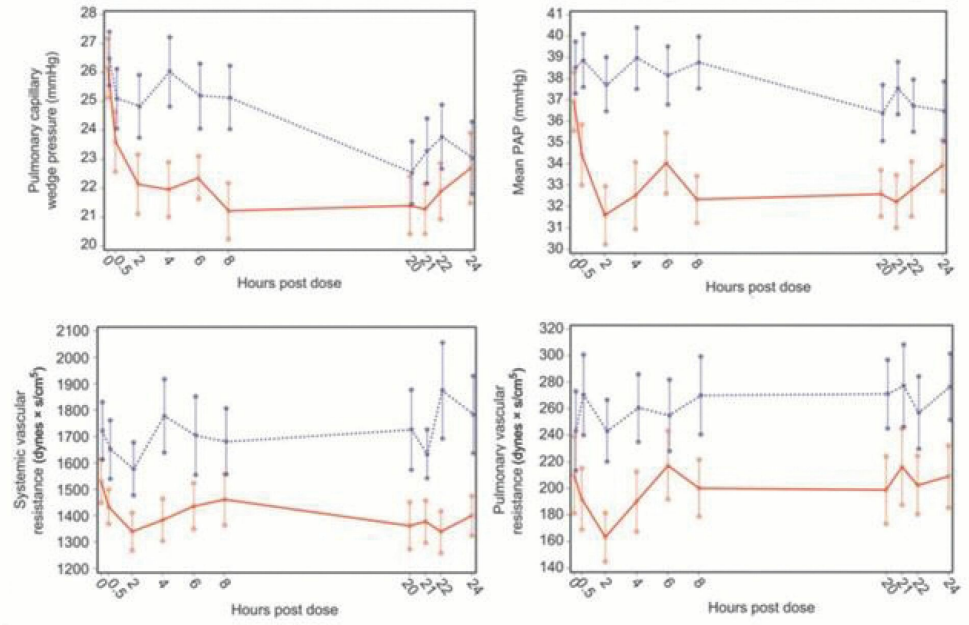


Figure 4 – Relaxin Improves Hemodynamics in Acute Heart Failure Patients Through Reduction of Pulmonary Capillary Wedge Pressure, Mean Pulmonary Artery Pressure, Pulmonary Vascular Resistance and Systemic Vascular Resistance.

Orange, serelaxin treatment for 20 hours (continuous infusion); Blue, placebo treatment.

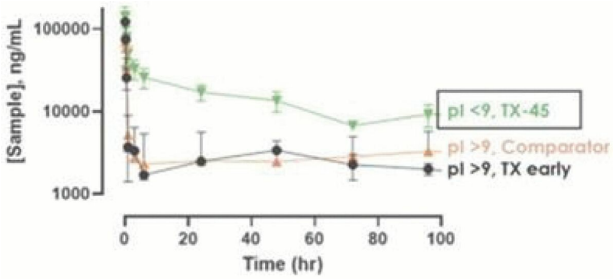
Note: improvements in some measures of placebo after 8 hours can be attributed to allowance of diuretics at that time

Additionally, in the study reported by Ponikowski P. et al in *European Heart Journal* in 2014, it was also reported that treatment with relaxin showed a beneficial impact on improvement in renal function in heart failure patients. This may stem from renal vasodilation with increased renal blood flow observed with treatment with relaxin. Since Group 2 / HFpEF patients also frequently present with compromised renal function, relaxin may also improve related clinical factors in our target population. We view these hemodynamic and renal function data as further evidence of relaxin's potential utility as a therapeutic for Group 2 PH.

Background on TX45

TX45 is a recombinant protein consisting of an engineered single chain human relaxin domain fused to the Fc domain of human immuno-globulin 1 (IgG1) using a peptide chain linker. The Fc portion of TX45 was modified to reduce Fcg receptor activation, and to increase binding to the neonatal Fc receptor (FcRn) with the goal of significantly increasing the half-life of the molecule in circulation, relative to the half-life of native human relaxin. TX45 was further engineered to reduce the isoelectric point (pI) of the molecule to enhance its pharmacokinetic properties and improve its biophysical profile. Reduction of the molecule's pI was deemed necessary to avoid the non-specific clearance of high pI molecules from the circulation that takes place immediately following administration as a result of binding to negatively charged heparin proteoglycans on the blood vessel wall. This effect can dramatically reduce the amount of bioavailable drug to exert pharmacologic action. Of note, native relaxin and most long-acting relaxin therapeutics have a high pI. Figure 5 compares the

pharmacokinetic profile of TX45 which has a reduced pI with earlier candidates in our program, and a different Fc-relaxin fusion described in the literature ("comparator") (Sun et al. J Am Heart Assoc. 2019 Dec 17; 8(24); Hao et al. US 2019/0352366 A1). Pharmacokinetic studies in rats were run with an early Tectonic relaxin compound (TX early), the comparator compound and TX-45 in consecutive studies at the same site and analyzed in the same way. Both of the latter are high pI molecules. No head-to-head studies have been conducted between TX-45 and the comparator compound or TX early.



Test Article	TX004 ("TX early")	Comparator	TX45
AUC	388,809	522,064	2,134,056

- FC of TX45 with comparator molecule = 4.1
- FC of TX45 with TX early = 5.5

Figure 5 – The pharmacokinetic profile of TX45 in rats showed an 11 to 15-fold reduction in the alpha phase decline at 6 hours post-dose which resulted in a 4.1 to 5.5 -fold increase in AUC (0-100 hrs) compared to a comparator molecule and an earlier TX molecule which have higher isoelectric points compared to TX45. Rats (n= 3 / group) were administered 5 mg/kg of drug intravenously in all cases.

TX45 Pharmacology Studies

TX45 has been tested in several non-clinical *in vivo* pharmacokinetic (PK) and pharmacology studies. These include a rat renal blood flow model that is used as a pharmacodynamic (PD) endpoint that demonstrates the vasodilatory effects of relaxin. TX45 administration shows a dose-response and exposure-response relationship on increasing rat renal blood flow (Figure 6). Renal arterial blood flow was measured with a perivascular flowmeter in anesthetized instrumented naïve rats. This study had 6-10 rats per group.

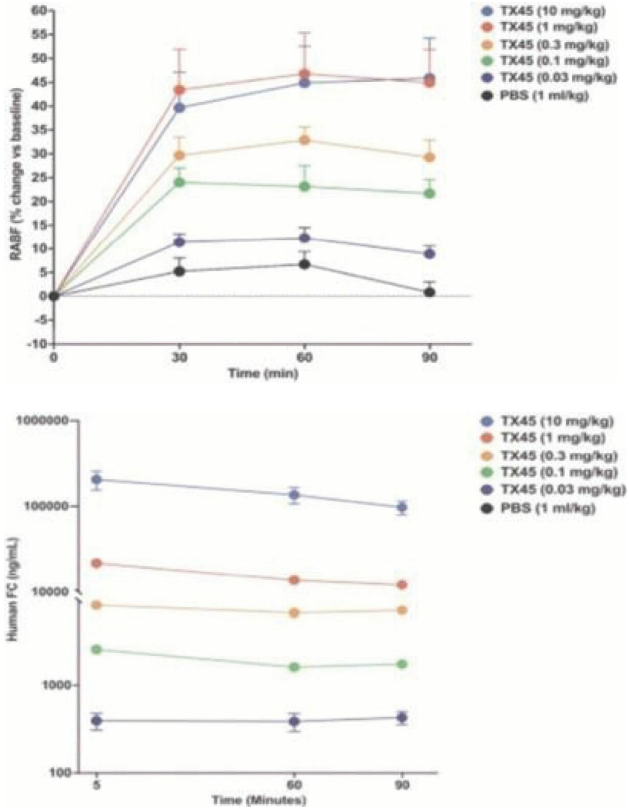


Figure 6 – Dose-Dependent Effect of TX45 on Rat Renal Arterial Blood Flow (RABF) (top panel) and Associated Pharmacokinetic Exposures (bottom panel)

To test the impact of improvements from protein engineering efforts, and particularly the effect of reducing the pI of the molecule, we conducted a comparative assessment of TX45 and a high pI comparator Fc-Relaxin fusion protein in the same rat renal blood flow model (n = 6-10 per group). In these experiments, a dose of 0.03 mg/ kg of TX45 produced a comparable pharmacodynamic effect to 0.3 mg/kg of the comparator high pI molecule, despite being 10-fold less potent in vitro. In these studies, TX45 is ~10-fold more potent by dose in vivo than the comparator molecule, which may be consistent with a differentiated clinical profile for TX45 (Figure 7).

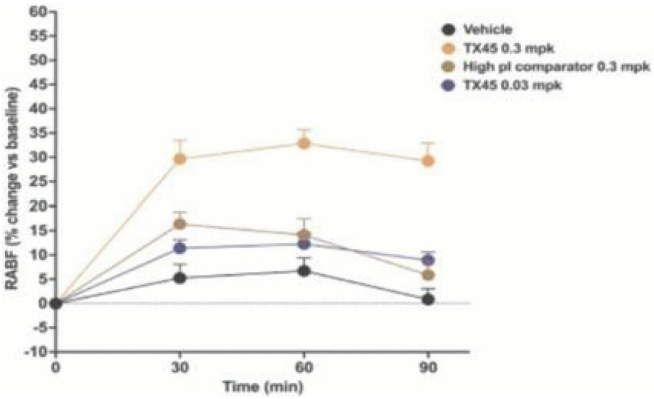


Figure 7 – The improved biophysical Profile of TX45 results in a comparable AUC at a 10-fold lower dose (0.03 mg/kg) compared to the high pI comparator (0.3 mg/kg).

The use of human relaxin or human relaxin-mimetics in chronic in vivo pharmacology experiments in rats and mice has been limited by the development of anti-human relaxin antibodies that reduce relaxin levels and activity. This is because human relaxin is only ~50% homologous to rat relaxin so the rat immune system perceives human relaxin as being a foreign antigen. The development of anti-human relaxin antibodies in rodents is triggered in inflammatory disease models. To address this problem, we developed a method to administer anti-CD20 antibodies to deplete B lymphocytes and reduce antibody production. Using this approach, TX45 demonstrated a significant effect on a number of clinically relevant parameters in the rat monocrotaline-induced (MCT) model of pulmonary hypertension. The MCT model was run in the therapeutic mode, which is more stringent than the prophylactic mode. There were 10-12 rats per group and TX45 was tested in three independent experiments where it showed comparable effects. In this model, significant reductions ($p<0.05$) in pulmonary artery pressure, right ventricular hypertrophy, NT-proBNP, and pulmonary artery muscularization were demonstrated along with 100% survival at 4 weeks compared with 75% for control animals (Figure 8, Figure 9, Figure 10). The determination of significance was done by a one-way anova test followed by Tukey's multiple comparison test. The p values are shown in the figures. Pulmonary hemodynamics were measured using a French pressure catheter inserted into the right ventricle and pulmonary artery in anesthetized animals. Histopathology analysis was used to evaluate lung inflammation and pulmonary artery muscularization.

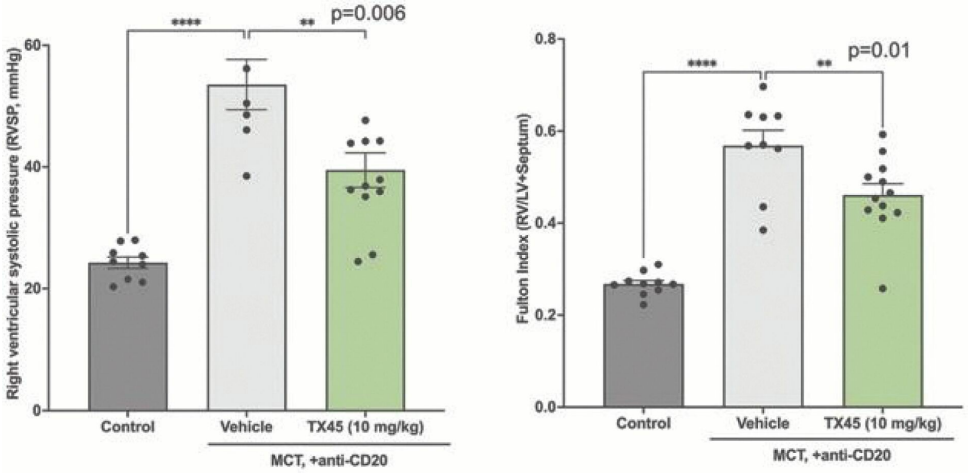


Figure 8 – TX45 had a significant effect on Right Ventricular Systolic Pressure (p=0.006) (a) and Fulton's Index (p=0.01) (b) in the MCT-PH Rat Model. Statistical significance was determined by a one-way anova test followed by Tukey's multiple comparison test.

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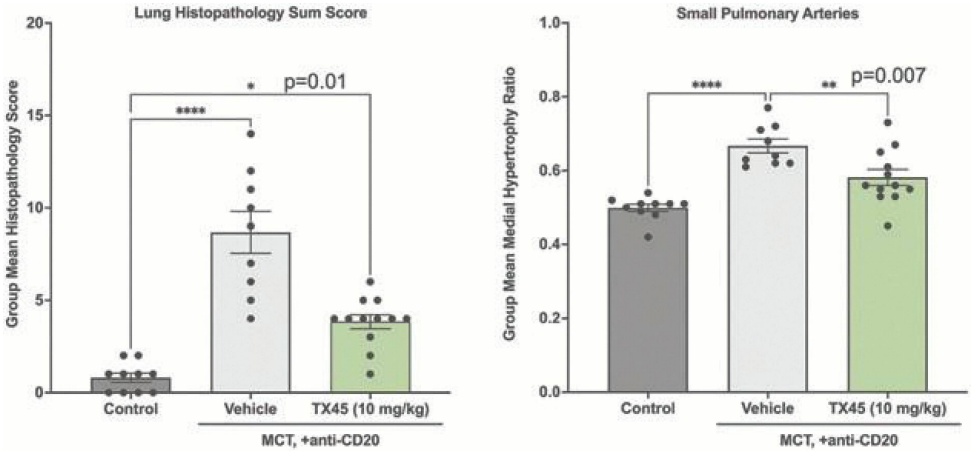

Figure 9 – Following Histopathological Analysis TX45 had a significant effect on Lung Inflammation (p=0.01) (a) and Muscularization of Small Pulmonary Arteries (p=0.007) (b) in MCT-PH Rats Treated with TX45 or Vehicle. Statistical significance was determined by a one-way anova test followed by Tukey's multiple comparison test.

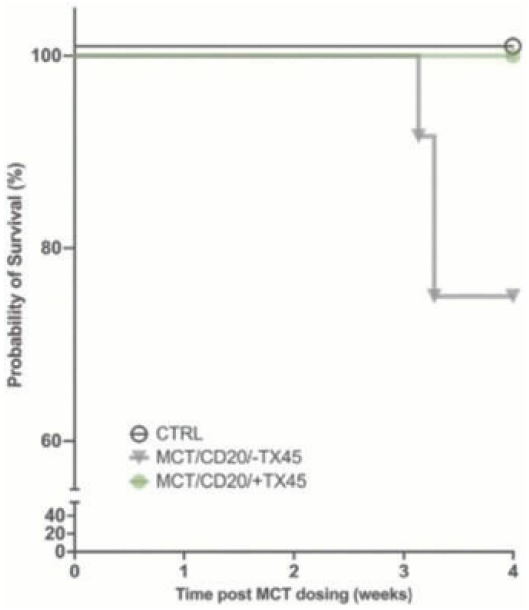

Figure 10 – TX45 Treated Animals had a 25% improvement on survival vs. Controls in MCT-PH Rats. TX45 Achieves 100% Survival in Experiment

TX45 and earlier compounds also demonstrated a significant effect on clinically relevant parameters such as improved pulmonary hemodynamics and a reduction in kidney and cardiac fibrosis in three other preclinical models where anti-CD20 was not administered; the mouse isoproterenol model of HFpEF, the rat Sugen-hypoxia model of pulmonary hypertension as well as in the mouse unilateral ureteral obstruction model of kidney fibrosis. All of these studies had an n = 6 to 10 animals per group and statistical significance was determined by a one-way anova test followed by Tukey's multiple comparison test. These preclinical data for TX45 have not yet been published.

TX45 Non-clinical Toxicology Studies

TX45 has been tested in rat and non-human primate (NHP) 1-month GLP toxicology and 6-month GLP toxicology studies at ITR in Canada. There is imperfect sequence homology between the active portion of TX45 and rat relaxin (~50%) or NHP relaxin (~73%). In the 1-month GLP toxicology studies, there were no specific toxicities identified and no observable adverse effect level (NOAEL), which is the greatest dose of a drug at which no detectable adverse effects occur in an exposed population, was 100 mg/kg for both species. Administration of TX45 resulted in the development of anti-drug antibodies (ADAs) in some rats and monkeys, but the ADA response was most prevalent in rats receiving TX45 by subcutaneous injection.

During weeks 6-9 of the 26-week GLP chronic toxicology study in NHPs, 5/32 monkeys treated with TX45 developed monkey anti-human anti-drug antibodies. ADAs formed in these 5 animals while they were recovering from an upper respiratory infection (URI) during weeks 5-9 of the study. Three animals were terminated prematurely due to severe immune related reactions, two of which had measured ADAs at the time of termination. We believe the URI acted as an adjuvant to heighten the immunologic response to TX45. Only animals that had URI symptoms developed ADAs and no additional animals developed ADAs as of week 25 (out of 26) of the study. The development of ADAs was not unexpected since there is only 75% homology between human and monkey relaxin, and ADAs were previously reported in serelaxin chronic toxicology studies. There is no expected correlation between the development of ADAs against a substantially human protein administered to NHPs and the immunogenicity profile of the same protein in humans. The absence of high sequence homology between non-clinical species and human protein therapeutics is a common cause of immunogenicity in toxicology studies, particularly in longer-term studies, and does not predict immunogenicity in human clinical studies.

TX45 Clinical Development Studies and Plans

The TX45 clinical development program is designed to provide data supporting key inflection points. TX000045-001, a first in human, single ascending dose study is designed to provide data on safety and tolerability, and pharmacokinetic and pharmacodynamic and immunogenicity data after single doses in healthy volunteers in the third quarter of 2024. Additionally, we anticipate that Phase 1b single dose hemodynamic data in Group 2 PH with HFpEF patients could be available in 2025, and that Phase 2 proof-of-concept efficacy data in Group 2 PH patients with HFpEF could be available in 2026.

Our Phase 1a study is being conducted in Australia and the Phase 1b study is currently being conducted in Moldova and the Netherlands. These studies are being conducted under ICH and GCP guidelines. We plan to conduct our Phase 2 study in the U.S., Australia, Europe and Eastern Europe. Prior to initiating the Phase 2 study in the U.S., the Phase 1a study being conducted in Australia will need to have confirmed the safety profile of TX45 and data from the study will determine the selected doses in the Phase 2 study.

A pre-IND consultation between Tectonic and the FDA occurred in early 2024. No significant issues were identified by the FDA with our planned clinical development strategy for TX45. The pre-IND consultation does not prevent the FDA from raising additional issues during the IND review. Additionally, in response to a Tectonic question about whether six minute walk distance was suitable as a pivotal endpoint in a registration study for the treatment of Group 2 PH / HFpEF, the FDA provided guidance that a six minute walk test is an acceptable assessment of functional capacity and could potentially support a label indication. Acceptance of an IND by the FDA is required before a Phase 2 clinical trial can be initiated in the U.S.

Provided the Phase 1 and 2 studies obtain sufficient safety and efficacy data to justify proceeding to Phase 3, the conduct of Global Phase 3 pivotal studies including sites in the U.S., and additional non-clinical development work including scale-up of GMP manufacturing to commercial scale would also be needed to generate the data package necessary to support regulatory approval for marketing authorization in the U.S. through the submission of a Biologic License Application (BLA) to the FDA. We would also seek similar regulatory approvals through equivalent submissions to regulatory bodies in territories outside of the U.S.

Study, Status, Location	Study Design	Treatments	Subject Population and Number
TX000045-001 Phase 1a (Ongoing) Australia	Randomized, double- blind, SAD	TX000045 or placebo Single ascending IV and SC doses per clinical study protocol: IV : 0.3mg/kg, 1mg/kg, 3mg/kg SC: 150mg, 300mg, 600mg	Healthy male and female subjects Each cohort will have 8 subjects, 6 on TX45 and 2 on placebo

Study, Status, Location	Study Design	Treatments	Subject Population and Number
TX000045-002 Phase 1b (Ongoing) Moldova, Netherlands	Open-label single dose	TX000045 0.3, 1, or 3 mg/kg IV	Up to 25 patients with PH-HFpEF, including approximately 12 patients with PVR>3 WU The 0.3 mg cohort will have 2 patients enrolled followed by up to 12 patients in the 1 and 3 mg/kg IV cohorts

Ongoing Phase 1a Trial

A Phase 1 randomized, placebo-controlled, double-blind study in healthy volunteers with TX45 is currently ongoing in Australia, and includes single ascending dose (SAD) and multiple dose cohorts. In the SAD portion of the trial, TX45 is being administered by intravenous (IV) or subcutaneous (SC) injection, and in the multiple dose portion TX45 is being administered subcutaneously. The primary objective of the Phase 1 study is to determine the safety and tolerability of TX45 after single doses in ascending dose levels. The number of patients in each dose cohort is eight, six on TX45 and two on placebo. Secondary objectives include the evaluation of the pharmacokinetic (PK) and pharmacodynamic (PD) properties of TX45 to determine a PK/PD relationship. The PD endpoint in this study is the percent change from baseline renal plasma flow (RPF).

As of January 18, 2024, the first three cohorts (0.3 mg/kg IV, 1 mg/kg IV, 150 mg SC) of the single ascending dose portion of the Phase 1 study have been dosed with TX45. No drug-related SAEs have been observed thus far. Modeling of data available as of January 15, 2024 from these cohorts suggests that a single 1-2 mL injection of TX45 given once monthly (corresponding to a 150 mg and/or 300 mg dose) could be the target dose regimen. The bioavailability of TX45 after SC administration is approximately 50%. Evaluation of renal plasma flow on Day 2 after the initial starting dose administration of 0.3 mg/kg TX45 IV showed approximately 30% increase in RPF compared to baseline that was maintained on Day 8. There has been no evidence of immune-mediated clearance in subjects dosed with TX45.

Ongoing Phase 1b Trial

A Phase 1b study with TX45 in patients with Group 2 PH and HFpEF has been initiated in Moldova and is being conducted in Moldova and the Netherlands. The study will enroll up to 25 patients with PH-HFpEF and approximately 12 patients will have elevated PVR (CpcPH). This study is a single dose, open-label study with intravenous administration of TX45 to evaluate the safety, tolerability and acute hemodynamic effects in patients. The doses of TX45 administered in this study will be 0.3 mg/kg IV, 1 mg/kg IV, and 3 mg/kg IV. The study will evaluate the change from baseline in pulmonary vascular resistance (PVR) as determined by right heart catheterization, as well as improvement in mean pulmonary artery pressure, pulmonary wedge pressure, cardiac output, systemic vascular resistance. We will explore change in NT-proBNP and several echocardiology endpoints.

Planned Phase 2 Proof of Concept Study in Group 2 PH and HFpEF after 24 weeks of treatment.

Our planned TX45 Phase 2 randomized, placebo-controlled, double-blind proof-of-concept (POC) clinical trial in patients with Group 2 PH and HFpEF is expected to begin in the second half of 2024 and will be conducted globally, including the U.S., Europe, Eastern Europe and Australia. Initiation of this study is contingent on data from the Phase 1a study demonstrating adequate safety and sufficient data to select doses and dose intervals for the Phase 2 study. This study is designed to enrich for patients with a PVR of >3 on baseline right heart catheterization with the goal of evaluating efficacy in both CpcPH as well as the whole Group 2 PH population with HFpEF. We currently expect that approximately 180 subjects will enter the trial. Each subject will be randomized to one of two treatment arms or a placebo arm. In this study, TX45 or placebo would be administered by subcutaneous injection for 24-weeks followed by an 8-week follow-up period. Endpoints may include the change from baseline in PVR, stroke volume index, cardiac output, and additional hemodynamic measures as determined by right heart catheterization, 6-minute walk distance, Kansas City Cardiomyopathy Questionnaire-12 score, NT-proBNP blood level, and relevant echocardiography endpoints.

Group 2 PH with HFpEF Anticipated Pivotal Development Pathway

Subject to the results of our Phase 2 trials and feedback received during the End of Phase 2 meeting with the FDA, we expect to initiate a randomized, placebo-controlled, double-blind Phase 3 clinical trial in Group 2 PH patients with HFpEF, as well as long term, open label extension study for safety evaluation. Based on historical precedent across multiple PH subtypes and our Pre-IND consultation with the FDA regarding the specific requirements for approval in Group 2 PH with HFpEF, we believe that the achievement of a clinically significant change in a functional endpoint, such as 6-minute walk distance could be sufficient for approval. The secondary endpoints may also include change from baseline to week 24 in: KCCQ-12 score, NT-proBNP level, and the percentage who improve in WHO functional class. An additional secondary endpoint may be the time to the first occurrence of a clinical worsening event or death. At this time, we do not anticipate that an assessment of TX45's impact on long term cardiovascular outcomes will be a requirement for approval. Commercialization in the U.S. and other countries will be contingent on approval by the regulatory authorities (the FDA in the U.S.) and an assessment by the regulators that the studies were conducted in accordance with accepted guidance and the data demonstrated that there was a positive benefit risk for patients.

Background on HHT Opportunity

Hereditary Hemorrhagic Telangiectasia (HHT), also known as Osler-Weber-Rendu syndrome, is the second most common genetic bleeding disorder. It has been estimated that there are approximately 70,000-75,000 HHT patients in the USA and it has also been estimated that up to 10-20% of them have severe disease. Symptoms of this disorder typically arise in late teenage years or older, and the most common manifestation is recurrent epistaxis (nosebleeds), or gastrointestinal bleeding, that can be severe in some patients, requiring iron infusions or blood transfusions, Epistaxis is typically due to abnormal small blood vessels (telangiectasias) in the nasal mucosa. Patients with HHT can also develop large arterio-venous malformations (AVMs) in various organs, such as the brain, liver and lung. The presence of liver AVMs can lead to high output heart failure. AVMs can spontaneously bleed on occasion with potentially devastating results. While some AVMs can be treated by

radiologic embolization, such as AVMs in the lung, others cannot, especially in the liver. Indeed, for patients with prominent liver AVMs, the only therapeutic option may be transplantation.

While there are no approved medical therapies for HHT, anti-VEGF therapies including bevacizumab have been used on an *ad hoc* basis with results demonstrating that an anti-angiogenic therapy has the potential to be an efficacious treatment. These therapies have been shown to reduce angiogenesis and bleeding in mouse models of HHT. Importantly, these data have translated to the clinic, as small investigator-sponsored trials in HHT patients have demonstrated reduced epistaxis episodes and reduced transfusion dependence. The effects of anti-VEGF therapy suggest that targeting an alternative pathway, similar to the VEGF-VEGFR pathway in its ability to more specifically regulate angiogenesis, could be a productive strategy to address HHT. In addition to bevacizumab, pazopanib, a tyrosine kinase inhibitor, has been explored in small investigator-initiated studies with early suggestion of clinical benefit.

HHT is a genetic disorder due to loss-of-function mutations in proteins in the BMP9/10-Endoglin-ALK1- SMAD4 signaling pathway. BMP9 is a member of the TGF-beta family of growth factors that regulate blood vessel development. “GPCR3” (the specific GPCR target is not disclosed at this stage) and its ligand (“L3”) have been described to play a role in angiogenesis and AVM formation. Expression of L3 is also upregulated in HHT disease models and likely contributes to the development of abnormal blood vessels.

Development Candidate for the Treatment of HHT

We have identified potential development candidates, from which one could be selected for further development as a potential treatment for HHT. These comprise a potent inhibitory anti-“GPCR3” antibody (VHH) fused to the Fc portion of IgG1. The Fc portion of these molecules was modified to reduce Fcg receptor activation and to increase binding to FcRn, in order to extend the half-life of the molecules.

Pharmacology Studies

Several murine models of HHT have been established. These include both genetic loss-of-function models that disrupt the BMP9/10-Endoglin-ALK1-SMAD4 signaling pathway at different points, and the BMP9/10 immunoblocked model. In these murine models of HHT, anti-VEGF or anti-VEGF receptor agents reduce AVM formation and bleeding. As referenced above, since bevacizumab, an anti-VEGF monoclonal antibody, has been shown to have a clinical impact in HHT patients at reducing epistaxis, the mouse models appear to be predictive of these human impacts. Despite these signs of clinical utility, neither bevacizumab nor small molecule VEGF receptor inhibitors have been approved for the treatment of HHT and they are not widely used likely because of the lack of approval, concerns about toxicity and lack of adequate information about dose. We have established a pharmacodynamic model of neonatal murine retinal angiogenesis. In this model, treatment with a potent mouse “GPCR3” Nanobody-Fc antagonist reduces neo-angiogenesis and the vascularized area in the neonatal mouse retina. We have also established the BMP9/10-immunoblocked mouse model of HHT. This model reliably leads to the development of hypervascularization, AVMs and bleeding in organs including the eye, GI tract and brain. In this model, our “GPCR3” antagonist significantly reduces both arteriovenous malformations formation (AVM) and retinal hypervascularization induced by BMP9/BMP10 blockade to a similar degree as a VEGF antagonist (Figure 11), N=7 retinas were used for AVM number determination. This demonstrates that pharmacologic inhibition of GPCR3 provides significant effects on endpoints relevant to HHT patients. Additional *in vivo* studies characterizing the effects of “GPCR3” antagonism on additional HHT relevant vascular pathology endpoints in mice are planned.

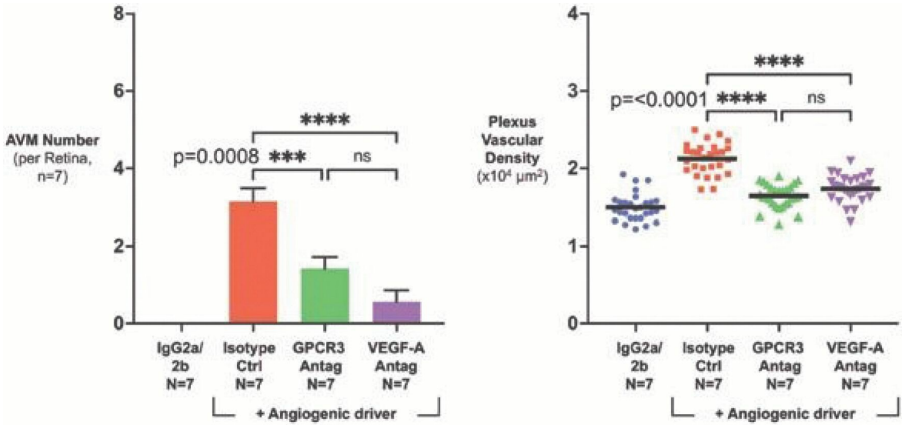

Figure 11 – Anti-"GPCR3" Antibody Treatment Significantly Reduces AVM Formation and Reduces Retinal Hypervascularization Induced by BMP9/10 Blockade Compared to Treatment with Inactive Control Antibody (IgG2a/2b). Left Panel: Determination of AVM number and right panel; determination of vascular density in the retinal plexus in neonatal mice at P6 comparing "GPCR3" antagonist, isotope control antibody and a VEGF-A antibody antagonist. In all cases, data analysis was blinded. Data are mean ± SEM and analyzed using one-way ANOVA. * p<0.05; **** p<0.0001. Data represents N=7 mice per group. The vascular density values were generated by collecting five 200 x 200 mm2 from different fields per retina and analyzed using the ImageJ, measure particles tool software. AVM and vascular density analysis was carried out in a blinded fashion.

Clinical Development Plans

Provided that it meets acceptable safety, tolerability and developability criteria in upcoming studies, we expect to select a development candidate (DC) in the second half of 2024 and anticipate initiating clinical studies, which could begin in the fourth quarter of 2025 or the first quarter of 2026.

The Phase 1 program for this DC would consist of a randomized, placebo-controlled, double-blind ascending-dose study that would be performed in healthy volunteers. Likely primary endpoints would be the safety and tolerability of the DC in these subjects, and likely secondary endpoints would be the pharmacokinetic properties of the DC and potentially PD endpoints in patients with HHT. Assuming adequate PK and safety are established in Phase 1, efficacy stud(ies) including a Phase 2 randomized, placebo-controlled, double-blind 3-month proof of concept (POC) study in HHT patients with frequent epistaxis and anemia would be conducted.

Background on GEODeTM Platform

We believe that our GEODeTM platform has the potential to advance the field of biologic drugs targeted to GPCRs. To date, only 12% of the more than 800 GPCRs in the human body have been successfully translated into targets for approved therapeutics with biologics representing only three of those approvals. GPCRs have proven to be elusive targets for biologics largely due to their dynamic structure and expression levels in the plasma membrane and the difficulty of translating them in a functional form outside of their native lipid microenvironment.

The majority of successful GPCR targeted therapeutics to date are small molecules, however, the success of this modality has been largely confined to just 6 GPCR subfamilies, many of which have a natural ligand that is also a small molecule. Establishing and maintaining target engagement and selectivity, therefore, for small

molecules has proven challenging for receptors of increased size and complexity, greater sequence homology in ligand binding sites, or where subfamilies have overlapping ligands.

GEODeTM was developed with the aim of addressing the challenges of GPCR targeted biologics via a combination of (1) GPCR protein engineering strategies that stabilize the pharmacologically relevant form of the receptor and increase the cell surface receptor expression, enabling purification and formulation of the receptor at scale and in the correct conformation for naïve antibody selection campaigns; (2) using an optimized cell free yeast display platform with proprietary, highly diverse Fab and VHH antibody libraries designed to target GPCRs; and (3) structure-guided protein engineering strategies to identify optimal GPCR targeted biologics. The original platform technology was developed in Dr. Andrew Kruse's lab at Harvard. This platform technology included yeast display selection protocols, first generation Fab and VHH library designs and protocols to detergent solubilize GPCRs. Our team has made significant changes and modifications to the original platform to optimize the quality of the molecules emerging from its naïve selections and affinity maturations including optimization of its receptor design strategy, the design of its naive and affinity maturation libraries and of the yeast display selection protocols.

Summary of Our Expertise in GPCRs and mAb Discovery

Our optimized GPCR-targeted antibody discovery process comprises the following steps:

1. **Optimization, stabilization, and formulation of GPCRs** using proprietary protein engineering and biochemistry techniques, to produce sufficient target material in the correct conformation, as a reagent for discovery campaigns. We use structure-based homology modeling and prediction to engineer changes to the receptor that can bias it into an active or inactive state. These changes can also increase receptor cell surface expression and stability. Also, because the lipid bilayer surrounding a receptor can strongly affect its activation, we have developed techniques to present our targets in a variety of different membrane mimetics that recapitulate the lipid bilayer environment that the receptor is embedded in. We have also taken a machine learning guided protein engineering approach to generate G-protein mimetics that can stabilize GPCRs in their active state conformation. This stabilized protein complex can be used to discover agonist antibodies during yeast display selection campaigns.

2. **Optimized and streamlined yeast display antibody selection protocols** that minimize false positive hits from non-specific binders and can productively pull initial hits from antibody discovery campaigns. We employ antibody libraries designed and optimized for targeting GPCRs, novel tagging strategies, and make extensive use of automated workflow. In some circumstances we compare multiple antibody discovery approaches, including animal immunization for generating initial hits against targets of interest.

3. **High throughput GPCR binding assessment** to confirm binding of purified antibodies to target of interest. This step enables rapid narrowing of the set of initial hits to focus on the most productive options available.

4. **GPCR signaling assays** to confirm that hits which were identified in the selection campaign and confirmed as target binders, are also functionally active to modulate signaling through the target of interest. We have implemented a wide range of signaling assays that can support characterization of hits against different GPCR targets.

5. **Antibody Lead optimization** via affinity maturation to further improve either potency, selectivity, cross-species reactivity, developability characteristics or any combination of the above.

Collaboration, License and Services Agreements

Harvard Option and License Agreement

In July 2020, we entered into an option agreement with the President and Fellows of Harvard College ("Harvard") and obtained an option to negotiate a license under Harvard's interest in certain patent rights (the "Patent Rights") in exchange for an option fee in the low five digits. In October 2021, we exercised the option and in February 2022 entered into a license agreement with Harvard (the "Harvard License Agreement"). Under the Harvard License Agreement, we obtained (i) an exclusive, worldwide, royalty-bearing license under Harvard's interests in the Patent Rights, and (ii) a non-exclusive, worldwide, royalty-bearing license to use Harvard's interest in certain know-how to develop, manufacture and commercialize licensed products and know-how enabled products, and (iii) a non-exclusive, worldwide, royalty-bearing license to use discovery materials to develop, manufacture and commercialize discovered products. Harvard retained the right for itself and for other not-for-profit research organizations and government agencies to practice the Patent Rights and to use Harvard's know-how and discovery materials within the scope of the license granted for research, educational and scholarly purposes.

We are required to use commercially reasonable efforts to develop royalty-bearing products and, once regulatory approval is received, to introduce and market such products into the commercial market and to make such products available at locally-affordable prices in certain countries outside the United States and Europe. We are also required to meet certain development and commercialization diligence milestones within specified time periods.

As partial consideration for the Harvard License Agreement, we agreed to pay Harvard a one-time license fee of $170,000, with such fee to be paid in equal installments over three years. In July 2022, we paid Harvard $56,666 and in July 2023 we paid Harvard $56,667. The final installment of $56,667 under the Harvard License Agreement is due in July 2024. As partial consideration for the Harvard License Agreement, we entered into a subscription agreement with Harvard in July 2022, pursuant to which Harvard was granted 227,486 shares of common stock of Legacy Tectonic with a fair market value in the mid six digits.

We are required to pay an annual maintenance fee ranging from the low five digits to the low six digits until the first commercial sale of a royalty-bearing product, following which the annual maintenance fee will increase to a low six digits for the remainder of the term of the Harvard License Agreement. We are required to pay a one-time milestone payment of $100,000 for each discovered product granted FDA marketing authorization as well as for the first licensed product or know-how enabled product to reach certain clinical development milestones, up to $8.5 million and for the first licensed product or know-how enabled product to reach certain commercial milestones, up to $2.0 million. We are also obligated to pay tiered royalties as a percentage in the low single digits on net sales of licensed products, as a percentage in the low single digits on the net sales of know-how enabled products and a single royalty as a percentage in the low single digits on the net sales of discovered products, subject to a reduction for third-party licenses, as well as a percentage between 10-20% of non-royalty income we receive in connection with a sublicense, strategic partnership or know-how enabled license. With respect to any net sales of licensed products and know-how enabled products sold in certain countries outside of the United States and Europe, our team and Harvard will negotiate a royalty percentage on a country-by-country basis.

The Harvard License Agreement expires upon the later of: (i) the expiry of the last valid claim within the licensed patent rights, expected to be not earlier than May 2041; and (ii) the earlier of (a) ten years after the first commercial sale of the first know-how enabled product or (b) twelve years after the first commercial sale of the first licensed product. Harvard may terminate the Harvard License Agreement if we fail to maintain insurance at specified levels or fails to comply with the notice requirements therein, upon our uncured material breach or insolvency. We may terminate the Harvard License Agreement at any time with or without cause upon a specified notice period and upon an uncured material breach by Harvard.

WuXi Master Development and Manufacturing Services Agreement

On May 6, 2022, we entered into a development and manufacturing agreement (the "WuXi Biologics Manufacturing Agreement") with WuXi Biologics. The WuXi Biologics Manufacturing Agreement governs the general terms under which WuXi Biologics, or one of its affiliates, will provide biologics development and manufacturing services as specified by our team on a project-by-project basis. Such services are performed under agreed-upon work orders. Under the terms of the WuXi Biologics Manufacturing Agreement, we have agreed to pay fees for WuXi Biologics' performance of services in addition to reimbursing WuXi Biologics for reasonable expenses authorized by us and as provided in each applicable work order.

The term of the WuXi Biologics Manufacturing Agreement will expire on the later of May 6, 2025 or the completion of the services under all work orders executed by the parties prior to May 6, 2025, provided that the term may be extended by our team for additional periods. We will have the right to terminate the WuXi Biologics Manufacturing Agreement or any work order upon thirty days' prior written notice or immediately if, in our reasonable judgment, WuXi Biologics is or will be unable to perform the Services or WuXi Biologics fails to obtain or maintain any necessary licenses or approvals. Either party may terminate the WuXi Biologics Manufacturing Agreement or any work order if the other party files for bankruptcy, fails to cure a material breach during the cure period or a force majeure event that has lasted for the time period specified within the WuXi Biologics Manufacturing Agreement. WuXi Biologics has the right to terminate if the parties are unable to reach an agreement on an amendment to the services if such services become impossible due solely to changes in applicable law. The term of each work order terminates upon completion of the services under such work order, unless terminated earlier.

The WuXi Biologics Manufacturing Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies and warranties.

Novotech Master Clinical Contract Services Agreement

In March 2023, we entered into a master clinical contract services agreement (the "Novotech CSA") with Novotech (Australia) Pty Limited ("Novotech"). The Novotech CSA governs the general terms under which Novotech, or one of its affiliates, will provide clinical development related services (excluding manufacturing services) as specified by our team on a project-by-project basis. Such services are performed under agreed statements of work. Under the terms of the Novotech CSA, we have agreed to pay fees for Novotech's performance of services in addition to reimbursing Novotech for reasonably incurred, pass through costs agreed to by our team and as provided in each applicable statement of work. Additionally, under the terms of the Novotech CSA, all documentation, information, and biological, chemical or other materials controlled by us and furnished to Novotech by or on behalf of us shall remain our exclusive property, and we shall own all rights to, and Novotech shall assigns all right, title and interest to, all inventions, discoveries, improvements, ideas, processes, formulations, products, co computer programs, works of authorship, databases, trade secrets, know-how, information, data, documentation, reports, research, creations and all other products and/or materials arising from or made in the performance of Novotech's service, except for Novotech's background intellectual property rights as defined under the Agreement.

The term of the Novotech CSA will expire on the later of (i) five years from the effective date of the Novotech CSA, or March 2028, or (ii) the completion of the services under all statements of work executed prior to the fifth anniversary of the effective date of the Novotech CSA, or March 2028. We may terminate the Novotech CSA or any statement of work thereunder immediately if Novotech has committed an uncurable breach or has failed to cure a breach after thirty days' written notice. We may also terminate the Novotech CSA or any statement of work thereunder for any reason upon thirty days' prior written notice to Novotech. Novotech may terminate the Novotech CSA or any statement of work thereunder immediately if we have failed to cure a material breach after thirty days' written notice.

The Novotech CSA includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, non-solicitation, remedies and warranties.

ARENSIA Master Agreement for Early Phase Clinical Services

In October 2023, we entered into a master agreement for early phase clinical services (the "Arensia CSA") with ARENSIA Exploratory Medicine GmbH ("Arensia"). The Arensia CSA governs the general terms under which Arensia, or one of its affiliates, will provide early phase clinical research services in connection with clinical research programs as specified by us on a project-by-project basis. Such services are performed under agreed work orders. Under the terms of the Arensia CSA, we have agreed to pay fees for Arensia's performance of services in addition to reimbursing Arensia for pre-approved, reasonable expenses actually and necessarily incurred by Arensia as specified in each applicable work order.

The term of the Arensia CSA will expire on the later of: (i) five years from the effective date of the Arensia CSA, or October 2028, or (ii) the completion of the services under all work orders executed prior to the fifth anniversary of the effective date of the Arensia CSA, or October 2028. Work orders shall expire upon the completion of the services specified thereunder, provided that we may terminate a work order if the study governed by such work order is suspended for more than thirty days and either party may terminate a work order for reasonable scientific safety reasons. We may terminate the Arensia CSA in its entirety for any reason upon thirty days' prior written notice to Arensia. Either party may terminate the Arensia CSA or any statement of work thereunder immediately if the other party has failed to cure a material breach after thirty days' written notice or for the other party's insolvency.

The Arensia CSA includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies and warranties.

QPS Holdings Master Contract Services Agreement

In October 2023, we entered into a master contract services agreement (the "QPS Agreement") with QPS Holdings, LLC ("QPS"). The QPS Agreement governs the general terms under which QPS, or one of its affiliates, will provide services (excluding GMP manufacturing and clinical development related services) as specified by us on a project-by-project basis. Such services are performed under agreed statements of work. Under the terms of the QPS Agreement, we have agreed to pay for QPS's performance of the services as specified in the applicable statement of work. Additionally, under the terms of the QPS Agreement, all documentation, information, and biological, chemical or other materials controlled by us and furnished to QPS by or on our behalf shall remain our exclusive property, and we shall own all rights to, and QPS shall assigns all right, title and interest to, all inventions, discoveries, improvements, ideas, processes, formulations, products, co computer programs, works of authorship, databases, trade secrets, know-how, information, data, documentation, reports, research, creations and all other products and/or materials arising from or made in the performance of QPS's services.

The term of the QPS Agreement will expire on the later of: (i) two years from the effective date of the QPS Agreement, or October 2025, or (ii) the completion of the services under all work orders executed prior to the second anniversary of the effective date of the QPS Agreement, or October 2025. We may terminate the QPS Agreement or any statement of work thereunder for any reason upon thirty days' prior written notice or immediately if QPS commits an uncurable breach of the QPS Agreement. QPS may terminate the QPS Agreement or any statement of work thereunder if we have failed to cure a material breach after thirty days' written notice or may terminate the QPS Agreement for any reason upon sixty days' prior written notice provided there are no active statements of work outstanding.

The QPS Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies and warranties.

ITR LABORATORIES Master Contract Services Agreement

In February 2022, we entered into a master contract services agreement (the "ITR Agreement") with ITR Laboratories Canada Inc. ("ITR"). The ITR Agreement governs the general terms under which ITR, or one of its

affiliates, will provide services (excluding GMP manufacturing and clinical development related services) as specified by us on a project-by-project basis. Such services are performed under agreed statements of work. Under the terms of the ITR Agreement, we have agreed to pay for ITR's performance of the services as specified in the applicable statement of work. Additionally, under the terms of the ITR Agreement, all documentation, information, and biological, chemical or other materials controlled by us and furnished to ITR by or on our behalf shall remain our exclusive property, and we shall own all rights to, and ITR shall assigns all right, title and interest to, all inventions, discoveries, improvements, ideas, processes, formulations, products, co computer programs, works of authorship, databases, trade secrets, know-how, information, data, documentation, reports, research, creations and all other products and/or materials arising from or made in the performance of ITR's services.

The term of the ITR Agreement will expire on the later of (i) two years from the effective date of the ITR Agreement, or February 2024; or (ii) the completion of the services under all work orders executed prior to the second anniversary of the effective date of the ITR Agreement, or February 2024. we may terminate the ITR Agreement or any statement of work thereunder for any reason upon thirty days' prior written notice or immediately if ITR commits an uncurable breach of the ITR Agreement. ITR may terminate the ITR Agreement or any statement of work thereunder if we have failed to cure a material breach after thirty days' written notice or may terminate the ITR Agreement for any reason upon sixty days' prior written notice provided there are no active statements of work outstanding.

The ITR Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies and warranties.

Intellectual Property

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and our product candidates that are important to the development and implementation of our business.

As of July 6, 2024, our patent portfolio includes two pending U.S. non-provisional applications, one pending international (Patent Cooperation Treaty) application, and nineteen pending foreign applications relating to Fc-relaxin fusion protein compositions (including TX45) and methods of use thereof. Specifically, we have exclusively in-licensed one patent family from the President and Fellows of Harvard College that consists of one pending U.S. non-provisional patent application and nine pending foreign applications in Australia, Canada, China, Europe, Israel, Japan, Korea, Mexico, and Singapore, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than May 2041. We also wholly own two patent families; the first family consists of one pending U.S. non-provisional patent application and nine pending foreign applications in Australia, Canada, China, Europe, Israel, Japan, Korea, Mexico, and Singapore, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than November 2042, and the second family consists of one pending Patent Cooperation Treaty application and one pending foreign application in Taiwan, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than May 2044. We also co-own one patent family with ModernaTX, Inc., which consists of one pending Patent Cooperation Treaty application relating to constitutively active modified G protein-coupled receptors and methods of use thereof, with any patent issuing from this application having an expected 20-year expiry date of not earlier than August 2043. Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period.

However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain its competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment agreements with our employees. We also have confidentiality agreements or invention assignment agreements with our collaborators and selected consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or its product candidates or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future product candidates may have an adverse impact on us. If third parties have prepared and filed patent applications prior to March 16, 2013 in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO, to determine priority of invention. For more information, please see "*Risk Factors — Risks Related to Intellectual Property*."

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our lead product candidate TX45. We currently rely, and expect to continue to rely for the foreseeable future, on third-party contract manufacturing organizations, or CMOs, to produce our product candidates for preclinical and clinical testing, as well as for future commercial manufacture of any products that we may commercialize.

We require our CMOs to conduct manufacturing activities in compliance with current good manufacturing practice, or cGMP, requirements. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight over its CMOs. Currently, we contract with one third-party manufacturer, WuXi Biologics, to provide biologics development and manufacturing services. In the future, we may engage additional third-party manufacturers to support any clinical trials for TX45 as well as commercialization of TX45, if approved, in the United States or other jurisdictions or the clinical development and potential commercialization of additional programs from its pipeline.

We rely on WuXi Biologics to perform all chemistry, manufacturing, and controls ("CMC") activities related to our TX45 program. We require that WuXi Biologics produces bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices ("cGMPs"), and all other applicable laws and

regulations. In addition, we rely on WuXi Biologics to operate facilities that meet regulatory requirements for production and testing of clinical and commercial products and to work closely with us to validate manufacturing processes prior to commercial launch. We oversee WuXi Biologics by performing technical and quality assurance review and/or approval of cGMP documentation, establishing quality agreements to define responsibilities and expectations for goods and services, and observing production and testing activities, among other activities.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or with their collaborations, 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. 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 enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition from companies that are pursuing development of engineered proteins based on human relaxin including Lilly and AstraZeneca, both of whom are currently conducting Phase 2 trials. To our knowledge, neither of these companies have a specific focus on the Group 2 PH / HFpEF population, and, instead, are pursuing either the broader HFpEF population (Lilly) or Group 2 PH in the setting of either HFpEF or HFrEF (AstraZeneca). AstraZeneca has also reported efforts with a small molecule agonist of the RXFP1 receptor and recently initiated a Phase 2 clinical trial. Lastly, Moderna is studying an mRNA encoding relaxin administered via IV infusion in patients with congestive heart failure in Phase 1.

In the HHT space, Vaderis has been pursuing development of an oral AKT inhibitor and Diagonal Therapeutics has been pursuing agonist antibodies for the treatment of this condition. Investigator-initiated studies of nintendanib (Boehringer Ingelheim) and pazopanib (Novartis) are also ongoing to explore the potential utility of these kinase inhibitors to treat this condition.

Our focus on biologic drugs differentiates us from many competitor GPCR companies whose primary focus is on small molecule drug discovery. Additionally, our GPCR membrane protein biochemistry experience, which is key for generating optimally stabilized and formulated receptors for antibody selection campaigns, combined with our experience using novel antigen formats differentiates us from in vitro display based antibody discovery. Specifically, our use of membrane mimetics that help maintain native receptor extra- cellular domain conformations combined with the membrane protein biochemistry expertise that we have built over the last three years is a key point of potential differentiation.

Several other companies are focused on discovery of GPCR-targeted therapeutics. Some may have an emphasis on small molecule approaches (Septerna, SOSEI-Heptares, Structure Therapeutics), on alternative biologic efforts (Abalone Bio, Orion Biotechnology), both (Abilitia Bio, Confo Therapeutic, Orion Biotechnology, Omeros), or on specific targets or target classes (GPCR Therapeutics).

Government Regulation

Government authorities in the United States, at the federal, state and local level and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Licensure and regulation of biologics in the United States

In the United States, any product candidates we may develop would be regulated as biological products, or biologics, under the Public Health Service Act ("PHSA") and the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. The failure to comply with the applicable U.S. requirements at any time during the product development process, including preclinical testing, clinical testing, the approval process, or post-approval process, may subject an applicant to delays in the conduct of the study, regulatory review and approval and/or administrative or judicial sanctions.

An applicant seeking approval to market and distribute a new biologic in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's applicable Good Laboratory Practices ("GLP") regulations;
- completion of the manufacture, under current good manufacturing practices ("cGMP") conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance with current good clinical practices ("GCP") regulations;
- preparation and submission to the FDA of a BLA for a biological product requesting marketing for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development and proposed labelling;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the preclinical studies and clinical trial sites to assure compliance with GLP, as applicable, and GCP, and the integrity of clinical data in support of the BLA;
- payment of Prescription Drug User Fee Act ("PDUFA") fees, securing FDA approval of the BLA and licensure of the new biological product; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS") and any post-approval studies or other post- marketing commitments required by the FDA.

Preclinical studies and investigational new drug application

Before testing any biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate the potential for efficacy and toxicity in animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application.

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin or recommence.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or allowing the trial to commence on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND review process, it may choose to impose a partial or complete clinical hold. Clinical holds are imposed by the FDA whenever there is concern for patient safety, may be a result of new data, findings, or developments in clinical, preclinical and/or chemistry, manufacturing and controls or where there is non-compliance with regulatory requirements. This order issued by the FDA would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. This could cause significant delays or difficulties in completing our planned clinical trials or future clinical trials in a timely manner.

Human clinical trials in support of a BLA

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease or condition to be treated under the supervision of a qualified principal investigator in accordance with GCP requirements. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain regulatory requirements of the FDA in order to use the trial as support for an IND or application for marketing approval. Specifically, the FDA requires that such trials be conducted in accordance with GCP, including review and approval by an independent ethics committee and informed consent from participants. The GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for clinical trials in the United States.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. An IRB must operate in compliance with FDA regulations. The FDA, IRB, or the clinical trial

sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board ("DSMB"). This group may recommend continuation of the trial as planned, changes in trial conduct, or cessation of the trial at designated check points based on certain available data from the trial to which only the DSMB has access.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

Phase 1 clinical trials are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a biologic; such Phase 3 studies are referred to as "pivotal."

In some cases, the FDA may approve a BLA for a product but require the sponsor to conduct additional clinical trials to further assess the product's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. The failure to exercise due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Information about applicable clinical trials must be submitted within specific timeframes to the National Institutes of Health ("NIH") for public dissemination on its *ClinicalTrials.gov* website.

Pediatric studies

Under the Pediatric Research Equity Act of 2003 ("PREA"), a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the

plan at any time. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

Compliance with cGMP requirements

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PHSA emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Any product manufactured by or imported from a facility that has not registered, whether foreign or domestic, is deemed misbranded under the FDCA. Establishments may be subject to periodic unannounced inspections by government authorities to ensure compliance with cGMPs and other laws. Inspections must follow a “risk-based schedule” that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

Review and approval of a BLA

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of a BLA requesting license to market the product. The BLA must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. Under federal law, the submission of most BLAs is subject to a substantial application user fee. The sponsor of a licensed BLA is also subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether it is sufficient to accept for filing based on the agency’s threshold determination that it is sufficiently complete to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under the PDUFA, the FDA has ten months in which to complete its initial review of a standard application and respond to the applicant, and six months for a priority review of the application. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process may often be significantly extended by FDA requests for additional information or clarification.

Under the PHSA, the FDA may approve a BLA if it determines that the product is safe, pure and potent, and the facility where the product will be manufactured meets standards designed to ensure that it continues to be safe, pure and potent. On the basis of the FDA’s evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of preclinical and clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter or a complete response letter (“CRL”). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. If the application is not approved, the FDA will issue a CRL, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a CRL may submit to the FDA information that represents a complete response to the issues identified by the FDA.

The FDA may also refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. In particular, the FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indication(s) for use of the product. It may also require that contraindications, warnings, or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's efficacy and/or safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited review programs

The FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, the sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review and accelerated approval.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.
- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval.* Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product

candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, for products being considered for accelerated approval, the FDA generally requires, as a condition for accelerated approval, pre-approval of promotional materials. *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.

- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval.* Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, for products being considered for accelerated approval, the FDA generally requires, as a condition for accelerated approval, pre-approval of promotional materials.

None of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates.

Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, the sponsor will be required to comply with all regular post-approval regulatory requirements as well as any post- approval requirements that the FDA have imposed as part of the approval process. The sponsor will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, the sponsor and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements.

A product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may in addition perform certain confirmatory tests on lots of some products before releasing the lots for distribution. Finally, the FDA will conduct laboratory research related to the safety, purity, potency and effectiveness of pharmaceutical products.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in 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 or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product recall, seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Although healthcare providers may prescribe products for uses not described in the drug's labeling, known as off-label uses, in their professional medical judgment, drug manufacturers are prohibited from soliciting, encouraging or promoting unapproved uses of a product. Drug manufacturers may only share truthful and non-misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

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

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

Biosimilars and exclusivity

The 2010 Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. A biosimilar is a biological product that is highly similar to an existing FDA-licensed "reference product." No interchangeable biosimilars, however, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidances are expected to be finalized by the FDA in the near term.

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

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. Since the passage of the BPCIA, many states have passed laws or amendments to laws, including laws governing pharmacy practices, which are state-regulated, to regulate the use of biosimilars.

Patent term restoration and extension

In the United States, a patent claiming a new biological product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND and the submission date of the BLA, plus the time between the submission date of the BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Other U.S. healthcare laws and compliance requirements

Healthcare providers, including physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and customers may implicate broadly applicable fraud and abuse and other healthcare laws and regulations. Restrictions under

applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- the civil False Claims Act ("FCA"), prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties, for each false claim and treble the amount of the government's damages. Manufacturers can be held liable under the False Claims Act 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 federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Anti-Kickback Statute prohibits, among other things, persons or entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. A violation of the federal Anti-Kickback Statute can also form the basis for FCA liability;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, including the final omnibus rule published on January 25, 2013, imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain, transmit, or obtain, protected health information in connection with providing a service for or on behalf of a covered entity, and their covered subcontractors. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- Federal price transparency laws, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Centers of Medicare & Medicaid Services ("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- 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, anti-bribery and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/ or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of AVROBIO's activities are potentially subject to federal and state consumer protection and unfair competition laws.

Payments made to physicians in certain European Union Member States must be publicly disclosed. 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 European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in criminal and civil sanctions, including significant fines and civil monetary penalties, reputational risk, public reprimands, administrative penalties, exclusion from participation in governmental healthcare programs, disgorgement, or imprisonment. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Healthcare reform

In the United States and some foreign jurisdictions, there have been and continue to be ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of any product candidates that we may develop, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Although we cannot predict what healthcare or other reform efforts will be successful, such efforts may result in more rigorous coverage criteria, in additional downward pressure on the price that we, or our future collaborators, may receive for any approved products or in other consequences that may adversely affect our ability to achieve or maintain profitability.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Reconciliation Act of 2010 (the "ACA"), and the ongoing efforts to modify or repeal that legislation. The ACA substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. Modifications have been implemented and additional modifications or repeal may occur.

In August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. The IRA contains several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high- cost drugs and

biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the U.S. Department of Health and Human Services ("HHS") rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although there is currently ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition to pricing regulations, reforms of regulatory approval frameworks may adversely affect our pricing strategy. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our potential product candidates. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. 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 may be required to conduct a clinical trial that compares the cost-effectiveness of any product candidates we may develop 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 harmed, possibly materially.

Coverage and reimbursement

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 or product licensing 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 one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, there is no uniform policy of coverage and reimbursement for products that exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for our product candidates, if approved, by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients find unacceptably high.

A primary trend in the U.S. healthcare industry 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, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Further, coverage policies and third-party payor reimbursement rates may change. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. If coverage and adequate reimbursement are not available or reimbursement 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 coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. 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 and may be incorporated into existing payments for other services. 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 United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

There can be no assurance that our product candidates, even if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell our product candidates profitably.

Regulation outside of the United States

In addition to regulations in the United States, we will be required to comply with comparable regulations in each jurisdiction outside of the United States in which we choose to manufacture, develop or seek marketing authorization for our product candidates.

European Union drug development

Most countries outside of the United States require that clinical trial applications be submitted to and approved by the local regulatory authority for each clinical study. In the European Union, for example, an application must be submitted to the national competent authority and an independent ethics committee in each country in which we intend to conduct clinical trials, much like the FDA and IRB, respectively. Under the new Clinical Trials Regulation (EU) No 536/2014, which replaced the previous Clinical Trials Directive 2001/20/EC on January 31, 2022, a single application is now made through the Clinical Trials Information System for clinical trial authorization in up to 30 EU or European Economic Area (Norway, Iceland and Liechtenstein) ("EEA") countries at the same time and with a single set of documentation.

The assessment of applications for clinical trials is divided into two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has been submitted (each, a "Member State Concerned") of a draft report prepared by a Reference Member State. Part II is assessed separately by each Member State Concerned. The role of the relevant ethics committees in the assessment procedure continues to be governed by the national law of the Member State Concerned, however overall related timelines are defined by the Clinical Trials Regulation. The new Clinical Trials Regulation also provides for simplified reporting procedures for clinical trial sponsors.

European Union drug review and approval

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

To obtain regulatory approval for our medicinal product candidates in the European Union, a marketing authorization application ("MAA") needs to be submitted. There are a number of potential routes open to obtain a marketing authorization ("MA") in the European Union. A centralized MA is issued by the European Commission through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use ("CHMP") of the EMA, and is valid throughout the European Union, and in the additional Member States of the EEA. The centralized procedure is compulsory for medicinal products manufactured using biotechnological processes, orphan medicinal products, advanced therapy medicinal products (gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products containing a new active substance which is not yet authorized in the European Union and which is intended for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, auto-immune and other immune dysfunctions, viral diseases or diabetes. The centralized procedure is optional for any other products containing new active substances not authorized in the European Union or for products which constitute a significant therapeutic, scientific, or technical innovation or for which a centralized authorization is in the interests of patients at European Union level.

National MAs are issued by the competent authorities of the EU Member States and only cover their respective territory. This procedure is available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU Member State, this national MA can be recognized in another Member State through the mutual recognition procedure. If the product has not received a national MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each Member State in which the MA is sought, one of which is selected by the applicant as the Reference Member State.

Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment. MAs in the European Union have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a re-evaluation of the risk-benefit balance.

Data protection regulation

In the European Economic Area ("EEA"), the collection and processing of personal data, including personal health data is regulated by the General Data Protection Regulation (EU) 2016/679 ("GDPR"). Similarly, in the United Kingdom, the collection and processing of personal data, including personal health data is regulated by the UK General Data Protection Regulation and the UK Data Protection Act 2018 ("UK GDPR" and together with the EU GDPR, referred to as "GDPR"). The GDPR has extra-territorial application and applies not only to organizations with a presence in the EEA and the UK but also to non-EEA/UK based businesses that carry out processing that is related to (i) an offer of goods or services to individuals in the EEA/UK or (ii) the monitoring of their behavior so long as this takes place in the EEA/UK, even if the data is stored outside the EEA/UK. The GDPR imposes obligations on businesses (including companies that operate in our industry) with respect to the processing of personal data and the cross-border transfer of such data. We will be subject to the GDPR to the extent we process the personal data of individuals based in the EEA/UK.

Employees and Human Capital

As of July 6, 2024, we had 45 full-time employees, 31 of whom were primarily engaged in research and development activities, and 21 of our employees had an M.D. or Ph.D. degree. None of our employees is represented by a labor union and we consider our employee relations to be good.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Facilities

Our headquarters are currently located in Watertown, Massachusetts and consist of approximately 19,000 square feet of leased research laboratory and office space under a lease that expires in January 2026. We believe that our facilities are adequate to meet our current needs.

Legal Proceedings

Prior to the Merger, three actions were filed by purported stockholders of AVROBIO in connection with the Merger. One action has been filed in the United States District Court for the Southern District of New York captioned *Garofalo v. Avrobio, Inc. et al.* , 24-cv-1493 (filed February 27, 2024), which was voluntarily dismissed without prejudice on June 13, 2024. Two actions have been filed in the Supreme Court of New York, captioned *Price v. Avrobio, Inc., et al.* , No. 652555/2024 (filed May 17, 2024) and *Keller v. Avrobio, Inc., et al.* , No. 652597/2024 (filed May 21, 2024). The foregoing actions are referred to as the "Merger Actions."

The Merger Actions generally allege that the Registration Statement misrepresents and/or omits certain purportedly material information in connection with the Merger, potential conflicts of interest of AVROBIO's officers and directors, and the events that led to the signing of the Merger Agreement. The *Garofalo* action asserted violations of Section 14(a) of the Exchange Act and Rule 14a-9 promulgated thereunder against all defendants (AVROBIO and the AVROBIO Board) and violations of Section 20(a) of the Exchange Act against AVROBIO's directors. The *Price* and *Keller* actions assert claims for breach of fiduciary duty against all defendants. The Merger Actions seek, among other things, an injunction enjoining the consummation of the Merger, rescission of the Merger if consummated, costs of the action, including plaintiff's attorneys' fees and experts' fees and other relief the court may deem just and proper.

AVROBIO also received the Demands from eleven purported AVROBIO stockholders. The Demands generally assert that the Registration Statement misrepresents and/or omits certain purportedly material information relating to the Merger.

AVROBIO believed that the disclosures set forth in the Registration Statement complied fully with all applicable law, that no supplemental disclosures were required under applicable law, and that the allegations in the Merger Actions and Demands were without merit. However, in order to moot the claims in the Merger Actions and Demands, avoid nuisance and possible expense and business delays, and provide additional information to its stockholders, and without admitting any liability or wrongdoing, AVROBIO decided voluntarily to provide the Supplemental Disclosures. On June 4, 2024, AVROBIO made certain Supplemental Disclosures on Form 8-K filed with the Securities and Exchange Commission.

The outcome of any current or future litigation is uncertain. Such litigation, if not resolved, could result in substantial costs to us, including any costs associated with the indemnification of directors and officers. If a plaintiff were successful in obtaining an injunction obtaining a rescission of the Merger, then such injunction may rescind the Merger after its consummation. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors.

Although we cannot predict the outcome of the Merger Actions or the Demands, we and our Board intend to vigorously defend the Merger Actions and the Demands.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Although the results of ordinary course litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business, financial condition, results of operations or cash flows. Regardless of the outcome, litigation can have an adverse impact because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table lists the names and ages, as of July 6, 2024, and positions of our executive officers and directors:

Name	Age	Position
Executive Officers:		
Alise Reicin, M.D.	63	President, Chief Executive Officer and Director
Daniel Lochner, M.B.A.	42	Chief Financial Officer
Peter McNamara, Ph.D.	53	Chief Scientific Officer
Marcella K. Ruddy, M.D.	62	Chief Medical Officer
Marc Schwabish, Ph.D.	44	Chief Business Officer
Non-Employee Directors:		
Phillip B. Donenberg	64	Director
Terrance McGuire M.S., M.B.A.	68	Director
Timothy A. Springer, Ph.D., M.B.A.	76	Director
Praveen Tipirneni, M.D.	55	Director
Stefan Vitorovic M.S., M.B.A.	39	Director

Executive Officers

Alise Reicin, M.D., has served as our President and Chief Executive Officer and member of the Board since completion of the Merger. Dr. Reicin previously served as Legacy Tectonic's President and Chief Executive Officer since August 2020. Prior to joining Legacy Tectonic, Dr. Reicin served as President, Global Clinical Development at Celgene Corporation, public pharmaceutical company, from November 2018 to December 2019 and was a member of the Executive Committee. Prior to Celgene, she served as Head of Global Clinical Development at EMD Serono Inc., a privately held pharmaceutical company, from May 2015 to October 2018. Prior to EMD Serono, Dr. Reicin served as Vice President, Program and Pipeline Leadership, Oncology at Merck & Co., Inc., a public pharmaceutical company. Prior to Merck, she was a faculty member at Columbia Medical School and a physician and researcher at Columbia Presbyterian Hospital. While at Merck, Dr. Reicin led the team that brought Keytruda from Phase 1 through its initial approvals and over the course of her career she has played a leadership role in the development and approval of over 10 novel medicines across a broad range of therapeutic areas. Dr. Reicin previously served on the board of directors of Homology Medicines, Inc., a public biopharmaceutical company and currently serves on the board of directors of Sana Biotechnology, Inc., a public cell and gene therapy company. Dr. Reicin earned a B.A. in Biochemistry from Barnard College of Columbia University. She earned a M.D. in Medicine from Harvard University. The Company believes that Dr. Reicin is qualified to serve on the Board due to her clinical expertise and leadership roles in the biotechnology and biopharmaceuticals industry.

Daniel Lochner, M.B.A., has served as our Chief Financial Officer since completion of the Merger. Mr. Lochner was previously appointed Legacy Tectonic's Chief Financial Officer in June 2024. Prior to joining Legacy Tectonic, Mr. Lochner served as Chief Financial Officer and Chief Business Officer for the Eye Care Division of Viatris Inc., a global healthcare company, from January 2023 to April 2024. Prior to Viatris, Mr. Lochner was the Chief Financial Officer and Chief Business Officer of Oyster Point Pharma, Inc., a biotechnology company that was acquired by Viatris in January 2023, from July 2019 to January 2023 where he led a successful initial public offering, other equity and debt financings, the transition to a commercial-stage company and the acquisition to Viatris. Previously, Mr. Lochner was a Managing Director within the Investment Management Division of Goldman Sachs & Co., where he served as a lead equity portfolio manager and healthcare investor for various fund strategies. Mr. Lochner joined the Investment Management Division of Goldman Sachs & Co. in 2005 as an equity investor, a position he maintained during his tenure at the firm.

Mr. Lochner received a B.A. in Economics from the University of Richmond and an Executive M.B.A. from Columbia University.

Peter McNamara, Ph.D., has served as our Chief Scientific Officer since completion of the Merger. Dr. McNamara previously served as Legacy Tectonic's Chief Scientific Officer since June 2022. Prior to that, Dr. McNamara served as Senior Vice President, Head of Research at Tectonic from June 2021 to June 2022. Prior to joining Tectonic, he held various positions at the Genomics Institute of the Novartis Research Foundation ("NIBR, San Diego"), a privately held pharmaceutical company, from 2005 to April 2021, most recently as Executive Director of Biotherapeutics and Biotechnology from June 2018 to April 2021 where he served on the executive committee and strategy council responsible for managing a portfolio of approximately 50 preclinical and early-stage clinical drug discovery programs across different modalities in a broad range of therapeutic areas. Over the course of his career, Dr. McNamara has played a critical role in the obtainment of over 10 INDs, two of which are now approved. Prior to Novartis, Dr. McNamara served as Director of Pharmacology at Phenomix Corporation, a privately-held biotechnology company. Prior to Phenomix, he was a faculty member of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania. Dr. McNamara earned both a Ph.D. and B.S. in Biochemistry from the National University of Ireland, at Galway.

Marcella K. Ruddy, M.D., has served as our Chief Medical Officer since completion of the Merger. Dr. Ruddy previously served as Legacy Tectonic's Chief Medical Officer since July 2021. She has over 20 years of experience in drug development across all stages of clinical drug development. She currently serves as a member of the board of directors of Polarean Imaging plc and Upstream Bio, Inc. and has since August 2022 and January 2023, respectively. Prior to joining Tectonic's team, Dr. Ruddy was the Head of Clinical Development for the Immunology/Inflammation Therapeutic Area at Regeneron Pharmaceuticals. In that role she led the clinical development of Dupixent® through over nine Phase 3 trial initiations and multiple regulatory approvals globally. Dr. Ruddy spent 10 years in early development at Merck and took many compounds from preclinical development through proof of concept in the clinic. Prior to entry into drug development, Dr. Ruddy was a member of the Pulmonary Unit at Massachusetts General Hospital/Harvard Medical School where she founded and directed the Adult Cystic Fibrosis Program. Dr. Ruddy earned an A.B. from Princeton University and a M.D. and M.S. from Washington University, St. Louis. She completed her internal medicine and pulmonary fellowship training at Harvard Medical School affiliated hospitals.

Marc Schwabish, Ph.D., has served as our Chief Operating Officer since completion of the Merger. Dr. Schwabish previously served as Legacy Tectonic's Chief Business Officer since March 2021. Prior to joining Legacy Tectonic, Dr. Schwabish served as SVP Business Development and US Operations at Fusion Pharmaceuticals Inc. from February 2018 to December 2020 where his transactions, amongst others, included the company's Series B financing, IPO, and an expansive partnership with AstraZeneca plc. Prior to working at Fusion Pharmaceuticals, Dr. Schwabish was Heard of U.S. Pharma Business Development at Bayer, Inc. He also held roles in Business Development and Alliance Management at Eisai Inc., Strategy Consulting at Leerink Swann and Healthcare Investment Banking at RBS. Dr. Schwabish earned a B.S. in Biological Sciences from Cornell University. He earned a Ph.D. in Biochemistry and Molecular Pharmacology from Harvard University.

Non-Employee Directors

Phillip B. Donenberg, has served as a member of the Board since completion of the Merger. Mr. Donenberg previously served as a member of the AVROBIO board of directors since June 2018. Mr. Donenberg served as senior vice president and chief financial officer of Jaguar Gene Therapy, LLC, a privately held early-stage gene therapy company from February 2020 to March 2023. From July 2018 to November 2018, Mr. Donenberg served as the chief financial officer and senior vice president of Assertio Therapeutics, Inc., a pharmaceutical company. Previously, Mr. Donenberg served at AveXis, Inc. (now a Novartis company), a gene therapy company, as senior vice president and chief financial officer from October 2017 to June 2018 and as vice president, corporate controller from September 2016 to October 2017. He was the chief financial officer of RestorGenex Corporation from May 2014 to January 2016, when RestorGenex merged

with Diffusion Pharmaceuticals LLC, a pharmaceutical company, and served as the merged company's consultant chief financial officer until September 2016, and the chief financial officer of 7wire Ventures LLC, an early-stage healthcare venture fund, from September 2013 to May 2014. Prior to that time, Mr. Donenberg served as the chief financial officer of BioSante Pharmaceuticals, Inc. from July 1998 to June 2013, when BioSante merged with ANIP Pharmaceuticals, Inc. Mr. Donenberg currently serves on the board of directors and as audit committee chair of Taysha Gene Therapies, Inc., a gene therapy company, and also has experience serving on the boards of directors of privately held companies. Mr. Donenberg holds a B.S. in accountancy from the University of Illinois Champaign-Urbana College of Business and is a Certified Public Accountant. The Company believes that Mr. Donenberg is qualified to serve on the Board because of his financial expertise and his experience as an executive of companies in the life sciences industry.

Terrance McGuire M.S., M.B.A, has served as a member of the Board since completion of the Merger. Mr. McGuire previously served as a member of the Legacy Tectonic board of directors since Legacy Tectonic commenced operations as an independent company in February 2020. Mr. McGuire was a co-founder and is currently a general partner of Polaris Partners. He serves on the board of directors of several private companies and currently serves on the board of directors of Cyclerion Therapeutics Inc., Alector Inc., Seer Inc. and Invivyd Inc. Mr. McGuire has also served on the board of Pulmatrix Inc. Mr. McGuire is the former chairman of the National Venture Capital Association, which represents ninety percent of the venture capitalists in the U.S., chairman of the board of the Thayer School of Engineering at Dartmouth College, and a member of the boards of The David H. Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology and The Arthur Rock Center for Entrepreneurship at Harvard Business School. Mr. McGuire earned a B.S. in physics and economics from Hobart College, an M.S. in engineering from The Thayer School at Dartmouth College, and an M.B.A. from Harvard Business School. The Company believes that Mr. McGuire is qualified to serve on the Board because of his extensive experiences as a venture capitalist focused on the biotechnology industry, as well as many years of experience as a director of biotechnology companies guiding them in the execution of their corporate strategy and objectives.

Timothy A. Springer, Ph.D., has served as a member of the Board since completion of the Merger. Dr. Springer co-founded Legacy Tectonic in June 2019 and previously served as a scientific advisor to Legacy Tectonic and as a member of the Legacy Tectonic board of directors since June 2019. Dr. Springer served as Chief Executive Officer of Legacy Tectonic from June 2019 until August 2019 and as President of Legacy Tectonic from June 2019 until August 2020. Since 1989, Dr. Springer has served as the Latham Family Professor at Harvard Medical School. He has also served as Senior Investigator in the Program in Cellular and Molecular Medicine at Boston Children's Hospital since 2012, and as a Professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School and Professor of Medicine at Boston Children's Hospital since 2011. He was also the founder of Morphic Technology, Inc. and has served as a scientific advisor and as a member of its board of directors since June 2015. He has also served Selecta Biosciences Inc. as a scientific advisor since December 2008 and as a member of its Board since June 2016. Dr. Springer is a member of the National Academy of Sciences and his honors include the Crafoord Prize, the American Association of Immunologists Meritorious Career Award, the Stratton Medal from the American Society of Hematology, and the Basic Research Prize from the American Heart Association, the Canada International Gairdner Award, and the Lasker Basic Medical Research Award. Dr. Springer received a B.A. in Biochemistry from the University of California, Berkeley, and a Ph.D. in Biochemistry and Molecular Biology from Harvard University. The Company believes that Dr. Springer is qualified to serve on the Board because of his extensive knowledge of the integrin field and his investment, business and board experience with biopharmaceutical companies.

Praveen Tipirneni, M.D., M.B.A., has served as a member of the Board since completion of the Merger. Dr. Tipirneni previously served as a member of the Legacy Tectonic board of directors since February 2020. Dr. Tipirneni currently serves as Chief Executive Officer and as a member of the board of directors of Morphic Holding, Inc., a position he has held since July 2015. Dr. Tipirneni received a B.A. in Mechanical Engineering from Massachusetts Institute of Technology, an M.D. from McGill University and an M.B.A. from the Wharton School of Business of the University of Pennsylvania. The Company believes Dr. Tipirneni is qualified to serve

on the Board because of his experience with biotechnology companies, including working with and serving in various executive positions in life sciences companies.

Stefan Vitorovic, M.S., M.B.A., has served as a member of the Board since completion of the Merger. Mr. Vitorovic previously served as a member of the Legacy Tectonic board of directors since August 2021. Mr. Vitorovic is the co-founder and Managing Director of Vida Ventures, a role he has served in since January 2017. Prior to founding Vida Ventures, Mr. Vitorovic was an investment professional at Third Rock Ventures, an early-stage life sciences venture capital firm, from July 2014 to January 2017. At Third Rock, he was part of the founding team of Decibel Therapeutics, Inc. (acquired by Regeneron Pharmaceuticals, Inc.), a hearing-focused drug discovery and development platform company. Before Third Rock, he was an investor at TPG Capital from August 2012 to June 2014, where he focused on majority, control stakes in healthcare companies. Mr. Vitorovic worked on a variety of equity and debt financings, including Aptalis Pharmaceutical Technologies (now Adare Pharma Solutions) and Biomet, Inc. (now Zimmer Biomet Holdings, Inc. (NYSE: ZBH)). Prior to TPG, Mr. Vitorovic was an investment banker at Credit Suisse's healthcare banking group from 2004 to 2008. Mr. Vitorovic currently serves on the board of directors of Vigil Neuroscience, Inc. (NASDAQ: VIGL), Volastra Therapeutics, Inc., and Souffle Therapeutics, Inc. He was previously a board observer of Oyster Point Pharma, Inc. (formerly NASDAQ: OYST), Dyne Therapeutics (NASDAQ: DYN) and Sutro Biopharma, Inc. (NASDAQ: STRO), and a board member of Kyverna Therapeutics, Inc. (NASDAQ: KYTX) and Praxis Precision Medicines, Inc. (NASDAQ: PRAX) from 2018 to 2022. He received a B.S. with Honors in Biological Sciences and an M.S. in Biology from Stanford University, where he conducted biomedical research in the lab of Dr. Helen Blau at Stanford Medical School. Mr. Vitorovic received his M.B.A. from Harvard Business School. The Company believes Mr. Vitorovic is qualified to serve on the Board because of his deep expertise in life sciences research and investing, as well as his extensive experience in new company formation and operations.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, our Board.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Involvement in Certain Legal Proceedings

There are no material legal proceedings to which any of our executive officers is a party adverse to the Company or the Company's subsidiaries or in which any such person has a material interest adverse to the Company or the Company's subsidiaries.

Corporate Governance

Composition of Our Board of Directors

Our Board currently consists of six directors divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term.

In accordance with the terms of our certificate of incorporation (the "Certificate of Incorporation"), our Board is divided into three classes, Class I, Class II and Class III, with one class of directors being elected in each year and each class serving a three-year term. There is no cumulative voting with respect to the election of directors, with the result that the holders of more than 50% of the shares voted for the election of directors can elect all of the directors. The Board is divided among the following classes:

- Class I, which consists of Alise Reicin, M.D. and Praveen Tipirneni, M.D., whose terms will expire at the annual meeting of stockholders to be held in 2025;

- Class II, which consists of Timothy A. Springer, Ph.D. and Stefan Vitorovic, whose terms will expire at the annual meeting of stockholders to be held in 2026; and
- Class III, which consists of Terrance McGuire and Phillip B. Donenberg, whose terms will expire at the annual meeting of stockholders to be held in 2027.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election and until their successors are duly elected and qualified, or their earlier resignation, removal, retirement or death. This classification of the Board may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66$^{2/3}$% of our voting stock.

Independence of Our Board of Directors

Other than Dr. Reicin, our president and chief executive officer, all members of the Board are independent, and all members of committees of the Board are independent. To determine independence, the Board reviewed all relevant identified transactions or relationships between each director, or any of such director's family members, and us, our senior management and our independent auditors. Our Board has affirmatively determined that the following five current directors are independent directors within the meaning of the applicable Nasdaq listing standards: Phillip B. Donenberg, Terrance McGuire, Timothy A. Springer, Ph.D., Praveen Tipirneni, M.D. and Stefan Vitorovic. In making this determination, our Board found that none of these directors or nominees for director had a material or other disqualifying relationship with Tectonic. Dr. Reicin was determined as not being independent by virtue of her executive leadership role with us.

Accordingly, a majority of our directors are independent, as required under applicable Nasdaq rules. In making this determination, our Board considered the applicable Nasdaq rules and the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including their beneficial ownership of our share capital.

Committees of Our Board of Directors

The standing committees of our Board are the following: audit committee, compensation committee and nominating and corporate governance committee, and each operates pursuant to a charter. Our Board may establish other committees from time to time to assist us and our Board.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee's oversight responsibilities include:

- our accounting and financial reporting processes, systems of internal control over financial reporting and audits of financial statements, as well as the quality and integrity of our financial statements and reports;
- the qualifications, independence and performance of our independent registered public accountant;
- our compliance with legal and regulatory requirements, including compliance with ethical standards adopted by us; and
- the review and assessment of our risk management, risk assessment and major risk exposures with respect to financial, accounting, operational, tax, privacy and cybersecurity and information technology risks.

The audit committee consists of Phillip Donenberg, Terrance McGuire and Stefan Vitorovic. Phillip Donenberg serves as the chair of the audit committee and is a financial expert under the rules of the SEC. To qualify as independent to serve on our audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from us, other than for service as a director, or be an affiliated person of us. We believe that the composition of the audit committee complies with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Committee

Our compensation committee oversees policies relating to compensation and benefits of our officers and directors. Among other matters, the compensation committee's responsibilities include:

- establishing and reviewing our overall compensation philosophy in light of our specific business objectives;
- setting compensation, or recommending to the full Board the compensation, for our Chief Executive Officer;
- setting compensation for our other executive officers and directors;
- administering incentive and equity-based compensation plans;
- overseeing our compensation-related disclosures required by the SEC; and
- overseeing our policies and strategies relating to human capital management.

The compensation committee consists of Praveen Tipirneni and Stefan Vitorovic. Praveen Tipirneni serves as the chair of the compensation committee. Each member of the compensation committee is a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. We believe that the composition of the compensation committee complies with the applicable requirements of the rules and regulations of Nasdaq.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee's responsibilities include:

- identifying individuals qualified to become members of the Board (consistent with criteria approved by the Board), reviewing the qualifications of, and considering stockholders' recommendations for, director candidates and recommending to the Board qualified director nominees for appointment, election or reelection to the Board at each annual stockholders' meeting and as necessary to fill vacancies and newly created directorships;
- developing and recommending to the Board for adoption the corporate governance guidelines applicable to us, periodically reviewing such guidelines, recommending changes to the same from time to time as appropriate and overseeing and monitoring compliance with such guidelines;
- overseeing evaluations of the Board, its committees, and Board members;
- identifying individuals qualified to become members of our board of directors;
- identifying directors qualified to serve on the various committees of the Board and recommending to the Board qualified nominees for membership on each such committee; and
- overseeing succession planning for the Board and key leadership roles on the Board and its committees.

The nominating and corporate governance committee consists of Timothy Springer and Terrance McGuire. Timothy Springer serves as the chair of the nominating and corporate governance committee. We believe that the composition of the nominating and corporate governance committee meets the requirements for independence under, and the functioning of such nominating and corporate governance committee complies with, any applicable requirements of the rules and regulations of Nasdaq.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

We have a Code of Business Conduct and Ethics (the "Code of Conduct") that is applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at *https://investors.tectonictx.com/governance-documents*. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only. The Board, and audit committee of the Board, will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We plan to disclose any amendments to the Code of Conduct, or any waivers of its requirements, on our website.

EXECUTIVE COMPENSATION

Unless the context otherwise requires, any reference in this section of this prospectus to "Legacy Tectonic" refers to Tectonic Operating Company, Inc., a Delaware corporation (previously named Tectonic Therapeutic, Inc.) and its consolidated subsidiaries prior to the consummation of the Merger and any reference to "the Company," "we," or "us" refers to Tectonic Therapeutic, Inc. and its consolidated subsidiaries after the Merger. Unless otherwise indicated, the information presented in this "Executive and Director Compensation" section reflects information for Legacy Tectonic, is as of December 31, 2023 and does not reflect the effects of the Merger or the Reverse Stock Split. Upon the closing of the Merger, the executive officers of Legacy Tectonic became the executive officers of the Company.

Compensation Overview

Legacy Tectonic's named executive officers ("NEOs") for the year ended December 31, 2023 who appear in the Summary Compensation Table below are:

- Alise Reicin, M.D., our President, Chief Executive Officer and Director;
- Marcella K. Ruddy, M.D., our Chief Medical Officer; and
- Christian Cortis, Ph.D., who served as Legacy Tectonic's Chief Operating Officer and Chief Financial Officer through the closing of the Merger. He served as our Chief Operating Officer from the closing of the Merger until his separation from our company effective July 5, 2024.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt could vary significantly from our historical practices and currently planned programs summarized in this discussion.

2023 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by and paid to Legacy Tectonic's NEOs for services during the fiscal year ended December 31, 2023.

Name and Principal Position	Year	Salary[1] ($)	Option Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	All Other Compensation ($)	Total ($)
Alise Reicin, M.D.[4] *President and Chief Executive Officer*	2023	575,050	112,563	231,600	12,749[5]	919,213
Marcella K. Ruddy, M.D. *Chief Medical Officer*	2023	451,962	78,794	159,341	9,678[6]	690,096
Christian Cortis, Ph.D.[7] *Chief Operating Officer and Chief Financial Officer*	2023	383,356	78,794	115,850	495[8]	578,000

(1) Salary amounts represent actual amounts paid during 2023 and reflect increases to base salary effective April 1, 2023. See "*—Narrative to the Summary Compensation Table—Base Salary*" below.

(2) The amounts reported represent the aggregate grant date fair value of the stock option awards granted during the year ended December 31, 2023, calculated in accordance with FASB ASC 718 for share-based compensation transactions. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in Note 2 to Legacy Tectonic's consolidated financial statements for each of the years ended December 31, 2022 and 2023 included elsewhere in this the registration statement of which this prospectus forms a part. These amounts do not correspond to the actual economic value that may be received by Legacy Tectonic's named executive officers upon the exercise of the stock options or any sale of the underlying shares of common stock.

(3) Amounts disclosed for fiscal year 2023 reflect performance-based cash bonuses earned in 2023 and paid in early 2024. See "*—Non-Equity Incentive Plan Compensation*" below for a description of the material terms of the program pursuant to which this compensation was awarded.

(4) Dr. Reicin also served as a member of the Legacy Tectonic Board but did not receive any additional compensation for her service as a director.
(5) Represents (i) commuting expenses in the amount of $12,221, and (ii) life insurance premiums in the amount of $528 paid by Legacy Tectonic on behalf of Dr. Reicin.
(6) Represents (i) $9,150 in matching employer contributions to a 401(k) plan, and (ii) life insurance premiums in the amount of $528 paid by Legacy Tectonic on behalf of Dr. Ruddy.
(7) Upon the closing of the Merger, Dr. Cortis became our Chief Financial Officer, and he separated from our company effective July 5, 2024.
(8) Represents life insurance premiums paid by Legacy Tectonic on behalf of Dr. Cortis.

Narrative to the 2023 Summary Compensation Table

Base Salary

Each NEO's base salary was a fixed component of annual compensation for performing specific duties and functions, and was established by the Legacy Tectonic Board taking into account each individual's role, responsibilities, skills, and expertise. Base salaries were reviewed annually, typically in connection with Legacy Tectonic's annual performance review process, approved by the Legacy Tectonic Board, and adjusted from time to time to realign salaries with market levels and internal benchmarking, after taking into account individual responsibilities, performance and experience. Please see the "Salary" column in the Summary Compensation Table above for the actual base salary amount received by each named executive officer during the year ended December 31, 2023. The annual base salaries for Drs. Reicin, Ruddy and Cortis were $562,380, $442,000 and $374,920, respectively for the period from January 1, 2023 through March 31, 2023, and $579,251, $455,260 and $386,168, respectively, for the period from April 1, 2023 to December 31, 2023.

Effective as of April 1, 2024, the annual base salaries for Drs. Reicin, Ruddy and Cortis were increased to $602,160, $473,200 and $401,440, respectively.

In connection with the completion of the Merger, the annual base salaries for Dr. Reicin and Dr. Ruddy were increased to $620,000 and $486,850, respectively.

Non-Equity Incentive Plan Compensation

Legacy Tectonic's annual incentive program is intended to reward its named executive officers for performance during a fiscal year. From time to time, Legacy Tectonic's compensation committee or the Legacy Tectonic Board, as applicable, in their discretion may have approved annual incentives for Legacy Tectonic's named executive officers based on individual performance, company performance, or as otherwise determined appropriate. Each of Legacy Tectonic's named executive officers were eligible to receive a target bonus at the discretion of the Legacy Tectonic Board with respect to the year ended December 31, 2023 (as a percentage of base salary) based upon their performance.

Name	2023 Bonus Target (%)	2024 Bonus Target (%)
Alise Reicin, M.D.	40	55
Marcella K. Ruddy, M.D.	35	40
Christian Cortis, Ph.D.	30	40

In February 2024, based on the named executive officer's performance, the Legacy Tectonic Board determined that Drs. Reicin, Ruddy and Cortis were eligible to receive 100% of their target annual bonus for the year ended December 31, 2023, and as a result, approved annual performance bonuses for Drs. Reicin, Ruddy, and Cortis in the amounts of $231,600, $159,341 and $115,850, respectively, as reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Equity-Based Incentive Awards

Legacy Tectonic's equity-based incentive awards granted to its named executive officers were designed to align the interests of Legacy Tectonic and those of Legacy Tectonic stockholders with those of Legacy Tectonic employees and consultants, including its executive officers. Legacy Tectonic executives were generally awarded an initial equity grant in the form of a stock option, or restricted stock in the case of Drs. Reicin and Cortis, in connection with their commencement of employment with Legacy Tectonic.

Other than as disclosed below regarding restricted stock awards granted to Dr. Reicin pursuant to the Former Reicin Employment Agreement (as defined below), Legacy Tectonic historically used stock options as an incentive for long-term compensation to its executive officers because the option awards allowed Legacy Tectonic executive officers to profit from this form of equity compensation only if Legacy Tectonic's stock price increased relative to the option's exercise price, which exercise price was set at the fair market value of Legacy Tectonic common stock on the date of grant. Vesting of equity awards was generally tied to each officer's continuous service with Legacy Tectonic and served as an additional retention measure. Legacy Tectonic granted equity awards at such times as the Legacy Tectonic Board or compensation committee determined appropriate. Additional grants may have occurred periodically in order to specifically incentivize executives with respect to achieving certain corporate goals or to reward executives for exceptional performance.

In the year ended December 31, 2023, Legacy Tectonic granted each of Drs. Reicin, Ruddy and Cortis options to purchase shares of Legacy Tectonic common stock. Dr. Reicin was granted an option covering 50,000 shares, Dr. Ruddy was granted an option covering 35,000 shares and Dr. Cortis was granted an option covering 35,000 shares. Each of these option awards have an exercise price of $2.87, and vest in 48 equal monthly installments beginning on January 1, 2024. See the section titled "*—Outstanding Equity Awards at Fiscal 2023 Year-End*."

Outstanding Equity Awards at Fiscal 2023 Year-End

The following table sets forth information regarding outstanding equity awards held by Legacy Tectonic's NEOs as of December 31, 2023. All awards were granted pursuant to the Tectonic 2019 Plan. See "*—Equity Incentive Plans—Tectonic 2019 Equity Incentive Plan*" for additional information.

			Option Awards(1)				Stock Awards	
Name and Principal Position	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)(2)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(3)
Alise Reicin, M.D.	8/26/2020						33,722(4)	96,926
Chief Executive Officer and President	6/28/2021	3/31/2021	144,644	114,470 (5)	1.27	6/27/2031		
	12/1/2023	12/01/2023		50,000 (7)	2.87	11/30/2033	12,836(6)	36,839
Marcella K. Ruddy, M.D.	9/17/2021	7/19/2021		56,301 (5)	1.27	9/16/2031		
Chief Medical Officer	12/1/2023	12/01/2023	85,932	35,000 (7)	2.87	11/30/2033	—	—
Christian Cortis, Ph.D.	6/28/2021	3/31/2021		94,175 (5)	1.27	6/27/2031		
Chief Operating Officer	12/01/2023	12/01/2023	207,184	35,000 (7)	2.87	11/30/2033	—	—

(1) All option awards have been granted pursuant to the terms of the Legacy Tectonic 2019 Plan, the terms of which are described below in the subsection titled "*—Equity Incentive Plans—Tectonic 2019 Equity Incentive Plan*."

(2) All of the option awards listed in the table were granted with an exercise price per share that is no less than the fair market value of Legacy Tectonic common stock on the date of grant of such award, as determined in good faith by the Legacy Tectonic Board.

(3) This amount reflects $2.87, the fair market value of a share of Legacy Tectonic common stock as of September 30, 2023 (the determination of the fair market value by the Legacy Tectonic Board as of the most proximate date) multiplied by the amount shown in the column for the number of shares that have not vested.

(4) Represents shares of restricted stock issued to Dr. Reicin that are subject to vesting and a repurchase right in favor of Legacy Tectonic, with 25% of the total shares vested on the first anniversary of August 10, 2020, with the remaining shares vesting in 36 equal monthly installments thereafter, subject to Dr. Reicin's continued service through each vesting date.

(5) 25% of the shares subject to the option vested on the first anniversary of the vesting commencement date, with the remaining shares vesting in 36 equal monthly installments thereafter, subject to the officer's continued service through each vesting date.
(6) Represents shares of restricted stock issued to Dr. Reicin upon the early exercise of stock options that are subject to vesting and a repurchase right in favor of Legacy Tectonic, with 5,204 shares vesting on November 30, 2024 and the remainder vesting on December 31, 2024, subject to Dr. Reicin's continued service through each vesting date.
(7) The shares subject to the option vest in 48 equal monthly installments beginning on January 1, 2024.

In connection with the closing of the Merger, our Compensation Committee approved option grants to certain of our employees, including Dr. Reicin, Mr. Lochner and Dr. Ruddy. As a result, on June 20, 2024, Dr. Reicin received an option grant to purchase 289,600 shares of our common stock, Mr. Lochner received an option grant to purchase 118,000 shares of our common stock and Dr. Ruddy received an option grant to purchase 81,700 shares of our common stock, each with an exercise price per share equal to $16.80, which was the closing price per share of our common stock as reported on the Nasdaq Global Market on the day of closing of the Merger (as adjusted for the Reverse Stock Split). The shares subject to these option grants will vest 25% on the first anniversary of the grant date, and thereafter the remaining 75% of the shares will vest in equal monthly installments over the following three years, in each case subject to the recipient's continuous service through the applicable vesting dates, such that the options are vested in full on the four-year anniversary of the grant date. Mr. Lochner also received an option grant to purchase 15,000 shares of our common stock with an exercise price per share equal to $16.80. The shares subject to this option grant will vest 50% on June 1, 2026 if we raise $100 million by June 1, 2026 and have a minimum of a two year cash runway as of June 1, 2026 (i.e. until June 1, 2028), and 50% on June 1, 2028 if we have a minimum of a two year cash runway as of June 1, 2028 (i.e. until June 1, 2030), in each case, as determined by our Board (or the Compensation Committee) in its sole discretion.

Employment Arrangements with Legacy Tectonic's Executive Officers

Below are descriptions of the material terms of Legacy Tectonic's employment agreement and offer letters with the NEOs.

Alise Reicin, M.D.

In August 2020, Legacy Tectonic entered into an executive employment agreement with Dr. Reicin (the "Reicin Employment Agreement") in connection with her appointment as Legacy Tectonic's President and Chief Executive Officer and as a member of the Legacy Tectonic Board. In connection with the Merger, we entered into an amended and restated executive employment agreement with Dr. Reicin. The material terms of the amendment are as follows: (i) Dr. Reicin shall remain President and Chief Executive Officer and shall continue to serve as an executive director to the Board; (ii) an annual base salary of $620,000; (iii) eligibility for an annual, performance-based cash bonus with a target bonus percentage of 55% of Dr. Reicin's base salary; (iv) following the closing of the Merger, issuance of an option award to purchase our common stock, such that when combined with Dr. Reicin's prior securities holdings or rights to acquire securities in the combined company, Dr. Reicin will hold or have the right to acquire shares representing at least 4.34% of our post-Merger common stock; and (v) eligibility to participate in our executive severance plan and other employee benefit, welfare and other plans, as may be maintained by us from time to time.

The above description of the employment related agreement for Dr. Reicin does not purport to be complete and is subject to and qualified in its entirety by reference to the copy of the amended and restated employment agreement for Dr. Reicin included as an exhibit to the registration statement of which this prospectus forms a part.

Marcella K. Ruddy, M.D.

Legacy Tectonic entered into an offer letter with Dr. Ruddy (the "Ruddy Offer Letter") in June 2021, in connection with her appointment as Legacy Tectonic's Chief Medical Officer. The Ruddy Offer Letter provides for a base salary and target bonus opportunity, which shall be reviewed and may be adjusted on an annual basis.

To qualify for the annual target bonus set at a percentage of her adjusted base salary in respect of any calendar year, Dr. Ruddy must remain employed with Legacy Tectonic through the time the bonus payment was paid by Legacy Tectonic in the following year. Under the Ruddy Offer Letter, Legacy Tectonic granted Dr. Ruddy an option to purchase 142,233 shares of Tectonic common stock pursuant to the terms of Legacy Tectonic's 2019 Equity Incentive Plan (the "Tectonic 2019 Plan"), at an exercise price of $1.27 per share. The option vests on the following schedule: 25% of the shares vested on the one-year anniversary of July 19, 2021, with the remaining shares vesting in 36 equal monthly installments thereafter such that the options will be fully vested on the four-year anniversary of July 19, 2021, subject to Dr. Ruddy's continuous service with Legacy Tectonic through each vesting date. The option award is subject to automatic acceleration in the event of (i) a Change in Control (as defined in the Tectonic 2019 Plan) and (ii) provided that within the twelve months after such Change in Control either (x) Dr. Ruddy's continuous service is terminated without Cause (as defined in the Ruddy Offer Letter) or (y) Dr. Ruddy resigns for Good Reason (as defined in the Ruddy Offer Letter). Dr. Ruddy is also eligible for additional equity awards under Legacy Tectonic equity compensation plans, as may be granted from time to time.

Christian Cortis, Ph.D

Legacy Tectonic entered into an offer letter with Dr. Cortis (the "Cortis Offer Letter") in July 2019. Dr. Cortis served as Tectonic's Chief Operating Officer until July 5, 2024. The Cortis Offer Letter provided for a base salary and target bonus opportunity, which was reviewed by the Legacy Tectonic Board on an annual basis. To qualify for the annual target bonus set at a percentage of his adjusted base salary in respect of any calendar year, Dr. Cortis had to remain employed with Legacy Tectonic through the time the bonus payment was paid by Legacy Tectonic in the following year. On July 5, 2024, we entered into a separation agreement with Dr. Cortis (the "Cortis Separation Agreement") pursuant to which Dr. Cortis' employment with us terminated effective July 5, 2024 (the "Separation Date"). Pursuant to the Cortis Separation Agreement, Dr. Cortis will receive nine months' base salary as severance in addition to his target annual bonus for the calendar year 2024 prorated based on the length of his employment during 2024. Under the Cortis Separation Agreement, Dr. Cortis will provide consulting services from the Separation Date until March 31, 2025 (the "Consulting Period") during which time any equity awards held by Dr. Cortis will continue to vest and any option award that is or becomes vested and exercisable on or after the Separation Date will remain exercisable for three months after the last day of the Consulting Period, or if earlier, until the latest date on which such option award could have expired by its original terms or the 10th anniversary of the grant date of such opinion, provided Dr. Cortis does not materially breach his obligations under the Cortis Separation Agreement.

Potential Payments and Benefits upon a Termination or Change in Control

In connection with the completion of the Merger, our Board adopted the Severance Plan pursuant to which certain employees are eligible to participate, including the NEOs (each a "Participant" and collectively, the "Participants"). Pursuant to the Severance Plan, the Participants are eligible to receive the severance and change in control benefits described below, contingent upon the respective Participant's execution of a participation agreement and a general release of claims as further described in the Severance Plan. The benefits provided pursuant to the Severance Plan supersede and replace any severance and/or change in control benefits to which the Participants were previously entitled, including pursuant to their employment agreements and offer letters.

If a Participant's employment with the Company is terminated by us without Cause or due to the Participant's resignation for Good Reason (each as defined in the Severance Plan) during the period commencing three months prior to, and ending 12 months following, the effective date of a Change in Control (as defined in the Severance Plan) (the "Change in Control Period"), the Participant will be entitled to (i) a cash payment in an amount equal to 12 months (or 18 months for Dr. Reicin) of the Participant's base salary; (ii) a cash payment of an amount equal to 100% (or 150% for Dr. Reicin) of the Participant's annual target bonus for the year in which the change in control termination occurs; (iii) a cash payment of an amount equal to the Participant's annual target bonus for the year in which the change in control termination occurs, pro-rated for the portion of the year elapsed in such year; (iv) 12 months (or 18 months for Dr. Reicin) of COBRA premiums; and (v) accelerated vesting of 100% of the Participant's then-outstanding time-vesting equity awards.

If a Participant's employment with the Company is terminated by us without Cause or due to the Participant's resignation for Good Reason at a time that is not during the Change in Control Period, the Participant will be entitled to (i) 9 months (or 12 months for Dr. Reicin) of the Participant's base salary; (ii) a cash payment of an amount equal to the Participant's annual target bonus for the year in which the termination occurs, pro-rated for the portion of the year elapsed in such year; and (iii) 9 months (or 12 months for Dr. Reicin) of COBRA premiums.

The foregoing summary does not purport to be complete and is qualified in its entirety by reference to the full text of the Severance Plan.

Health and Welfare and Retirement Benefits; Perquisites

These payments and benefits discussed above are in addition to eligibility to participate in benefits available generally to salaried employees, including medical, vision, dental, and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances.

Retirement Benefits

Beginning in 2022, Legacy Tectonic maintained a tax-qualified 401(k) retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax-advantaged basis. Pursuant to the terms of such 401(k) plan, depending on facts and circumstances of the employee population in any given year, Legacy Tectonic may have made a 3% mandatory contribution under and pursuant to the terms of the plan and applicable law. Legacy Tectonic did not maintain, and none of the Legacy Tectonic named executive officers was eligible to participate in, any defined benefit pension plan or nonqualified deferred compensation plan.

Employee Employment Arrangements After the Merger

Executive Employment Arrangements

Dr. Alise Reicin, M.D.

In connection with and effective as of the closing of the Merger, on June 20, 2024, we entered into an amended and restated executive employment agreement with Dr. Reicin. For additional information regarding the material terms of the amendment, see "*Executive and Director Compensation—Employment Arrangements with Legacy Tectonic's Executive Officers*."

Daniel Lochner

On May 28, 2024, we entered into an employment agreement with Daniel Lochner. The material terms of the employment agreement are as follows: (i) Mr. Lochner shall be employed as Chief Financial Officer of the Company, effective June 3, 2024; (ii) an annual base salary of $475,000; (iii) eligibility for an annual, performance-based cash bonus with a target bonus percentage of 40% of Mr. Lochner's base salary; (iv) an issuance of an option award to purchase shares of common stock of the Company, representing 0.80% of the combined Company's post-merger outstanding shares of common stock; (v) a performance-based equity award to purchase a number of shares of common stock equal to 0.10% of the combined Company's post-merger outstanding shares of common stock; and (vi) eligibility to participate in the Company's executive severance plan and other employee benefit, welfare and other plans, as may be maintained by the Company from time to time.

Equity Incentive Plans

2024 Equity Incentive Plan

Our Board adopted the 2024 Equity Incentive Plan (the "2024 Plan") in connection with and effective as of the closing of the Merger. The following summary does not contain all of the terms and conditions of the 2024 Plan and is qualified in its entirety by reference to the 2024 Plan included as an exhibit to the registration statement of which this prospectus forms a part.

Eligibility. The 2024 Plan provides for the grant of incentive stock options ("ISOs") within the meaning of Section 422 of the Code to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, directors and consultants, including employees and consultants of the combined company's affiliates.

Authorized Shares. Initially, the maximum number of shares of Company common stock that may be issued under the 2024 Plan will not exceed 12.5% of the Company's fully diluted shares outstanding determined as of immediately after the Effective Time (the "2024 Plan's initial share reserve"). In addition, the number of shares of Company common stock reserved for issuance under the 2024 Plan will automatically increase on January 1 of each year, starting on January 1, 2025, through and including January 1, 2034, in an amount equal to (1) 5% of the total number of shares of Company common stock outstanding on the last day of the preceding calendar year, or (2) a lesser number of shares of Company common stock determined by the Company Board prior to the date of the increase. The maximum number of shares of Company common stock that may be issued on the exercise of ISOs under the 2024 Plan is three multiplied by the 2024 Plan's initial share reserve.

Shares subject to stock awards granted under the 2024 Plan that expire or terminate without being exercised or otherwise issued in full or that are paid out in cash rather than in shares do not reduce the number of shares available for issuance under the 2024 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation do not reduce the number of shares available for issuance under the 2024 Plan. If any shares of Company common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by the Company (1) because of the failure to vest, (2) to satisfy the exercise, strike or purchase price, or (3) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2024 Plan.

Plan Administration. The Company Board, or a duly authorized committee thereof, will administer the 2024 Plan and is referred to as the "plan administrator" herein. The Company Board may also delegate to one or more persons or bodies the authority to (1) designate recipients (other than officers) to receive specified stock awards; (2) determine the number of shares subject to such stock awards; and (3) determine the terms of such awards. Under the 2024 Plan, the Company Board has the authority to determine award recipients, grant dates, the numbers and types of stock awards to be granted, the applicable fair market value, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under the 2024 Plan, The Company Board also generally has the authority to effect, with the consent of any materially adversely affected participant, (1) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (2) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (3) any other action that is treated as a repricing under generally accepted accounting principles.

Stock Options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2024 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of a share of combined company common stock on the date of grant. Options granted under the 2024 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

The plan administrator determines the term of stock options granted under the 2024 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with the Company or any of the Company's affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is

prohibited by applicable securities laws. If an optionholder's service relationship with the Company or any of the Company's affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with the Company or any of the Company's affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of shares of the Company's common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of combined company common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, or (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options and stock appreciation rights generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of the Company common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of the Company's stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of the Company's total combined voting power or that of any of the Company's parent or subsidiary corporations unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to the Company's Board and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of shares of Company common stock, a combination of cash and shares of Company common stock as determined by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, services to the Company, or any other form of legal consideration that may be acceptable to the Company's Board and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with the Company ends for any reason, the Company may receive any or all of the shares of Company common stock held by the participant under such participant's restricted stock award that have not vested as of the date the participant terminates service with the combined company through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights are granted under stock appreciation right agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of Company common stock on the date of grant. A stock appreciation right granted under the 2024 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may be settled in

cash or shares of Company common stock or in any other form of payment, as determined by the Company's Board and specified in the stock appreciation right agreement.

The plan administrator determines the term of stock appreciation rights granted under the 2024 Plan, up to a maximum of 10 years. If a participant's service relationship with the Company or any of the Company's affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with the Company, or any of the Company's affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2024 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain preestablished performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, combined company common stock.

The performance goals may be based on any measure of performance selected by the Company's Board. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Company's Board when the performance award is granted, the Company's Board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any portion of the combined company's business which is divested achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of combined company common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the combined company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to Company common stock. The plan administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year that begins on or after the effective date of the merger, including awards granted and cash fees paid by the Company to such non-employee director, will not exceed (1) $750,000 in total value or (2) if such non-employee director is first appointed or elected to the combined company's board of directors during such calendar year, $1,000,000 in total value.

Changes to Capital Structure. In the event there is a specified type of change in the Company's capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2024 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued on the exercise of ISOs, and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. The following applies to stock awards under the 2024 Plan in the event of a corporate transaction (as defined in the 2024 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with the Company or one of the Company's affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2024 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by the Company with respect to the stock award may be assigned to the Company's successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by the Company with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction), and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by the Company with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the per share amount payable to holders of common stock in connection with the corporate transaction, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn-out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of Company common stock.

Under the 2024 Plan, a corporate transaction is generally defined as the consummation of: (1) a sale of all or substantially all of the Company's assets, (2) the sale or disposition of at least 50% of the Company's outstanding securities, (3) a merger or consolidation where the Company does not survive the transaction, or (4) a merger or consolidation where the Company does survive the transaction but the shares of Company common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Awards granted under the 2024 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control as may be provided in the applicable stock award agreement or in any other written agreement between the Company or any of the Company's affiliates and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under the 2024 Plan, a change in control is generally defined as: (1) the acquisition by any person or company of more than 50% of the combined voting power of the Company's then outstanding stock; (2) a consummated merger, consolidation or similar transaction in which Company stockholders immediately before

the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (3) a consummated sale, lease, exclusive license or other disposition of all or substantially all of the Company's assets other than to an entity more than 50% of the combined voting power of which is owned by Company stockholders in substantially the same proportions as their ownership of the Company's outstanding voting securities immediately prior to such transaction; or (4) when a majority of the Company's Board becomes comprised of individuals who were not serving on the Company's Board on the date the 2024 Plan was adopted, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Plan Amendment or Termination. The Company's Board has the authority to amend, suspend, or terminate the 2024 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of Company stockholders. No ISOs may be granted after the tenth anniversary of the date the board of directors adopts the 2024 Plan. No stock awards may be granted under the 2024 Plan while it is suspended or after it is terminated.

2024 Employee Stock Purchase Plan

Our Board adopted the 2024 Employee Stock Purchase Plan (the "2024 ESPP") The following summary does not contain all of the terms and conditions of the 2024 ESPP and is qualified in its entirety by reference to the 2024 ESPP included as an exhibit to the registration statement of which this prospectus forms a part.

Purpose. The purpose of the 2024 ESPP is to provide eligible employees with an opportunity to purchase shares of the Company's common stock through accumulated contributions. The 2024 ESPP will be designed to allow eligible U.S. employees to purchase Company common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code.

Share Reserve. Following the merger, the 2024 ESPP will authorize the issuance of a number of shares of Company common stock equal to 1% of the total number of shares of Company common stock issued and outstanding determined as of immediately after the effective time (the "2024 ESPP's initial share reserve"), pursuant to purchase rights granted to the Company's employees or to employees of any of the Company's designated affiliates. The number of shares of Company common stock reserved for issuance will automatically increase on January 1 of each year, from January 1, 2025 through and including January 1, 2034, by the lesser of (1) 1% of the total number of shares of Company common stock outstanding on the last day of the preceding calendar year, and (2) a number of shares of Company common stock equal to three times the 2024 ESPP's initial share reserve; *provided*, that prior to the date of any such increase, the Company's Board may determine that such increase will be less than the amount set forth in clauses (1) and (2).

Administration. The Company's Board intends to delegate concurrent authority to administer the 2024 ESPP to the Company's compensation committee. The 2024 ESPP is implemented through a series of offerings under which eligible employees are granted rights to purchase shares of Company common stock on specified dates during such offerings. Under the 2024 ESPP, the Company may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of Company common stock will be purchased for employees participating in the offering. An offering under the 2024 ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by the Company or by any of the Company's designated affiliates, may participate in the 2024 ESPP and may contribute, normally through payroll deductions, up to a specified percentage of their earnings (as set forth in, and as defined in, the offering memorandum the Company's Board or compensation committee may adopt from time to time with respect to offerings under the 2024 ESPP) for the purchase of shares of Company common stock under the 2024 ESPP. Unless otherwise determined by the Company's Board, shares of Company common

stock will be purchased for the accounts of employees participating in the 2024 ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a share of Company common stock on the first trading date of an offering or (b) 85% of the fair market value of a share of Company common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the 2024 ESPP, as determined by the Company's Board, including: (1) being customarily employed for more than 20 hours per week; (2) being customarily employed for more than 5 months per calendar year; or (3) continuous employment with the Company or one of the Company's affiliates for a period of time (not to exceed two years). No employee may purchase shares under the 2024 ESPP at a rate in excess of $25,000 worth of Company common stock based on the fair market value per share of Company common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the 2024 ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of the Company's outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in the Company's capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the Company's Board will make appropriate adjustments to (1) the number of shares reserved under the 2024 ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of a corporate transaction (as defined in the 2024 ESPP), any then-outstanding rights to purchase Company stock under the 2024 ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of Company common stock within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately after such purchase.

Under the 2024 ESPP, a corporate transaction is generally the consummation of: (1) a sale of all or substantially all of the Company's assets; (2) the sale or disposition of more than 50% of the Company's outstanding securities; (3) a merger or consolidation where the Company does not survive the transaction; and (4) a merger or consolidation where the Company does survive the transaction but the shares of Company common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction.

2024 ESPP Amendments, Termination. The Company's Board has the authority to amend or terminate the 2024 ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. The Company will obtain stockholder approval of any amendment to the 2024 ESPP, as required by applicable law or listing requirements.

Tectonic 2019 Equity Incentive Plan

The Legacy Tectonic Board adopted the Tectonic 2019 Plan and Legacy Tectonic stockholders approved the Tectonic 2019 Plan in June 2019. No additional awards have been made under the Tectonic 2019 Plan after the 2024 Plan became effective, and all awards under the Tectonic 2019 Plan were assumed by the Company after application of the exchange ratio. The terms and conditions of such assumed awards are the same as they were under the Tectonic 2019 Plan.

Administration. Our Board, or a duly authorized committee thereof, has the authority to administer the equity awards made under the Tectonic 2019 Plan. We may also delegate to one or more officers the authority to

(1) designate recipients (other than officers) of stock options or stock appreciation rights and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the Tectonic 2019 Plan, the our Board or the authorized committee, referred to herein as the plan administrator, has the authority to modify outstanding awards under the Tectonic 2019 Plan; however, the plan administrator does not have the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, without the consent of any adversely affected participant.

Stock Awards. The Tectonic 2019 Plan provided for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other forms of equity compensation, which are referred to collectively as stock awards, to employees, non-employee directors and consultants of Legacy Tectonic and its affiliates. ISOs were granted only to employees.

If any portion of a stock award (i) expires or otherwise terminates without the shares covered by such portion of the stock award having been issued or (ii) is settled in cash, such expiration, termination, or settlement will not reduce the number of shares available for issuance under the 2024 Plan. Shares forfeited back to or repurchased by Legacy Tectonic because of the failure to meet a contingency or condition required to vest will revert to and again become available for issuance under the 2024 Plan. Shares reacquired by us to satisfy the exercise price or purchase price of a stock award and shares withheld to satisfy a tax withholding obligation in connection with a stock award will again become available for issuance under the 2024 Plan.

Stock Options. ISOs and NSOs were granted pursuant to stock option agreements adopted by the plan administrator. The exercise price of stock options granted under the Tectonic 2019 Plan was not less than 100% of the fair market value of Legacy Tectonic common stock on the date of grant. Options granted under the Tectonic 2019 Plan vest at the rate specified by the plan administrator.

The plan administrator determined the term of stock options granted under the Tectonic 2019 Plan, up to a maximum of 10 years. Unless the terms of an option holder's stock option agreement provide otherwise, if an option holder's service relationship with Legacy Tectonic or any of its affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or any applicable insider trading policy. If an optionholder's service relationship with Legacy Tectonic or any of its affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of Legacy Tectonic common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) according to a deferred payment or similar arrangement with the optionholder; or (6) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Restricted Stock Awards. Restricted stock awards were granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check,

bank draft or money order, past services, or any other form of legal consideration that may be acceptable to the plan administrator and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with Legacy Tectonic or any of its affiliates ceases for any reason, Legacy Tectonic may receive any or all of the shares of Legacy Tectonic common stock held by the participant that have not vested as of the date the participant terminates service through a forfeiture condition or a repurchase right.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company and to take certain other actions with respect to stock awards.

The plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

2023 Non-Employee Director Compensation

Non-Employee Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee director of Legacy Tectonic's Board during the year ended December 31, 2023. Dr. Reicin, Legacy Tectonic's Chief Executive Officer and President, did not receive any additional compensation for her service on Legacy Tectonic's Board. The compensation received by Dr. Reicin as a named executive officer, is set forth in "*2023 Executive Compensation—2023 Summary Compensation Table.* " Unless otherwise noted, the information in this section, including any equity ownership, does not reflect the effect of the Merger, the conversion of Legacy Tectonic's common stock into our common stock or the Reverse Stock Split.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(2)	Total ($)
Andrew Kruse, Ph.D.	80,004(1)	—	80,004
Terrance McGuire	—	—	—
Timothy A. Springer, Ph.D.	—	—	—
Praveen Tipirneni, M.D.	—	—	—
Stefan Vitorovic	—	—	—

(1) Represents consulting fees for services provided to Legacy Tectonic's Scientific Advisory Board pursuant to Dr. Kruse's consulting agreement with Legacy Tectonic, dated September 25, 2019.

(2) The following table provides information regarding the number of shares of common stock underlying options and restricted stock held by Legacy Tectonic non-employee directors that were outstanding as of December 31, 2023:

Name	Option Awards Outstanding at Year-End
Andrew Kruse, Ph.D.	—
Terrance McGuire	—
Timothy A. Springer, Ph.D.	—
Praveen Tipirneni, M.D.	22,765
Stefan Vitorovic	—

Narrative to 2023 Director Compensation Table

Legacy Tectonic did not have a formal non-employee director compensation program in 2023. On September 25, 2019, Legacy Tectonic entered into a consulting agreement with Andrew Kruse, Ph.D., pursuant to which Dr. Kruse is entitled to receive $6,667 per month, along with reimbursement of reasonable travel expenses and other reasonable out-of-pocket costs, in consideration for his performance of services provided to Legacy Tectonic's scientific advisory board. The consulting agreement was amended to reduce his monthly compensation to $5,000 in April 2024.

Non-Employee Director Compensation After the Merger

Prior to the Merger, Legacy Tectonic did not have a formal compensation policy with respect to service on its board of directors. Legacy Tectonic reimbursed its non-employee directors for their reasonable out-of-pocket expenses incurred in attending board and committee meetings, and occasionally granted stock options and restricted stock awards as compensation for service.

Our Board intends to adopt a non-employee director compensation policy in the future that is designed to provide a total compensation package that enables us to attract and retain, on a long-term basis, high-caliber directors who are not our employees or officers or of our subsidiaries.

In connection with the closing of the Merger, our Board approved certain option grants to our directors, other than Dr. Reicin. As a result, on June 20, 2024, each of Phillip B. Donenberg, Terrance McGuire, Timothy A. Springer, Ph.D., Praveen Tipirneni, M.D. and Stefan Vitorovic received an option grant to purchase 11,760 shares of our common stock, in each case, with an exercise price per share equal to $16.80, which was the closing price per share of our common stock as reported on the Nasdaq Global Market on the closing date of the Merger (as adjusted for the Reverse Stock Split). The shares subject to these option grants will vest 1/3 on the first anniversary of the grant date, and thereafter the remaining 2/3 of the shares will vest in equal monthly installments over the following two years, in each case subject to the recipient's continuous service through the applicable vesting dates, such that the options are vested in full on the three-year anniversary of the grant date.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation agreements and other arrangements with the Company and the Company's directors and executive officers in the section titled "*Executive and Director Compensation*" elsewhere in this prospectus, the following is a description of each transaction involving the Company, AVROBIO or Legacy Tectonic since January 1, 2022 in which:

- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of the average of Legacy Tectonic's or the Company's total assets at year-end for the last two completed fiscal years, as applicable; and
- any of our directors, executive officers, or holders of more than 5% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Legacy Tectonic's Transactions and Agreements

Private Financings

Series A Preferred Stock Financing – Subsequent Milestone Closing

In June 2022, the Legacy Tectonic Board determined that Legacy Tectonic had achieved the milestone events pursuant to the terms of its Series A Preferred Stock Purchase Agreement and issued and sold to certain investors (i) an aggregate additional 2,450,163 shares of Legacy Tectonic's Series A-1 Preferred Stock, and (ii) an additional 437,282 shares of Legacy Tectonic's Series A-2 Preferred Stock in a subsequent closing, at a purchase price of $13.1876 per share for an aggregate purchase price of $38,028,475.61 (the "Milestone Closing").

The following table summarizes purchases of shares of Legacy Tectonic Series A Preferred Stock by Legacy Tectonic's related persons in the Milestone Closing:

Stockholder	Shares of Series A-1 Preferred Stock (#)	Shares of Series A-2 Preferred Stock (#)	Total Purchase Price ($)
Timothy A. Springer	971,238	437,282	18,574,998
Entities affiliated with Vida Ventures (1)	659,980	—	8,703,552
Polaris Partners IX, L.P. (2)	568,716	—	7,499,999
Polaris Founders Capital Fund I, L.P. (3)	18,957	—	249,997
Reicin Inc. (4)	11,374	—	149,995

(1) Represents (i) 642,161 shares purchased by Vida Ventures II, LLC ("Vida II Main Fund") and (ii) 17,819 shares purchased by Vida Ventures II-A, LLC ("Vida II Parallel Fund," and together with the Vida II Main Fund, "Vida II"). VV Manager II, LLC ("VV Manager II") is the manager of Vida II. Stefan Vitorovic served as a director on the Legacy Tectonic Board, serves as a director of the Board and is a member of the investment committee of VV Manager II, which is affiliated with Vida Ventures. Entities affiliated with Vida Ventures collectively owned more than five percent of Legacy Tectonic's outstanding capital stock and hold more than five percent of the Company's outstanding capital stock.

(2) Polaris Partners IX, L.P. ("PP IX") owned more than five percent of Legacy Tectonic's outstanding capital stock and owns more than five percent of the Company's outstanding capital stock. Terrance McGuire served as a director on the Legacy Tectonic Board, serves as a director on the Board and holds an interest in Polaris Partners GP IX, L.L.C., the general partner of PP IX.

(3) Terrance McGuire served as a director on the Legacy Tectonic Board, serves as a director of the Board and is a managing member of Polaris Founders Capital Management Co. I, L.L.C., the general partner of Polaris Founders Capital Fund I, L.P.

(4) Reicin Inc. is controlled by Cheryl Reicin. Cheryl Reicin is the sister of Dr. Reicin, who served as the Chief Executive Officer of Legacy Tectonic and a director on the Legacy Tectonic Board and serves as the Chief Executive Officer and President of the Company and a director of the Company's Board.

Legacy Tectonic Subscription Agreement and SAFEs

On January 30, 2024, concurrently with the execution and delivery of the Merger Agreement, Legacy Tectonic entered into the Subscription Agreement with certain investors named therein, pursuant to which such investors agreed to purchase shares of Legacy Tectonic common stock, at a purchase price of $12.39908 per

share, and certain investors consummated certain additional purchases of Legacy Tectonic common stock pursuant to the terms of the SAFEs entered into by such investors and Legacy Tectonic, for an aggregate purchase price among the private financings contemplated by the Subscription Agreement and such SAFEs of approximately $130.7 million.

The following table summarizes the purchase of Legacy Tectonic common stock pursuant to the Subscription Agreement and the entry into the SAFEs by Legacy Tectonic's related persons:

Stockholder	Total Purchase Price ($)
Entities affiliated with Timothy A. Springer, Ph.D. (1)	41,999,997
Polaris Partners IX, L.P. (2)	8,999,989
Entities affiliated with Vida Ventures (3)	7,499,987
Polaris Founders Capital Fund II, L.P. (4)	1,499,991
Andrew Kruse, Ph.D. (5)	125,000

(1) Represents entry into the SAFEs and purchase of Legacy Tectonic common stock pursuant to the Subscription Agreement. Dr. Timothy A. Springer served as a director on the Legacy Tectonic Board and serves as a director of the Board.

(2) Represents entry into the SAFEs and purchase of Legacy Tectonic common stock pursuant to the Subscription Agreement. PP IX owned more than five percent of Legacy Tectonic's outstanding capital stock and owns more than five percent of the Company's outstanding capital stock. Terrance McGuire served as a director of the Legacy Tectonic Board, serves as a director on the Board and holds an interest in Polaris Partners GP IX, L.L.C., the general partner of PP IX.

(3) Represents entry into the SAFEs and purchase of Legacy Tectonic common stock pursuant to the Subscription Agreement. Stefan Vitorovic served as a director on the Legacy Tectonic Board, serves as a director of the Board and is a member of the investment committee of VV Manager II, LLC, which is affiliated with Vida Ventures. Entities affiliated with Vida Ventures collectively owned more than five percent of Legacy Tectonic's outstanding capital stock and own more than five percent of the Company's outstanding capital stock.

(4) Represents purchase of Legacy Tectonic common stock pursuant to the Subscription Agreement. Terrance McGuire served as a director on the Legacy Tectonic Board, serves as a director of the Company Board and is a managing member of Polaris Founders Capital Management Co. II, L.L.C., the general partner of Polaris Founders Capital Fund II, L.P.

(5) Represents entry into the SAFEs. Dr. Andrew Kruse served as a director on the Legacy Tectonic Board.

Agreements with Stockholders

In connection with Legacy Tectonic's Series A preferred stock financing, Legacy Tectonic entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of Legacy Tectonic's preferred stock and certain holders of Legacy Tectonic's common stock. These stockholder agreements terminated upon the closing of the Merger.

Support Agreements Under the Merger

Certain Legacy Tectonic stockholders entered into support agreements with Legacy Tectonic pursuant to which, among other things, each such stockholder, solely in his, her or its capacity as a Legacy Tectonic stockholder, agreed to vote all of such stockholder's shares of Legacy Tectonic capital stock in favor of (i) the adoption of the Merger Agreement, (ii) the approval of the merger and related transactions contemplated by the Merger Agreement, (iii) the approval of an amendment to Legacy Tectonic's certificate of incorporation to increase its authorized stock, (iv) to the extent such person was entitled to vote or exercise a right to consent with respect to such matter, effecting the preferred stock conversion immediately prior to conversion of the SAFEs, which SAFEs conversion occurred immediately prior to the consummation of the private placement financings, (v) waiving any preemptive right, right of participation, right of maintenance, anti-dilution right or any similar right as may otherwise have been provided to such stockholder under Legacy Tectonic's certificate of incorporation or bylaws in connection with the Merger and related transactions contemplated by the Merger Agreement and (vi) against any Acquisition Proposal from a third party.

Indemnification Agreements

In connection with the closing of the Merger, we entered into indemnification agreements with each of its directors and executive officers. These agreements, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in the Company's right, on account of any services undertaken by such person on the Company's behalf or that person's status as a member of the Board to the maximum extent allowed under Delaware law.

The foregoing description of the indemnification agreements does not purport to be complete and is qualified in its entirety by the full text of the form of indemnification agreement, which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of AVROBIO and Legacy Tectonic entered into lock-up agreements, pursuant to which such parties agreed not to, except in limited circumstances, sell or transfer their shares of Tectonic common stock, for the 180-day period following the closing of the Merger.

The foregoing description of the lock-up agreements does not purport to be complete and is qualified in its entirety by the full text of the form of lock-up agreement, which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Policies and Procedures for Related Party Transactions

While Legacy Tectonic did not have a formal written policy or procedure for the review, approval or ratification of related party transactions, it was the practice of the Legacy Tectonic Board to consider the nature of and business reason for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, Legacy Tectonic's best interests.

In connection with the closing of the Merger, the Board approved a policy for the review and approval or ratification of related party transactions of the Company. All of the transactions described in this section were entered into prior to the application of this policy.

AVROBIO's Transactions and Agreements

License Agreements and Related Agreements with University Health Network

Fabry License Agreement

On January 27, 2016, AVROBIO entered into an option agreement with UHN pursuant to which UHN granted AVROBIO an exclusive option to enter into an exclusive license under certain intellectual property rights related to Fabry disease. On November 4, 2016, AVROBIO executed its option and entered into an exclusive license agreement with UHN. Under this agreement (the "Fabry license agreement"), UHN granted AVROBIO an exclusive worldwide license under certain intellectual property rights and a non-exclusive worldwide license under certain know-how, in each case subject to certain retained rights, to develop, commercialize and sell products for use in the treatment of Fabry disease. Under the terms of the Fabry license agreement, AVROBIO paid to UHN a one-time upfront fee and was obligated to pay an annual maintenance fee until the first sale of a licensed product in certain markets. AVROBIO was also required to make payments to UHN in connection with the achievement of certain development and regulatory milestones in an aggregate amount of up to CAD$2.45 million, as well as royalties on a country-by-country basis of a low to mid-single digit percentage on annual sales of licensed products and a lower single digit royalty in certain circumstances. Additionally,

AVROBIO was required to pay a low double digit percentage of all sublicensing revenue. AVROBIO also made a philanthropic commitment to donate funds to organizations for the benefit of the Canadian Fabry community in an amount equal to a low double digit percentage of AVROBIO's royalty payments and regulatory milestone payments, up to a maximum of CAD$500,000 in any calendar year. In connection with this agreement, AVROBIO also entered into three separate letter agreements with UHN, dated November 4, 2016, June 2, 2017 and December 11, 2019, pursuant to which AVROBIO agreed to provide certain funding and costs and expenses associated with a clinical trial conducted by UHN for the treatment of Fabry disease. For the years ended December 31, 2022 and 2023, AVROBIO paid $161 and $93 thousand, respectively, to UHN in connection with these agreements, which consists of reimbursable funded study trial costs and license maintenance fees. Effective as of January 4, 2024, AVROBIO terminated the Fabry license agreement with UHN. Following the termination of the Fabry license agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Fabry license agreement.

Interleukin-12 Agreement

On January 27, 2016, AVROBIO entered into an exclusive license agreement (the "IL-12 Agreement") with UHN pursuant to which UHN granted AVROBIO an exclusive license to certain intellectual property rights relating to Interleukin-12 proteins ("IL-12"). AVROBIO entered into an amendment to the IL-12 Agreement on September 28, 2017. Under the IL-12 Agreement, as amended (the "Amended IL-12 Agreement"), AVROBIO paid an upfront license fee and reimbursement of certain patent expenses, and AVROBIO was also obligated to pay an annual license fee as well as payments in connection with the achievement of certain performance and development milestones for an aggregate total of up to CAD$19.275 million in milestone payments. Additionally, the Amended IL-12 Agreement required AVROBIO to pay a low to mid-single digit royalty percentage on annual sales of licensed products, and a low double digit percentage of all sublicensing revenue. For the years ended December 31, 2022 and 2023, AVROBIO paid $39 and $37 thousand to UHN under the Amended IL-12 Agreement, respectively, which consists of license maintenance fees. Effective as of August 24, 2023, AVROBIO and UHN agreed to terminate the Amended IL-12 Agreement. Following the termination of the Amended IL-12 Agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Amended IL-12 Agreement.

In connection with the Amended IL-12 Agreement, AVROBIO has also entered into two separate sponsored research agreements with UHN, one in March 2017 and one in July 2017. The March 2017 agreement was amended and restated and subsequently amended in November 2017. Pursuant to each of these sponsored research agreements, AVROBIO agreed to fund certain research projects related to IL-12 and Fabry disease, including salaries of certain researchers of up to CAD$200,000 and CAD$164,652 under the March 2017 and July 2017 agreements, respectively.

At the time AVROBIO entered into each of the above agreements with UHN, other than the letter agreement dated December 11, 2019, UHN was a greater than 5% beneficial owner of AVROBIO's outstanding capital stock. Additionally, Christopher Paige is a senior scientist at UHN and is currently a member of the AVROBIO Board. As an inventor of certain of the intellectual property rights related to IL-12 that AVROBIO licenses from UHN, Dr. Paige would have been entitled to a portion of the consideration that AVROBIO would have been required to pay to UHN pursuant to the Amended IL-12 Agreement.

Agreements with Stockholders

In connection with AVROBIO's prior preferred stock financings, AVROBIO entered into investors' rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of AVROBIO's preferred stock and certain holders of AVROBIO's common stock. These stockholder agreements terminated upon the closing of AVROBIO's IPO, except for the registration rights granted under its investors' rights agreement, which terminated five years following AVROBIO's IPO.

Concurrently with the execution of the Merger Agreement, certain stockholders of AVROBIO holding approximately 10.8% of the outstanding shares of AVROBIO common stock as of January 30, 2024 entered into support agreements with AVROBIO. These stockholders included executive officers and directors of AVROBIO, as well as certain other stockholders owning a significant portion of the outstanding shares of AVROBIO capital stock.

Indemnification Agreements

AVROBIO entered into agreements to indemnify AVROBIO's directors and executive officers. These agreements, among other things, required AVROBIO to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in AVROBIO's right, on account of any services undertaken by such person on behalf of AVROBIO or that person's status as a member of the AVROBIO Board or as an officer of AVROBIO to the maximum extent allowed under Delaware law.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, certain executive officers, directors and stockholders of AVROBIO and Legacy Tectonic entered into the lock-up agreements, pursuant to which such parties agreed not to, except in limited circumstances, sell or transfer their shares of AVROBIO common stock, for the 180-day period following the closing of the Merger.

The foregoing description of the lock-up agreements does not purport to be complete and is qualified in its entirety by the full text of the form of lock-up agreement, which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Related Person Transaction Policy

We have adopted a written related person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related person transactions." For purposes of the policy only, a "related person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we or any of our subsidiaries are participants involving an amount that exceeds $120,000, in which any "related person" has a material interest.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities (including the common stock), including any of their immediate family members and affiliates, including entities owned or controlled by such persons.

Under the policy, the related person in question or, in the case of transactions with a holder of more than 5% of any class of our voting securities, an officer with knowledge of a proposed transaction, must present information regarding the proposed related person transaction to the audit committee (or, where review by the audit committee would be inappropriate, to another independent body of the board) for review. The audit committee will approve only those transactions that it determines are fair to us and in our best interests.

All of the transactions described above were entered into prior to the adoption of such policy.

PRINCIPAL SECURITYHOLDERS

The following table sets forth certain information regarding beneficial ownership of the Company's common stock as of July 6, 2024, after giving effect to the Merger, by:

- each person known to be the beneficial owner of more than 5% of the Company's outstanding common stock;
- each of the Company's executive officers and directors; and
- all of the Company's executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power with respect to the securities as well as any shares of common stock that the individual or entity has the right to acquire within 60 days of July 6, 2024 the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Except as noted by footnote, and subject to community property laws where applicable, the Company believes, based on the information provided to them, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The table lists applicable percentage ownership based on 14,734,325 shares of common stock outstanding as of July 6, 2024.

	Shares beneficially owned	
Name and address of beneficial owner	**Number**	**Percentage**
5% or Greater Stockholders:		
Entities affiliated with Timothy A. Springer, Ph.D. (1)	4,243,121	28.80%
FMR LLC(2)	1,077,538	7.31%
Polaris Partners IX, L.P. (3)	1,073,062	7.28%
Entities affiliated with Vida Ventures (4)	1,028,674	6.98%
Entities affiliated with EcoR1 (5)	849,143	5.76%
Named Executive Officers and Directors:		
Timothy A. Springer, Ph.D.(1)	4,243,121	28.80%
Terrance McGuire(6)	1,157,976	7.86%
Stefan Vitorovic(4)	1,028,674	6.98%
Alise Reicin, M.D.(7)	320,711	2.17%
Marcella K. Ruddy, M.D.(8)	62,099	*
Praveen Tipirneni, M.D.(9)	15,203	*
Daniel Lochner	—	—
Phillip B. Donenberg(10)	9,535	*
All executive officers and directors as a group (10 persons) (11)	6,981,700	47.38%

* Represents beneficial ownership of less than one percent.

(1) Consists of (i) 2,692,005 shares of common stock held by Dr. Springer and (ii) 1,551,116 shares of common stock held by TAS Partners, LLC ("TAS"). Dr. Springer is the sole managing member of TAS. Dr. Springer exercises sole voting and dispositive power over the shares held by him directly and the shares held by TAS. Dr. Springer disclaims beneficial ownership of the shares held by TAS. The principal business address of each of Dr. Springer and TAS is 36 Woodman Road, Newton, MA, 02467.

(2) These shares of common stock are owned by funds and accounts managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of these funds and accounts is 245 Summer Street, Boston, MA 02210.

(3) Consists of 1,073,062 shares of common stock held by Polaris Partners IX, L.P. ("PP IX"). Polaris Partners GP IX, L.L.C. ("PP GP IX") is the general partner of PP IX and may be deemed to have sole voting and dispositive power with respect to the shares held by PP IX. David Barrett, Brian Chee, Amir Nashat and Amy Schulman (collectively, the "PP GP IX Managing Members") are the managing members of PP GP IX, and Terrance McGuire, a member of the board of directors, holds an interest in PP GP IX. Each of the PP GP IX Managing Members and Terrance McGuire, in their respective capacities with respect to PP GP IX, may be deemed to have shared voting and dispositive power with respect to the shares held by PP IX. The principal business address for all entities and individuals affiliated with Polaris Partners is c/o Polaris Partners, One Marina Park Drive, 8th Floor, Boston, Massachusetts 02210.

(4) Consists of (i) 1,000,900 shares of common stock held by Vida Ventures II, LLC ("Vida II Main Fund") and (ii) 27,774 shares of common stock held by Vida Ventures II-A, LLC ("Vida II Parallel Fund," and together with the Vida II Main Fund, "Vida II"). VV Manager II, LLC ("VV Manager II") is the manager of Vida II. Arie Belldegrun, Fred Cohen, and Leonard Potter are the members of the management committee of VV Manager II (the "Management Committee") and Arie Belldegrun, Fred Cohen, Stefan Vitorovic, Arjun Goyal, Helen Kim, Rajul Jain, and Joshua Kazam are the members of the investment committee of VV Manager II (the "Investment Committee"). Stefan Vitorovic serves as a director on the board of directors. Each of the Management Committee, the Investment Committee and the respective members thereof may be deemed to share voting and dispositive power over the shares held by Vida II. VV Manager II, the Management Committee, the Investment Committee and each member of each of the Management Committee and Investment Committee disclaim beneficial ownership over the securities held of record by Vida II. The address of all entities affiliated with Vida is 40 Broad Street, Suite 201, Boston, Massachusetts 02109.

(5) Consists of (i) 55,535 shares of common stock held by EcoR1 Capital Fund, L.P. ("Capital Fund"), (ii) 783,214 shares of common stock held by EcoR1 Capital Fund Qualified, L.P. ("Qualified Fund") and (iii) 10,394 shares of common stock held by EcoR1 Venture Opportunity Fund, L.P. ("Opportunity Fund"). EcoR1 Capital LLC ("EcoR1") is the general partner of Capital Fund and Qualified Fund, and the investment advisor to Opportunity Fund. Biotech Opportunity GP, LLC is the general partner of Opportunity Fund. Oleg Nodelman is the control person of EcoR1 and Biotech Opportunity GP, LLC and may be deemed to share dispositive voting power over the shares held by Qualified Fund, Capital Fund and Opportunity Fund. Mr. Nodelman, EcoR1 and Biotech Opportunity GP, LLC each disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address of the above person and entities is 357 Tehama Street #3, San Francisco, CA 94103.

(6) Consists of (i) 20,262 shares of common stock held by Polaris Founders Capital Fund I, L.P. ("PF I"), (ii) consists of 64,652 shares of common stock held by Polaris Founders Capital Fund II, L.P. ("PF II") and (iii) 1,073,062 shares of common stock held by PP IX. Polaris Founders Capital Management Co. I, L.L.C. ("PFC I GP") is the general partner of PF I and may be deemed to have sole voting and dispositive power with respect to the shares held by PF I. Polaris Founders Capital Management Co. II, L.L.C. ("PFC II GP") is the general partner of PF II and may be deemed to have sole voting and dispositive power with respect to the shares held by PFC II. Terrance McGuire, a member of the board of directors, and Jonathan Flint (together, the "PFC GP Managing Members") are the managing members of PFC I GP and PFC II GP. Each of the PFC GP Managing Members, in their respective capacities with respect to PFC I GP and PFC II GP, may be deemed to have shared voting and dispositive power with respect to the shares held by PF I and PF

II. PP GP IX is the general partner of PP IX and may be deemed to have sole voting and dispositive power with respect to the shares held by PP IX. The PP GP IX Managing Members are the managing members of PP GP IX, and Terrance McGuire, a member of the board of directors, holds an interest in PP GP IX. Each of the PP GP IX Managing Members and Terrance McGuire, in their respective capacities with respect to PP GP IX, may be deemed to have shared voting and dispositive power with respect to the shares held by PP IX. The principal business address for all entities and individuals affiliated with Polaris Partners is c/o Polaris Partners, One Marina Park Drive, 8th Floor, Boston, Massachusetts 02210.

(7) Consists of (i) 166,580 shares of common stock held by Dr. Reicin, 11,372 of which are subject to repurchase as of July 6, 2024, (ii) 124,530 shares of common stock held by the 2020 Reicin-Boiarsky Family Trust (the "2020 Reicin Trust") and (iii) 29,601 shares of common stock issuable upon exercise of options granted to Dr. Reicin that are exercisable within 60 days of July 6, 2024. Robert Boiarsky is a co-trustee of the 2020 Reicin Trust and the spouse of Dr. Reicin. Dr. Reicin may be deemed to have shared voting and dispositive power over the securities held by the 2020 Reicin Trust.

(8) Consists of (i) 32,065 shares of common stock held by Dr. Ruddy and (ii) 30,034 shares of common stock issuable upon exercise of options granted to Dr. Ruddy that are exercisable within 60 days of July 6, 2024.

(9) Consists of (i) 3,037 shares of common stock held by Dr. Tipirneni and (ii) 12,166 shares of common stock issuable upon exercise of options granted to Dr. Tipirneni that are exercisable within 60 days of July 6, 2024.

(10) Consists of (i) 166 shares of common stock held by Mr. Donenberg and (ii) 9,372 shares of common stock issuable upon exercise of options granted to Mr. Donenberg that are exercisable within 60 days of July 6, 2024.

(11) Consists of (i) 6,766,837 shares of common stock and (ii) 212,906 shares of common stock issuable upon exercise of options that are exercisable within 60 days of July 6, 2024.

SELLING SECURITYHOLDERS

The selling stockholders acquired shares of common stock from us in the Merger upon exchange of shares of Legacy Tectonic acquired from Legacy Tectonic immediately prior to the Merger pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act. Under the Subscription Agreement that we assumed in the Merger, we agreed to file a registration statement with the SEC for the purposes of registering for resale from time to time the shares of common stock.

The table below lists the selling stockholders and other information regarding their ownership of the shares of common stock offered hereby. The second column lists the number of shares of common stock beneficially owned by the selling stockholders as of July 6, 2024 immediately following consummation of the Merger. The selling stockholders may have sold or transferred some or all of the common stock indicated below and may in the future sell or transfer some or all of the common stock indicated below in transactions exempt from the registration requirements of the Securities Act rather than under this prospectus. The third column lists the shares of common stock being offered by this prospectus by the selling stockholders. The fourth column assumes the sale of all of the shares of common stock offered by the selling stockholders pursuant to this prospectus. The selling stockholders may sell all, some or none of their shares of common stock in this offering. See "*Plan of Distribution*."

Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the selling stockholders have sole voting and investment power with respect to all shares of common stock that they own, subject to applicable community property laws. Beneficial ownership for the purposes of the table below is determined in accordance with the rules and regulations of the SEC. These rules generally provide that a person is the beneficial owner of securities if such person has or shares the power to vote or direct the voting thereof, or to dispose or direct the disposition thereof or has the right to acquire such powers within 60 days. Percentage of beneficial ownership is based on 14,734,325 shares of common stock outstanding as of July 6, 2024.

Name and Address of Selling Stockholders	Number of Shares Beneficially Owned Before the Offering	Number of Shares that May Be Offered Hereby	Shares Beneficially Owned After the Offering	
			Number	Percentage
Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund(1)	72,841	72,841	—	—
Fidelity Growth Company Commingled Pool (1)	400,394	400,394	—	—
Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund(1)	230,656	230,656	—	—
Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund(1)	94,586	94,586	—	—
Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund(1)	63,553	63,553	—	—
Fidelity Select Portfolios: Biotechnology Portfolio (1)	215,508	215,508	—	—
5AM Opportunities II, L.P. (2)	646,524	646,524	—	—
Entities affiliated with EcoR1 (3)	838,749	573,139	265,610	1.80%
Entities affiliated with Farallon (4)	431,014	431,014	—	—
The Stuart Partners, LLC (5)	215,508	215,508	—	—
Entities affiliated with GC&H Investments (6)	25,860	25,860	—	—

* Represents beneficial ownership of less than one percent.

(1) These funds and accounts are managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting

common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. The address of these funds and accounts is 245 Summer Street, Boston, MA 02210.

(2) Consists of 646,524 shares of common stock held by 5AM Opportunities II, L.P. ("Opportunities II"). 5AM Opportunities II (GP), LLC ("Opportunities II GP") is the sole general partner of Opportunities II. Dr. Kush M. Parmar and Andrew J. Schwab are the managing members of Opportunities II GP and may be deemed to have shared voting and investment power over the securities beneficially owned by Opportunities II. Each of Opportunities II GP, Dr. Parmar, and Mr. Schwab disclaims beneficial ownership of such securities except to the extent of its or his respective pecuniary interest therein. The address of the above persons and entities is 4 Embarcadero Center, Suite 3110, San Francisco, CA 94111.

(3) Consists of (i) 55,535 shares of common stock held by EcoR1 Capital Fund, L.P. ("Capital Fund") and (ii) 783,214 shares of common stock held by EcoR1 Capital Fund Qualified, L.P. ("Qualified Fund"). EcoR1 Capital LLC ("EcoR1") is the general partner of Capital Fund and Qualified Fund. Oleg Nodelman is the control person of EcoR1 and may be deemed to share dispositive voting power over the shares held by Qualified Fund and Capital Fund. Mr. Nodelman and EcoR1 each disclaim beneficial ownership of all shares except to the extent of their pecuniary interest. The address of the above person and entities is 357 Tehama Street #3, San Francisco, CA 94103.

(4) Consists of (i) 88,961 shares of common stock held by Farallon Capital Partners, L.P. ("FCP"), (ii) 66,937 shares of common stock held by Farallon Capital Institutional Partners, L.P. ("FCIP"), (iii) 23,835 shares of common stock held by Farallon Capital Institutional Partners II, L.P. ("FCIP II"), (iv) 8,706 shares of common stock held by Farallon Capital Institutional Partners III, L.P. ("FCIP III"), (v) 14,870 shares of common stock held by Four Crossings Institutional Partners V, L.P. ("FCIP V"), (vi) 167,622 shares of common stock held by Farallon Capital Offshore Investors II, L.P. ("FCOI II"), (vii) 11,508 shares of common stock held by Farallon Capital (AM) Investors, L.P. ("FCAMI"), and (viii) 48,575 shares of common stock held by Farallon Capital F5 Master I, L.P. ("F5 MI" and, together with FCP, FCIP, FCIP II, FCIP III, FCIP V, FCOI II, and FCAMI, the "Farallon Funds"). Farallon Partners, L.L.C. (the "Farallon General Partner"), as the general partner of each of FCP, FCIP, FCIP II, FCIP III, FCOI II and FCAMI, may be deemed a beneficial owner of the shares held by FCP, FCIP, FCIP II, FCIP III, FCOI II and FCAMI. Farallon Institutional (GP) V, L.L.C. (the "FCIP V General Partner"), as the general partner of FCIP V, may be deemed a beneficial owner of the shares held by FCIP V. Farallon F5 (GP), L.L.C. (the "F5MI General Partner"), as the general partner of F5 MI, may be deemed a beneficial owner of the shares held by F5 MI. Each of Joshua J. Dapice, Philip D. Dreyfuss, Hannah E. Dunn, Richard B. Fried, Varun N. Gehani, Nicolas Giauque, David T. Kim, Michael G. Linn, Rajiv A. Patel, Thomas G. Roberts, Jr., Edric C. Saito, William Seybold, Daniel S. Short, Andrew J. M. Spokes, John R. Warren and Mark C. Wehrly (collectively, the "Farallon Managing Members"), as a senior managing member or managing member, as the case may be, of the Farallon General Partner, and a manager or senior manager, as the case may be, of the FCIP V General Partner and the F5MI General Partner, in each case with the power to exercise investment discretion, may be deemed a beneficial owner of all such shares held by the Farallon Funds. Each of the Farallon General Partner, the FCIP V General Partner, the F5MI General Partner, and the Farallon Managing Members hereby disclaims any beneficial ownership of such shares. The address of the above persons and entities is One Maritime Plaza, Suite 2100, San Francisco, CA 94111.

(5) Consists of 215,508 shares of common stock held by The Stuart Partners, LLC ("Stuart Partners"). Anastasios Parafestas is the sole managing member of Stuart Partners and exercises sole voting and dispositive power over the securities beneficially owned by Stuart Partners. Mr. Parafestas disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein. The address of the above person and entity is One Joy Street, Boston, MA 02108.

(6) Consists of (i) 10,775 shares of common stock held by GC&H Investments, L.P. ("GC&H") and (ii) 15,085 shares of common stock held by GC&H Investments A5, L.P. ("GC&H A5"). Jordan Silber, Mark Tanoury, Peter Werner, Derek Colla, Kenneth Guernsey are the control persons of GC&H and GC&H A5 and may be deemed to share dispositive voting power over the shares held by GC&H and GC&H A5. The address of the above persons and entities is 3 Embarcadero Center, 20th Floor, San Francisco, CA 94111.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our charter and bylaws are summaries and are qualified by reference to such charter and bylaws and applicable provisions of Delaware corporate law. Copies of these documents are filed as exhibits to the registration statement of which this prospectus forms a part.

Authorized Capital Stock

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

Dividends

Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by the our Board out of legally available funds, subject to any preferential dividend rights of any our preferred stock then outstanding.

Voting

Holders of our common stock are entitled to one vote for each share of our common stock held of record for the election of directors of the Company and on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights.

Distributions on Liquidation

In the event of the Company's dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. All outstanding shares are fully paid and non-assessable.

Other Rights

Holders of our common stock are not entitled to preemptive, subscription, redemption or conversion rights, and no sinking fund provisions are applicable to our common stock.

Preferred Stock

Our charter provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable the Board to discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, the Board were to determine that a takeover proposal is not in the best interests of the Company stockholders, the Board could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our charter grants the Board broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of the Company.

Anti-Takeover Effects of Delaware Law and Provisions of the Company's Charter and Bylaws

Certain provisions of the DGCL and of the Company's charter and bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of the Company. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of the Company to first negotiate with its board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, the Company holds that the advantages gained by protecting its ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the date that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which 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 commenced, excluding for purposes of determining the voting stock outstanding shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by the board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition (in one or more transactions) involving the interested stockholder of 10% or more of either the aggregate market value of all (i) the assets of the corporation or (ii) the outstanding capital stock of the corporation, involving the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or any subsidiary to the interested stockholder;
- subject to exceptions, any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation or of any subsidiary beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an “interested stockholder” as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person that is an affiliate or associate of the corporation and who beneficially owned 15% or more of the outstanding voting stock of the corporation at any time within the three year period immediately prior to the date of determining whether such entity or person is an interested stockholder, and any affiliate or associate of that entity or person.

Board Composition and Filling Vacancies

Our charter provides for the division of the Board into three classes serving staggered three-year terms, with one class being elected each year. Our charter also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on the Board, however occurring, including a vacancy resulting from an increase in the size of the Board, may only be filled by the affirmative vote of a majority of directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of the Board.

No Written Consent of Stockholders

Our charter provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of the Company’s bylaws or removal of directors by stockholders without holding a meeting of stockholders.

Meetings of Stockholder

Our charter and bylaws provide that only a majority of the members of the Board then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of Company stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders’ notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

MATERIAL UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS

Material U.S. Federal Income Tax Consequences for Holders of Common Stock

The following is a discussion of certain material U.S. federal income tax consequences of the acquisition, ownership and disposition of our shares of common stock, which we refer to as our securities. This discussion applies only to securities that are held as capital assets for U.S. federal income tax purposes and is applicable only to holders who are receiving our securities in this offering.

This discussion is a summary only and does not describe all of the tax consequences that may be relevant to you in light of your particular circumstances, including but not limited to the alternative minimum tax, the Medicare tax on certain investment income and the different consequences that may apply if you are subject to special rules that apply to certain types of investors (such as the effects of Section 451 of the Code), including but not limited to:

- financial institutions or financial services entities;
- broker-dealers;
- governments or agencies or instrumentalities thereof;
- regulated investment companies;
- real estate investment trusts;
- expatriates or former long-term residents of the United States;
- persons that actually or constructively own 5% or more of our voting shares;
- insurance companies;
- dealers or traders subject to a mark-to-market method of accounting with respect to the securities;
- persons holding the securities as part of a “straddle,” hedge, integrated transaction or similar transaction;
- U.S. holders (as defined below) whose functional currency is not the U.S. dollar;
- partnerships or other pass-through entities for U.S. federal income tax purposes and any beneficial owners of such entities; and
- tax-exempt entities.

This discussion is based on the Code, and administrative pronouncements, judicial decisions and final, temporary and proposed Treasury regulations as of the date hereof, which are subject to change, possibly on a retroactive basis, and changes to any of which subsequent to the date of this prospectus may affect the tax consequences described herein. This discussion does not address any aspect of state, local or non-U.S. taxation, or any U.S. federal taxes other than income taxes (such as gift and estate taxes).

We have not sought, and will not seek, a ruling from the Internal Revenue Service, or the IRS, as to any U.S. federal income tax consequence described herein. The IRS may disagree with the discussion herein, and its determination may be upheld by a court. Moreover, there can be no assurance that future legislation, regulations, administrative rulings or court decisions will not adversely affect the accuracy of the statements in this discussion. You are urged to consult your tax advisor with respect to the application of U.S. federal tax laws to your particular situation, as well as any tax consequences arising under the laws of any state, local or foreign jurisdiction.

This discussion does not consider the tax treatment of partnerships or other pass-through entities or persons who hold our securities through such entities. If a partnership (or other entity or arrangement classified as a

partnership or other pass-through entity for U.S. federal income tax purposes) is the beneficial owner of our securities, the U.S. federal income tax treatment of a partner or member in the partnership or other pass-through entity generally will depend on the status of the partner or member and the activities of the partnership or other pass-through entity. If you are a partner or member of a partnership or other pass-through entity holding our securities, we urge you to consult your tax advisor.

THIS DISCUSSION IS ONLY A SUMMARY OF CERTAIN UNITED STATES FEDERAL INCOME TAX CONSIDERATIONS ASSOCIATED WITH THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES. EACH PROSPECTIVE INVESTOR IN OUR SECURITIES IS URGED TO CONSULT ITS TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH INVESTOR OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF OUR SECURITIES, INCLUDING THE APPLICABILITY AND EFFECT OF ANY UNITED STATES FEDERAL NON-INCOME, STATE AND LOCAL, AND NON-U.S. TAX LAWS.

Material U.S. Federal Income Tax Consequences for U.S. Holders

For purposes of this discussion, a "U.S. Holder" is any beneficial owner of our common stock that, for U.S. federal income tax purposes, is or is treated as:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and all substantial decisions of which are subject to the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Taxation of Distributions. If we pay distributions in cash or other property (other than certain distributions of our stock or rights to acquire our stock) to U.S. holders of shares of common stock, such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Distributions in excess of current and accumulated earnings and profits will constitute a return of capital that will be applied against and reduce (but not below zero) the U.S. holder's adjusted tax basis in common stock. Any remaining excess will be treated as gain realized on the sale or other disposition of the common stock and will be treated as described under "*U.S. Holders-Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock*" below.

Dividends we pay to a U.S. holder that is a taxable corporation generally will qualify for the dividends received deduction if the requisite holding period is satisfied. With certain exceptions (including, but not limited to, dividends treated as investment income for purposes of investment interest deduction limitations), and provided certain holding period requirements are met, dividends we pay to a non-corporate U.S. holder may constitute "qualified dividends" that will be subject to tax at the maximum tax rate accorded to long-term capital gains. If the holding period requirements are not satisfied, then a corporation may not be able to qualify for the dividends received deduction and would have taxable income equal to the entire dividend amount, and non-corporate holders may be subject to tax on such dividend at regular ordinary income tax rates instead of the preferential rate that applies to qualified dividend income.

Gain or Loss on Sale, Taxable Exchange or Other Taxable Disposition of common stock . Upon a sale or other taxable disposition of common stock, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. holder's adjusted tax basis in the

common stock. Any such capital gain or loss generally will be long-term capital gain or loss if the U.S. holder's holding period for the common stock so disposed of exceeds one year. If the holding period requirements are not satisfied, any gain on a sale or taxable disposition of the shares would be subject to short-term capital gain treatment and would be taxed at regular ordinary income tax rates. Long-term capital gains recognized by non-corporate U.S. holders will be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Generally, the amount of gain or loss recognized by a U.S. holder is an amount equal to the difference between (i) the sum of the amount of cash and the fair market value of any property received in such disposition and (ii) the U.S. holder's adjusted tax basis in its common stock so disposed of. A U.S. holder's adjusted tax basis in its common stock generally will equal the U.S. holder's acquisition cost for the common stock or less, in the case of a share of common stock, any prior distributions treated as a return of capital. In the case of any shares of common stock originally acquired as part of an investment unit, the acquisition cost for the share of common stock that were part of such unit would equal an allocable portion of the acquisition cost of the unit based on the relative fair market values of the components of the unit at the time of acquisition.

Information Reporting and Backup Withholding. In general, information reporting requirements may apply to dividends paid to a U.S. holder and to the proceeds of the sale or other disposition of our shares of common stock, unless the U.S. holder is an exempt recipient. Backup withholding may apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn).

Any amounts withheld under the backup withholding rules generally should be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Material U.S. Federal Income Tax Consequences for Non-U.S. Holders

The following summary describes the material U.S. federal income tax consequences of the ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, and does not deal with non-U.S., state and local tax consequences that may be relevant to Non-U.S. Holders, nor does it address any U.S. federal tax consequences (such as gift and estate taxes) other than income taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the U.S. Internal Revenue Code of 1986, as amended, or the Code, such as:

- banks, insurance companies and other financial institutions,
- tax-exempt organizations,
- brokers, dealers and certain electing traders in securities who mark their securities positions to market for U.S. tax purposes,
- certain former U.S. citizens or long-term residents,
- "controlled foreign corporations,"
- "passive foreign investment companies,"
- corporations that accumulate earnings to avoid U.S. federal income tax, corporations organized outside of the United States, any state thereof or the District of Columbia that are nonetheless treated as U.S. income taxpayers for U.S. federal tax purposes,
- persons that hold our common stock as part of a "straddle," "conversion transaction," "synthetic security," integrated investment or other risk reduction strategy,

- persons subject to the alternative minimum tax, the federal Medicare contribution tax on net investment income or the special tax accounting rules under Section 451(b) of the Code,
- tax-qualified retirement plans,
- persons who acquire our common stock through the exercise of an option or otherwise as compensation,
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds,
- persons that own or have owned, actually or constructively, more than 5% of our common stock, and
- partnerships and other pass-through entities or arrangements, and investors in such pass-through entities or arrangements.

Such Non-U.S. Holders are urged to consult their tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them.

In addition, this discussion assumes that the Non-U.S. Holder holds our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). Furthermore, the discussion below is based upon the provisions of the Code, Treasury regulations promulgated thereunder, rulings and judicial decisions, in each case as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

Persons considering the purchase of our common stock pursuant to this offering should consult their tax advisors concerning the U.S. federal income, estate and other tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or non-U.S. tax consequences.

For the purposes of this discussion, a ”Non-U.S. Holder” is, for U.S. federal income tax purposes, a beneficial owner of common stock that is neither a U.S. Person, nor a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes regardless of its place of organization or formation). A “U.S. Person” means any person that is, for U.S. federal income tax purposes, any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or other entity treated as a corporation for U.S. federal income tax purposes created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more “United States persons” (within the meaning of Code Section 7701(a)(30)) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable Treasury regulations to be treated as a United States person.

In the case of a beneficial owner of our common stock that is classified as a partnership for U.S. federal income tax purposes, the tax treatment of a person treated as a partner in such partnership for U.S. federal income tax purposes generally will depend on the status of the partner, the activities of the partner and the partnership and certain determinations made at the partner level. A person treated as a partner in a partnership or who holds our common stock through another pass-through entity should consult his, her or its tax advisor regarding the tax consequences of the ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

Distributions. Distributions, if any, made on our common stock to a Non-U.S. Holder to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. federal income tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, subject to the discussions below regarding effectively connected income, backup withholding and foreign accounts. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us or the applicable withholding agent with a properly executed IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying the Non-U.S. Holder's entitlement to benefits under that treaty and, in certain circumstances, providing such Non-U.S. Holder's U.S. taxpayer identification number and/or foreign tax identifying number. This certification must be provided prior to the payment of dividends and must be updated periodically. In the case of a Non-U.S. Holder that is an entity, Treasury regulations and the relevant income tax treaty provide rules to determine whether, for purposes of determining the applicability of an income tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds our common stock through a financial institution or other agent acting on its behalf, it will be required to provide appropriate documentation to such agent, which will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If the Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty and does not timely file the required certification, it may be able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

We and other applicable withholding agents are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that it maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to the applicable withholding agent prior to the payment of such dividends. In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular rates applicable to U.S. Persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional "branch profits tax," which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder's effectively connected earnings and profits, subject to certain adjustments. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will first reduce the Non-U.S. Holder's adjusted basis in our common stock, but not below zero, and then will be treated as capital gain to the extent of any excess, and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Gain on Disposition of Our Common Stock. Subject to the discussions below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless:

(a) the gain is effectively connected with a trade or business of the Non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base that such Non-U.S. Holder maintains in the United States),

(b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or

(c) we are or have been a "United States real property holding corporation," or USRPHC, within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition and such Non-U.S. Holder's holding period.

In general, we would be a USRPHC if the aggregate fair market value of our "United States real property interests" (within the meaning of Code Section 897(c)(1)), or USRPIs, equaled or exceeded fifty percent (50%) of the combined fair market value of our USRPIs, our non-U.S. real property interests and our other business assets. We believe that we have not been and are not, and do not anticipate becoming, a USRPHC. Even if we are or were to become a USRPHC, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax under the provisions applicable to USRPIs so long as our common stock is "regularly traded," as defined by applicable Treasury regulations, on an established securities market. There can be no assurance that we are not or will not become a USRPHC or that our common stock will qualify as regularly traded on an established securities market.

Non-U.S. Holders described in (a) above will be required to pay tax on the gain derived from the sale or other taxable disposition at regular U.S. federal income tax rates applicable to U.S. Persons, and corporate Non-U.S. Holders described in (a) above may, in addition, be subject to a branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty, as adjusted for certain items. A Non-U.S. Holder described in (b) above will be subject to U.S. federal income tax at a flat 30% rate, or such lower rate as may be specified by an applicable income tax treaty, on gain realized upon the sale or other taxable disposition, which gain may be offset by certain U.S.-source capital losses of the Non-U.S. Holder (even though the Non-U.S. Holder is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

Information Reporting Requirements and Backup Withholding. Generally, we or an applicable withholding agent will be required to report information to the IRS with respect to any distributions we pay on our common stock (even if the payments are exempt from withholding), including the amount of any such distributions, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the Non-U.S. Holder to whom any such distributions are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient's country of residence.

Distributions to a Non-U.S. Holder that are classified as dividends paid by us may also be subject to U.S. backup withholding currently at a rate of 24%. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or otherwise establishes an exemption. Notwithstanding the foregoing, backup withholding may apply if the applicable payor has actual knowledge, or reason to know, that the Non-U.S. Holder is a U.S. Person who is not an exempt recipient.

U.S. information reporting and backup withholding requirements generally will apply to the proceeds of a sale or other taxable disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or otherwise meets documentary evidence requirements for establishing non-U.S. Person status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the payor has actual knowledge, or reason to know, that the Non-U.S. Holder is, in fact, a U.S. Person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. payors.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or credit against the U.S. federal income tax liability of a Non-U.S. Holder subject to backup withholding, provided that the required information is timely furnished to the IRS.

Foreign Accounts. Sections 1471 through 1474 of the Code and the related Treasury regulations, together with other U.S. Treasury and IRS guidance issued thereunder and intergovernmental agreements, legislation,

rules and other official guidance adopted pursuant to such intergovernmental agreements (commonly referred to as FATCA) impose a U.S. federal withholding tax of 30% on certain payments to a "foreign financial institution" (as defined in the Code) which does not provide the withholding agent with sufficient documentation evidencing either (x) an exemption from FATCA or (y) its compliance (or deemed compliance) with FATCA (which may alternatively be in the form of compliance with an intergovernmental agreement with the United States) to withhold on certain payments and to collect and provide to the U.S. tax authorities certain information regarding U.S. account holders of such institution (which includes certain equity holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). FATCA also generally imposes a federal withholding tax of 30% on certain payments to a non-financial foreign entity (as defined in the Code) which does not provide the withholding agent with sufficient documentation evidencing either (x) an exemption from FATCA or (y) either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. An intergovernmental agreement between the United States and an applicable foreign country may modify those requirements. The withholding tax described above will not apply if the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from FATCA. Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

The withholding provisions described above generally apply to payments of dividends. Under proposed Treasury regulations, the preamble to which states that taxpayers may rely on them until final Treasury regulations are issued, this withholding tax does not apply to payments of gross proceeds from a sale or other disposition of common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY CHANGES IN APPLICABLE LAW SUBSEQUENT TO THE DATE HEREOF.

PLAN OF DISTRIBUTION

Each selling stockholder of the securities and any of their pledgees, assignees, donees, transferees or other successors-in-interest may, from time to time, sell, transfer or otherwise dispose of any or all of their securities covered hereby on the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, or the New York Stock Exchange or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities that require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). The selling stockholders also may transfer the securities in other circumstances, in which case the transferees, pledgees, donees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales (it being

understood that the selling stockholders shall not be deemed to be underwriters solely as a result of their participation in this offering). In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

We are required to pay certain fees and expenses incurred by us incident to the registration of the securities. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of the date that the securities (i) have been sold, pursuant to this prospectus or pursuant to Rule 144, or (ii) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, and without the requirement for us to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

We will not receive any proceeds from sales of any shares of common stock by the selling stockholders.

We cannot assure you that the selling stockholders will sell all or any portion of the shares of common stock offered hereby. We are registering the resale of shares of our common stock to provide the selling stockholders with freely tradable securities, but the registration of such shares does not necessarily mean that any of such shares will be offered or sold by the selling stockholders pursuant to this prospectus or at all.

To the extent required, this prospectus may be amended and/or supplemented from time to time to describe a specific plan of distribution.

LEGAL MATTERS

The validity of the common stock being offered by this prospectus has been passed upon for us by Cooley LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of AVROBIO, Inc. as of December 31, 2023 and 2022, and for each of the two years in the period ended December 31, 2023, appearing in this registration statement of which this prospectus forms a part, have been audited by Ernst & Young LLP ("EY"), independent registered public accounting firm, as stated in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The financial statements of Tectonic Therapeutic, Inc. (now known as Tectonic Operating Company, Inc.) as of December 31, 2023 and 2022, and for the years then ended, included in this registration statement of which this prospectus forms a part, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

CHANGE IN CERTIFYING ACCOUNTANT

(a) Dismissal of Independent Registered Public Accounting Firm

Ernst & Young LLP ("EY") served as AVROBIO's independent registered public accounting firm prior to completion of the Merger. On June 20, 2024, following the completion of the Merger, EY was dismissed as the Company's independent registered public accounting firm. The decision to dismiss EY was approved by the Company's board of directors.

The reports of EY on AVROBIO's consolidated financial statements for the fiscal years ended December 31, 2023 and 2022 did not contain an adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles, or other similar opinion as defined in Item 304(a)(1)(ii) of Regulation S-K (17 CFR § 229.304(a)(1)(ii)) except for an explanatory paragraph regarding existence of substantial doubt about AVROBIO's ability to continue as a going concern in the report for the year ended December 31, 2022.

During AVROBIO's two most recent fiscal years and the subsequent period from January 1, 2024 to June 20, 2024, there were (i) no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) with EY on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of EY, would have caused it to make reference to the subject matter of the disagreement in connection with its report for such years and (ii) no reportable events (as described in Item 304(a)(1)(v) of Regulation S-K). The Company provided EY with a copy of the disclosures made in this Item 4.01 and requested EY to furnish us with a letter addressed to the SEC stating whether it agrees with the statements made by us and, if not, stating the respects in which it does not agree. A copy of EY's letter to the SEC dated June 20, 2024 regarding these statements is filed as Exhibit 16.1 to the registration statement of which this prospectus forms a part.

(b) Engagement of New Independent Registered Public Accounting Firm

Deloitte & Touche LLP ("Deloitte") served as the independent registered public accounting firm of Legacy Tectonic prior to the completion of the Merger. On June 20, 2024, following the completion of the Merger, the Company's Board approved the appointment of Deloitte as the Company's independent registered public accounting firm.

During Legacy Tectonic's two most recent fiscal years and the subsequent period from January 1, 2024 to June 20, 2024, Legacy Tectonic did not consult with Deloitte regarding any of the matters or events set forth in Item 304(a)(2)(i) and (ii) of Regulation S-K.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and in accordance therewith, file annual, quarterly and current reports, proxy statements and other information with the SEC electronically, and the SEC maintains a website that contains our filings as well as reports, proxy and information statements, and other information issuers file electronically with the SEC at www.sec.gov.

We also make available free of charge on or through our website at www.tectonictx.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnishes it to the SEC. The website addresses are inactive textual references and except as specifically incorporated by reference into this prospectus, information on those websites is not part of this prospectus.

This prospectus and any prospectus supplement are part of a registration statement that we filed with the SEC and do not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Other documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement or documents incorporated by reference in the registration statement. Statements in this prospectus or any prospectus supplement about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement through the SEC's website, as provided above.

If you would like to request documents, please send a request in writing or by telephone to the following address:

Tectonic Therapeutic, Inc.
490 Arsenal Way
Suit 210
Watertown, MA 02472
Attn: Daniel Lochner
(339) 666-3320
Email: investor@tectonictx.com

AVROBIO, INC.
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TECTONIC THERAPEUTIC, INC.
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AVROBIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 90,481	$ 98,020
Restricted cash	283	283
Prepaid expenses and other current assets	1,074	1,958
Total current assets	91,838	100,261
Operating lease assets	110	432
Restricted cash, net of current portion	400	400
Total assets	$ 92,348	$ 101,093
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 243	$ 27
Accrued expenses and other current liabilities	3,042	5,449
Operating lease liabilities	224	878
Total current liabilities	3,509	6,354
Total liabilities	3,509	6,354
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized and no shares issued or outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 150,000 shares authorized; 44,882 and 44,654 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	572,918	572,010
Accumulated deficit	(484,083)	(477,275)
Total stockholders' equity	88,839	94,739
Total liabilities and stockholders' equity	$ 92,348	$ 101,093

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

AVROBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(unaudited)
(in thousands, except per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 683	$ 17,333
General and administrative	7,258	7,887
Total operating expenses	7,941	25,220
Loss from operations	(7,941)	(25,220)
Other income:		
Interest income, net	1,146	248
Other (expense) income, net	(13)	15
Total other income, net	1,133	263
Net loss and comprehensive loss attributable to common stockholders—basic and diluted	$ (6,808)	$ (24,957)
Earnings per share:		
Net loss per share — basic and diluted	$ (0.15)	$ (0.57)
Shares used in computing earnings per share:		
Weighted-average number of common shares outstanding — basic and diluted	44,791	44,037

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

AVROBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Three Months Ended March 31, 2023				
	Common Stock				
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2022	**43,916**	**$ 4**	**$ 564,798**	**$ (489,432)**	**$ 75,370**
Vesting of restricted stock units	105	—	—	—	—
Exercise of stock options	46	—	42	—	42
Issuance of common stock under the 2018 employee stock purchase plan	21	—	13	—	13
Stock-based compensation expense	—	—	2,530	—	2,530
Net loss	—	—	—	(24,957)	(24,957)
Balance as of March 31, 2023	**44,088**	**$ 4**	**$ 567,383**	**$ (514,389)**	**$ 52,998**

	Three Months Ended March 31, 2024				
	Common Stock				
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2023	**44,654**	**$ 4**	**$ 572,010**	**$ (477,275)**	**$ 94,739**
Vesting of restricted stock units	191	—	—	—	—
Exercise of stock options	33	—	26	—	26
Issuance of common stock under the 2018 employee stock purchase plan	4	—	4	—	4
Stock-based compensation expense	—	—	878	—	878
Net loss	—	—	—	(6,808)	(6,808)
Balance as of March 31, 2024	**44,882**	**$ 4**	**$ 572,918**	**$ (484,083)**	**$ 88,839**

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

AVROBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	$ (6,808)	$ (24,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	878	2,530
Depreciation and amortization expense	—	328
Non-cash interest expense	—	80
Non-cash lease expense	322	592
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	884	2,187
Accounts payable	216	207
Current and non-current operating lease liabilities	(654)	(600)
Accrued expenses and other current liabilities	(2,407)	(651)
Net cash used in operating activities	(7,569)	(20,284)
Cash flows from investing activities:		
Purchases of property and equipment	—	(8)
Net cash used in investing activities	—	(8)
Cash flows from financing activities:		
Proceeds from exercise of stock options	26	42
Proceeds from issuance of ESPP shares	4	13
Net cash provided by financing activities	30	55
Net decrease in cash, cash equivalents and restricted cash	(7,539)	(20,237)
Cash, cash equivalents and restricted cash at beginning of period	98,703	92,846
Cash, cash equivalents and restricted cash at end of period	$ 91,164	$ 72,609
Supplemental disclosure of non-cash investing and financing activities:		
Interest paid	$ —	$ 463
Lease liability arising from obtaining right-of-use assets	—	2,392
Reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets:		
Cash and cash equivalents, end of period	$ 90,481	$ 72,326
Restricted cash	683	283
Cash, cash equivalents and restricted cash, end of period	$ 91,164	$ 72,609

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

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

1. Nature of the Business

AVROBIO, Inc. (the "Company" or "AVROBIO") is a gene therapy company which has been focused on developing potentially curative hematopoietic stem cell, or HSC, gene therapies to treat rare diseases following a single dose treatment regimen.

On July 12, 2023, following a comprehensive review of the Company's business by its Board of Directors (the "Board"), the Company announced its intention to halt development of its programs and explore strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture. The decision was not related to any safety or medical issues or negative regulatory feedback related to the Company's programs. On January 30, 2024, the Company entered into the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), with Alpine Merger Subsidiary, Inc. ("Merger Sub"), a direct, wholly owned subsidiary of the Company, and Tectonic Therapeutic, Inc. ("Tectonic") pursuant to which Merger Sub will merge with and into Tectonic, with Tectonic surviving as a wholly-owned subsidiary of the Company (the "Merger").

The Company is subject to risks and uncertainties including, should it resume development of its product candidates, risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Should the Company resume development of its product candidates, significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization, would be required. These efforts would require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, should the Company resume development of its product candidates, it is uncertain when, if ever, the Company would realize revenue from product sales.

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The Company has devoted substantially all of its efforts to research and development, business planning, acquiring operating assets, seeking protection for its technology and product candidates, and raising capital. Since inception, the Company has had recurring losses and has funded its operations through sales of preferred stock and common stock, a term loan facility and the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. As of March 31, 2024, the Company had an accumulated deficit of $484,083. The Company expects that its cash and cash equivalents of $90,481 as of March 31, 2024 will be sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months from the filing date of this Quarterly Report on Form 10-Q with the Securities and Exchange Commission ("SEC").

On May 19, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Novartis Pharma AG and Novartis Pharmaceuticals Corporation (collectively, "Novartis"), providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. The aggregate consideration to the Company

consisted of a cash payment of $87,500 upon closing of the transaction. The Company completed the Asset Sale on June 9, 2023 and recognized $83,736 as a gain on asset sale, net of $3,764 transaction costs, in the condensed consolidated statement of operations and comprehensive income (loss) for the three months ended March 31, 2024. See Note 3 for further discussion.

In July 2023, the Board approved a reduction in the Company's workforce by approximately 50% across different areas and functions in the Company (the "July 2023 Workforce Reduction"). The July 2023 Workforce Reduction was substantially completed by the end of July 2023. The Company informed affected employees in the July 2023 Workforce Reduction on July 12, 2023. Since the date of the July 2023 Workforce Reduction, the Company's remaining employees have primarily focused on activities relating to halting further development of the Company's programs, the pursuit of strategic alternatives, and the provision of services under the previously disclosed Separation Services Agreement between the Company and Novartis in connection with the sale to Novartis of the Company's cystinosis gene therapy program. The Company's remaining workforce was further reduced by 11 employees in a workforce reduction implemented effective as of October 31, 2023 (the "October 2023 Workforce Reduction"). The Company's workforce was further reduced by 8 employees in the December 2023 Workforce Reduction effective as of December 31, 2023 (the "December 2023 Workforce Reduction"). Affected employees in the July 2023 Workforce Reduction, October 2023 Workforce Reduction, December 2023 Workforce Reduction, and February 2024 Workforce Reduction were offered separation benefits, including severance payments. See Note 12 for further discussion.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements (the "unaudited condensed consolidated financial statements") have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and ASU of the FASB.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements as of and for the year ended December 31, 2023, and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2024, and the results of its operations for the three months ended March 31, 2024 and 2023, its statements of stockholders' equity for the three months ended March 31, 2024 and 2023 and its statement of cash flows for the three months ended March 31, 2024 and 2023.

The results for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2023, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 14, 2024.

The unaudited condensed consolidated financial statements reflect the application of certain significant accounting policies as described below and elsewhere in these notes to the unaudited condensed consolidated financial statements. As of March 31, 2024, there have been no changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer ("CEO"). The Company and the CEO view the Company's operations and manage its business as one operating segment. All material long-lived assets of the Company reside in the United States.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with GAAP requires that the Company make estimates and judgments that may affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Significant estimates relied upon in preparing the unaudited condensed consolidated financial statements include the determination of the fair value of share-based awards issued and the estimation of accrued research and development expenses.

Stock-based Compensation

For stock-based awards issued to employees and members of the Company's Board for their services on the Board, the Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance- or market-based vesting conditions. The Company accounts for forfeitures as they occur.

Prior to the adoption of ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, the measurement date for non-employee awards was generally the date the services are completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. After adoption of ASU 2018-07, the measurement date for non-employee awards is the later of the adoption date of ASU 2018-07, or the date of grant, without change in the fair value of the award. For stock-based awards granted to nonemployees subject to graded vesting that only contain service conditions, the Company has elected to recognize stock-based compensation expense using the straight-line recognition method.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

Subsequent Event Considerations

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required.

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13. ASU 2016-13 requires that credit losses be reported as an allowance using an expected losses model, representing the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. On January 1, 2023 the Company adopted this standard, which had no impact on its financial position or results of operations.

In November 2019, the FASB issued ASU 2019-11, "*Codification Improvements to Topic 326, Financial Instruments – Credit Losses* ," or ASU 2019-11. ASU 2019-11 is an accounting pronouncement that amends ASU 2016-13, "*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*." The amendments update guidance on reporting credit losses for financial assets. These amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. On January 1, 2023 the Company adopted this standard, which had no impact on its financial position or results of operations.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09 "*Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* " This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statement disclosures.

In October 2023, the FASB issued ASU 2023-06 "*Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*," which incorporates certain SEC disclosure requirements into the FASB Accounting Standards Codification ("Codification"). The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety Codification topics, allow investors to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The amendments in this ASU should be applied prospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statement disclosures.

3. License and Purchase Agreements

Agreement with The University of Manchester

On September 30, 2020, the Company entered into an agreement ("MPSII License Agreement") with The University of Manchester, England ("UoM"), whereby UoM granted to the Company an exclusive worldwide license under certain patent and other intellectual property rights, subject to certain retained rights, to develop, commercialize and sell an *ex vivo* lentiviral gene therapy for use in the treatment of Hunter syndrome, or mucopolysaccharidosis type II ("MPSII"). As consideration for the MPSII License Agreement, the Company

agreed to pay UoM an upfront, one-time fee of $8,000, which was recognized as research and development expense during the year ended December 31, 2020.

As part of the agreement, the Company was obligated to make milestone payments of up to an aggregate of $80,000 upon the achievement of specified development and regulatory milestones, to pay royalties, on a product-by-product and country-by-country basis, of a mid-single digit percentage based on net sales of products licensed under the agreement and to pay a low double digit percentage of any sublicense fees received by the Company. During the third quarter of 2022, a $2,000 milestone payment under the MPSII License Agreement became due following the date of regulatory approval of the CTA for the investigator-sponsored Phase 1/2 clinical trial sponsored by UoM.

Concurrently with the MPSII License Agreement, the Company entered into a collaborative research funding agreement with UoM ("CRFA"). Under the CRFA, the Company had agreed to fund the budgeted costs of an investigator-sponsored Phase 1/2 clinical trial to be sponsored by UoM in connection with the development activities under the MPSII License Agreement, which were expected to equal approximately £9,900 in the aggregate.

On September 8, 2023 the Company and UoM terminated the MPSII License Agreement and the CFRA, and in connection with such termination, the Company paid UoM £3,900. Following the termination of the MPSII License Agreement and the CFRA, the Company does not have any remaining financial obligations to UoM.

For the three months ended March 31, 2024, the Company did not incur costs related to the CRFA. For the three months ended March 31, 2023, the Company incurred $1,610 related to the CRFA.

Agreements with University Health Network ("UHN")

Fabry License Agreement—

On January 27, 2016, the Company entered into an agreement with UHN, pursuant to which UHN granted the Company an option to enter into an exclusive license under the UHN intellectual property related to Fabry disease in accordance with the pre-negotiated licensing terms. On November 4, 2016, the Company exercised its option and entered into a license agreement with UHN, pursuant to which UHN granted the Company an exclusive worldwide license under certain intellectual property rights and a non-exclusive worldwide license under certain know-how, in each case subject to certain retained rights, to develop, commercialize and sell products for use in the treatment of Fabry disease. In addition, for three years following the execution of the agreement, UHN granted the Company an exclusive option to obtain a license under certain improvements to the licensed intellectual property rights as well as an option to negotiate a license under certain other improvements.

Under this agreement, the Company paid an option fee of CAD $20, an upfront license fee of CAD $75, plus the annual license maintenance fee for the first year. Thereafter, the Company is also required to pay UHN future annual license maintenance fees until the first sale of a licensed product in certain markets. The Company is also obligated to make future milestone payments in an aggregate amount of up to CAD $2,450 upon the achievement of specified milestones as well as royalties on a country-by-country basis of a low to mid-single-digit percentage of annual net sales of licensed products and a lower single-digit royalty percentage in certain circumstances. Additionally, the Company has agreed to pay a low double-digit royalty percentage of all sublicensing revenue.

The agreement requires the Company to meet certain performance milestones within specified timeframes. UHN may terminate the agreement if the Company fails to meet these performance milestones despite using commercially reasonable efforts and the Company is unable to reach agreement with UHN on revised timeframes. The Company's royalty obligation expires on a licensed product-by-licensed product and country-by-country basis upon the latest to occur of the expiration or termination of the last valid claim under the licensed intellectual property rights in such country, the tenth anniversary of the first commercial sale of such licensed product in such country and the expiration of any applicable regulatory exclusivity in such country.

Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products. UHN can terminate the agreement if the Company fails to make any payments within a specified period after receiving written notice of such failure, or in the event that the Company fails to obtain or maintain insurance. Either the Company or UHN may terminate the license agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company can voluntarily terminate the agreement with prior notice to UHN.

Effective January 4, 2024, AVROBIO terminated the Fabry license agreement with UHN, and in connection with such termination, the Company paid UHN CAD$194. Following the termination of the agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Fabry license agreement.

For the three months ended March 31, 2024, the Company did not incur research and development expense related to this agreement with UHN. For the three months ended March 31, 2023 the Company recorded research and development expense related to this agreement with UHN of $34, which consists of reimbursable funded study trial costs. No milestone or maintenance fees were incurred related to this agreement in the three months ended March 31, 2024 and 2023.

Interleukin 12 License Agreement—

On January 27, 2016, the Company entered into an exclusive license agreement with UHN, pursuant to which UHN granted the Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights related to Interleukin 12. Upon execution of this agreement, the Company paid an upfront license fee of CAD $264. In addition, as part of the initial consideration for the license, the Company issued to UHN 1,161,665 shares of the Company's common stock and agreed to pay UHN up to $2,000 upon the closing of an IPO if certain criteria are met. The fair value of the shares issued to UHN of $480 and the upfront fee was expensed upon the execution of the agreement. Upon the closing of the IPO in 2018, as the criteria were met, the Company paid UHN $2,000. The Company was also required to pay UHN future annual license maintenance fees of CAD $50 on each anniversary of the effective date of the license agreement prior to expiration or termination and potential future milestone payments of up to CAD $19,275 upon the achievement of specified clinical and regulatory milestones. The Company also agreed to pay UHN royalties of a low single-digit percentage of net sales of licensed products sold by the Company. If the Company granted any sublicense rights under the license agreement, the Company agreed to pay UHN a low double-digit royalty percentage of any sublicense income received by the Company. The agreement also required the Company to meet certain diligence requirements based upon specified milestones.

Effective as of August 24, 2023, the Company and UHN agreed to terminate the Interleukin 12 License Agreement, and in connection with such termination there were no payments made to UHN. Following the termination of the agreement, the Company does not have any remaining financial obligations to UHN pursuant to the Interleukin 12 License Agreement.

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

For the three months ended March 31, 2024, the Company did not incur research and development expense related to this agreement with UHN. For the three months ended March 31, 2023 the Company recorded research and development expense related to this agreement with UHN of $37. No milestone fees were incurred related to this agreement in the three months ended March 31, 2024 and 2023.

Agreement with BioMarin Pharmaceutical Inc. ("BioMarin")

On August 31, 2017, the Company entered into a license agreement with BioMarin, pursuant to which BioMarin granted the Company an exclusive worldwide license under certain intellectual property rights owned or controlled by BioMarin to develop, commercialize and sell products for use in the treatment of Pompe disease. The license agreement was amended in February 2018 and again in January 2020 to, among things, provide that BioMarin would supply the Company with certain technology materials. As consideration for this agreement, the Company paid an upfront license fee of $500 in cash and issued 233,765 shares of Series B Preferred Stock to BioMarin at the time of the Company's Series B Preferred Stock financing in January 2018. The Company has a license agreement with BioMarin, pursuant to which BioMarin granted the Company an exclusive worldwide license under certain intellectual property rights owned or controlled by BioMarin to develop, commercialize and sell products for use in the treatment of Pompe disease. The Company is also obligated to make future milestone payments of up to $13,000 upon the achievement of certain specified milestones and agreed to pay BioMarin royalties of a low single-digit percentage of net sales of licensed products sold by the Company or its affiliates covered by patent rights in a relevant country.

The Company has recognized no expenses related to the license for the three months ended March 31, 2024 and 2023.

Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products throughout the world. BioMarin and the Company can terminate the agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company may terminate the agreement at will upon written notice to BioMarin. BioMarin has the right to terminate the agreement upon the Company's bankruptcy or insolvency, or in the event of any challenge or opposition to the licensed patent rights or related actions brought by the Company or its affiliates or sublicensees, or if the Company, its affiliates or sublicensees knowingly assist a third-party in challenging or otherwise opposing the licensed patent rights, except as required under a court order or subpoena.

Agreement with Papillon Therapeutics, Inc. (previously GenStem Therapeutics, Inc.)

On October 2, 2017, the Company entered into a license agreement with GenStem, pursuant to which GenStem granted the Company an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights owned or controlled by GenStem to develop, commercialize and sell products for use in the treatment of cystinosis. Under this agreement, the Company paid an upfront license fee of $1,000 and is required to make payments upon completion of certain milestones up to an aggregate of $16,000. The Company also agreed to pay GenStem a tiered mid to high single-digit royalty percentage on annual net sales of licensed products as well as a low double-digit percentage of sublicense income received from certain third-party licensees. The Company's royalty obligation expires on a licensed product-by-licensed product and country-by-country basis on the eleventh anniversary of the first commercial sale of such licensed product in such country or the expiration of the last valid claim under the licensed patent rights covering such licensed product in such country, whichever is later. Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products throughout the world. GenStem and the Company can terminate the agreement in the event of a material breach by the other party and failure to cure such breach

within a certain period of time. The Company may terminate the agreement at will upon the specified prior written notice to GenStem. In October 2021, the Company received notice that the license agreement with GenStem had been assigned to Papillon Therapeutics, Inc. ("Papillon"). On June 9, 2023, in connection with the close of the Asset Purchase Agreement, discussed and defined above, the Company transferred this agreement to Novartis.

The Company has recognized no expenses related to this agreement for the three months ended March 31, 2024 and 2023.

Agreement with Lund University Rights Holders

On November 17, 2016, the Company entered into a license agreement with affiliates of Lund University, along with certain other relevant rights holders that may be added from time to time, pursuant to which such rights holders granted to the Company an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights to develop, commercialize and sell products in any and all uses relevant to Gaucher disease. As consideration for the license, the Company is required to make payments in connection with the achievement of certain milestones up to an aggregate of $550. The agreement expires on the latest of (i) the twentieth anniversary of the end of a certain research project the Company is funding pursuant to an agreement with Lund University, (ii) the expiration of the term of any patent filed on the licensed rights that covers a licensed product, (iii) the expiration of any applicable marketing exclusivity right and (iv) such time that neither the Company nor any sublicensees, partners or contractors are commercializing a licensed product. Either the Company or the rights holders acting together may terminate the license agreement if the other such party commits a material breach and fails to cure such breach within a certain period of time, or if the other party enters into liquidation, becomes insolvent, or enters into composition or statutory reorganization proceedings.

The Company has recognized no expenses related to this agreement for the three months ended March 31, 2024 and 2023.

Sale of Cystinosis Program

On May 19, 2023, the Company entered into the Asset Purchase Agreement with Novartis, providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. In addition, pursuant to the Asset Purchase Agreement, the Company has granted an exclusive license to Novartis to use certain intellectual property of the Company, which consists of certain proprietary elements of the Company's plato®gene therapy platform technology specifically within the field of cystinosis. The foregoing transactions contemplated by the Asset Purchase Agreement are referred to as the "Asset Sale." The Company has also agreed not to assert claims against Novartis for violations of certain other Company intellectual property rights in connection with Novartis's exercise of the exclusive license granted to it under the Asset Purchase Agreement, and for violations of the licensed intellectual property, except in connection with activities by Novartis in the fields of Gaucher disease, Pompe disease, Hunter syndrome and Fabry disease, or indemnification claims under the Asset Purchase Agreement. The aggregate consideration to the Company consisted of a cash payment of $87,500 upon closing of the transaction. During the year ended December 31, 2023, the Company recognized $83,736 as a gain on asset sale, net of $3,764 in transaction costs, in the consolidated statement of operations and comprehensive income (loss).

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

4. Fair Value Measurement

The following table presents information about the Company's financial assets measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of March 31, 2024 and December 31, 2023:

	Fair Value Measurements as of March 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$89,229	$ —	$ —	$89,229
	$89,229	$ —	$ —	$89,229

	Fair Value Measurements as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents — money market funds	$96,707	$ —	$ —	$96,707
	$96,707	$ —	$ —	$96,707

The fair value of cash equivalents was determined through quoted prices by third-party pricing services.

During the three months ended March 31, 2024, there were no transfers between levels.

5. Supplemental Balance Sheet Information

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

	March 31, 2024	December 31, 2023
Other current assets	$ 626	$ 570
Prepaid insurance	411	816
Prepaid research and development expenses	37	572
Prepaid expenses and other current assets	$ 1,074	$ 1,958

Restricted cash

As of March 31, 2024 and December 31, 2023, the Company had restricted cash as presented in the table below, which consists of cash used to secure letters of credit for the benefit of the landlord in connection with the Company's lease agreements as well as restricted cash related to the Company's corporate credit card program. The cash will be restricted until the termination or modification of the lease arrangement and corporate credit card program, respectively.

	March 31, 2024	December 31, 2023
Restricted cash	$ 283	$ 283
Restricted cash, net of current portion	400	400

(in thousands, except share and per share data)

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2024	December 31, 2023
Consulting and professional fees	$ 1,630	$ 892
Compensation and benefit costs	686	3,463
Research and development expenses	396	711
Other liabilities	330	383
Accrued expenses and other current liabilities	$ 3,042	$ 5,449

6. Leases

On August 31, 2018, the Company entered into a sublease agreement for office and lab space located in Cambridge Massachusetts, United States, which originally was set to expire in October 2020 but was subsequently amended and expired on April 30, 2024. In July 2022, the Company moved its corporate headquarters to this subleased location. Effective January 24, 2023, the Company amended the terms of the sublease, which expired on April 30, 2024. In accordance with the sublease agreement, the Company was required to maintain a security deposit of $283, which was recorded in restricted cash as of March 31, 2024 and December 31, 2023. In July 2023, the Company ceased use of the lab space. This resulted in an impairment of the right of use asset of $940, recognized in the third quarter of 2023. Effective as of April 22, 2024, the Company moved its corporate headquarters to its current location at One Broadway, 14th Floor, Cambridge, Massachusetts 02142.

On June 1, 2020, the Company entered into a lease agreement for office space located in Toronto, Ontario, Canada, which was set to expire in June 2025. On October 31, 2023, the lease agreement was terminated. In accordance with the lease agreement, the Company was required to maintain a security deposit of CAD$27. In October 2022, the Company entered into a sublease agreement to sublease this space. The term of the sublease agreement commenced on October 1, 2022 and was set to expire on June 29, 2025. The sublease was also terminated on October 31, 2023.

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations and comprehensive loss:

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Operating lease costs	$ 339	$ 670
Sublease income	—	(23)
Total lease costs	$ 339	$ 647

During the three months ended March 31, 2024 and 2023, the Company made cash payments for operating leases of $672 and $687, respectively.

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

As of March 31, 2024, future minimum payments of operating lease liabilities are as follows:

	March 31, 2024
2024	$ 224
2025	—
2026	—
2027	—
Thereafter	—
Total lease payments	$ 224
Less: interest	—
Present value of lease liabilities	$ 224

As of March 31, 2024, the weighted average remaining lease term was 0.1 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 16.15%. As of March 31, 2023, the weighted average remaining lease term was 1.2 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 15.67%.

7. Commitments and Contingencies

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three months ended March 31, 2024 and 2023 and to the best of the Company's knowledge, no material legal proceedings are currently pending or threatened.

Other

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met at March 31, 2024 and December 31, 2023, or royalties on future sales. No milestone or royalty payments under these agreements are expected to be payable in the immediate future, except as disclosed in Note 3 *"License Agreements."*

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company agrees to indemnify, hold harmless, and to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third-party with respect to the Company's products. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of March 31, 2024. The Company does not anticipate recognizing any significant losses relating to these arrangements. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

8. Stockholders' Equity

Common Stock

As of March 31, 2024 and December 31, 2023, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value and 10,000,000 shares of undesignated preferred stock. As of March 31, 2024 and December 31, 2023, no undesignated preferred stock was outstanding.

Through March 31, 2024, no cash dividends have been declared or paid.

Common Stock Reserved for Future Issuance

As of March 31, 2024 and December 31, 2023, the Company has reserved the following shares of common stock for future issuance:

	March 31, 2024	December 31, 2023
Shares reserved for exercise of outstanding stock options	4,812,817	5,142,272
Shares reserved for vesting of restricted stock units	677,785	936,358
Shares reserved for issuance under the 2018 Stock Option and Grant Plan	8,299,245	7,978,667
Shares reserved for issuance under the 2018 Employee Stock Purchase Plan	1,771,748	1,771,748
Shares reserved for issuance under the 2019 Inducement Plan	1,511,183	1,407,211
Shares reserved for issuance under the 2020 Inducement Plan	1,700,000	1,700,000
Total shares of authorized common stock reserved for future issuance	18,772,778	18,936,256

9. Stock-based Compensation

Stock Option Valuation

The following table summarizes the Company's stock option activity for the three months ended March 31, 2024:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	5,142,272	$ 7.33	6.24	$ 663
Granted	—	$ —		
Exercised	(32,756)	$ 0.79		
Cancelled or forfeited	(296,699)	$ 9.71		
Outstanding as of March 31, 2024	4,812,817	$ 7.23	6.09	$ 519
Exercisable as of March 31, 2024	3,639,245	$ 8.45	5.46	$ 346

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock.

The aggregate intrinsic value of options exercised during the three months ended March 31, 2024 and 2023 was $16 and $1, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted common stock units for the three months ended March 31, 2024:

	Number of Shares	Weighted-Average Grant Date Fair Value
Issued and unvested as of December 31, 2023	936,358	$ 2.13
Granted	60,251	$ 1.31
Vested	(190,973)	$ 1.71
Forfeited, cancelled or expired	(127,851)	$ 2.49
Issued and unvested as of March 31, 2024	677,785	$ 2.11

The total fair value of restricted stock units vested during the three months ended March 31, 2024 and 2023 was $326 and $194, respectively.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 170	$ 622
General and administrative	708	1,908
Total stock-based compensation expense	$ 878	$ 2,530

As of March 31, 2024, total unrecognized compensation cost related to the unvested stock-based awards was $2,911, which is expected to be recognized over a weighted-average period of 1.91 years.

10. Net Income (Loss) Per Share

For purposes of the diluted net loss per share calculation, stock options and unvested restricted stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share is the same.

AVROBIO, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(in thousands, except share and per share data)

The following potentially dilutive common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the computation of diluted net loss per share for the periods indicated:

	Three Months Ended March 31,	
	2024	2023
Options to purchase common stock	4,812,817	9,154,769
Restricted stock units	677,785	2,026,338

11. Related Party Transactions

UHN

For the three months ended March 31, 2024, the Company did not recognize research and development expense related to the license agreements with UHN. For the three months ended March 31, 2023, the Company recognized $71 of research and development expense related to the license agreements with UHN. Refer to Note 3 "*License Agreements*" for additional information regarding the UHN license agreements.

Others

In the first quarter of 2023, the sublease for space that was previously provided by an entity affiliated with a member of the Company's Board was assigned to Novartis. Therefore, for the three months ended March 31, 2024 the Company did not record expense related to a sublease to rent office and lab space provided by an entity affiliated with a member of the Company's Board. For the three months ended March 31, 2023 the Company recorded $652 related to the sublease to rent office and lab space previously provided by an entity affiliated with a member of the Company's Board.

12. Restructuring Activities

In July 2023, the Board approved a reduction in the Company's workforce by approximately 50% across different areas and functions in the Company's July 2023 Workforce Reduction. The July 2023 Workforce Reduction was substantially completed by the end of July 2023. The Company informed affected employees in the July 2023 Workforce Reduction on July 12, 2023. Since the date of the July 2023 Workforce Reduction, the Company's remaining employees have primarily focused on activities relating to halting further development of the Company's programs, the pursuit of strategic alternatives, and the provision of services under the previously disclosed Separation Services Agreement between the Company and Novartis in connection with the sale to Novartis of the Company's cystinosis gene therapy program. Under the July 2023 Workforce Reduction, the Company recognized total restructuring expenses of $3,015 for the year ended December 31, 2023, recognized as $1,800 and $1,215 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive income (loss). For the three months ended March 31, 2024 and 2023, no related expense was recognized. These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. Approximately $479 of these expenses were related to non-cash stock-based compensation expense, and there are no remaining accrued payments as of March 31, 2024.

The Company's workforce was reduced by 11 employees in the October 2023 Workforce Reduction effective as of October 31, 2023. Under the October 2023 Workforce Reduction, the Company recognized total restructuring expenses of $1,093 for the year ended December 31, 2023 recognized as research and development expense in the consolidated statement of operations and comprehensive income (loss). For the three months

(in thousands, except share and per share data)

ended March 31, 2024 and 2023, no related expense was recognized. These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. There are no remaining accrued payments as of March 31, 2024.

The Company's workforce was reduced by 8 employees in the December 2023 Workforce Reduction effective as of December 31, 2023. Under the December 2023 Workforce Reduction, the Company recognized total restructuring expenses of $950 for the year ended December 31, 2023 recognized as $866 and $64 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive income (loss). For the three months ended March 31, 2024 the Company recognized $74 and $9 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive loss. For the three months ended March 31, 2023, no related expense was recognized. These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. There are no remaining accrued payments as of March 31, 2024.

The Company's workforce was reduced by 2 employees in the February 2024 Workforce Reduction effective as of February 29, 2024. Under the February 2024 Workforce Reduction, the Company recognized total restructuring expenses of $241 for the three months ended March 31, 2024 recognized as $146 and $96 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive loss. For the three months ended March 31, 2023, no related expense was recognized. These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. There are no remaining accrued payments as of March 31, 2024.

	Three Months Ended March 31, 2024
Restructuring expenses	$ 5,299
Cash payments	(4,820)
Non-cash expenses	(479)
Liability included in accrued expenses and other current liabilities at March 31, 2024	$ —

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of AVROBIO, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AVROBIO, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. We determined that there are no critical audit matters.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.
Boston, Massachusetts
March 14, 2024

AVROBIO, INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 98,020	$ 92,563
Restricted cash	283	283
Prepaid expenses and other current assets	1,958	7,112
Total current assets	100,261	99,958
Operating lease assets	432	1,057
Property and equipment, net	—	2,894
Restricted cash, net of current portion	400	—
Other assets	—	40
Total assets	$ 101,093	$ 103,949
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 27	$ 384
Accrued expenses and other current liabilities	5,449	11,732
Operating lease liabilities	878	999
Total current liabilities	6,354	13,115
Note payable, net of discount	—	15,276
Operating lease liabilities, net of current portion	—	188
Total liabilities	6,354	28,579
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized and no shares issued or outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 150,000 shares authorized as of December 31, 2023 and 2022; 44,654 and 43,916 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4	4
Additional paid-in capital	572,010	564,798
Accumulated deficit	(477,275)	(489,432)
Total stockholders' equity	94,739	75,370
Total liabilities and stockholders' equity	$ 101,093	$ 103,949

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

AVROBIO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
(amounts in thousands, except per share data)

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 47,700	$ 72,186
General and administrative	23,967	33,248
Total operating expenses	71,667	105,434
Gain on asset sale	83,736	—
Loss on impairment	(1,877)	—
Income (loss) from operations	10,192	(105,434)
Other income (expense):		
Interest income (expense), net	2,420	(299)
Other expense, net	(78)	(157)
Total other income (expense), net	2,342	(456)
Income (loss) before income taxes	12,534	(105,890)
Provision for income tax expense	377	—
Net income (loss) and comprehensive income (loss) attributable to common stockholders—basic and diluted	$ 12,157	$ (105,890)
Earnings per share:		
Net income (loss) per share applicable to common stockholders—basic	$ 0.27	$ (2.42)
Net income (loss) per share applicable to common stockholders—diluted	$ 0.27	$ (2.42)
Shares used in computing earnings per share:		
Weighted-average common shares outstanding—basic	44,327	43,739
Weighted-average common shares outstanding—diluted	44,568	43,739

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

AVROBIO, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(amounts in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2021	43,652	$ 4	$553,014	$ (383,542)	$ 169,476
Vesting of restricted stock awards and units	1	—	—	—	—
Exercise of stock options	142	—	58	—	58
Issuance of common stock under 2018 employee stock purchase plan	121	—	204	—	204
Stock-based compensation expense	—	—	11,522	—	11,522
Net loss	—	—	—	(105,890)	(105,890)
Balance as of December 31, 2022	43,916	4	564,798	(489,432)	75,370
Vesting of restricted stock units	306	—	—	—	—
Exercise of stock options	298	—	235	—	235
Issuance of common stock under 2018 employee stock purchase plan	134	—	86	—	86
Stock-based compensation expense	—	—	6,891	—	6,891
Net loss	—	—	—	12,157	12,157
Balance as of December 31, 2023	44,654	$ 4	$572,010	$ (477,275)	$ 94,739

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

AVROBIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(amounts in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	$ 12,157	$ (105,890)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on asset sale	(83,736)	—
Stock-based compensation expense	6,891	11,522
Depreciation and amortization expense	617	1,440
Non-cash asset impairment charges	1,877	—
Loss on disposal of property and equipment	—	59
Non-cash interest expense	1,074	331
Non-cash income tax expense	377	—
(Gain)/loss on impairment of leasehold improvements	—	86
(Gain)/loss on extinguishment of operating lease	(72)	(81)
Non-cash lease expense	1,912	2,726
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	5,154	2,466
Other assets	40	34
Accounts payable	(357)	(3,102)
Current and non-current operating lease liabilities	(2,464)	(2,893)
Accrued expenses and other current liabilities	(6,660)	(3,906)
Net cash used in operating activities	(63,190)	(97,208)
Cash flows from investing activities:		
Proceeds from asset sale, net	83,736	—
Proceeds from the sale of property, plant, and equipment	1,348	—
Purchases of property and equipment	(8)	(267)
Net cash provided by (used in) investing activities	85,076	(267)
Cash flows from financing activities:		
Repayment of note payable, including end of term charge	(16,350)	—
Exercise of stock options	235	58
Proceeds from issuance of common stock under 2018 employee stock purchase plan	86	204
Net cash (used in) provided by financing activities	(16,029)	262
Net increase (decrease) in cash, cash equivalents and restricted cash	5,857	(97,213)
Cash, cash equivalents and restricted cash at beginning of period	92,846	190,059
Cash, cash equivalents and restricted cash at end of period	$ 98,703	$ 92,846
Supplemental Cash:		
Interest paid	$ 831	$ 1,425
Supplemental disclosure of non-cash investing and financing activities:		
Right of use asset obtained in exchange for operating lease liabilities	$ 2,392	$ 4,319
Reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets:		
Cash and cash equivalents, end of period	$ 98,020	$ 92,563
Restricted cash	683	283
Cash, cash equivalents and restricted cash, end of period	$ 98,703	$ 92,846

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

AVROBIO, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data)

1. Nature of the Business

AVROBIO, Inc. (the "Company" or "AVROBIO") is a gene therapy company which has been focused on developing potentially curative hematopoietic stem cell, or HSC, gene therapies to treat rare diseases following a single dose treatment regimen.

On July 12, 2023, following a comprehensive review of the Company's business by its Board of Directors (the "Board"), the Company announced its intention to halt development of its programs and explore strategic alternatives focused on maximizing stockholder value, which may include, but are not limited to, an acquisition, a merger, business combination or divestiture. The decision was not related to any safety or medical issues or negative regulatory feedback related to the Company's programs. See Note 15 for further discussion. On January 30, 2024, the Company entered into the Merger Agreement with Tectonic Therapeutic, Inc. ("Tectonic") pursuant to which a wholly-owned subsidiary of the Company will merge with and into Tectonic, with Tectonic surviving as a wholly-owned subsidiary of the Company (the "Merger"). See Note 16 for further discussion.

The Company is subject to risks and uncertainties including, should it resume development of its product candidates, risks and uncertainties common to early-stage companies in the biotechnology industry, including but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Should the Company resume development of its product candidates, significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization, would be required. These efforts would require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, should the Company resume development of its product candidates, it is uncertain when, if ever, the Company would realize revenue from product sales.

In accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The Company has devoted substantially all of its efforts to research and development, business planning, acquiring operating assets, seeking protection for its technology and product candidates, and raising capital. Since inception, the Company has had recurring losses and has funded its operations through sales of preferred stock and common stock, a term loan facility and the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. As of December 31, 2023, the Company had an accumulated deficit of $477,275. The Company expects that its cash and cash equivalents of $98,020 as of December 31, 2023 will be sufficient to fund current planned operations and capital expenditure requirements for at least the next twelve months from the filing date of this Annual Report on Form 10-K with the Securities and Exchange Commission ("SEC").

On May 19, 2023, the Company entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Novartis Pharma AG and Novartis Pharmaceuticals Corporation (collectively, "Novartis"), providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. The aggregate consideration to the Company

consisted of a cash payment of $87,500 upon closing of the transaction. The Company completed the Asset Sale (as defined below) on June 9, 2023 and recognized $83,736 as a gain on asset sale, net of $3,764 transaction costs, in the consolidated statement of operations and comprehensive income (loss). See Note 3 for further discussion.

In July 2023, the Board approved a reduction in the Company's workforce by approximately 50% across different areas and functions in the Company (the "July 2023 Workforce Reduction"). The July 2023 Workforce Reduction was substantially completed by the end of July 2023. The Company informed affected employees in the July 2023 Workforce Reduction on July 12, 2023. Since the date of the July 2023 Workforce Reduction, the Company's remaining employees have primarily focused on activities relating to halting further development of the Company's programs, the pursuit of strategic alternatives, and the provision of services under the previously disclosed Separation Services Agreement between the Company and Novartis in connection with the sale to Novartis of the Company's cystinosis gene therapy program. The Company's remaining workforce was further reduced by 11 employees in a workforce reduction implemented effective as of October 31, 2023 (the "October 2023 Workforce Reduction"). The Company's workforce was further reduced by 8 employees in the December 2023 Workforce Reduction effective as of December 31, 2023 (the "December 2023 Workforce Reduction"). Affected employees in the July 2023 Workforce Reduction, October 2023 Workforce Reduction, and December 2023 Workforce Reduction were offered separation benefits, including severance payments. See Note 15 for further discussion.

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 ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and ASU of FASB.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of AVROBIO, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's chief operating decision maker is the chief executive officer ("CEO"). The Company and the CEO view the Company's operations and manage its business as one operating segment. All material long-lived assets of the Company reside in the United States.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires that the Company make estimates and judgments that may affect the reported amounts of assets, liabilities and expenses and the related disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. On an on-going basis, the Company evaluates its estimates, judgments and

methodologies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates. Changes in estimates are reflected in reported results in the period in which they become known.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less at acquisition to be cash equivalents. As of December 31, 2023 and 2022, cash and cash equivalents were primarily held in interest-bearing money market funds.

Concentrations of Credit Risk

The Company has no significant off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and restricted cash. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash and cash equivalents in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

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— Fair values are determined utilizing prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access.
- 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 that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying amounts of the Company's financial instruments, which include cash equivalents, accounts payable, and accrued expenses, approximated their fair values as of December 31, 2023 and 2022 due to the short-term nature of these instruments.

The Company has evaluated the estimated fair value of financial instruments using available market information. The use of different market assumptions, estimation methodologies, or both, could have a significant effect on the estimated fair value amounts. See Note 4 *"Fair Value of Financial Assets and Liabilities"* for further discussion.

AVROBIO, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Property and Equipment

Property and equipment are recorded at cost. Depreciation and amortization is calculated using the straight-line method over the following estimated useful lives of the assets:

	Estimated Useful Life
Laboratory and office equipment	5 years
Computer equipment	2 years
Leasehold improvements	Lesser of lease term or 10 years

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. During the year ended December 31, 2023, the Company recognized a $937 loss on impairment of property, plant, and equipment as a result of the reclassification of these assets to held for sale. The Company did not record any impairment loss during the year ended December 31, 2022.

Leases

Prior to January 1, 2022, the Company accounted for leases in accordance with FASB ASC 840, Leases. At lease inception, the Company determined if an arrangement was an operating or capital lease. For operating leases, the Company recognized rent expense, inclusive of rent escalations, on a straight-line basis over the lease term.

Effective on January 1, 2022, the Company accounts for leases in accordance with ASC Topic 842, Leases (“ASC 842”). Upon transition, the Company applied the package of practical expedients permitted under ASC 842 transition guidance to its entire lease portfolio at January 1, 2022. As a result, the Company was not required to reassess (i) whether any expired or existing contracts are or contain leases, (ii) the classification of any expired or existing leases, and (iii) initial direct costs for any existing leases. Furthermore, as a lessee the Company elected to combine lease and non-lease components together for the majority of its leases. As a result, for these applicable classes of underlying assets, the Company accounted for each separate lease component and the non-lease components associated with that lease component as a single lease component.

In accordance with ASC 842, the Company determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company records leases at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as operating or finance leases and records a right-of-use (“ROU”) asset and a lease liability on the consolidated balance sheet for all leases with a lease term of greater than twelve months. The Company has elected to not recognize leases with a lease term of twelve months or less on the balance sheet and will recognize lease payments for such short-term leases as an expense on a straight-line basis.

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The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include items such as maintenance, utilities, or other operating costs. For leases of real estate, the Company combines the lease and associated non-lease components in its lease arrangements as a single lease component. Variable costs, such as utilities or maintenance costs, are not included in the measurement of right-of-use assets and lease liabilities, but rather are expensed when the event determining the amount of variable consideration to be paid occurs.

Operating lease assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term using the discount rate implicit in the lease if readily determinable. If the rate implicit is not readily determinable, the Company utilizes its incremental borrowing rate based upon the available information at the lease commencement date. ROU assets are further adjusted for items such as initial direct costs, prepaid rent, or lease incentives. Operating lease payments are expensed using the straight-line method as an operating expense over the lease term. The Company's lease terms may include options to extend the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated into (i) a portion that is recorded as interest expense and (ii) a portion that reduces the finance lease liability associated with the lease.

During the year ended December 31, 2023, the Company recognized a $940 loss on impairment of ROU assets as a result of the discontinued use of lab space in Cambridge, Massachusetts, United States. The Company did not record any impairment loss during the year ended December 31, 2022.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in stockholders' equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity (deficit) which includes certain changes in equity that are excluded from net income (loss). Comprehensive loss has been disclosed in the accompanying consolidated statements of operations and comprehensive loss and equals the Company's net loss for all periods presented.

Foreign Currency Translation

The functional currency of the Company's international operations in Canada and Australia is the U.S. dollar. Accordingly, all operating assets and liabilities of these international subsidiaries are remeasured into U.S. dollars using the exchange rates in effect at the balance sheet date or historical rates, as appropriate, while expenses are remeasured into U.S. dollars at the average rates in effect during the period. Any differences resulting from the remeasurement of assets, liabilities, and operations of the Canadian and Australian subsidiaries are recorded within other (expense) income, net in the consolidated statements of operations and comprehensive loss. During the years ended December 31, 2023 and 2022, the Company recorded foreign exchange losses of $122 and $92, respectively, in other expense in the consolidated statements of operations and comprehensive loss.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, stock-based compensation and benefits, facilities costs, depreciation, third-party license fees, and external costs of outside vendors engaged to conduct preclinical development activities and clinical trials as well as to manufacture research and

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development materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed or until it is no longer expected that the goods will be delivered or the services rendered.

The Company has entered into various research and development related contracts with parties both inside and outside of the United States. The payments related to these agreements are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research 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 from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

For stock-based awards issued to employees and members of the Company's Board for their services on the Board, the Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock-based awards with performance- or market-based vesting conditions. The Company accounts for forfeitures as they occur.

The measurement date for non-employee awards is the later of the adoption date of ASU 2018-07, or the date of grant. For stock-based awards granted to nonemployees subject to graded vesting that only contain service conditions, the Company has elected to recognize stock-based compensation expense using the straight-line recognition method.

The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. As there was no public market for its common stock prior to June 21, 2018, which was the first day of trading, and as the trading history of the Company's common stock was limited through December 31, 2022, the Company determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The 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. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

Income Taxes

Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which

the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established.

The Company accounts for uncertain tax positions recognized in the consolidated financial statements by prescribing a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net Income (Loss) per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by adjusting the weighted-average shares outstanding for the potential dilutive effects of common stock equivalents outstanding during the period calculated in accordance with the treasury stock method. For purposes of the diluted net loss per share calculation, stock options and restricted stock units are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Subsequent Event Considerations

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated as required. See Note 16.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, or ASU 2016-13. ASU 2016-13 requires that credit losses be reported as an allowance using an expected losses model, representing the entity's current estimate of credit losses expected to be incurred. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. On January 1, 2023 the Company adopted this standard, which had no impact on its financial position or results of operations.

In November 2019, the FASB issued ASU 2019-11, "Codification Improvements to Topic 326, Financial Instruments – Credit Losses," or ASU 2019-11. ASU 2019-11 is an accounting pronouncement that amends ASU 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." The amendments update guidance on reporting credit losses for financial assets. These amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. On January 1, 2023 the Company adopted this standard, which had no impact on its financial position or results of operations.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued Accounting Standard Update ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This guidance is intended to enhance the transparency and

decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively. Early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statement disclosures.

In October 2023, the FASB issued ASU 2023-06 "Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative." which incorporates certain SEC disclosure requirements into the FASB Accounting Standards Codification ("Codification"). The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety Codification topics, allow investors to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. The effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The amendments in this ASU should be applied prospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statement disclosures.

3. License and Purchase Agreements

Agreement with The University of Manchester

On September 30, 2020, the Company entered into an agreement ("MPSII License Agreement") with The University of Manchester, England ("UoM"), whereby UoM granted to the Company an exclusive worldwide license under certain patent and other intellectual property rights, subject to certain retained rights, to develop, commercialize and sell an *ex vivo* lentiviral gene therapy for use in the treatment of Hunter syndrome, or mucopolysaccharidosis type II ("MPSII"). As consideration for the MPSII License Agreement, the Company agreed to pay UoM an upfront, one-time fee of $8,000, which was recognized as research and development expense during the year ended December 31, 2020.

As part of the agreement, the Company was obligated to make milestone payments of up to an aggregate of $80,000 upon the achievement of specified development and regulatory milestones, to pay royalties, on a product-by-product and country-by-country basis, of a mid-single digit percentage based on net sales of products licensed under the agreement and to pay a low double-digit percentage of any sublicense fees received by the Company. During the third quarter of 2022, a $2,000 milestone payment under the MPSII License Agreement became due following the date of regulatory approval of the CTA for the investigator-sponsored Phase 1/2 clinical trial sponsored by UoM.

Concurrently with the MPSII License Agreement, the Company entered into a collaborative research funding agreement with UoM ("CRFA"). Under the CRFA, the Company has agreed to fund the budgeted costs of an investigator-sponsored Phase 1/2 clinical trial to be sponsored by UoM in connection with the development activities under the MPSII License Agreement, which were estimated to equal approximately £9,900 in the aggregate.

On September 8, 2023 the Company and UoM terminated the MPSII License Agreement and the CFRA, and in connection with such termination, the Company paid UoM £3,900. Following the termination of the MPSII License Agreement and the CFRA, the Company does not have any remaining financial obligations to UoM.

For the years ended December 31, 2023 and 2022, the Company recognized $1,610 and $2,346, respectively, of costs related to the CRFA, excluding the payment made in connection with the termination.

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Agreements with University Health Network ("UHN")

Fabry License Agreement—

On January 27, 2016, the Company entered into an agreement with UHN, pursuant to which UHN granted the Company an option to enter into an exclusive license under the UHN intellectual property related to Fabry disease in accordance with the pre-negotiated licensing terms. On November 4, 2016, the Company exercised its option and entered into a license agreement with UHN, pursuant to which UHN granted the Company an exclusive worldwide license under certain intellectual property rights and a non-exclusive worldwide license under certain know-how, in each case subject to certain retained rights, to develop, commercialize and sell products for use in the treatment of Fabry disease. In addition, for three years following the execution of the agreement, UHN granted the Company an exclusive option to obtain a license under certain improvements to the licensed intellectual property rights as well as an option to negotiate a license under certain other improvements.

Under this agreement, the Company paid an option fee of CAD$20, an upfront license fee of CAD$75, plus the annual license maintenance fee for the first year. Thereafter, the Company was also required to pay UHN future annual license maintenance fees until the first sale of a licensed product in certain markets. The Company was also obligated to make future milestone payments in an aggregate amount of up to CAD$2,450 upon the achievement of specified milestones as well as royalties on a country-by-country basis of a low to mid-single-digit percentage of annual net sales of licensed products and a lower single-digit royalty percentage in certain circumstances. Additionally, the Company had agreed to pay a low double-digit royalty percentage of all sublicensing revenue.

The agreement required the Company to meet certain performance milestones within specified timeframes. UHN could terminate the agreement if the Company failed to meet these performance milestones despite using commercially reasonable efforts and the Company is unable to reach agreement with UHN on revised timeframes. The Company's royalty obligation was to expire on a licensed product-by-licensed product and country-by-country basis upon the latest to occur of the expiration or termination of the last valid claim under the licensed intellectual property rights in such country, the tenth anniversary of the first commercial sale of such licensed product in such country and the expiration of any applicable regulatory exclusivity in such country.

Unless terminated earlier, the agreement was to expire upon the expiration of the Company's royalty obligation for all licensed products. UHN could terminate the agreement if the Company failed to make any payments within a specified period after receiving written notice of such failure, or in the event that the Company fails to obtain or maintain insurance. Either the Company or UHN could terminate the license agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company could voluntarily terminate the agreement with prior notice to UHN.

Effective January 4, 2024, AVROBIO terminated the Fabry license agreement with UHN, and in connection with such termination, the Company paid UHN CAD$194. Following the termination of the agreement, AVROBIO does not have any remaining financial obligations to UHN pursuant to the Fabry license agreement. For the years ended December 31, 2023 and 2022, the Company recorded research and development expense related to this agreement with UHN of $93 and $161, respectively, which consists of reimbursable funded study trial costs and license maintenance fees. No milestone fees were incurred related to the Fabry license agreement in the years ended December 31, 2023 and 2022.

Interleukin 12 License Agreement—

On January 27, 2016, the Company entered into an exclusive license agreement with UHN, pursuant to which UHN granted the Company a license to certain patent rights for the commercial development,

manufacture, distribution and use of any products or processes resulting from development of those patent rights related to Interleukin 12. Upon execution of this agreement, the Company paid an upfront license fee of CAD $264. In addition, as part of the initial consideration for the license, the Company issued to UHN 1,161,665 shares of the Company's common stock and agreed to pay UHN up to $2,000 upon the closing of an IPO if certain criteria are met. The fair value of the shares issued to UHN of $480 and the upfront fee was expensed upon the execution of the agreement. Upon the closing of the Company's initial public offering (the "IPO") in 2018, as the criteria were met, the Company paid UHN $2,000. The Company was also required to pay UHN future annual license maintenance fees of CAD $50 on each anniversary of the effective date of the license agreement prior to expiration or termination and potential future milestone payments of up to CAD $19,275 upon the achievement of specified clinical and regulatory milestones. The Company also agreed to pay UHN royalties of a low single-digit percentage of net sales of licensed products sold by the Company. If the Company granted any sublicense rights under the license agreement, the Company agreed to pay UHN a low double-digit royalty percentage of any sublicense income received by the Company. The agreement also required the Company to meet certain diligence requirements based upon specified milestones.

Effective as of August 24, 2023, the Company and UHN agreed to terminate the Interleukin 12 License Agreement, and in connection with such termination there were no payments made to UHN. Following the termination of the agreement, the Company does not have any remaining financial obligations to UHN pursuant to the Interleukin 12 License Agreement.

For the years ended December 31, 2023 and 2022, the Company recorded research and development expense related to this agreement with UHN of $37 and $39, respectively, which consists of license maintenance fees. No milestone fees were incurred related to the Interleukin 12 license agreement in the years ended December 31, 2023 and 2022.

Agreement with BioMarin Pharmaceutical Inc. ("BioMarin")

On August 31, 2017, the Company entered into a license agreement with BioMarin, pursuant to which BioMarin granted the Company an exclusive worldwide license under certain intellectual property rights owned or controlled by BioMarin to develop, commercialize and sell products for use in the treatment of Pompe disease. The license agreement was amended in February 2018 and again in January 2020 to, among things, provide that BioMarin would supply the Company with certain technology materials. As consideration for this agreement, the Company paid an upfront license fee of $500 in cash and issued 233,765 shares of Series B Preferred Stock to BioMarin at the time of the Company's Series B Preferred Stock financing in January 2018. The Company is also obligated to make future milestone payments of up to $13,000 upon the achievement of certain specified milestones and agreed to pay BioMarin royalties of a low single-digit percentage of net sales of licensed products sold by the Company or its affiliates covered by patent rights in a relevant country. No expenses related to the license were recorded for the years ended December 31, 2023 and 2022.

Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products throughout the world. BioMarin and the Company can terminate the agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company may terminate the agreement at will upon written notice to BioMarin. BioMarin has the right to terminate the agreement upon the Company's bankruptcy or insolvency, or in the event of any challenge or opposition to the licensed patent rights or related actions brought by the Company or its affiliates or sublicensees, or if the Company, its affiliates or sublicensees knowingly assist a third-party in challenging or otherwise opposing the licensed patent rights, except as required under a court order or subpoena.

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Agreement with Papillon Therapeutics, Inc. (previously GenStem Therapeutics, Inc.)

On October 2, 2017, the Company entered into a license agreement with GenStem, pursuant to which GenStem granted the Company an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights owned or controlled by GenStem to develop, commercialize and sell products for use in the treatment of cystinosis. Under this agreement, the Company paid an upfront license fee of $1,000 and is required to make payments upon completion of certain milestones up to an aggregate of $16,000. The Company also agreed to pay GenStem a tiered mid to high single-digit royalty percentage on annual net sales of licensed products as well as a low double-digit percentage of sublicense income received from certain third-party licensees. The Company's royalty obligation expires on a licensed product-by-licensed product and country-by-country basis on the eleventh anniversary of the first commercial sale of such licensed product in such country or the expiration of the last valid claim under the licensed patent rights covering such licensed product in such country, whichever is later. Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products throughout the world. GenStem and the Company can terminate the agreement in the event of a material breach by the other party and failure to cure such breach within a certain period of time. The Company may terminate the agreement at will upon the specified prior written notice to GenStem. In October 2021, the Company received notice that the license agreement with GenStem had been assigned to Papillon. The license agreement with Papillon was assigned to Novartis on May 19, 2023 in conjunction with the Company's Asset Purchase Agreement with Novartis which provided for the sale of the Company's cystinosis gene therapy program and all other assets of the Company specifically related to this program (see "Sale of Cystinosis Program" below).

No expenses related to the license were recorded for the years ended December 31, 2023 and 2022.

Agreement with Lund University Rights Holders

On November 17, 2016, the Company entered into a license agreement with affiliates of Lund University, along with certain other relevant rights holders that may be added from time to time, pursuant to which such rights holders granted to the Company an exclusive worldwide license, subject to certain retained rights, under certain intellectual property rights to develop, commercialize and sell products in any and all uses relevant to Gaucher disease. As consideration for the license, the Company is required to make payments in connection with the achievement of certain milestones up to an aggregate of $550. The agreement expires on the latest of (i) the twentieth anniversary of the end of a certain research project the Company is funding pursuant to an agreement with Lund University, (ii) the expiration of the term of any patent filed on the licensed rights that covers a licensed product, (iii) the expiration of any applicable marketing exclusivity right and (iv) such time that neither the Company nor any sublicensees, partners or contractors are commercializing a licensed product. Either the Company or the rights holders acting together may terminate the license agreement if the other such party commits a material breach and fails to cure such breach within a certain period of time, or if the other party enters into liquidation, becomes insolvent, or enters into composition or statutory reorganization proceedings. No expenses related to the license were recorded for the years ended December 31, 2023 and 2022.

Sale of Cystinosis Program

On May 19, 2023, the Company entered into the Asset Purchase Agreement with Novartis, providing for the sale of the Company's cystinosis gene therapy program (designated AVR-RD-04) and all other assets of the Company specifically related to this program. In addition, pursuant to the Asset Purchase Agreement, the Company has granted an exclusive license to Novartis to use certain intellectual property of the Company, which consists of certain proprietary elements of the Company's plato®gene therapy platform technology specifically within the field of cystinosis. The foregoing transactions contemplated by the Asset Purchase Agreement are referred to as the "Asset Sale." The Company has also agreed not to assert claims against Novartis for violations of certain other Company

intellectual property rights in connection with Novartis's exercise of the exclusive license granted to it under the Asset Purchase Agreement, and for violations of the licensed intellectual property, except in connection with activities by Novartis in the fields of Gaucher disease, Pompe disease, Hunter syndrome and Fabry disease, or indemnification claims under the Asset Purchase Agreement. The aggregate consideration to the Company consisted of a cash payment of $87,500 upon closing of the transaction. The Company recognized $83,736 as a gain on asset sale, net of $3,764 in transaction costs, in the consolidated statement of operations and comprehensive income (loss).

4. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values as of December 31, 2023 and 2022:

	Fair Value Measurements as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$96,707	$ —	$ —	$96,707
	$96,707	$ —	$ —	$96,707

	Fair Value Measurements as of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents—money market funds	$91,095	$ —	$ —	$91,095
	$91,095	$ —	$ —	$91,095

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

5. Supplemental Balance Sheet Information

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2023	2022
Prepaid research and development expenses	$ 572	$4,509
Prepaid insurance	816	999
Prepaid compensation benefits	—	327
Tax incentive refund, net of reserve	—	269
Other current assets	570	1,008
Prepaid expenses and other current assets	$1,958	$7,112

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Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
Laboratory and office equipment	$ 5,973	$ 5,967
Leasehold improvements	629	629
Computer equipment	104	102
	6,706	6,698
Less: Accumulated depreciation and amortization	(4,421)	(3,804)
Impairment	(937)	—
Sale of assets	(1,348)	—
Property and equipment, net	$ —	$ 2,894

Depreciation and amortization expense for the years ended December 31, 2023 and 2022 was $617 and $1,440, respectively.

Restricted Cash

As of December 31, 2023 and 2022, the Company had restricted cash as presented in the table below, which consists of cash used to secure a letter of credit for the benefit of the landlord in connection with the Company's lease agreement as well as restricted cash related to the Company's corporate credit card program. The cash will be restricted until the termination or modification of the lease arrangement and corporate credit card program, respectively.

	December 31,	
	2023	2022
Restricted cash	$283	$283
Restricted cash, net of current portion	400	—

Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2023	2022
Research and development expenses	$ 711	$ 6,122
Compensation and benefit costs	3,463	4,175
Consulting and professional fees	892	1,224
Other liabilities	383	211
	$5,449	$11,732

6. Leases

On August 31, 2018, the Company entered into a sublease agreement for lab space located in Cambridge Massachusetts, United States, which was set to expire in October 2020. On June 9, 2020, the Company amended the terms of the sublease, which was set to expire in April 2022. Effective January 1, 2022, the Company

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amended the terms of the sublease, to extend the term through April 2023. In July 2022, the company moved its corporate headquarters to our subleased space in this location. Effective January 24, 2023, the Company amended the terms of the sublease, which is now set to expire in April 2024. The annual lease payments are subject to a 5% increase each year. In accordance with the lease agreement, the Company is required to maintain a security deposit of $283, which was recorded in restricted cash as of December 31, 2023 and 2022.

On June 1, 2020, the Company entered into a lease agreement for office space located in Toronto, Ontario, Canada, which was set to expire in June 2025. On October 31, 2023, the lease agreement was terminated. The annual lease payments were fixed for years 1 and 2, and then subject to a 6.67% increase for years 3 through 5. In accordance with the lease agreement, the Company was required to maintain a security deposit of CAD$27, which was recorded in other long-term assets as of December 31, 2022. In October 2022, the Company entered into a sublease agreement to sublease this space. The term of the sublease agreement commenced on October 1, 2022 and expires on June 29, 2025. The sublease was also terminated on October 31, 2023.

The following table summarizes the effect of lease costs in the Company's consolidated statement of operations and comprehensive loss:

	Year Ended December 31,	
	2023	2022
Operating lease costs	$ 2,195	$ 2,994
Sublease income	(77)	(23)
Total lease costs	$ 2,118	$ 2,971

During the years ended December 31, 2023 and 2022 the Company made cash payments for operating leases of $2,771 and $3,167, respectively.

As of December 31, 2023, future minimum payments of operating lease liabilities are as follows (in thousands):

	As of December 31, 2023
2024	896
2025	—
2026	—
2027	—
Thereafter	—
Total lease payments	$ 896
Less: interest	(18)
Present value of lease liabilities	$ 878

As of December 31, 2023, the weighted average remaining lease term was 0.3 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 16.15%. As of December 31, 2022, the weighted average remaining lease term was 0.9 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 10.58%.

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7. Note Payable

On November 2, 2021 (the "Closing Date"), the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank pursuant to which a term loan in an aggregate principal amount of up to $50,000 (the "Term Loan Facility") was available to the Company in three tranches, subject to certain terms and conditions. The first tranche of $15,000 was advanced to the Company on the Closing Date. Subject to the terms and conditions of the Loan Agreement, the first tranche allowed the Company to borrow an additional $15,000 through October 31, 2023. Upon satisfaction of certain milestones, the second and third tranches were available under the Term Loan Facility which allowed the Company to borrow an additional amount up to $10,000 in each tranche through October 31, 2023. Additionally, the Company could seek to borrow up to an additional $15,000 at the sole discretion of the lender through the term of the Loan Agreement. The Loan Agreement provided for an October 1, 2026 maturity date (the "Maturity Date"). The Company was required to pay an end of term fee ("End of Term Charge") equal to 9.00% of the aggregate principal amount of the Term Loan advances upon repayment.

Advances under the Term Loan Facility bore interest at a rate equal to the greater of either (i) the Prime Rate (as reported in The Wall Street Journal) plus 4.85%, and (ii) 8.10%. The Company was obligated to make interest only payments through November 1, 2024. Following the interest only period, the Company was to repay the principal balance and interest of the advances in equal monthly installments through October 1, 2026.

The Company could prepay advances under the Loan Agreement, in whole or in part, at any time subject to a prepayment charge (the "Prepayment Premium") equal to: (a) 1.50% of amounts so prepaid, if such prepayment occurred during the first year following the Closing Date; (b) 1.00% of the amount so prepaid, if such prepayment occurred during the second year following the Closing Date, and (c) 0.00% of the amount so prepaid, if such prepayment occurred after the second year following the Closing Date.

Upon prepayment or repayment of all or any of the term loans under the Term Loan Facility, the Company was required to pay (in addition to any Prepayment Premium) an end of term charge of 9.0% of the aggregate funded amount under the Term Loan Facility.

The Term Loan Facility was secured by substantially all of the Company's assets, other than the Company's intellectual property. The Company agreed to not pledge or secure its intellectual property to others.

The End of Term Charge is recorded as a debt discount with an initial carrying balance of $1,350. During the year ended December 31, 2021 the Company recognized $103 of debt issuance costs related to legal expenses that has been included in the debt discount balance. The debt discount costs are being accreted to the principal amount of debt and being amortized from the date of issuance through the Maturity Date to interest expense using the effective-interest rate method. The effective interest rate of the outstanding debt under the Loan Agreement was approximately 16.29%.

On June 9, 2023, upon the closing of the Asset Sale, all outstanding amounts due and owed, including principal, interest, and other charges, under the Term Loan Facility, dated as of November 2, 2021, by and among the Company, Silicon Valley Bank, a division of First-Citizens Bank & Trust and the other parties thereto, were repaid in full and the Term Loan Facility was terminated. Upon repayment, the obligations of the Company under the Term Loan Facility were satisfied in full, the Term Loan Facility and all related loan documents were terminated and all liens and security interests granted thereunder were released and terminated (excluding certain indemnification obligations that expressly survive termination of the Term Loan Facility).

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As of December 31, 2022 the carrying value of the note payable consists of the following:

	December 31, 2022
Note payable, including End of Term Charge	$ 16,350
Debt discount, net of accretion	(1,074)
Note payable, net of discount, long-term	$ 15,276

During the year ended December 31, 2023, the Company recognized $1,917 of interest expense related to the Loan Agreement, of which $939 is related to the loss on the extinguishment of debt due to the write off of the debt discount balance, which is reflected in other expense, net on the consolidated statements of operations and comprehensive loss. During year ended December 31, 2022, the Company recognized $1,808 of interest expense related to the Loan Agreement.

8. Common Stock

As of December 31, 2023 and 2022, the authorized capital stock of the Company included 150,000,000 shares of common stock, $0.0001 par value, and 10,000,000 shares of undesignated preferred stock. As of December 31, 2023 and 2022, no undesignated shares of preferred stock were outstanding.

In accordance to the Fourth Amended and Restated Certificate of Incorporation, the holders of the common stock shall have the exclusive right to vote for the election of directors of the Company and on all other matters requiring stockholder action, each outstanding share entitling the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote; provided, however, that, except as otherwise required by law, holders of common stock, as such, shall not be entitled to vote on any amendment to any amendment to a certificate of designations of any series of undesignated preferred stock that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of undesignated preferred stock if the holders of such affected series of undesignated preferred stock are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to a certificate of designations of any series of undesignated preferred stock.

Through December 31, 2023, no cash dividends have been declared or paid.

Public Offerings

In July 2019, the Company closed an underwritten public offering of 7,475,000 shares of its common stock at a public offering price of $18.50 per share (the “July 2019 Follow-on Offering”), which included 975,000 shares of the Company’s common stock resulting from the full exercise of the underwriters’ option to purchase additional shares at the public offering price, less underwriting discounts and commissions. The net proceeds to the Company from the July 2019 Follow-on Offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were $129,464.

In February 2020, the Company closed an underwritten public offering of 4,350,000 shares of its common stock at a public offering price of $23.00 per share (the “February 2020 Follow-on Offering”). The net proceeds to the Company from the February 2020 Follow-on Offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were $93,627.

In June 2020, the Company sold an aggregate of 384,140 shares of common stock under its 2019 “at-the-market” facility (the “2019 ATM Facility”) for net proceeds, after deducting commissions and other offering expenses payable by the Company, of $8,130.

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In November 2020, the Company closed an underwritten public offering of 5,000,000 shares of its common stock at a public offering price of $15.00 per share (the "November 2020 Follow-on Offering"). The net proceeds to the Company from the November 2020 Follow-on Offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, were $70,221.

In May 2021, the Company sold an aggregate of 1,829,268 shares of common stock under the 2019 ATM Facility for net proceeds, after deducting commissions and other offering expenses payable by the Company, of $14,550.

There were no public offerings during the years ended December 31, 2023 and 2022.

Common Stock Reserved for Future Issuance

As of December 31, 2023 and 2022, the Company has reserved the following shares of common stock for future issuance:

	December 31,	
	2023	2022
Shares reserved for exercise of outstanding stock options	5,142,272	9,423,271
Shares reserved for vesting of restricted stock units	936,358	940,392
Shares reserved for issuance under the 2018 Stock Option and Incentive Plan	7,978,667	5,005,295
Shares reserved for issuance under the 2018 Employee Stock Purchase Plan	1,771,748	1,467,026
Shares reserved for issuance under the 2019 Inducement Plan	1,407,211	786,656
Shares reserved for issuance under the 2020 Inducement Plan	1,700,000	1,637,000
Total shares of authorized common stock reserved for future issuance	18,936,256	19,259,640

9. Stock-Based Compensation

Amended and Restated 2015 Stock Option and Grant Plan

The Company's Amended and Restated 2015 Stock Option and Grant Plan, (the "2015 Plan") provides for the Company to issue restricted stock awards and restricted stock units, or to grant incentive stock options or non-statutory stock options. Incentive stock options may be granted only to the Company's employees including officers and members of the Board who are also employees. Restricted stock awards and restricted stock units and non-statutory stock options may be granted to employees, members of the Board, outside advisors, and consultants of the Company.

The total number of common shares that may be issued under the 2015 Plan was 2,008,564 shares. Following the IPO, no further grants have been made under 2015 plan.

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Shares that expire, are terminated, surrendered or cancelled under the 2015 Plan without having been fully exercised will be available for future awards under the 2018 Plan (as defined below). In addition, shares of common stock that are tendered to the Company by a participant to exercise an award are added to the number of shares of common stock available for future awards.

The 2015 Plan is administered by the Board. Equity awards granted to employees and members of the Board typically vest over four years.

2018 Stock Option and Incentive Plan

The Company's 2018 Stock Option and Incentive Plan (the "2018 Plan") was adopted by the Board on June 1, 2018 and approved by stockholders on June 7, 2018 and became effective upon the effectiveness of the Company's Registration Statement on Form S-1. The 2018 Plan replaced the 2015 Plan as the Board determined not to make additional awards under the 2015 Plan following the pricing of the Company's IPO. The 2018 Plan allows the Board, compensation committee or other designated committee to make equity-based and cash-based incentive awards to its officers, employees, directors and other key persons (including consultants).

The Company initially reserved 616,300 shares of its common stock for the issuance of awards under the 2018 Plan. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by its Board or compensation committee (the "Plan Evergreen"). This number is subject to adjustment in the event of a stock split, stock dividend or other change in its capitalization.

On April 16, 2020, the Board adopted an amendment to the 2018 Plan (the "Amendment"), to (i) increase the number of shares of common stock currently reserved for issuance under the 2018 Plan by 3,300,000 shares and (ii) automatically terminate the 2018 Plan's annual increase (or "evergreen") provision after January 2022. The Amendment was approved by the Board on June 4, 2020 and the Company's stockholders on June 4, 2020.

The number of shares of common stock available for future grant under the 2018 Plan was 7,978,667 as of December 31, 2023, which does not include the shares added to the 2018 Plan reserve on January 1, 2024 as a result of the Plan Evergreen for the year ended December 31, 2023.

During the years ended December 31, 2023 and 2022, the Company granted options to purchase 123,501 and, 5,369,650 shares, respectively, of common stock to employees, nonemployees and members of the Board.

2018 Employee Stock Purchase Plan

The Company's 2018 Employee Stock Purchase Plan (the "ESPP") was adopted by the Board on June 1, 2018 and approved by stockholders on June 7, 2018 and became effective upon the effectiveness of the Company's Registration Statement on Form S-1. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of 223,200 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and each January 1 thereafter through January 1, 2028, by the least of (i) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31; (ii) 1,115,700 shares or (iii) such number of shares as determined by the ESPP administrator (the "ESPP Evergreen"). With respect to the January 1, 2024 ESPP Evergreen, the Company's Compensation Committee opted to allocate zero additional shares to the ESPP share reserve. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization.

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During the years ended December 31, 2023 and 2022, the Company issued 134,439 and 120,947 shares, respectively of common stock. The total number of shares of common stock available for future grant was 1,771,748 as of December 31, 2023.

2019 Inducement Plan

The Company's 2019 Inducement Plan (the "2019 Plan") was adopted by the Board on December 11, 2019. The purpose of the 2019 Plan is to allow the Company to grant equity awards to new employees as inducements material to such new employee's acceptance of employment with the Company. The Company intends that the shares underlying the 2019 Plan be reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Nasdaq marketplace rules.

The Company initially reserved 1,800,000 shares of its common stock for the issuance of awards under the 2019 Plan.

The number of shares of common stock available for future grant under the 2019 Plan was 1,407,211 as of December 31, 2023.

2020 Inducement Plan

The Company's 2020 Inducement Plan (the "2020 Plan") was adopted by the Board on December 9, 2020. The purpose of the 2020 Plan is to allow the Company to grant equity awards to new employees as inducements material to such new employee's acceptance of employment with the Company. The Company intends that the shares underlying the 2020 Plan be reserved for persons to whom the Company may issue securities without stockholder approval as an inducement pursuant to Rule 5635(c)(4) of the Nasdaq marketplace rules.

The Company initially reserved 1,700,000 shares of its common stock for the issuance of awards under the 2020 Plan.

The number of shares of common stock available for future grant under the 2020 Plan was 1,700,000 as of December 31, 2023.

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and members of the Board were as follows, presented on a weighted-average basis:

	Year Ended December 31,	
	2023	2022
Expected option life (years)	6.00	5.98
Risk-free interest rate	3.82%	2.47%
Expected volatility	83.36%	80.43%
Expected dividend yield	— %	— %

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The following table summarizes the Company's stock option activity for the year ended December 31, 2023:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2022	9,423,271	$ 7.26	8.14	$ 22
Granted	123,501	$ 1.09		
Exercised	(297,604)	$ 0.79		
Cancelled or forfeited	(4,106,896)	$ 7.44		
Outstanding as of December 31, 2023	5,142,272	$ 7.33	6.24	$ 663
Exercisable as of December 31, 2023	3,670,053	$ 8.84	5.44	$ 376

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock.

The aggregate intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $123 and $50, respectively.

The weighted-average grant-date fair value of the Company's stock options granted during the years ended December 31, 2023 and 2022 was $0.79 and $0.99, respectively.

Restricted Common Stock

The Company has granted restricted common stock (or restricted stock awards) with time-based vesting conditions to certain employees of the Company. The purchase price of the restricted stock awards are determined by the Board. Unvested shares of restricted stock awards may not be sold or transferred by the holder. These restrictions lapse according to the time- based vesting conditions of each award. The Company has the option to repurchase the restricted stock awards at the original purchase price if the grantee terminates its working relationship with the Company prior to the vesting date. There were no unvested restricted stock awards as of December 31, 2023.

Restricted Stock Units

Restricted stock units represent an unsecured promise to grant at no cost a set number of shares of common stock upon vesting. With respect to restricted stock units, recipients are not entitled to cash dividends and have no voting rights during the vesting period.

The following table summarizes the Company's restricted stock award and restricted stock unit activity for the year ended December 31, 2023:

	Number of Shares	Weighted-Average Grant Date Fair Value
Issued and unvested as of December 31, 2022	940,392	$ 3.62
Granted	1,548,117	1.65
Vested	(305,502)	4.74
Forfeited, cancelled or expired	(1,246,649)	2.02
Issued and unvested as of December 31, 2023	936,358	$ 2.13

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The total fair value of restricted stock awards and restricted stock units vested during the years ended December 31, 2023 and 2022 was $1,449 and $9, respectively.

Stock-Based Compensation

Stock-based compensation expense was allocated as follows:

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,927	$ 2,785
General and administrative	4,964	8,737
Total stock-based compensation expense	$ 6,891	$ 11,522

As of December 31, 2023, total unrecognized compensation cost related to unvested stock-based awards was $4,221, which is expected to be recognized over a weighted-average period of 1.6 years.

10. 401(k) Savings Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. Eligible employees may make pretax contributions to the 401(k) Plan up to statutory limits. At the election of the Board, the Company may elect to match employee contributions. Currently, the Company makes matching contributions at a rate of 50% of the first 8% of employee contributions. The Company recorded $388 and $599 of expenses related to its 401(k) match for the years ended December 31, 2023 and 2022, respectively.

11. Commitments and Contingencies

Lease Agreements

Refer to Note 6 “*Leases*” for discussion of the commitments associated with the Company’s lease portfolio.

Other Funding Commitments

The Company enters into contracts in the normal course of business with contract research organizations and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts are generally cancellable, with notice, at the Company’s option and do not have significant cancellation penalties.

Guarantees

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, landlords and clinical sites. Under these provisions, the Company generally indemnifies and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company’s activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions is unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal.

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Litigation

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the years ended December 31, 2023 and 2022, and to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Other

The Company is also party to various agreements, principally relating to licensed technology, that require future payments relating to milestones not met as of December 31, 2023 and 2022, or royalties on future sales of specified products. No milestone or royalty payments under these agreements are expected to be payable in the immediate future. See Note 3 *"Licenses Agreements"* for discussion of these arrangements.

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to the agreements, the Company agrees to indemnify, hold harmless, and to reimburse the indemnified party for losses suffered or incurred by the indemnified party, generally the Company's business partners, in connection with any U.S. patent or any copyright or other intellectual property infringement claim by any third-party with respect to the Company's products. The term of these indemnification agreements is generally perpetual any time after execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

12. Income Taxes

For the year ended December 31, 2023, the Company recorded $377 of current income tax expense as a result of the Asset Sale completed on June 9, 2023, and for the year ended December 31, 2022, the Company did not record a current income tax expense or (benefit) due to current and historical losses incurred by the Company. For the years ended December 31, 2023 and 2022 the Company did not record a deferred income tax expense or (benefit) due to current and historical losses incurred by the Company. The Company's operations are predominantly based in the United States and the Company's foreign subsidiaries generated *de minimis* losses for the years ended December 31, 2023 and 2022.

A reconciliation of income tax expense (benefit) computed at the statutory federal income tax rate to the Company's effective tax rate as reflected in the consolidated financial statements is as follows:

	Year Ended December 31,	
	2023	2022
Federal income tax expense at statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	3.7	5.2
Permanent differences	4.4	(1.2)
Foreign rate differential	(0.4)	—
Research and development tax credits	(4.3)	0.8
Change in valuation allowance	(48.2)	(25.8)
Stock based compensation	37.0	—
State rate changes	(8.0)	—
Deferred true ups	(2.2)	—
Provision to return	—	—
Effective income tax rate	3.0%	— %

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Deferred taxes are recognized for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. The significant components of the Company's deferred tax assets and liabilities are comprised of the following:

	December 31,	
	2023	2022
Deferred tax assets:		
U.S., foreign and state net operating loss carryforwards	$ 80,185	$ 91,416
Research and development credits	8,356	8,471
Capitalized start up and organizational costs	21	23
Equity based compensation	313	3,610
Licensing agreements	3,710	3,929
Section 174 R&D capitalization	25,045	16,307
Lease liability	240	227
Accruals and other	906	1,032
Total deferred tax assets	118,776	125,015
Valuation allowance	(118,658)	(124,695)
Net deferred tax assets	$ 118	$ 320
Deferred tax liabilities:		
Property and equipment	$ —	$ (102)
ROU Asset	(118)	(218)
Total deferred tax liabilities	(118)	(320)
Net deferred tax liabilities	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. As of December 31, 2023 and 2022 based on the Company's history of operating losses, the Company has concluded that it is not more likely than not that the benefit of its deferred tax assets will be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2023 and 2022. The valuation allowance decreased by $6,037 during the year ended December 31, 2023, due primarily to net operating income, and increased by $23,802 during the year ended December 31, 2022, due primarily to net operating losses generated.

As of December 31, 2023 and 2022, the Company had U.S. federal net operating loss carryforwards of $298,282 and $340,350, respectively, that may be available to offset future income tax liabilities. All of the U.S. federal tax operating losses can be carried forward indefinitely. As of December 31, 2023 and 2022, the Company also had U.S. state net operating loss carryforwards of $277,626 and $316,668, respectively, which may be available to offset future taxable income. These losses expire at various dates beginning in 2041.

As of December 31, 2023 and 2022, the Company had federal research and development tax credit carryforwards of $6,395 and $6,824, respectively. Included in the $6,395 of federal tax credit carryforwards are $2,162 of orphan drug credits. Through the year ended December 31, 2020 the Company qualifies for, and has elected to, apply part of its federal research credits against its payroll tax liability in accordance with certain provisions of the Internal Revenue Code. The amount applied towards the Company's payroll tax liability is capped at $250 per year. The federal research credits generated in excess of the $250 cap are able to be carried forward for 20 years. As of December 31, 2023 and 2022, the Company had state research and development tax credit carryforwards of approximately $2,482 and $2,084, respectively, available to reduce future tax liabilities

which expire at various dates beginning in 2035. For all years through December 31, 2023, the Company generated research credits but has not conducted a study to document the qualified activities. This study may result in an adjustment to the Company's research and development credit carryforwards.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percentage points, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. The Company performed an analysis to determine if an ownership change and subsequent limitation of its attributes had occurred. Subsequent ownership changes may further affect the limitation in future years. The Company has completed numerous financings since its inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future and may result in a limitation in future years.

The Company files income tax returns in the United States, Australia and Canada, and in several states. The foreign, federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2020 through December 31, 2023. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by foreign tax authorities, the Internal Revenue Service, or state tax authorities to the extent utilized in a future period.

13. Net Income (Loss) per Share

The following table sets forth the computation of the Company's basic and diluted net income (loss) per share for the years ended December 31, 2023 and 2022 (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net income (loss) attributable to common stockholders—basic and diluted	$ 12,157	$ (105,890)
Denominator:		
Weighted-average common shares outstanding—basic	44,327,204	43,738,739
Effect of dilutive securities:		
Options to purchase common shares	119,677	—
Unvested restricted stock units	95,010	—
Employee stock purchase plan	26,027	—
Weighted-average common shares outstanding—diluted	44,567,918	43,738,739
Net income (loss) per share applicable to common stockholders—basic	$ 0.27	$ (2.42)
Net income (loss) per share applicable to common stockholders—diluted	$ 0.27	$ (2.42)

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Diluted earnings per share includes the assumed exercise of dilutive options, the assumed issuance of unvested restricted stock units, and the assumed issuance of shares under the employee stock purchase plan using the treasury stock method unless the effect is anti-dilutive. The treasury stock method assumes that proceeds, including cash received from the exercise of employee stock options and the average unrecognized compensation expense for unvested share-based compensation awards, would be used to purchase the Company's common stock at the average market price during the period.

For the year ended December 31, 2022, for purposes of the diluted net income (loss) per share calculation, stock options, unvested restricted stock units are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net income (loss) per share attributable to common stockholders is the same.

The following potentially dilutive common stock equivalents, presented based on amounts outstanding at each period end, were excluded from the computation of diluted net income (loss) per share attributable to common stockholders for the periods indicated:

	Year Ended December 31,	
	2023	2022
Options to purchase common stock	3,765,482	9,423,271
Restricted stock units	662,103	940,392
Total anti-dilutive shares	4,427,585	10,363,663

14. Related Party Transactions

UHN

In connection with the Company's entry into a license agreement with UHN on January 27, 2016, the Company issued UHN 1,161,665 shares of its common stock. Upon the closing of the IPO in 2018, as UHN's fully-diluted percentage ownership of the Company was reduced within a range of specified percentages, the Company was obligated to pay UHN an amount of $2,000, which was paid in July 2018. For the years ended December 31, 2023 and 2022, the Company recognized $130 and $200, respectively, of research and development expense related to the license agreements with UHN. Refer to Note 3 *"License and Purchase Agreements"* for additional information regarding the UHN license agreements.

Others

For the years ended December 31, 2023 and 2022, the Company recorded expenses of $934 and $3,200, respectively, related to a sublease to rent lab space, provided by an entity affiliated with a member of the board.

15. Restructuring

In July 2023, the Board approved a reduction in the Company's workforce by approximately 50% across different areas and functions in the Company's July 2023 Workforce Reduction. The July 2023 Workforce Reduction was substantially completed by the end of July 2023. The Company informed affected employees in the July 2023 Workforce Reduction on July 12, 2023. Since the date of the July 2023 Workforce Reduction, the Company's remaining employees have primarily focused on activities relating to halting further development of the Company's programs, the pursuit of strategic alternatives, and the provision of services under the previously disclosed Separation Services Agreement between the Company and Novartis in connection with the sale to Novartis of the Company's cystinosis gene therapy program. Under the July 2023 Workforce Reduction, the

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Company recognized total restructuring expenses of $3,015 for the year ended December 31, 2023, recognized as $1,800 and $1,215 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive income (loss). These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. Approximately $479 of these expenses were related to non-cash stock-based compensation expense and there are no remaining accrued payments at December 31, 2023.

The Company's workforce was reduced by 11 employees in the October 2023 Workforce Reduction effective as of October 31, 2023. Under the October 2023 Workforce Reduction, the Company recognized total restructuring expenses of $1,093 for the year ended December 31, 2023 recognized as research and development expense in the consolidated statement of operations and comprehensive income (loss). These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. There are no remaining accrued payments at December 31, 2023.

The Company's workforce was reduced by 8 employees in the December 2023 Workforce Reduction effective as of December 31, 2023. Under the December 2023 Workforce Reduction, the Company recognized total restructuring expenses of $950 for the year ended December 31, 2023 recognized as $866 and $64 of research and development and general and administrative expense, respectively, in the consolidated statement of operations and comprehensive income (loss). The Company estimates an additional $86 of expense related to future one-time employee benefits. These one-time employee termination benefits are related to affected employees, who were offered separation benefits, including severance payments. As of December 31, 2023, the Company had $521 in accrued payments. The Company expects that payments of these costs will substantially be made through the end of the first quarter of 2024.

	Employee Severance and Other Benefits
Restructuring expenses	$ 5,058
Cash payments	(4,058)
Non-cash expenses	(479)
Liability included in accrued expenses and other current liabilities at December 31, 2023	$ 521

16. Subsequent Events

On January 30, 2024, following a comprehensive review of strategic alternatives, the Company entered into the Merger Agreement with Tectonic pursuant to which a wholly-owned subsidiary of the Company will merge with and into Tectonic, with Tectonic surviving as a wholly-owned subsidiary of the Company. The Merger was unanimously approved by the Company's Board, and the Company's Board resolved to recommend approval of the Merger Agreement to the Company's stockholders.

The closing of the Merger is subject to approval by the Company's and Tectonic's stockholders as well as other customary closing conditions, including the effectiveness of a registration statement on Form S-4 filed with the SEC in connection with the transaction and Nasdaq's approval of the listing of the shares of the Company's common stock to be issued in connection with the Merger. If the Company is unable to satisfy certain closing conditions or if other mutual closing conditions are not satisfied, Tectonic will not be obligated to complete the Merger. The Merger Agreement contains certain termination rights of each of the Company and Tectonic. Under certain circumstances detailed in the Merger Agreement, the Company could be required to pay Tectonic a termination fee of approximately $2,713 or Tectonic could be required to pay the Company a termination fee of approximately $4,900. In addition, in certain circumstances upon the termination of the Merger Agreement, the Company could be required to pay the costs and expenses of Tectonic in an amount not to exceed $650. If the Merger is completed, the business of Tectonic will continue as the business of the combined company.

TECTONIC THERAPEUTIC, INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 18,748	$ 28,769
Prepaid expenses and other current assets	1,810	2,115
Total current assets	20,558	30,884
Property, equipment and improvements, net	2,864	3,122
Finance right-of-use assets, net	1,323	1,437
Operating right-of-use assets	2,375	2,669
Deferred offering costs	3,444	669
Restricted cash	587	587
Other assets	4	31
Total assets	$ 31,155	$ 39,399
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 2,563	$ 409
Accrued expenses and other current liabilities	11,048	8,141
SAFE liabilities	32,590	30,515
Operating lease liability - current portion	1,388	1,348
Finance lease liability - current portion	475	475
Total current liabilities	48,064	40,888
Operating lease liability - net of current portion	1,280	1,644
Finance lease liability - net of current portion	758	876
Total liabilities	50,102	43,408
Commitments and contingencies (Note 6)		
Convertible preferred stock (Series A-1, A-2, A-3 and A-4), $0.0001 par value; 6,825,483 shares authorized as of March 31, 2024 and December 31, 2023; 6,825,483 shares issued and outstanding as of March 31, 2024 and December 31, 2023; aggregate liquidation preference of $87,459 as of March 31, 2024 and December 31, 2023	80,627	80,627
Stockholders' Deficit		
Common stock, $0.0001 par value; 11,947,558 shares authorized as of March 31, 2024 and December 31, 2023; 2,637,120 and 2,634,246 shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Additional paid-in capital	6,304	5,979
Accumulated other comprehensive loss	(53)	(11)
Accumulated deficit	(105,825)	(90,604)
Total stockholders' deficit	(99,574)	(84,636)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 31,155	$ 39,399

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

TECTONIC THERAPEUTIC, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 10,818	$ 12,985
General and administrative	2,150	1,546
Total operating expenses	12,968	14,531
Loss from operations	(12,968)	(14,531)
Other income (expense), net:		
Change in fair value of SAFE liabilities	(2,075)	—
Interest income	256	128
Interest expense	(31)	(42)
Other expense	(403)	—
Total other (expense) income, net	(2,253)	86
Net loss	(15,221)	(14,445)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.83)	$ (6.50)
Weighted-average common shares outstanding, basic and diluted	2,608,740	2,222,800
Other comprehensive loss:		
Foreign currency translation adjustment	(50)	—
Comprehensive loss	$ (15,271)	$ (14,445)

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

TECTONIC THERAPEUTIC, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
Balances as of December 31, 2023	6,825,483	$ 80,627	2,634,246	$ —	$ 5,979	$ (11)	$ (90,604)	$ (84,636)
Exercise of stock options	—	—	2,874	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	321	—	—	321
Foreign currency translation adjustment	—	—	—	—	—	(42)	—	(42)
Net loss	—	—	—	—	—	—	(15,221)	(15,221)
Balances as of March 31, 2024	6,825,483	$ 80,627	2,637,120	$ —	$ 6,304	$ (53)	$ (105,825)	$ (99,574)

	Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
Balances as of December 31, 2022	6,825,483	$ 80,627	2,525,771	$ —	$ 2,127	$ —	$ (47,781)	$ (45,654)
Exercise of stock options	—	—	1,285	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	275	—	—	275
Net loss	—	—	—	—	—	—	(14,445)	(14,445)
Balances as of March 31, 2023	6,825,483	$ 80,627	2,527,056	$ —	$ 2,403	$ —	$ (62,226)	$ (59,823)

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

TECTONIC THERAPEUTIC, INC.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$(15,221)	$(14,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	377	364
Stock-based compensation expense	321	275
Non-cash lease expense	294	274
Change in fair value of SAFE liabilities	2,075	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	289	(335)
Other non-current assets	24	(20)
Accounts payable	1,510	1,039
Accrued expenses and other current liabilities	1,382	2,326
Operating lease liabilities	(324)	(293)
Net cash used in operating activities	(9,273)	(10,815)
Cash flows from investing activities:		
Purchase of property, equipment and improvements	(4)	(136)
Net cash used in investing activities	(4)	(136)
Cash flows from financing activities:		
Payment for deferred offering costs	(554)	—
Proceeds from exercise of common stock options	4	1
Repayment of finance lease obligations	(118)	(144)
Net cash used in financing activities	(668)	(143)
Effect of exchange rate changes on cash and cash equivalents	(76)	—
Net decrease in cash and cash equivalents and restricted cash	(10,021)	(11,094)
Cash and cash equivalents and restricted cash as of beginning of period	29,356	36,553
Cash and cash equivalents and restricted cash as of end of period	$ 19,335	$ 25,459
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 18,748	$ 24,872
Restricted cash	587	587
Total cash, cash equivalents and restricted cash	$ 19,335	$ 25,459
Supplemental disclosure of non-cash financing activities:		
Deferred offering costs included in accrued expenses and other current liabilities	$ 1,576	$ —
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 31	$ 42

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

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Business

Tectonic Therapeutic, Inc. ("Company") is a biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of G-protein coupled receptors ("GPCRs"). Leveraging its proprietary technology platform called GEODe™ ("GPCRs Engineered for Optimal Discovery"), the Company is focused on developing biologic medicines that overcome the existing challenges of GPCR-targeted drug discovery and harness the human body to modify the course of disease. The Company focuses on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality of life. The Company was incorporated on June 5, 2019 under the laws of the State of Delaware and has its principal headquarters in Watertown, Massachusetts.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities.

The Company's proprietary GEODe™ platform is currently in development. There can be no assurance that current and future research and development activities will be successfully completed, that adequate protection for owned intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

Liquidity and Going Concern

As of March 31, 2024, the Company had an accumulated deficit of $ 105.8 million and has incurred losses and negative cash flows from operations since inception, including a net loss of $15.2 million for the three months ended March 31, 2024. To date, the Company has financed its operations primarily through the issuance of common stock, convertible preferred stock, convertible promissory notes and Simple Agreements for Future Equity ("SAFEs"). The Company has devoted substantially all of its financial resources and efforts to business planning, conducting research and development, recruiting management and technical staff, and raising capital. Management expects that the Company's operating losses and negative cash flows will continue for the foreseeable future as it continues to develop its product candidates.

As the Company continues to develop its proprietary platform and potential product candidates, it will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. It may never achieve profitability, and unless and until it does, it will continue to need to raise additional capital to fund its operations. On June 20, 2024, the Company completed a merger with AVROBIO, Inc. ("AVROBIO") pursuant to which the Company received $77.3 million of cash from AVROBIO and completed the sale of $ 96.6 million of common stock (see Note 14). Management believes that its current cash on hand along with the cash received from the

closing of the merger agreement are sufficient to fund the Company's planned operations for at least one year from the date of issuance of these unaudited condensed consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to GAAP, as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of its financial position and its results of operations, changes in convertible preferred stock and stockholders' deficit and cash flows. The information as of December 31, 2023 included in the unaudited interim condensed consolidated balance sheets was derived from audited annual consolidated financial statements but does not contain all of the footnote disclosures from the audited annual consolidated financial statements.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited annual consolidated financial statements as of and for the years ended December 31, 2023 and 2022.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include the contract research accruals, stock-based compensation expense, the fair value of the Company's common stock, the income tax valuation allowance, and the fair value determination of the SAFEs. Management's estimates are based on historical experience and various other assumptions that it believes are reasonable under the circumstances. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Recent 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 dates. Unless otherwise discussed, the impact of recently issued standards that are not yet effective are not anticipated to have a material impact on the Company's condensed consolidated financial statements upon adoption.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in an Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (i) those not carried at fair value with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for the Company beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company adopted this guidance on January 1, 2024 with no material impact on the condensed consolidated financial statements and disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting* (Topic 280) ("ASU 2023-07"), which enhances the segment disclosure requirements for public entities on an annual and interim basis. Under ASU 2023-07, public entities will be required to disclose significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss. Additionally, current annual disclosures about a reportable segment's profit or loss and assets will be required on an interim basis. Entities will also be required to disclose information about the CODM's title and position at the Company along with an explanation of how the CODM uses the reported measures of segment profit or loss in their assessment of segment performance and deciding whether how to allocate resources. Finally, ASU 2023-07 requires all segment disclosures for public entities that have only a single reportable segment. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-07 on its condensed consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes* (Topic 740) ("ASU 2023-09"), which enhances the income tax disclosure requirements for public entities on an annual basis. Under ASU 2023-09, public entities will be required to disclose in their rate reconciliation, on an annual basis, both percentages and amounts in their reporting currency for certain categories in a tabular format, with accompanying qualitative disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-09 on its condensed consolidated financial statements.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

3. FAIR VALUE MEASUREMENTS

The following tables present information about financial assets and liabilities 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):

	March 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$17,213	$ —	$ —	$17,213
	$17,213	$ —	$ —	$17,213
Liabilities:				
SAFE liabilities	$ —	$ —	$32,590	$32,590
	$ —	$ —	$32,590	$32,590

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$27,278	$ —	$ —	$27,278
	$27,278	$ —	$ —	$27,278
Liabilities:				
SAFE liabilities	$ —	$ —	$30,515	$30,515
	$ —	$ —	$30,515	$30,515

As of March 31, 2024 and December 31, 2023, the Company's cash equivalents, which were invested in money market funds, were valued based on Level 1 inputs.

SAFE Liabilities

From October through December 2023, the Company entered into multiple SAFE agreements with certain existing investors and received $34.1 million (see Note 13). The SAFE liabilities are included within the Level 3 fair value hierarchy. The SAFE liabilities were valued using a probability weighted scenario analysis and discount rates derived by application of the build-up method to reflect the cost of equity. The valuation model requires a variety of inputs, including the probability of occurrence of events that would trigger conversion or redemption of the SAFEs, the expected timing of such events, and a discount rate.

The valuations of the SAFE liabilities as of March 31, 2024 and December 31, 2023, were determined based on a probability-weighted scenario analysis that assumed the probabilities of the occurrence of an equity financing, public listing transaction and dissolution to be 10.0%, 87.5% and 2.5% respectively. The estimated time to redemption used in the March 31, 2024 valuation was two months for an equity financing and dissolution and one month for a public listing transaction. The estimated time to redemption used in the December 31, 2023 valuation was five months for an equity financing and dissolution and four months for a public listing transaction. The valuations used a discount rate of 30.2% to approximate the cost of equity, which was derived from application of a build-up method that incorporated the risk-free rate at the valuation

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

date, and adjustments to reflect market risk, a small stock premium, and a selected company-specific risk premium. The valuation of the SAFE liabilities at the October issuance date was determined using the same methodology; however, the discount rate was 30.9% due to the higher risk-free rate at the valuation date. In October 2023, the probabilities of the occurrence of an equity financing, public listing transaction and dissolution used were 87.5%, 10.0%, and 2.5%, respectively. The estimated time to redemption used was 1.5 months for an equity financing and 5.5 months for a public listing transaction and dissolution.

The following table presents activity for the SAFE liabilities that were measured at fair value using significant unobservable Level 3 inputs during the three months ended March 31, 2024 and the year ended December 31, 2023 (in thousands):

	SAFE Liabilities
Balance as of January 1, 2023	$ —
Initial fair value recognition	31,515
Loss on issuance	255
Fair value adjustments	(1,255)
Balance as of December 31, 2023	30,515
Fair value adjustments	2,075
Balance as of March 31, 2024	$ 32,590

4. PROPERTY, EQUIPMENT AND IMPROVEMENTS, NET

Property, equipment and improvements, net is comprised of the following (in thousands):

	March 31, 2024	December 31, 2023
Laboratory equipment	$ 4,548	$ 4,510
Furniture and office equipment	244	244
Computer equipment	165	161
Construction in progress	—	38
Leasehold improvements	25	25
	4,982	4,978
Less: accumulated depreciation	(2,118)	(1,856)
Property and equipment, net	$ 2,864	$ 3,122

Depreciation expense was $0.3 million and $0.2 million during the three months ended March 31, 2024 and 2023 and was recorded as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
General and administrative	$ 4	$ 4
Research and development	258	226
	$ 262	$ 230

These amounts are exclusive of amortization related to finance lease assets of $ 0.1 million during the three months ended March 31, 2024 and 2023.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	March 31, 2024	December 31, 2023
Employee compensation related costs	$ 3,769	$ 2,840
Accrued office and laboratory costs	141	211
Accrued contract research organization fees	3,207	2,298
Accrued contract development and manufacturing organization fees	604	660
Accrued professional fees	2,935	1,798
Other current liabilities	392	334
	$ 11,048	$ 8,141

6. COMMITMENTS AND CONTINGENCIES

Leases

The Company's commitments under its operating and finance leases are described in Note 7.

Harvard Agreement

In July 2020, the Company entered into an agreement with the President and Fellows of Harvard College ("Harvard"), for an option fee in the low five digits, whereby Harvard granted the Company an exclusive option to negotiate a worldwide, exclusive, royalty-bearing license under Harvard's interest in the patent rights covering certain technology that was developed by Harvard. In October 2021, the Company exercised the option and on February 10, 2022, entered into a license agreement ("License Agreement") with Harvard to conduct research and development activities using certain materials, technology and patent rights owned by Harvard, with the intent to develop, obtain regulatory approval for, and commercialize products. The License Agreement will remain in effect until the expiration of the last valid claim within the patent rights covering a product developed under the License Agreement or the termination of the License Agreement. Management concluded that the acquisition of patents and materials received under the License Agreement represents an asset acquisition of an in-progress research and development asset without future alternative use; therefore, any consideration paid was expensed.

As consideration for the License Agreement, the Company agreed to pay Harvard a non-refundable license fee, consisting of a cash payment due in three equal annual installments, in total amounting to $170,000 and 227,486 shares of common stock. The installments became due on July 2, 2022 ("First Payment Due Date") and the first and second anniversaries of the First Payment Due Date. The first payment of $56,666 was paid in July 2022. The common stock issued to Harvard had a fair value of $ 0.4 million. Both the cash payment and the issuance of shares were expensed to research and development during the year ended December 31, 2022. The second payment of $56,666 was made in July 2023. The remaining installment amount of $ 56,668 is due in July 2024.

The Company also will be responsible for payment of (1) annual maintenance fees ranging from the low five digits to the low six digits during the term of the License Agreement (through the first commercial sale of a royalty-bearing product); (2) royalty payments as a percentage in the low single digits of the annual net sales that the Company generates from products that utilize the license technology ("Licensed Products") and royalty payments as a percentage in the low single digits of the annual net sales that the

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Company generates from know-how enabled product licenses ("Know-How Enabled Products") and (3) a percentage between 10-20% of all non-royalty income received by the Company under sublicenses, strategic partnerships and know-how enabled product licenses that utilize the license technology. Subsequent to the first commercial sale of a royalty-bearing product, annual maintenance fees will increase to a low six digits for the remainder of the term of the License Agreement. The royalty term from sales of Licensed Products will terminate on a country-by-country and product-by-product basis on the earlier of (i) the expiration of the patent rights covering the product, expected to be no earlier than May 2041, and (ii) the termination of the License Agreement. The royalty term from sales of Know-How Enabled Products will terminate on the earlier of (i) ten years after the first commercial sale of the first Know-How Enabled Product and (ii) twelve years after the first commercial sale of the first Licensed Product. There was less than $0.1 million due to Harvard as of March 31, 2024. During the three months ended March 31, 2024 and 2023, the Company paid $0.1 million to Harvard.

Alloy Therapeutics License Agreement

On November 29, 2021, the Company executed a license agreement with Alloy Therapeutics, LLC ("ATX"), whereby the Company will use ATX technology for the purpose of preclinical development, clinical development and commercialization of potential product candidates, for an initial period of three years, with an option to extend the term for an additional two years. The Company will pay ATX a non-refundable and non-creditable annual fee of $0.1 million on each anniversary of the agreement. On November 7, 2022, the Company and ATX amended the agreement and extended the period of payment for the first fee due in May 2023. Additionally, the Company will be responsible for annual partnering fees if the Company decides to pursue clinical development of a product candidate using the ATX technology. The partnering fees may be creditable against future milestone development fees paid by the Company. The Company will also be responsible to pay ATX development milestone payments for the movement of certain product candidates through clinical trials, which range from the low six digits to the low seven digits upon completion of each milestone and amount to $4.8 million in total milestone payments under the license agreement. Provided the Company is able to commercialize a product using ATX technology, the Company will be responsible to pay ATX commercial payments in the low seven digits per year during the first six years of commercial sales, amounting to an amount in the high eight digits in total commercial payments under the license agreement.

During the three months ended March 31, 2024 and 2023, the Company paid $ 0.1 million and $0 to ATX, respectively.

Adimab Agreement

On May 1, 2023, the Company entered into a discovery agreement with Adimab, LLC ("Adimab"), an antibody discovery company, whereby the Company and Adimab are collaborating on human antibody discovery in accordance with an agreed upon research program. The Company paid an upfront technology access fee totaling $20,000 upon execution of the agreement.

The Company also will be responsible for payment of (1) quarterly funding equal to 100% of the actual full-time employee ("FTE") expended by Adimab in the performance of its obligations in accordance with the agreed upon research program at an annual rate of $0.4 million per FTE (subject to annual consumer price index increases) per the agreement, (2) delivery fees equal to $ 0.1 million upon both Adimab's initial delivery of sequences or physical materials and completion pursuant to the research program (initial and completion fees payable once per target for a total of up to $0.4 million), (3) a non-creditable, non-refundable fee of $0.5 million upon the exercise of an option to obtain the licenses and assignments for

information discovered during the research program, (4) development milestone payments for the movement of certain product candidates thought clinical trials, which range in the low seven digits, and (5) royalty payments based on the annual net sales that the Company generates from products that utilize Adimab technology. The Company has the right to terminate the agreement if certain criteria are met. As of March 31, 2024, the Company recorded $0.1 million of costs associated with the FTEs in accrued expenses and other current liabilities and $0.1 million of discovery delivery fees in accounts payable.

Indemnification Agreements

In accordance with the Company's amended and restated certificate of incorporation ("ARCOI") and certain indemnification agreements, the Company indemnifies certain officers and directors for specified events or occurrences, subject to certain limits, in which the officer or director is or was serving at the Company's request in such capacity.

The Company enters into certain types of contracts that contingently requires it to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which it must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship with the Company, (ii) contracts under which it must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the its products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on future business, operating results or financial condition. It is not possible to estimate the maximum amount potentially payable under these contracts since there is no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

As of March 31, 2024 and December 31, 2023, the Company did not have any liabilities or other commitments related to indemnification claims.

7. LEASES

The Company has entered into operating leases for office and laboratory facilities and financing leases for laboratory equipment used in research and development activities. The remaining lease terms for its leases range from two years to four years. These leases often include options to extend the term of the lease. When it is reasonably certain that the option will be exercised, the impact of the renewal term is included in the lease term for purposes of determining total future lease payments and measuring the ROU asset and lease liability. The Company is not reasonably certain to exercise any available renewal options, which are therefore excluded from the measurement of leases. The Company applies the short-term lease policy election for its real estate and equipment leases, which allows it to exclude from recognition leases with an original term of twelve months or less.

In November 2020, the Company executed a facilities lease agreement to occupy 18,768 square feet of office and laboratory space, that was subsequently amended on April 21, 2022. The lease requires the Company to pay fixed base rent, which is included in the measurement of the lease, as well as its proportionate share of the facilities operating expenses which are treated as variable lease costs based on the Company's election to combine lease and associated non-lease components and are excluded from the

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

measurement of the lease. The lease expires on January 31, 2026, and contains a five-year renewal option exercisable by the Company which is not included in the measurement of the lease.

In April 2021, the Company entered into an agreement to sublease a portion of its facility lease to a related party (see Note 13) in exchange for $28,333 per month. The sublease agreement was an operating lease with a term of 18 months and was set to expire on September 30, 2022. In July 2022, the Company granted the sublessee permission to terminate the agreement on July 31, 2022. An immaterial adjustment to straight-line rental income and accrued rent receivable was recorded as part of the early termination. The proceeds from the sublease agreement are recorded as an offset to facilities costs in the periods in which they are earned.

The following table sets forth information about lease costs for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
Finance lease cost	2024	2023
Amortization of ROU assets	$ 114	$ 134
Interest on lease liabilities	31	42
Operating lease cost	351	351
Short-term lease cost	176	150
Variable lease cost	249	206
Total lease costs	$ 921	$ 883

The following table sets forth information about the Company's leases for the three months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
Cash paid for amounts included in the measurement of lease liabilities	2024	2023
Finance leases - financing cash flows	$ 118	$ 144
Finance leases - operating cash flows	31	42
Operating leases - operating cash flows	381	370
Weighted-average remaining lease terms (in years)		
Finance leases	2.99	3.97
Operating leases	1.84	2.84
Weighted-average discount rate		
Finance leases	9.65%	9.54%
Operating leases	8.25%	8.25%

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table presents the maturity of the Company's finance and operating lease liabilities for the three months ended March 31, 2024 (in thousands):

Year ended December 31,	Finance Leases	Operating Leases
2024 (remaining)	$ 434	$ 1,154
2025	552	1,580
2026	363	132
2027	44	—
2028	—	—
Thereafter	—	—
Total lease payments	1,393	2,866
Less: interest	(160)	(198)
Total lease liabilities	$ 1,233	$ 2,668

8. CONVERTIBLE PREFERRED STOCK

The Company issued Series A-1 convertible preferred stock (the "Series A-1 Preferred Stock"), Series A-2 convertible preferred stock (the "Series A-2 Preferred Stock"), Series A-3 convertible preferred stock (the "Series A-3 Preferred Stock"), and Series A-4 convertible preferred stock (the "Series A-4 Preferred Stock" and collectively with the Series A-1 Preferred Stock, the Series A-2 Preferred Stock, and the Series A-3 Preferred Stock, the "Preferred Stock").

The Preferred Stock as of March 31, 2024 and December 31, 2023 consisted of the following (in thousands, expect share and per share amounts):

		March 31, 2024 and December 31, 2023				
	Par Value	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	$ 0.0001	4,118,120	4,118,120	$45,016	$ 54,308	4,118,120
Series A-2 Preferred Stock	$ 0.0001	1,649,188	1,649,188	21,654	21,749	1,649,188
Series A-3 Preferred Stock	$ 0.0001	696,516	696,516	9,187	7,348	696,516
Series A-4 Preferred Stock	$ 0.0001	361,659	361,659	4,770	4,054	361,659
		6,825,483	6,825,483	$80,627	$ 87,459	6,825,483

Upon the issuance of each series of the Preferred Stock, the Company assessed the embedded conversion and liquidation features of the issued Preferred Stock and determined that such features did not require the Company to separately account for these features.

The Preferred Stock have the following rights and privileges:

Dividends

The holders of the Preferred Stock are entitled to receive noncumulative dividends if and when declared by the Board at a rate of 8% per annum. The Company may not declare, pay or set aside any dividends on shares of any other series of capital stock of the Company, other than dividends on common stock payable in common stock, unless the holders of the Preferred Stock first receive, or simultaneously receive, a dividend on each outstanding share of the Preferred Stock. No dividends were declared or paid during through the period ended March 31, 2024.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Liquidation

In the event of any involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event, holders of the Preferred Stock shall be paid out of the assets of the Company available for distribution an amount per share equal to the greater of (i) the applicable original issue price, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all shares of the Preferred Stock been converted into shares of common stock.

If the assets available for distribution to its stockholders are insufficient to pay the holders of shares of the Preferred Stock the full amount which they shall be entitled, the holders of shares of Preferred Stock shall share ratably in any distribution in proportion to the respective amounts which would otherwise be payable if all amounts payable were paid in full.

Voting

On any matter presented to the stockholders of the Company for their actions or consideration at any meeting of the Company, each holder of outstanding shares of Series A-1, Series A-3 and Series A-4 (the "Voting Preferred Stock") shall be entitled to the number of votes equal to the number of whole shares of common stock into which the shares of the Voting Preferred Stock are convertible. Holders of outstanding shares of Series A-2 Preferred Stock are not entitled to voting rights.

Redemption

The Preferred Stock is conditionally redeemable upon the occurrence of a Deemed Liquidation Event. A Deemed Liquidation Event is defined as (a) a merger or consolidation (an "event") in which the Company is a constituent party (or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to the event), except those in which the shares Company's stock outstanding immediately before the event continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following the event, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such event, the parent corporation of the surviving or resulting corporation and (b) the sale or disposition of the Company or one or more subsidiaries of the Company.

Mandatory Conversion

All outstanding shares of the Preferred Stock shall automatically convert into shares of common stock, at the conversion price upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $39.56280 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten initial public offering, resulting in at least $75.0 million of gross proceeds and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved by the Board of Directors, including the approval of a majority of the preferred directors or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the voting preferred stock (the "Requisite Holders").

As discussed in Note 14, all of the Company's outstanding preferred stock converted into common stock immediately prior to the closing of the Merger.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Optional Conversion

Each share of the Preferred Stock shall be convertible at any time and from time to time and without the payment of additional consideration by the holder into such number of fully paid and non-assessable shares of common stock as determined by dividing the original issue price by the conversion price. Each share of Series A-2 Preferred Stock shall be convertible into one share of Series A-1 Preferred Stock.

The conversion price for the Series A-1 Preferred Stock and the Series A-2 Preferred Stock initially is equal to $13.18760, and the initial conversion price for the Series A-3 Preferred Stock and the Series A-4 Preferred Stock is $10.55008 and $11.20946, respectively. The conversion price is subject to adjustment for any stock-splits, stock dividends, combinations or other similar recapitalizations and other adjustments as set forth in the Company's ARCOI.

9. COMMON STOCK

As of March 31, 2024, the Company's ARCOI authorized the Company to issue up to 11,947,558 shares of $0.0001 par value common stock, of which, 2,637,120 shares were issued and outstanding.

Voting, dividend and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock. Holders of common stock are entitled to one vote for each share of common stock; however, the holders of the common stock shall not be entitled to vote on any amendment to the ARCOI that relates solely to the terms of one or more outstanding series of preferred stock.

The Company has included in issued and outstanding common stock shares of restricted common stock granted by the Company. As of March 31, 2024, there were 2,637,120 common shares issued and outstanding, of which 2,615,555 relate to shares of unrestricted common stock.

10. STOCK-BASED COMPENSATION

In June 2019, the Company adopted the 2019 Equity Incentive Plan (the "2019 Plan"), which provides employees, consultants and advisors and non-employee members of the Board of Directors and its affiliates with the opportunity to receive grants of stock options, stock awards and equity awards. Since inception, the Company has only issued stock options. Under the 2019 Plan, the Company may grant equity awards that could require the issuance of up to 1,991,264 shares of the Company's common stock.

For incentive stock options and non-statutory stock options, the option exercise price may not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. The options expire ten years from the grant date.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

A summary of the activity in the 2019 Plan for the three months ended March 31, 2024 is as follows (in thousands except share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance as of January 1, 2024	1,875,932	$ 1.66	8.2	$ 2,276
Granted	—	—		
Exercised	(2,874)	1.54		$ 4
Forfeited and expired	(19,558)	1.36		
Balance as of March 31, 2024	1,853,500	$ 1.66	7.9	$ 2,242
Options vested and exercisable as of March 31, 2024	1,068,487	$ 1.34	7.3	$ 1,634
Options vested and expected to vest as of March 31, 2024	1,853,500	$ 1.66	7.9	$ 2,242

There were no options granted during the three months ended March 31, 2024. The weighted-average grant-date fair value of options granted during the three months ended March 31, 2023 was $1.34 per share. The total intrinsic value of options exercised during the three months ended March 31, 2024 and 2023 was $3,828 and $411, respectively. Forfeitures of options are recorded as incurred.

Cash received from option exercises for the three months ended March 31, 2024 and 2023 was $ 4,420 and $0, respectively.

The fair values of the options granted in the three months ended March 31, 2023 were estimated based on the BSM option pricing model, using the following assumptions:

	Three Months Ended March 31, 2023
Fair value per share of underlying common stock	$1.34
Expected term (in years)	5.93
Expected volatility	111.05% -111.21%
Risk-free interest rate	3.65%
Expected dividend yield	0%

Restricted Common Stock

Since 2019, the Company has granted restricted common stock to founders, employees and consultants. The purchase price of the restricted common stock is the estimated fair value on the grant date and the restricted stock is subject to various vesting schedules. Unvested restricted common stock are subject to repurchase rights held by the Company at the original issuance price in the event the restricted common stockholders' service to the Company is terminated either voluntarily or involuntarily. As of March 31, 2024, there were 21,565 shares of unvested restricted common stock, with a repurchase liability of less than $ 0.1 million, that is classified in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The following table summarizes restricted stock activity:

	Number of Shares
Unvested restricted common stock as of January 1, 2024	35,494
Granted	—
Vested	(13,929)
Forfeited	—
Unvested restricted common stock as of March 31, 2024	21,565

The weighted-average grant date fair value of unvested restricted common stock and restricted common stock vested and forfeited for the three months ended March 31, 2024 and 2023 was immaterial.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense regarding its employees and nonemployees as follows (in thousands):

	Three Months Ended March 31,	
	2024	2023
General and administrative	$ 193	$ 174
Research and development	128	101
	$ 321	$ 275

The Company records compensation expense on a straight-line basis over the vesting period. As of March 31, 2024, total compensation cost not yet recognized related to unvested stock options was $2.0 million, which is expected to be recognized over a weighted-average period of 2.4 years.

11. INCOME TAXES

During the three months ended March 31, 2024 and 2023, the Company recorded no income tax provision or benefit.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of March 31, 2024, the Company has maintained a full valuation allowance against its net deferred tax assets.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

12. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (15,221)	$ (14,445)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	2,608,740	2,222,800
Net loss per share attributable to common stockholders, basic and diluted	$ (5.83)	$ (6.50)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. For the three months ended March 31, 2024 and 2023, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders for the period because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2024	2023
Convertible preferred stock (as converted to common stock)	6,825,483	6,825,483
Stock options to purchase common stock	1,853,500	1,597,259
Unvested restricted common stock	21,565	294,733
SAFEs (as converted to common stock)	2,752,216	—
	11,452,764	8,717,475

13. RELATED PARTY TRANSACTIONS

Scientific Advisory Board Member

One of the Company's co-founders is a member of the Company's Scientific Advisory Board ("SAB") and meets the criteria of a related party. For each of the three months ended March 31, 2024 and 2023, the Company paid the SAB member fees in the amount of less than $0.1 million for advisory services provided. There were no amounts due to or from this related party as of March 31, 2024 and December 31, 2023.

License Agreement

Harvard College ("Harvard") meets the criteria of a related party resulting from the Company's co-founders' employment as professors in the Harvard Department of Molecular Pharmacology. Additionally, both co-founders were members of the Board during the three months ended March 31, 2024 and one co-founder is a major shareholder in the Company. Core intellectual property utilized by the Company is licensed from Harvard in exchange for license fees, future milestones and royalties, and equity in the Company in the form of common stock.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

For the three months ended March 31, 2024 and 2023, the Company paid Harvard $ 0.1 and $0.1 million in cash considerations, respectively (see Note 6). Accounts payable to Harvard amounted to less than $0.1 million and $0.1 million as of March 31, 2024 and December 31, 2023, respectively.

SAFE Agreements

From October through December 2023, the Company entered into multiple SAFE agreements with certain existing investors and received $34.1 million representing the purchase amount. All investors are considered related parties of the Company.

The SAFE agreements have no maturity date, bear no interest, and will be redeemed by the Company upon the occurrence of a triggering event, including an equity financing, public listing transaction, change of control or dissolution. Equity financing is defined as a sale of the Company's preferred stock at a fixed valuation. In the event of an equity financing, the SAFEs will automatically be redeemed through delivery of a variable number of shares of Company preferred stock equal to the SAFE purchase amount divided by the preferred stock per share issuance price in the equity financing. In the case of the SAFE agreements issued in October 2023, a 10% discount will be applied to the per share issuance price in the equity financing in determining the number of shares of Company preferred stock issued to the investors upon redemption.

Public listing transaction is defined as a direct listing, initial public offering ("IPO") of the Company's common stock, a reverse merger or a SPAC transaction. In any of these instances, the SAFEs will automatically be redeemed through delivery of a variable number of shares of the Company's common stock determined by dividing the SAFE purchase amount by the offering or conversion price in the respective transaction. In the event of a change in control transaction, the SAFE investors will be entitled to receive a portion of the transaction proceeds equal to the greater of the SAFE purchase amount, payable in cash or other consideration, or the amount payable on the number of shares of the Company's common stock equal to the SAFE purchase amount divided by the change in control conversion price, as defined in the agreement. In a dissolution event, the investor will automatically be entitled to receive a portion of the dissolution purchase amount equal to the SAFE proceeds.

The SAFEs are not in the legal form of an outstanding share or debt and therefore were evaluated under ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). Because the SAFEs allow for redemption based upon certain triggering events that are outside the Company's control, the SAFEs were classified as liabilities pursuant to ASC 480 and initially measured at their fair value upon issuance. In addition, until redemption, the SAFEs are measured at fair value on a recurring basis with subsequent changes in fair value recoded in the Company's statement of operations and comprehensive loss.

The SAFEs issued in October 2023 were recognized at their fair value of $ 10.4 million on the issuance date. The issuance date fair value exceeded the proceeds received by approximately $0.3 million and this difference was recognized as loss at issuance in the consolidated statement of operations and comprehensive loss. The SAFEs issued in December 2023 were recognized at their fair value of approximately $21.4 million on the issuance date. The proceeds received exceeded the issuance date fair value by approximately $2.6 million and this difference was recognized as a capital contribution from the related party investors in additional paid-in capital in the consolidated statement of stockholders' deficit. The subsequent measurement to the total SAFE liabilities fair value of $32.6 million is recorded in the condensed consolidated statement of operations and comprehensive loss.

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

14. SUBSEQUENT EVENTS

Management has evaluated subsequent events through June 20, 2024, which is the date the unaudited condensed consolidated financial statements were available to be issued, to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements and events which occurred but were not recognized in the consolidated financial statements.

Merger with AVROBIO

As discussed in Note 1, on January 30, 2024, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with AVROBIO, pursuant to which the subsidiaries of AVROBIO merged with and into the Company on June 20, 2024, with the Company continuing as a wholly owned subsidiary of the surviving corporation of the merger (the "Merger"). The Merger is being accounted for as a reverse recapitalization in accordance with GAAP, with AVROBIO treated as the acquired company for financial reporting purposes, and the Company treated as the accounting acquirer.

Upon the closing of the Merger, each outstanding share of the Company's common stock, including outstanding and unvested restricted stock, was converted into the right to receive a number of shares of AVROBIO's common stock based on the Exchange Ratio, as defined in the Merger Agreement. Each outstanding and unexercised option to purchase shares of the Company's common stock immediately prior to closing was assumed by AVROBIO and was converted into an option to purchase shares of AVROBIO common stock, with necessary adjustments to the number of shares and exercise price to reflect the Exchange Ratio. All of the Company's restricted common stock outstanding and unvested immediately prior to the closing that was assumed by AVROBIO in the Merger remains unvested to the same extent and is subject to the same repurchase option, risk of forfeiture or other condition under any applicable restricted stock purchase agreement.

The Company's stockholders received approximately 10,956,614 shares of AVROBIO common stock in connection with the Merger, including 11,448 shares of AVROBIO common stock subject to vesting terms, based on the number of shares of the Company's common stock outstanding immediately prior to the Merger, including restricted stock, the number of shares of common stock issued to investors participating in the Subscription Agreements (as defined below) and SAFEs, and the Company's convertible preferred stock outstanding immediately prior to the Merger, which was converted into shares of the Company's common stock on a one-for-one basis immediately prior to the closing of the Merger.

Subscription Agreement

Concurrently with the closing of the Merger, certain investors of the Company completed the purchase of 7,790,889 shares of the Company's common stock pursuant to that certain subscription agreement dated January 30, 2024 (the "Subscription Agreement") at a purchase price of approximately $12.40 per share for an aggregate purchase price of approximately $96.6 million. Shares of the Company's common stock issued pursuant to the Subscription Agreements were converted into 4,163,606 shares of AVROBIO common stock at the closing of the Merger based on the exchange ratio, pursuant to the Merger Agreement.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and Board of Directors of Tectonic Therapeutic, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tectonic Therapeutic, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and other comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

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

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

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

Critical Audit Matter

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

SAFE Liabilities — Refer to Notes 2, 3, and 13 to the financial statements

Critical Audit Matter Description

In October and December 2023, the Company entered into Simple Agreements for Future Equity ("SAFEs") with certain existing investors. The SAFEs allow for redemption based upon certain triggering events that are outside of the control of the Company. As disclosed in Note 2 to the financial statements, the Company accounts for the SAFEs as liabilities at fair value on a recurring basis. Triggering events include an equity financing, public listing transaction, change of control or dissolution. On December 31, 2023, the probabilities of an equity financing, public listing transaction, and dissolution were estimated to be 10%, 87.5%, and 2.5%, respectively. The estimated time to redemption was five months for an equity financing or dissolution and four months for a public listing transaction. Changes in fair value are recognized in the Company's statements of operations and other comprehensive loss. As of December 31, 2023, the Company has recorded SAFE liabilities of $30.5 million.

We identified the valuation of the SAFE liabilities as a critical audit matter due to the level of judgment required by management. This requires a high degree of auditor judgment, subjectivity, and an increased extent of effort in performing procedures to evaluate the reasonableness of management's estimate, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the valuation of the SAFE liabilities included the following, among others:

- We read and obtained an understanding of the key terms of the SAFE agreements, including the triggering events.
- We evaluated the reasonableness of the valuation assumptions, including triggering event probabilities and the estimated time to triggering events, by comparing the assumptions to known and knowable information at the valuation date.
- With the assistance of our fair value specialists, we evaluated the reasonableness of (i) the valuation methodology, and (ii) the discount rate, including testing the source information underlying the determination of the discount rate.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
April 12, 2024

We have served as the Company's auditor since 2022.

TECTONIC THERAPEUTIC, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 28,769	$ 35,966
Prepaid expenses and other current assets	2,115	1,076
Total current assets	30,884	37,042
Property, equipment and improvements, net	3,122	3,608
Finance right-of-use assets, net	1,437	2,159
Operating right-of-use assets	2,669	3,787
Deferred offering costs	669	—
Restricted cash	587	587
Other assets	31	26
Total assets	$ 39,399	$ 47,209
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 409	$ 574
Accrued expenses and other current liabilities	8,141	5,814
SAFE liabilities	30,515	—
Operating lease liability - current portion	1,348	950
Finance lease liability - current portion	475	499
Total current liabilities	40,888	7,837
Operating lease liability - net of current portion	1,644	2,992
Finance lease liability - net of current portion	876	1,351
Other noncurrent liabilities	—	56
Total liabilities	43,408	12,236
Commitments and contingencies (Note 6)		
Convertible preferred stock (Series A-1, A-2, A-3 and A-4), $0.0001 par value; 6,825,483 shares authorized as of December 31, 2023 and 2022; 6,825,483 shares issued and outstanding as of December 31, 2023 and 2022; aggregate liquidation preference of $87,459 as of December 31, 2023 and 2022	80,627	80,627
Stockholders' Deficit		
Common stock, $0.0001 par value; 11,947,558 shares authorized as of December 31, 2023 and 2022; 2,634,246 and 2,525,771 shares issued and outstanding as of December 31, 2023 and 2022;	—	—
Additional paid-in capital	5,979	2,127
Accumulated other comprehensive loss	(11)	—
Accumulated deficit	(90,604)	(47,781)
Total stockholders' deficit	(84,636)	(45,654)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 39,399	$ 47,209

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

TECTONIC THERAPEUTIC, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS and COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 36,966	$ 25,654
General and administrative	7,682	7,176
Total operating expenses	44,648	32,830
Loss from operations	(44,648)	(32,830)
Other income (expense), net:		
Change in fair value of preferred stock tranche liability	—	643
Loss on issuance of SAFEs	(255)	—
Change in fair value of SAFE liabilities	1,255	—
Interest income	581	149
Interest expense	(152)	(144)
Other income	396	2
Total other income, net	1,825	650
Loss before provision for income taxes	(42,823)	(32,180)
Net loss attributable to common stockholders	(42,823)	(32,180)
Net loss per share attributable to common stockholders, basic and diluted	$ (18.04)	$ (16.34)
Weighted-average common shares outstanding, basic and diluted	2,373,674	1,969,418
Other comprehensive loss:		
Foreign currency translation adjustment	(11)	—
Comprehensive loss	$ (42,834)	$ (32,180)

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

TECTONIC THERAPEUTIC, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances as of January 1, 2022	3,941,829	$42,610	2,297,901	$ —	$ 641	$ —	$ (15,601)	$ (14,960)
Issuance of Series A preferred stock—net of issuance costs of $12	2,883,654	38,017	—	—	—	—	—	—
Exercise of stock options	—	—	3,233	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	1,119	—	—	1,119
Issuance of common stock	—	—	227,486	—	363	—	—	363
Repurchase of common stock	—	—	(2,849)	—	—	—	—	—
Net loss	—	—	—	—	—	—	(32,180)	(32,180)
Balances as of December 31, 2022	6,825,483	80,627	2,525,771	—	2,127	—	(47,781)	(45,654)
Exercise of stock options	—	—	108,475	—	121	—	—	121
Stock-based compensation expense	—	—	—	—	1,121	—	—	1,121
Contribution from related party investors related to SAFEs	—	—	—	—	2,610	—	—	2,610
Foreign currency translation adjustment	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	(42,823)	(42,823)
Balances as of December 31, 2023	6,825,483	$80,627	2,634,246	$ —	$ 5,979	$ (11)	$ (90,604)	$ (84,636)

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

TECTONIC THERAPEUTIC, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	December 31, 2023	December 31, 2022
Cash flows from operating activities:		
Net loss	$(42,823)	$(32,180)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,478	1,006
Stock-based compensation expense	1,121	1,119
Loss on fixed asset disposal	9	—
Loss on issuance of SAFEs	255	—
Non-cash lease expense	1,118	862
Non-cash issuance of common stock for the exchange of license	—	363
Change in fair value of preferred stock tranche liability	—	(643)
Change in fair value of SAFE liabilities	(1,255)	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,019)	(376)
Other non-current assets	(5)	(14)
Accounts payable	(165)	(1,234)
Accrued expenses and other current liabilities	1,611	4,509
Operating lease liabilities	(950)	(1,105)
Other non-current liabilities	(56)	56
Net cash used in operating activities	(40,681)	(27,637)
Cash flows from investing activities:		
Purchase of property, equipment and improvements	(279)	(2,088)
Net cash used in investing activities	(279)	(2,088)
Cash flows from financing activities:		
Proceeds from the issuance of SAFEs	34,125	—
Proceeds from issuance of convertible preferred stock - net of issuance costs	—	38,017
Proceeds from exercise of common stock options	121	4
Repayment of finance lease obligations	(499)	(393)
Net cash provided by financing activities	33,747	37,628
Effect of exchange rate changes on cash and cash equivalents	16	—
Net increase (decrease) in cash and cash equivalents and restricted cash	(7,197)	7,903
Cash and cash equivalents and restricted cash as of beginning of period	36,553	28,650
Cash and cash equivalents and restricted cash as of end of period	$ 29,356	$ 36,553
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 28,769	$ 35,966
Restricted cash	587	587
Total cash, cash equivalents and restricted cash	$ 29,356	$ 36,553
Supplemental disclosure of non-cash financing activities:		
Purchase of equipment through finance leases	$ 234	$ 1,340
Deferred offering costs included in accrued expenses and other current liabilities	$ 669	$ —
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 152	$ 144

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

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Business

Tectonic Therapeutic, Inc. ("Company") is a biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of G-protein coupled receptors ("GPCRs"). Leveraging its proprietary technology platform called GEODe™ ("GPCRs Engineered for Optimal Discovery"), the Company is focused on developing biologic medicines that overcome the existing challenges of GPCR-targeted drug discovery and harness the human body to modify the course of disease. The Company focuses on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality of life. The Company was incorporated on June 5, 2019 under the laws of the State of Delaware and has its principal headquarters in Watertown, Massachusetts.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities.

The Company's proprietary GEODe™ platform is currently in development. There can be no assurance that current and future research and development activities will be successfully completed, that adequate protection for owned intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

Liquidity and Going Concern

As of December 31, 2023, the Company had an accumulated deficit of $ 90.6 million and has incurred losses and negative cash flows from operations since inception, including a net loss of $42.8 million for the year ended December 31, 2023. To date, the Company has financed its operations primarily through the issuance of convertible preferred stock, convertible promissory notes and Simple Agreements for Future Equity ("SAFEs"). The Company has devoted substantially all of its financial resources and efforts to business planning, conducting research and development, recruiting management and technical staff, and raising capital. Management expects that the Company's operating losses and negative cash flows will continue for the foreseeable future as it continues to develop its product candidates.

As the Company continues to develop its proprietary platform and potential product candidates, it will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. It may never achieve profitability, and unless and until it does, it will continue to need to raise additional capital to fund its operations. The Company is seeking to complete a planned reverse merger with AVROBIO, Inc. ("AVROBIO") (see Note 14). In the event the Company does not complete the reverse merger, the Company plans to seek additional funding through private equity financings, debt financings or other capital sources, including collaboration agreements, strategic alliances and licensing arrangements. The Company may not be able to obtain

financing on acceptable terms, or at all. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all. Management believes that the Company's cash and cash equivalents of $28.8 million as of December 31, 2023 is not sufficient to maintain its current and planned operations for at least the next twelve months following the issuance date of these consolidated financial statements. Management has concluded that these conditions, in aggregate, raise substantial doubt about the Company's ability to continue as a going concern.

The Company intends to fund future operations through private and potentially public equity financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. The availability of sufficient funding to alleviate the conditions that raise substantial doubt are not within management's control and cannot be assessed as being probable of occurring. If the Company is unable to obtain adequate financing, management will evaluate alternatives, which may include a delay, reduction or elimination of research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect future business prospects, and the ability to continue operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include the contract research accruals, stock-based compensation expense, the fair value of the Company's common stock, the income tax valuation allowance, the fair value determination of the SAFEs and the preferred stock tranche liability settled in 2022. Management's estimates are based on historical experience and various other assumptions that it believes are reasonable under the circumstances. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Foreign Currency

The functional currency of the Company's wholly-owned foreign subsidiary in Australia is Australian Dollars.

Accounts and transactions denominated in currencies other than an entity's functional currency are remeasured into the functional currency using the appropriate foreign exchange rate in accordance with FASB ASC Topic 830, *Foreign Currency Matters.* All foreign currency transaction gains and losses arising

from transactions denominated in foreign currencies are recorded in the statements of operations and comprehensive loss as other income or expenses. The financial statements of the Australian subsidiary will be translated into the Company's U.S. dollar reporting currency at each reporting date, and the translation adjustments will be recognized as an unrealized gain or loss within the cumulative translation adjustment.

Segment Information

The Company considered the Company's organizational structure and the information regularly reviewed and evaluated by the Company's chief operating decision maker ("CODM") when deciding how to allocate resources and assess performance. The Company has determined that its CODM is its Chief Executive Officer. The CODM reviews the financial information on a consolidated basis for purposes of evaluating financial performance and allocating resources. On the basis of this factor, the Company determined that it operates and manages its business as a single operating segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. As of December 31, 2023, cash equivalents were comprised primarily of money market funds.

Restricted Cash

The Company classifies all cash whose use is limited by contractual provisions as restricted cash. Restricted cash arises from the requirement for the Company to maintain cash of $0.6 million as collateral in connection with a letter of credit issued with the corporate headquarters and lab space lease agreement entered into on November 19, 2020 and may not access these funds until after the expiration of the initial lease term on December 31, 2025. The Company has classified the certificate of deposits collateralizing the letter of credits issued as a security deposit as restricted cash in the noncurrent asset section of the balance sheets.

Deferred Offering Costs

Deferred offering costs consist of direct legal, accounting and other fees and costs directly attributable to the Company's proposed Merger (see Note 14). The Company capitalized deferred offering costs incurred prior to the close of the Merger which are included in deferred offering costs within the consolidated balance sheet as of December 31, 2023. The deferred offering costs were $0.7 million as of December 31, 2023.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. Periodically, the Company maintains deposits in accredited financial institutions in excess of governmental insured limits. The Company deposits its cash and cash equivalents in financial institutions that it believes have a high credit quality and have not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Property, Equipment and Improvements

Property, equipment and improvements are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of each asset. Construction in process is capitalized and once the asset is operational, the Company will commence depreciation of the asset.

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized. Expenditures for major renewals and improvements that extend the useful life of the asset are capitalized as part of the asset. Expenditures for repairs and maintenance are expensed as incurred.

The estimated useful lives for property and equipment are as follows:

	Estimated Useful Life
Laboratory equipment	5 years
Furniture and office equipment	5 years
Computer equipment	3 years
Leasehold improvements	Shorter of the lease term or 10 years

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist primarily of property, equipment and improvements, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The carrying amount of a long-lived asset is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. If the carrying amount of the asset is not recoverable, an impairment will be recognized and measured as the amount by which the carrying amount of the asset exceeds its fair value. No impairments were identified during the years ended December 31, 2023 and 2022.

Fair Value Measurements

Fair value is defined 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. Market participants are independent buyers or sellers in the principal (or most advantageous) market for the asset or liability. Fair value measurements are categorized into a three-tier hierarchy on the basis of the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy are as follows:

- ***Level 1***—Unadjusted quoted prices in active markets for identical, unrestricted assets or liabilities that are accessible at the measurement date;
- ***Level 2***—Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar asset or liabilities in markets that are not active or valuations with significant inputs other than quoted prices that are observable, either directly or indirectly; and,
- ***Level 3***—Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety in the same level of the fair value hierarchy as the lowest level input that is significant to the entire fair value measurement.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of costs incurred for the development of the proprietary platform and product candidates and include (1) expenses incurred under agreements with third parties and contract research organizations

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

("CROs"), (2) costs to acquire and develop supplies for research, (3) salaries and related costs, including stock-based compensation, (4) depreciation and other facility-related and overhead expenses, (5) licensing and license maintenance fees incurred under license option and license agreements where no alternative future use exists, and (6) costs related to compliance with regulatory requirements. The Company recognizes external research and development costs based on an evaluation of the progress to completion of specific tasks using information provided from the Company's contracted service providers.

Prepaid and Accrued Research and Development Costs

Substantial portions of the Company's research are performed by third-party laboratories, CROs and other vendors. These vendors generally bill monthly for services performed, or bill based upon milestone achievement. The Company accrues expenses based upon estimates of percentage of work completed and the contract milestones remaining. On occasion, the Company is obligated to make upfront payments upon execution of research and development agreements. Advance payments, including nonrefundable amounts, for goods or services that will be used or rendered for future research and development activities are capitalized as prepaid expenses until such goods are delivered or the related services are performed. The Company estimates the period over which such services will be performed based on the terms of the agreements as well as the level of effort to be expended in each period. Since inception, the Company has not experienced any material differences between the actual and estimated timing of performance or level of effort.

Leases

Effective January 1, 2022, the Company adopted ASC Topic 842, *Leases* ("ASC 842"), and elected to apply the modified retrospective transition approach using the effective date as the initial date of application. ASC 842 requires that lessees recognize leases with a term greater than twelve months on the balance sheet. The Company's existing capital leases will now be referred to as finance leases. The Company's existing operating sublease arrangement in which it is the sublessor will remain off balance sheet and lease income will continue to be recognized on a straight-lined basis. ASC 842 provided a number of optional practical expedients in transition. The Company applied the package of three practical expedients to leases that commenced prior to the January 1, 2022. Use of these practical expedients allowed the Company not to reassess: (i) whether any expired or existing contracts were or contained leases; (ii) the lease classification for any expired or existing leases; and (iii) the treatment of initial direct costs for existing leases.

On January 1, 2022, the Company recorded operating lease liabilities and their corresponding right-of-use ("ROU") assets based on the present value of lease payments over the remaining lease term. The Company used its incremental borrowing rate ("IBR") on January 1, 2022, to calculate the present value of the Company's leases. The IBR approximates the rate of interest the Company would have to pay to borrow on a collateralized basis over a similar term. The determination of the appropriate IBR was dependent on several factors, including the economic environment, the amount of the borrowing, the Company's estimated credit rating and the lease term at the time of measurement. The Company's unsecured credit rating was estimated via a synthetic credit rating model which included fundamental analysis. The Company's unsecured credit rating was then adjusted upward using a notching technique to reflect collateralization.

For leases entered into after January 1, 2022, the Company applies the guidance in ASC 842, and determines whether an arrangement is or contains a lease at inception. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. The Company classifies a lease at the lease commencement date, when control of the underlying asset is transferred from the lessor to the lessee, as an operating or finance lease and records a

ROU asset and a lease liability on the consolidated balance sheet for any lease with a lease term greater than twelve months. The Company has elected the practical expedient to not recognize leases with a lease term of twelve months or less on the balance sheet ("short-term leases") and will recognize lease payments for such short-term leases as an expense on a straight-line basis.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components may include items such as maintenance, utilities, or other operating costs. The Company has elected to combine the lease and associated non-lease components in its lease arrangements as a single lease component for all real estate and equipment leases. Variable lease costs, such as utilities or maintenance costs, are not included in the measurement of ROU assets and lease liabilities, but rather are expensed when the events determining the amount of variable lease consideration to be paid occurs.

For lease arrangements in which the Company is a lessee, finance and operating ROU assets and liabilities are recognized at the lease commencement date based on the present value of the lease payments over the lease term determined using the discount rate implicit in the lease if readily determinable. When the rate implicit in the lease is not readily determinable, the Company utilizes its IBR, which is determined on the basis of information that is available at the lease commencement date. ROU assets are further adjusted for items such as initial direct costs, prepaid rent, or lease incentives. Operating lease costs are expensed using the straight-line method as an operating expense over the lease term unless the operating lease ROU asset has been impaired. The Company's lease terms may include options to extend the lease when it is reasonably certain that the Company will exercise that option. Finance lease assets are amortized to depreciation expense using the straight-line method over the shorter of the useful life of the related asset or the lease term. Finance lease payments are bifurcated between (i) a portion that is recorded as interest expense and (ii) a portion that reduces the finance lease liability associated with the lease.

Simple Agreements for Future Equity

SAFE instruments do not represent legal form debt (i.e., no creditor rights), but allow for redemption based upon certain triggering events that are outside of the control of the Company. The Company accounts for a SAFE as a liability at fair value on a recurring basis. Triggering events include an equity financing, public listing transaction, change of control or dissolution. Changes in the liability's fair value are recognized in the Company's statements of operations and comprehensive loss.

Convertible Preferred Stock

The Company classifies convertible preferred stock outside of stockholders' deficit on the consolidated balance sheets as it is redeemable upon the occurrence of a Deemed Liquidation Event, as defined below, that is not strictly within the Company's control. The issuance of convertible preferred stock is recorded at the issuance price less any amounts allocated to freestanding liabilities associated with the issuance and related allocable issuance costs. The carrying values of the convertible preferred stock have not been adjusted to their liquidation preferences because it is not considered probable that a Deemed Liquidation Event will occur and make such stock redeemable.

Stock-Based Compensation

The Company measures and records the expense related to stock-based payment awards based on the fair value of those awards as determined on the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grant, which is generally equal to the vesting period, using the straight-line method. For stock options with performance conditions, the Company records stock-based compensation expense when it is deemed probable that the performance

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

The Company calculates the fair value of stock options granted by using the BSM option-pricing model with the following assumptions:

Expected Volatility—The estimated volatility is determined by evaluating the average historical volatility of a peer group of companies for the period preceding the stock option grant for a term that is approximately equal to the stock options' expected term.

Expected Term—The expected life represents the period of time that the stock options are expected to be outstanding. Because the Company does not have substantial historical exercise behavior, it determines the expected life assumption using the simplified method, for employees and nonemployees, which is an average of the contractual term of the stock option and its vesting period.

Risk-Free Interest Rate—The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a term that is equal to the stock options' expected term at the grant date.

Dividend Yield—The Company has not declared or paid dividends to date and does not anticipate declaring dividends for the foreseeable future. As such, the dividend yield is estimated to be zero.

Forfeitures—The Company records forfeitures as they occur.

The purchase price of restricted common stock granted to founders, employees and consultants is the estimated fair value on the grant date and is subject to various vesting schedules. Unvested restricted common stock are subject to repurchase rights held by the Company at the original issuance price in the event the restricted common stockholders' service to the Company is terminated either voluntarily or involuntarily. The associated liability is classified in accrued expenses and other current liabilities in the consolidated balance sheets. The balance of this liability as of December 31, 2023 and 2022 is immaterial.

All stock-based compensation expense is recorded in research and development expense or general and administrative expense in the consolidated statements of operations and comprehensive loss, on the basis of the respective employee and nonemployee's role within the Company.

Income Taxes

The Company accounts for income taxes under the asset and liability method under ASC Topic 740, *Income Taxes* ("ASC 740"), which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, the Company determined deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

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

Related Party Transactions

Related parties are directly or indirectly related to the Company, through one or more intermediaries and are in control, controlled by, or under common control with the Company. Related parties also include principal owners of the Company, its management, members of the immediate families of principal owners of the Company and its management, and other parties with which the Company may transact with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests. The Board reviews and approves transactions with directors, officers and holders of 5% or more of the Company's voting securities and their affiliates or their family members. The material facts as to the related party's relationship or interest in the transaction are disclosed to the Board prior to its consideration of such transaction, and the transaction is not considered approved by the Board unless a majority of the directors who are not interested in the transaction approve the transaction.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. The comprehensive loss for the Company equals its net loss plus changes in foreign currency translation for all periods presented.

Net Loss per Share

The Company applies the two-class method when computing earnings per share attributable to common stockholders as the Company has issued securities that meet the definition of participating securities. The two-class method determines earnings per share for each class of common and participating securities according to dividends declared or accumulated in the current period and participation rights in undistributed earnings. The Company considers its convertible preferred stock and SAFEs to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock and SAFEs would be entitled to receive dividends on a basis consistent with the common stockholders. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, excluding potentially dilutive common shares. Diluted net loss per share attributable to common

stockholders is computed by adjusting net loss attributable to common stockholders to reallocate earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, the Company's outstanding convertible preferred stock, stock options, unvested restricted common stock and the SAFEs are considered potential dilutive common shares.

The Company generated a net loss for each of the years presented. Accordingly, basic and diluted net loss per share attributable to common stockholders are the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Recent 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 dates. Unless otherwise discussed, the impact of recently issued standards that are not yet effective are not anticipated to have a material impact on the Company's consolidated financial statements upon adoption.

Recently Issued Accounting Pronouncement Not Yet Adopted

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in an Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (i) those not carried at fair value with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for the Company beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is in the process of evaluating the impact of the adoption of ASU 2020-06 will have on the consolidated financial statements and disclosures.

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting* (Topic 280) ("ASU 2023-07"), which enhances the segment disclosure requirements for public entities on an annual and interim basis. Under ASU 2023-07, public entities will be required to disclose significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss. Additionally, current annual disclosures about a reportable segment's profit or loss and assets will be required on an interim basis. Entities will also be required to disclose information about the CODM's title and position at the Company along with an explanation of how the CODM uses the reported measures of segment profit or loss in their assessment of segment performance and deciding whether how to allocate resources. Finally, ASU 2023-07 requires all segment disclosures for public entities that have only a single reportable segment. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-07 on its consolidated financial statements.

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In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes* (Topic 740) ("ASU 2023-09"), which enhances the income tax disclosure requirements for public entities on an annual basis. Under ASU 2023-09, public entities will be required to disclose in their rate reconciliation, on an annual basis, both percentages and amounts in their reporting currency for certain categories in a tabular format, with accompanying qualitative disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-09 on its consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

The following tables present information about financial assets and liabilities 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):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 27,278	$ —	$ —	$ 27,278
	$ 27,278	$ —	$ —	$ 27,278
Liabilities:				
SAFE liabilities	$ —	$ —	$ 30,515	$ 30,515
	$ —	$ —	$ 30,515	$ 30,515

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 33,640	$ —	$ —	$ 33,640
	$ 33,640	$ —	$ —	$ 33,640

As of December 31, 2023 and 2022, the Company's cash equivalents, which were invested in money market funds, were valued based on Level 1 inputs.

SAFE Liabilities

From October through December 2023, the Company entered into multiple SAFE agreements with certain existing investors and received $34.1 million (see Note 13). The SAFE liabilities are included within the Level 3 fair value hierarchy. The SAFE liabilities were valued using a probability weighted scenario analysis and discount rates derived by application of the build-up method to reflect the cost of equity. The valuation model requires a variety of inputs, including the probability of occurrence of events that would trigger conversion or redemption of the SAFEs, the expected timing of such events, and a discount rate.

The valuation of the SAFE liabilities as of December 31, 2023, was determined based on a probability-weighted scenario analysis that assumed the probabilities of the occurrence of an equity financing, public listing transaction and dissolution to be 10.0%, 87.5% and 2.5% respectively. The estimated time to redemption used was five months for an equity financing and dissolution and four months for a public listing transaction. The valuation used a discount rate of 30.2% to approximate the cost of equity, which was derived from application of a build-up method that incorporated the risk-free rate at the valuation date, and

adjustments to reflect market risk, a small stock premium, and a selected company-specific risk premium. The valuation of the SAFE liabilities at the October issuance date was determined using the same methodology; however, the discount rate was 30.9% due the higher risk-free rate at the valuation date. In October 2023, the probabilities of the occurrence of an equity financing, public listing transaction and dissolution used were 87.5%, 10.0%, and 2.5%, respectively. The estimated time to redemption used was 1.5 months for an equity financing and 5.5 months for a public listing transaction and dissolution.

Valuation of Preferred Stock Tranche Liability

The fair value of the preferred stock tranche liability was based on significant inputs not observable in the market and is a Level 3 measurement within the fair value hierarchy. The valuations were made using Black-Scholes-Merton pricing model with inputs based on certain subjective assumptions, including (a) estimated conversion dates, (b) expected stock price volatility, (c) a risk-free interest rates and (d) implied debt yields.

The fair value of the preferred stock tranche liability was determined at the issuance of the Preferred Stock, as defined below, in 2021 and re-measured at each balance sheet date until its settlement in September 2022. Accordingly, there was no outstanding preferred stock tranche liability as of December 31, 2022.

The following table presents activity for the preferred stock tranche liability and the SAFE liabilities that were measured at fair value using significant unobservable Level 3 inputs during the years ended December 31, 2023 and 2022 (in thousands):

	Preferred Stock Tranche Liability	SAFE Liabilities
Balance as of January 1, 2022	$ 643	$ —
Fair value adjustments	(643)	—
Balance as of December 31, 2022	—	—
Initial fair value recognition	—	31,515
Loss on issuance	—	255
Fair value adjustments	—	(1,255)
Balance as of December 31, 2023	$ —	$ 30,515

There were no transfers between the Level 1, Level 2 or Level 3 categories during the years ended December 31, 2023 and 2022.

4. PROPERTY, EQUIPMENT AND IMPROVEMENTS, NET

Property, equipment and improvements, net is comprised of the following (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 4,510	$4,018
Furniture and office equipment	244	244
Computer equipment	161	149
Construction in progress	38	49
Leasehold improvements	25	25
	4,978	4,485
Less: accumulated depreciation	(1,856)	(877)
Property and equipment, net	$ 3,122	$3,608

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Depreciation expense was $1.0 million and $0.6 million and was recorded as follows (in thousands):

	Year Ended December 31,	
	2023	2022
General and administrative	$ 17	$ 12
Research and development	973	635
	$ 990	$ 647

These amounts are exclusive of amortization related to finance lease and capital lease assets of $ 0.5 million and $0.3 million in 2023 and 2022, respectively.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31,	
	2023	2022
Employee compensation related costs	$ 2,840	$ 2,158
Accrued office and laboratory costs	211	481
Accrued contract research organization fees	2,298	1,345
Accrued contract development and manufacturing organization fees	660	842
Accrued professional fees	1,798	489
Other current liabilities	334	499
	$ 8,141	$ 5,814

6. COMMITMENTS AND CONTINGENCIES

Leases

The Company's commitments under its operating and finance leases are described in Note 7.

University of Texas Research Agreement

The Company executed a research agreement with the University of Texas, whereby the Company and the University of Texas are conducting joint research activities in accordance with an agreed upon research program. An upfront fee of $25,000 was paid upon execution of the agreement in 2020, with the remaining balance due in two payments of $37,500 each. The first payment was due upon the completion of the joint research activities and the second due upon the receipt of the final research report by the Company. The agreement was terminated on June 30, 2022.

During the year ended December 31, 2022, the Company did not pay any amounts to the University of Texas under this agreement because the joint research activities were not completed before the research agreement terminated.

Harvard Agreement

In July 2020, the Company entered into an agreement with the President and Fellows of Harvard College ("Harvard"), for an option fee in the low five digits, whereby Harvard granted the Company an

exclusive option to negotiate a worldwide, exclusive, royalty-bearing license under Harvard's interest in the patent rights covering certain technology that was developed by Harvard. In October 2021, the Company exercised the option and on February 10, 2022, entered into a license agreement ("License Agreement") with Harvard to conduct research and development activities using certain materials, technology and patent rights owned by Harvard, with the intent to develop, obtain regulatory approval for, and commercialize products. The License Agreement will remain in effect until the expiration of the last valid claim within the patent rights covering a product developed under the License Agreement or the termination of the License Agreement. Management concluded that the acquisition of patents and materials received under the License Agreement represents an asset acquisition of an in-progress research and development asset without future alternative use; therefore, any consideration paid were expensed.

As consideration for the License Agreement, the Company agreed to pay Harvard a non-refundable license fee, consisting of a cash payment due in three equal annual installments, in total amounting to $170,000 and 227,486 shares of common stock. The installments became due on July 2, 2022 ("First Payment Due Date") and the first and second anniversaries of the First Payment Due Date. The first payment of $56,666 was paid in July 2022. The common stock issued to Harvard had a fair value of $ 0.4 million. Both the cash payment and the issuance of shares were expensed to research and development during the year ended December 31, 2022. The second payment of $56,666 was made in July 2023.

The Company also will be responsible for payment of (1) annual maintenance fees ranging from the low five digits to the low six digits during the term of the License Agreement (through the first commercial sale of a royalty-bearing product); (2) royalty payments as a percentage in the low single digits of the annual net sales that the Company generates from products that utilize the license technology ("Licensed Products") and royalty payments as a percentage in the low single digits of the annual net sales that the Company generates from know-how enabled product licenses ("Know-How Enabled Products") and (3) a percentage between 10-20% of all non-royalty income received by the Company under sublicenses, strategic partnerships and know-how enabled product licenses that utilize the license technology. Subsequent to the first commercial sale of a royalty-bearing product, annual maintenance fees will increase to a low six digits for the remainder of the term of the License Agreement. The royalty term from sales of Licensed Products will terminate on a country-by-country and product-by-product basis on the earlier of (i) the expiration of the patent rights covering the product, expected to be no earlier than May 2041, and (ii) the termination of the License Agreement. The royalty term from sales of Know-How Enabled Products will terminate on the earlier of (i) ten years after the first commercial sale of the first Know-How Enabled Product and (ii) twelve years after the first commercial sale of the first Licensed Product. There was less than $0.1 million due to Harvard as of December 31, 2023.

Alloy Therapeutics License Agreement

On November 29, 2021, the Company executed a license agreement with Alloy Therapeutics, LLC ("ATX"), whereby the Company will use ATX technology for the purpose of preclinical development, clinical development and commercialization of potential product candidates, for an initial period of three years, with an option to extend the term for an additional two years. The Company will pay ATX a non-refundable and non-creditable annual fee of $0.1 million on each anniversary of the agreement. On November 7, 2022, the Company and ATX amended the agreement and extended the period of payment for the first fee due in May 2023. Additionally, the Company will be responsible for annual partnering fees if the Company decides to pursue clinical development of a product candidate using the ATX technology. The partnering fees may be creditable against future milestone development fees paid by the Company. The Company will also be responsible to pay ATX development milestone payments for the movement of certain product candidates through clinical trials, which range from the low six digits to the low seven digits upon completion of each milestone and amount to $4.8 million in total milestone payments under the license agreement. Provided the Company is able to commercialize a product using ATX technology, the Company

will be responsible to pay ATX commercial payments in the low seven digits per year during the first six years of commercial sales, amounting to an amount in the high eight digits in total commercial payments under the license agreement.

During the years ended December 31, 2023 and 2022, the Company paid $ 0.1 million and zero to ATX, respectively.

Adimab Agreement

On May 1, 2023, the Company entered into a discovery agreement with Adimab, LLC ("Adimab"), an antibody discovery company, whereby the Company and Adimab are collaborating on human antibody discovery in accordance with an agreed upon research program. The Company paid an upfront technology access fee totaling $20,000 upon execution of the agreement.

The Company also will be responsible for payment of (1) quarterly funding equal to 100% of the actual full-time employee ("FTE") expended by Adimab in the performance of its obligations in accordance with the agreed upon research program at an annual rate of $0.4 million per FTE (subject to annual consumer price index increases) per the agreement, (2) delivery fees equal to $ 0.1 million upon both Adimab's initial delivery of sequences or physical materials and completion pursuant to the research program (initial and completion fees payable once per target for a total of up to $0.4 million), (3) a non-creditable, non-refundable fee of $0.5 million upon the exercise of an option to obtain the licenses and assignments for information discovered during the research program, (4) development milestone payments for the movement of certain product candidates thought clinical trials, which range in the low seven digits, and (5) royalty payments based on the annual net sales that the Company generates from products that utilize Adimab technology. The Company has the right to terminate the agreement if certain criteria are met. During the year ended December 31, 2023, the Company incurred $0.1 million of costs associated with the FTEs.

Indemnification Agreements

In accordance with the Company's amended and restated certificate of incorporation ("ARCOI") and certain indemnification agreements, the Company indemnifies certain officers and directors for specified events or occurrences, subject to certain limits, in which the officer or director is or was serving at the Company's request in such capacity.

The Company enters into certain types of contracts that contingently requires it to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which it must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship with the Company, (ii) contracts under which it must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the its products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on future business, operating results or financial condition. It is not possible to estimate the maximum amount potentially payable under these contracts since there is no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

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As of December 31, 2023 and 2022, the Company did not have any liabilities or other commitments related to indemnification claims.

7. LEASES

The Company has entered into operating leases for office and laboratory facilities and financing leases for laboratory equipment used in research and development activities. The remaining lease terms for its leases range from two years to four years. These leases often include options to extend the term of the lease. When it is reasonably certain that the option will be exercised, the impact of the renewal term is included in the lease term for purposes of determining total future lease payments and measuring the ROU asset and lease liability. The Company is not reasonably certain to exercise any available renewal options, which are therefore excluded from the measurement of leases. The Company applies the short-term lease policy election for its real estate and equipment leases, which allows it to exclude from recognition leases with an original term of twelve months or less.

In November 2020, the Company executed a facilities lease agreement to occupy 18,768 square feet of office and laboratory space, that was subsequently amended on April 21, 2022. The lease requires the Company to pay fixed base rent, which is included in the measurement of the lease, as well as its proportionate share of the facilities operating expenses which are treated as variable lease costs based on the Company's election to combine lease and associated non-lease components and are excluded from the measurement of the lease. The lease expires on January 31, 2026, and contains a five-year renewal option exercisable by the Company which is not included in the measurement of the lease.

In April 2021, the Company entered into an agreement to sublease a portion of its facility lease to a related party (see Note 13) in exchange for $28,333 per month. The sublease agreement was an operating lease with a term of 18 months and was set to expire on September 30, 2022. In July 2022, the Company granted the sublessee permission to terminate the agreement on July 31, 2022. An immaterial adjustment to straight-line rental income and accrued rent receivable was recorded as part of the early termination. The proceeds from the sublease agreement are recorded as an offset to facilities costs in the periods in which they are earned.

During 2022, the Company entered into four additional finance leases that resulted in an increase of $ 1.3 million in ROU assets, inclusive of lease payments made prior to commencement, and $1.3 million in related lease liabilities.

The following table sets forth information about lease costs for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
Finance lease cost	2023	2022
Amortization of ROU assets	$ 488	$ 359
Interest on lease liabilities	151	106
Operating lease cost	1,404	1,404
Short-term lease cost	749	389
Variable lease cost	786	907
Sublease income	—	(253)
Total lease costs	$ 3,578	$ 2,912

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The following table sets forth information about the Company's leases for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
Cash paid for amounts included in the measurement of lease liabilities	2023	2022
Finance leases - financing cash flows	$ 499	$ 393
Finance leases - operating cash flows	151	106
Operating leases - operating cash flows	1,235	1,470
ROU assets obtained in exchange for lease liabilities		
Finance leases	—	1,340
Weighted-average remaining lease terms (in years)		
Finance leases	3.23	4.19
Operating leases	2.09	3.09
Weighted-average discount rate		
Finance leases	9.62%	9.49%
Operating leases	8.25%	8.25%

The following table presents the maturity of the Company's finance and operating lease liabilities for the year ended December 31, 2023 (in thousands):

Year ended December 31,	Finance Leases	Operating Leases
2024	$ 583	$ 1,534
2025	552	1,580
2026	363	132
2027	44	—
2028	—	—
Thereafter	—	—
Total lease payments	1,542	3,246
Less: interest	(191)	(254)
Total lease liabilities	$ 1,351	$ 2,992

8. CONVERTIBLE PREFERRED STOCK

The Company issued Series A-1 convertible preferred stock (the "Series A-1 Preferred Stock"), Series A-2 convertible preferred stock (the "Series A-2 Preferred Stock"), Series A-3 convertible preferred stock (the "Series A-3 Preferred Stock"), and Series A-4 convertible preferred stock (the "Series A-4 Preferred Stock"); collectively the "Preferred Stock."

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Preferred Stock consisted of the following (in thousands, expect share and per share amounts):

		December 31, 2023				
	Par Value	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	$ 0.0001	4,118,120	4,118,120	$ 45,016	$ 54,308	4,118,120
Series A-2 Preferred Stock	$ 0.0001	1,649,188	1,649,188	21,654	21,749	1,649,188
Series A-3 Preferred Stock	$ 0.0001	696,516	696,516	9,187	7,348	696,516
Series A-4 Preferred Stock	$ 0.0001	361,659	361,659	4,770	4,054	361,659
		6,825,483	6,825,483	$ 80,627	$ 87,459	6,825,483

		December 31, 2022				
	Par Value	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	$ 0.0001	4,118,120	4,118,120	$ 45,016	$ 54,308	4,118,120
Series A-2 Preferred Stock	$ 0.0001	1,649,188	1,649,188	21,654	21,749	1,649,188
Series A-3 Preferred Stock	$ 0.0001	696,516	696,516	9,187	7,348	696,516
Series A-4 Preferred Stock	$ 0.0001	361,659	361,659	4,770	4,054	361,659
		6,825,483	6,825,483	$ 80,627	$ 87,459	6,825,483

Upon the issuance of each series of the Preferred Stock, the Company assessed the embedded conversion and liquidation features of the issued Preferred Stock and determined that such features did not require the Company to separately account for these features.

On September 7, 2022, the Company issued 2,446,372 shares of Series A-1 Preferred Stock and 437,282 shares of Series A-2 Preferred Stock at a price of $13.1876 per share, for aggregate gross proceeds of $38.0 million and incurred $11,966 of issuance costs.

The Preferred Stock have the following rights and privileges:

Dividends

The holders of the Preferred Stock are entitled to receive noncumulative dividends if and when declared by the Board at a rate of 8% per annum. The Company may not declare, pay or set aside any dividends on shares of any other series of capital stock of the Company, other than dividends on common stock payable in common stock, unless the holders of the Preferred Stock first receive, or simultaneously receive, a dividend on each outstanding share of the Preferred Stock. No dividends were declared or paid during the year ended December 31, 2023 or 2022.

Liquidation

In the event of any involuntary liquidation, dissolution or winding up of the Company or Deemed Liquidation Event, holders of the Preferred Stock shall be paid out of the assets of the Company available for distribution an amount per share equal to the greater of (i) the applicable original issue price, plus any dividends declared but unpaid, or (ii) such amount per share as would have been payable had all shares of the Preferred Stock been converted into shares of common stock.

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If the assets available for distribution to its stockholders are insufficient to pay the holders of shares of the Preferred Stock the full amount which they shall be entitled, the holders of shares of Preferred Stock shall share ratably in any distribution in proportion to the respective amounts which would otherwise be payable if all amounts payable were paid in full.

Voting

On any matter presented to the stockholders of the Company for their actions or consideration at any meeting of the Company, each holder of outstanding shares of Series A-1, Series A-3 and Series A-4 (the "Voting Preferred Stock") shall be entitled to the number of votes equal to the number of whole shares of common stock into which the shares of the Voting Preferred Stock are convertible. Holders of outstanding shares of Series A-2 Preferred Stock are not entitled to voting rights.

Redemption

The Preferred Stock is conditionally redeemable upon the occurrence of a Deemed Liquidation Event. A Deemed Liquidation Event is defined as (a) a merger or consolidation (an "event") in which the Company is a constituent party (or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to the event), except those in which the shares Company's stock outstanding immediately before the event continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following the event, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such event, the parent corporation of the surviving or resulting corporation and (b) the sale or disposition of the Company or one or more subsidiaries of the Company.

Mandatory Conversion

All outstanding shares of the Preferred Stock shall automatically convert into shares of common stock, at the conversion price upon either (a) the closing of the sale of shares of common stock to the public at a price of at least $39.56280 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten initial public offering, resulting in at least $75.0 million of gross proceeds and in connection with such offering the common stock is listed for trading on the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved by the Board of Directors, including the approval of a majority of the preferred directors or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the voting preferred stock (the "Requisite Holders").

Additionally, shares of Series A-1 Preferred Stock and A-2 Preferred Stock held by stockholders that did not exercise their tranche rights as part of the September 7, 2022 second tranche closing of the Preferred Stock financing were automatically converted into shares of common stock at the conversion price in effect immediately prior to this closing.

Optional Conversion

Each share of the Preferred Stock shall be convertible at any time and from time to time and without the payment of additional consideration by the holder into such number of fully paid and non-assessable shares of common stock as determined by dividing the original issue price by the conversion price. Each share of Series A-2 Preferred Stock shall be convertible into one share of Series A-1 Preferred Stock.

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The conversion price for the Series A-1 Preferred Stock and the Series A-2 Preferred Stock initially is equal to $13.18760, and the initial conversion price for the Series A-3 Preferred Stock and the Series A-4 Preferred Stock is $10.55008 and $11.20946, respectively. The conversion price is subject to adjustment for any stock-splits, stock dividends, combinations or other similar recapitalizations and other adjustments as set forth in the Company's ARCOI.

9. COMMON STOCK

As of December 31, 2023, the Company's ARCOI authorized the Company to issue up to 11,947,558 shares of $0.0001 par value common stock, of which, 2,634,246 shares were issued and outstanding.

Voting, dividend and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock. Holders of common stock are entitled to one vote for each share of common stock; however, the holders of the common stock shall not be entitled to vote on any amendment to the ARCOI that relates solely to the terms of one or more outstanding series of preferred stock.

The Company has included in issued and outstanding common stock shares of restricted common stock granted by the Company. As of December 31, 2023, there were 2,634,246 common shares issued and outstanding, of which 2,598,752 relate to shares of unrestricted common stock.

10. STOCK-BASED COMPENSATION

In June 2019, the Company adopted the 2019 Equity Incentive Plan (the "2019 Plan"), which provides employees, consultants and advisors and non-employee members of the Board of Directors and its affiliates with the opportunity to receive grants of stock options, stock awards and equity awards. Since inception, the Company has only issued stock options. Under the 2019 Plan, the Company may grant equity awards that could require the issuance of up to 1,991,264 shares of the Company's common stock.

For incentive stock options and non-statutory stock options, the option exercise price may not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. The options expire ten years from the grant date.

A summary of the activity in the 2019 Plan for the year ended December 31, 2023 is as follows (in thousands except share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance as of January 1, 2023	1,556,819	$ 1.32	8.7	$ 420
Granted	441,615	2.74		
Exercised	(108,475)	1.27		$ 172
Forfeited and expired	(14,027)	1.53		
Balance as of December 31, 2023	1,875,932	$ 1.66	8.2	$ 2,276
Options vested and exercisable as of December 31, 2023	972,054	$ 1.30	7.6	$ 1,525
Options vested and expected to vest as of December 31, 2023	1,875,932	$ 1.66	8.2	$ 2,276

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The weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was $ 2.16 and $1.57 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $171,915 and $1,458, respectively.

Cash received from option exercises for the years ended December 31, 2023 and 2022 was $ 111,770 and $4,105, respectively.

The fair values of the options granted were estimated based on the BSM option pricing model, using the following assumptions:

	Year Ended December 31,	
	2023	2022
Fair value per share of underlying common stock	$2.16	$1.57
Expected term (in years)	6.01	6.02
Expected volatility	93.44 - 111.21%	87.02 - 91.24%
Risk-free interest rate	4.14%	3.01%
Expected dividend yield	0%	0%

Restricted Common Stock

Since 2019, the Company has granted restricted common stock to founders, employees and consultants. The purchase price of the restricted common stock is the estimated fair value on the grant date and the restricted stock is subject to various vesting schedules. Unvested restricted common stock are subject to repurchase rights held by the Company at the original issuance price in the event the restricted common stockholders' service to the Company is terminated either voluntarily or involuntarily. As of December 31, 2023, there were 35,494 unvested restricted common stock, with a repurchase liability of less than $ 0.1 million, that is classified in accrued expenses and other current liabilities in the accompanying consolidated balance sheet.

The following table summarizes restricted stock activity:

	Number of Shares
Unvested restricted common stock as of January 1, 2023	312,826
Granted	—
Vested	(277,332)
Forfeited	—
Unvested restricted common stock as of December 31, 2023	35,494

The weighted-average grant date fair value of unvested restricted common stock and restricted common stock vested and forfeited for the years ended December 31, 2023 and 2022 was immaterial.

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense regarding its employees and nonemployees as follows (in thousands):

	Year Ended December 31,	
	2023	2022
General and administrative	$ 705	$ 738
Research and development	416	381
	$1,121	$1,119

The Company records compensation expense on a straight-line basis over the vesting period. As of December 31, 2023, total compensation cost not yet recognized related to unvested stock options was $2.4 million, which is expected to be recognized over a weighted-average period of 2.6 years.

11. INCOME TAXES

Income tax expense consists of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Current expense (benefit):		
Federal	$ —	$ —
State	—	—
Total current expense (benefit):	$ —	$ —
Deferred expense (benefit):		
Federal	$ 11,207	$ 7,407
State	3,361	2,189
Deferred tax benefit	14,568	9,596
Less change in valuation allowance	(14,568)	(9,596)
Total income tax expense (benefit):	$ —	$ —

The components of the Company's loss before income tax expense are compromised solely of domestic sources. The reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2023	2022
Federal statutory income tax rate	21.0%	21.0%
State income taxes	7.8%	6.8%
Foreign rate differential	0.1%	0.0%
Permanent differences	1.2%	-0.3%
Equity-based compensation	-0.4%	-0.6%
Preferred stock liability fair value adjustment	0.0%	0.4%
Tax credits	4.4%	2.5%
Change in valuation allowance	-34.0%	-29.8%
Effective income tax rate	0.0%	0.0%

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Significant components of the Company's deferred tax assets and liabilities consist of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets		
Net operating loss carryforward	$ 11,392	$ 7,765
Research credits	4,336	1,579
Lease liability	817	1,575
Capitalized R&D expenses	14,595	7,027
Accruals & other	1,027	859
Total deferred tax assets	32,167	18,805
Valuation allowance	(30,228)	(15,658)
Net deferred tax assets	$ 1,939	$ 3,147
Deferred tax liabilities		
Depreciation	$ (1,210)	$ (1,530)
Right of use asset	(729)	(1,617)
Total deferred tax liabilitites	(1,939)	(3,147)
Net deferred tax assets (liability)	$ —	$ —

Future realization of the tax benefits of existing temporary differences and net operating loss ("NOL") carryforwards ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2023 and 2022, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all of the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance as of December 31, 2023 and 2022.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code ("IRC") of 1986, as amended, a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of the IRC Section 382 and 383 have occurred as of December 31, 2023 and 2022. An ownership change would restrict its ability to use its NOLs or tax credit carryforwards and could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

The Company's valuation allowance increased for the year ended December 31, 2023 by $ 14.6 million due primarily to the generation of NOLs. As of December 31, 2023, the Company has NOL carryforwards for federal and state tax reporting purposes of $43.6 million and $35.3 million, respectively. NOL carryforwards generated after December 31, 2017 for federal tax reporting purposes of $43.6 million have an indefinite life. NOL carryforwards for state purposes of $ 35.3 million begin to expire in 2039. As of December 31, 2023, the Company also has federal and state research and development tax credits of

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

$2.9 million and $1.9 million, which being to expire in 2039 and 2034, respectively. The Tax Cuts and Jobs Act resulted in significant changes to the treatment of research and developmental expenses under Section 174. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all research and development expenses that are paid or incurred in connection with their trade or business. Specifically, costs for U.S. based research and development activities must be amortized over five years and costs for foreign research and development activities must be amortized over 15 years using a midyear convention. During the year ended December 31, 2023, the Company capitalized $36.2 million of research and development expenses.

The Company evaluates its uncertain tax positions under ASC 740-10, which requires that realization of an uncertain income tax position be recognized. The benefit to be recorded is the amount most likely to be realized assuming a review by tax authorities having all relevant information and applying current conventions. The Company concluded that there are no uncertain tax positions in any of the periods presented. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet.

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. The earliest tax years that remain subject to examination by jurisdiction is the year ended December 31, 2020 for both federal and state. However, to the extent the Company utilizes NOLs from years ending prior to 2020, the statute remains open to the extent of the NOLs or other credits are utilized.

12. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders	$ (42,823)	$ (32,180)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	2,373,674	1,969,418
Net loss per share attributable to common stockholders, basic and diluted	$ (18.04)	$ (16.34)

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. For the years ended December 31, 2023 and 2022, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders for the period because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2023	2022
Convertible preferred stock (as converted to common stock)	6,825,483	6,825,483
Stock options to purchase common stock	1,875,932	1,556,819
Unvested restricted common stock	35,494	312,826
SAFEs (as converted to common stock)	2,842,954	—
	11,579,863	8,695,128

13. RELATED PARTY TRANSACTIONS

Scientific Advisory Board Member

One of the Company's co-founders is a member of the Company's Scientific Advisory Board ("SAB") and meets the criteria of a related party. For each of the years ended December 31, 2023 and 2022, the Company paid the SAB member fees in the amount of $0.1 million for advisory services provided. There were no amounts due to or from this related party as of December 31, 2023 or 2022.

License Agreement

Harvard College ("Harvard") meets the criteria of a related party resulting from the Company's co-founders' employment as professors in the Harvard Department of Molecular Pharmacology. Additionally, both co-founders are members of the Board and one co-founder is a major shareholder in the Company. Core intellectual property utilized by the Company is licensed from Harvard in exchange for license fees, future milestones and royalties, and equity in the Company in the form of common stock.

For the years ended December 31, 2023 and 2022, the Company paid Harvard $ 0.2 and $0.1 million in cash considerations, respectively (see Note 6). Accounts payable to Harvard amounted to less than $0.1 million and zero as of December 31, 2023 and 2022.

Sublease Agreement

The Company entered into a sublease agreement with a company controlled by the Company's co-founders. The sublease agreement was terminated in July 2022. For the years ended December 31, 2023 and 2022, the Company received cash considerations and recorded sublease income in the amount of zero and $0.3 million, respectively (see Note 7). There were no amounts due to or from this related party as of December 31, 2023 or 2022.

Issuance of Preferred Stock

On September 7, 2022, the Company issued 2,237,846 shares of Series A-1 Preferred Stock and 437,282 shares of Series A-2 Preferred Stock to related parties (see Note 8). These related parties include

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

key members of management, members of the Board, and certain of the Chief Executive Officer's family members.

SAFE Agreements

From October through December 2023, the Company entered into multiple SAFE agreements with certain existing investors and received $34.1 million representing the purchase amount. All investors are considered related parties of the Company.

The SAFE agreements have no maturity date, bear no interest, and will be redeemed by the Company upon the occurrence of a triggering event, including an equity financing, public listing transaction, change of control or dissolution. Equity financing is defined as a sale of the Company's preferred stock at a fixed valuation. In the event of an equity financing, the SAFEs will automatically be redeemed through delivery of a variable number of shares of Company preferred stock equal to the SAFE purchase amount divided by the preferred stock per share issuance price in the equity financing. In the case of SAFE agreements issued in October 2023, a 10% discount will be applied to the per share issuance price in the equity financing in determining the number of shares of Company preferred stock issued to the investors upon redemption.

Public listing transaction is defined as a direct listing, initial public offering ("IPO") of the Company's common stock, a reverse merger or a SPAC transaction. In any of these instances, the SAFEs will automatically be redeemed through delivery of a variable number of shares of the Company's common stock determined by dividing the SAFE purchase amount by the offering or conversion price in the respective transaction. In the event of a change in control transaction, the SAFE investors will be entitled to receive a portion of the transaction proceeds equal to the greater of the SAFE purchase amount, payable in cash or other consideration, or the amount payable on the number of shares of the Company's common stock equal to the SAFE purchase amount divided by the change in control conversion price, as defined in the agreement. In a dissolution event, the investor will automatically be entitled to receive a portion of the dissolution purchase amount equal to the SAFE proceeds.

The SAFEs are not in the legal form of an outstanding share or debt and therefore were evaluated under ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480"). Because the SAFEs allow for redemption based upon certain triggering events that are outside the Company's control, the SAFEs were classified as liabilities pursuant to ASC 480 and initially measured at their fair value upon issuance. In addition, until redemption, the SAFEs are measured at fair value on a recurring basis with subsequent changes in fair value recoded in the Company's statement of operations and comprehensive loss.

The SAFEs issued in October 2023 were recognized at their fair value of $ 10.4 million on the issuance date. The issuance date fair value exceeded the proceeds received by approximately $0.3 million and this difference was recognized as loss at issuance in the consolidated statement of operations and comprehensive loss. The SAFEs issued in December 2023 were recognized at their fair value of approximately $21.4 million on the issuance date. The proceeds received exceeded the issuance date fair value by approximately $2.6 million and this difference was recognized as a capital contribution from the related party investors in additional paid-in capital in the consolidated statement of stockholders' deficit. The subsequent measurement to the total SAFE liabilities fair value of $30.5 million is recorded in the consolidated statement of operations and comprehensive loss.

14. SUBSEQUENT EVENTS

Management has evaluated subsequent events through March 25, 2024, which is the date the consolidated financial statements were available to be issued and April 12, 2024, which is the date the consolidated financial statements were available to be re-issued, to ensure that these consolidated financial

statements include appropriate disclosure of events both recognized in the consolidated financial statements and events which occurred but were not recognized in the consolidated financial statements.

Proposed Merger with AVROBIO

As discussed in Note 1, on January 30, 2024, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with AVROBIO, pursuant to which the subsidiaries of AVROBIO will merge with and into the Company, with the Company continuing as a wholly owned subsidiary of the surviving corporation of the merger (the "Merger"). The Merger is expected to be accounted for as a reverse recapitalization in accordance with GAAP, with AVROBIO treated as the acquired company for financial reporting purposes, and the Company treated as the accounting acquirer.

Subscription Agreement

Concurrently with the Merger Agreement, certain parties will enter into certain subscription agreements (the "Subscription Agreements") with the Company to purchase, prior to the consummation of the merger, approximately 7,790,903 shares of the Company's common stock for an aggregate purchase price of approximately $96.6 million. Shares of the Company's common stock issued pursuant to the Subscription Agreements will be converted into shares of AVROBIO common stock at the closing of the merger based on an exchange ratio, pursuant to the Merger Agreement.

Up to 2,969,583 Shares of Common Stock

PROSPECTUS

, 2024

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following is an estimate of the expenses (all of which are to be paid by the registrant) that we may incur in connection with the securities being registered hereby.

	Amount
SEC registration fee	$ 7,350.47
Legal fees and expenses	150,000.00
Accounting fees and expenses	80,000
Miscellaneous	95,000
Total	$ 332,350.47

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

Section 102(b)(7) of the DGCL provides that a corporation's certificate of incorporation may contain a provision eliminating or limiting the personal liability of a director or officer to the corporation or its stockholders for monetary damages for breach of fiduciary duty, provided that such provision shall not eliminate or limit the liability (i) for any breach of the duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (iii) under Section 174 of the DGCL, or (iv) for any transaction from which an improper personal benefit was derived. The Bylaws provide that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. The Bylaws provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal

therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We also maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Under the Merger Agreement, from the effective time of the Merger through the sixth anniversary of the date of the effective time, we agreed to indemnify and hold harmless each person who was, as of January 30, 2024, the signing date of the Merger Agreement, or had been at any time prior, or who becomes prior to the effective time of the Merger, a director or officer of our company or Legacy Tectonic, against all claims, losses, liabilities, damages, judgments, fines and reasonable fees, costs and expenses, including attorneys' fees and disbursements, pertaining to claims arising out of the fact that such person was a director or officer of our company or Legacy Tectonic, at or prior to the effective time of the merger, to the fullest extent permitted under the DGCL.

Under the Merger Agreement, we agreed not to amend, modify or repeal provisions in the Fourth Amended and Restated Certificate of Incorporation and the Amended and Restated Bylaws that were in effect as of January 30, 2024, the date of the Merger Agreement, with respect to indemnification, advancement of expenses and exculpation of our present and former directors and officers for a period of six years from the effective time of the Merger in a manner that would adversely affect the rights of such individuals who at the effective time of the Merger were our officers or directors.

In connection with the Merger, we purchased an insurance policy in effect for six years from the effective time of the Merger, providing no less favorable coverage as the current directors' and officers' liability insurance policies maintained by us with respect to any actual or alleged error, misstatement, misleading statement, act, omission, neglect, breach of duty or any matter claimed against our current and former officers and directors.

Item 15. Recent Sales of Unregistered Securities.

We have sold the securities described below within the past three years which were not registered under the Securities Act. All of the sales listed below were made pursuant to an exemption from registration afforded by Section 4(a)(2) of the Securities Act (and Regulation D thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act.

Shares of Legacy Tectonic stock have not been adjusted to reflect the exchange for our common stock in the Merger and reflect actual shares issued by Legacy Tectonic.

In March 2021, Legacy Tectonic (i) issued and sold to certain investors 2,883,654 shares of its Series A-1 Preferred Stock and Series A-2 Preferred Stock at a purchase price of $13.1876 per share for an aggregate

purchase price of $38,028,475.61, (ii) issued 696,516 shares of its Series A-3 Preferred Stock upon the conversion of certain outstanding convertible notes at a conversion price of $10.55008 per share and (iii) issued 361,659 shares of its Series A-4 Preferred Stock upon the conversion of certain outstanding convertible notes at a conversion price of $11.20946 per share. In June 2022, the Legacy Tectonic Board determined that Legacy Tectonic had achieved the milestone events pursuant to the terms of its Series A Preferred Stock Purchase Agreement and issued and sold to certain investors (i) an aggregate additional 2,450,163 shares of Legacy Tectonic's Series A-1 Preferred Stock, and (ii) an additional 437,282 shares of Legacy Tectonic's Series A-2 Preferred Stock in a subsequent closing, at a purchase price of $13.1876 per share for an aggregate purchase price of $38,028,475.61.

In connection with the Merger, Legacy Tectonic entered into a Subscription Agreement on January 30, 2024 with certain investors to consummate the Pre-Closing Financing. Pursuant to the Subscription Agreement, the investors agreed to purchase an aggregate of 7,790,889 shares of Legacy Tectonic common stock, at a price of $12.39908 per share, for aggregate gross proceeds of approximately $96.6 million. In addition, in connection with the closing of the Merger, Legacy Tectonic's outstanding SAFEs converted into 2,752,216 shares of Legacy Tectonic common stock at a conversion price of $12.39908 per share. The aggregate purchase price between the Pre-Closing Financing and the SAFEs was approximately $130.7 million.

Item 16. Exhibits

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File No	Exhibit	Filing Date	
2.1	Agreement and Plan of Merger and Reorganization, dated as of January 30, 2024, by and among AVROBIO, Inc., Alpine Merger Subsidiary, Inc. and Tectonic Therapeutic, Inc.	8-K	001-38537	2.1	1/30/2024	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated June 20, 2024 (Stock Split Amendment).	8-K	001-38537	3.1	6/20/2024	
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated June 20, 2024 (Exculpation Amendment).	8-K	001-38537	3.2	6/20/2024	
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the Company, dated June 20, 2024 (Name Change Amendment).	8-K	001-38537	3.3	6/20/2024	
3.5	Amended and Restated Bylaws, as currently in effect.	8-K	001-38537	3.2	6/25/2018	
5.1	Opinion of Cooley LLP.					X
10.1	Contingent Value Rights Agreement dated June 20, 2024, by and between Tectonic Therapeutic, Inc. and Computershare Trust Company, LLC.	8-K	001-38537	10.1	6/20/2024	
10.2#	Form of Indemnification Agreement between Tectonic Therapeutic, Inc. and each of its directors and executive officers.	8-K	001-38537	10.2	6/20/2024	

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File No	Exhibit	Filing Date	
10.3	Subscription Agreement, dated as of January 29, 2024, by and among Tectonic and the purchasers thereunder.	8-K	001-38537	10.3	6/20/2024	
10.4#	2019 Equity Incentive Plan of Tectonic Therapeutic, Inc., and form of award agreements thereunder.	S-4	333-277048	10.42	6/20/2024	
10.5#	Tectonic Therapeutic, Inc. 2024 Equity Incentive Plan.	8-K	001-38537	10.6	6/20/2024	
10.6#	Forms of Option Grant Notice, Option Agreement and Notice of Exercise under Tectonic Therapeutic, Inc. 2024 Equity Incentive Plan.	8-K	001-38537	10.7	6/20/2024	
10.7#	Tectonic Therapeutic, Inc. 2024 Employee Stock Purchase Plan.	8-K	001-38537	10.8	6/20/2024	
10.8#	Form of Tectonic Support Agreement.	S-4	333-277048	10.30	4/29/2024	
10.9#	Form of Lock-Up Agreement.	S-4	333-277048	10.31	4/29/2024	
10.10†	License Agreement, dated February 10, 2022, by and between Tectonic Therapeutic, Inc. and President and Fellows of Harvard College.	S-4	333-277048	10.35	3/26/2024	
10.11†	Master Agreement for Early Phase Clinical Services, dated October 23, 2023, by and between Tectonic Therapeutic, Inc. and ARENSIA Exploratory Medicine GmbH.	S-4	333-277048	10.36	3/26/2024	
10.12†	Master Contract Services Agreement, dated October 17, 2023, by and between Tectonic Therapeutic, Inc. and QPS Holdings, LLC.	S-4	333-277048	10.37	3/26/2024	
10.13†	Master Contract Services Agreement, dated February 16, 2022, by and between Tectonic Therapeutic, Inc. and ITR LABORATORIES CANADA INC.	S-4	333-277048	10.38	3/26/2024	
10.14†	Development and Manufacturing Services Agreement, dated May 6, 2022, by and between Tectonic Therapeutic, Inc. and WuXi Biologics (Hong Kong) Limited.	S-4	333-277048	10.39	3/26/2024	
10.15†	Master Clinical Contract Services Agreement, dated March 6, 2023, by and between Tectonic Therapeutic, Inc. and Novotech (Australia) Pty Limited CAN.	S-4	333-277048	10.40	3/26/2024	
10.16#	Amended and Restated Employment Agreement, dated as of June 20, 2024, by and between Tectonic Therapeutic, Inc. and Alise Reicin, M.D.	8-K	001-38537	10.4	6/20/2024	

Table of Contents

Exhibit Number	Description	Incorporation by Reference				Filed Herewith
		Form	File No	Exhibit	Filing Date	
10.17#	Consulting Agreement, dated September 25, 2019, by and between Tectonic Therapeutic, Inc. and Andrew Kruse.	S-4	333-277048	10.41	3/26/2024	
10.18#	Offer Letter dated June 16, 2021, by and between Tectonic Therapeutic, Inc. and Marcella Ruddy.	S-4	333-277048	10.43	4/15/2024	
10.19#	Offer Letter dated July 29, 2019, by and between Tectonic Therapeutic, Inc. and Christian Cortis.	S-4	333-277048	10.44	4/15/2024	
10.20#	Form of Severance Plan and Form of Participation Agreement of Tectonic Therapeutic, Inc.	S-4	333-277048	10.47	4/15/2024	
16.1	Letter from Ernst & Young LLP dated June 20, 2024.	8-K	001-38537	16.1	6/20/2024	
21.1	List of Subsidiaries					X
23.1	Consent of Deloitte & Touche LLP, independent registered public accounting firm of Tectonic Therapeutic, Inc.					X
23.2	Consent of Ernst & Young LLP, independent registered public accounting firm of AVROBIO, Inc.					X
23.3	Consent of Cooley LLP (included in Exhibit 5.1 hereto).					X
24.1	Power of Attorney (included on signature page).					X
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					
107	Filing Fee Table					X

† Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) is the type of information that the registrant treats as private or confidential.

Indicates a management contract or any compensatory plan, contract or arrangement.

* Annexes, schedules and exhibits have been omitted pursuant to Item 601(b)(2) or 601(a)(5), as applicable, of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission (the "Commission") pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, *however*, that: Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the

initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Watertown, Commonwealth of Massachusetts, on July 19, 2024.

TECTONIC THERAPEUTIC, INC.

/s/ Alise Reicin
Name: Alise Reicin
Title: Chief Executive Officer, President and Director

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENT, that each individual whose signature appears below hereby constitutes and appoints Alise Reicin and Daniel Lochner, as such person's true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Alise Reicin Alise Reicin	Chief Executive Officer, President and Director *Principal Executive Officer*	July 19, 2024
/s/ Daniel Lochner Daniel Lochner	Chief Financial Officer *Principal Financial Officer and Principal Accounting Officer*	July 19, 2024
/s/ Terrance McGuire Terrance McGuire	Director	July 19, 2024
/s/ Stefan Vitorovic Stefan Vitorovic	Director	July 19, 2024
/s/ Timothy A. Springer Timothy A. Springer	Director	July 19, 2024
/s/ Praveen Tipirneni Praveen Tipirneni	Director	July 19, 2024
/s/ Phillip B. Donenberg Phillip B. Donenberg	Director	July 19, 2024

Cooley

Marc A. Recht
T: +1 617 937 2316
mrecht@cooley.com

July 19, 2024

Tectonic Therapeutic, Inc.
490 Arsenal Way, Suite 210
Watertown, MA 02472

Re: Tectonic Therapeutic, Inc.

Ladies and Gentlemen:

We have acted as counsel to Tectonic Therapeutic, Inc., (f/k/a AVROBIO, Inc.) a Delaware corporation (the " ***Company***"), in connection with the filing by the Company of a Registration Statement on Form S-1 (the "***Registration Statement***") with the Securities and Exchange Commission (the "***Commission***"), including the prospectus included in the Registration Statement (the "***Prospectus***"), covering the registration for resale of up to 2,969,583 shares (the "***Shares***") of the Company's common stock, par value $0.0001 per share, issued pursuant to that certain Agreement and Plan of Merger and Reorganization by and among AVROBIO, Inc., Alpine Merger Subsidiary, Inc. and Tectonic Therapeutic, Inc. (currently known as Tectonic Operating Company, Inc.) ("***Legacy Tectonic***") dated January 30, 2024 (the "***Merger Agreement***"). The Shares were received in exchange for shares of Legacy Tectonic issued to investors in a private placement pursuant to a subscription agreement dated January 30, 2024 (the "***Subscription Agreement***"), by and between Legacy Tectonic and the investors named therein.

In connection with this opinion, we have examined and relied upon (a) the Registration Statement and the Prospectus, (b) the Company's certificate of incorporation and bylaws, each as currently in effect, (c) the Merger Agreement, (d) the Subscription Agreement and (e) such other records, documents, certificates, memoranda and instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures; the authenticity of all documents submitted to us as originals; the conformity to originals of all documents submitted to us as copies; the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

Our opinion herein is expressed solely with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares are validly issued, fully paid and nonassessable.

Our opinion is limited to the matters expressly set forth in this letter, and no opinion has been or should be implied, or may be inferred, beyond the matters expressly stated. This opinion speaks only as to law and facts in effect or existing as of the date hereof, and we have no obligation or responsibility to update or supplement this letter to reflect any facts or circumstances that may hereafter come to our attention or any changes in law that may hereafter occur.

We hereby consent to the reference to our firm under the caption “Legal Matters” in the Prospectus and to the filing of this opinion as an exhibit to the Registration Statement. In giving such consents, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended, or the rules and regulations of the Commission thereunder.

Sincerely,

COOLEY LLP

By: /s/ Marc A. Recht
Marc A. Recht

Exhibit 21.1

List of Subsidiaries

Subsidiary	Jurisdiction of incorporation or organization
AVROBIO Inc.	Ontario, Canada
AVROBIO Australia Pty Ltd	Australia
AVROBIO Securities Corporation	Massachusetts
Tectonic Therapeutic Pty Ltd.	Australia
Tectonic Therapeutic Securities Corp.	Massachusetts
Tectonic Operating Company, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement on Form S-1 of our report dated April 12, 2024, relating to the financial statements of Tectonic Therapeutic, Inc. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
July 19, 2024

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated March 14, 2024, with respect to the consolidated financial statements of AVROBIO, Inc. included in the Registration Statement (Form S-1) and related Prospectus of Tectonic Therapeutic, Inc. for the registration of up to 2,969,583 shares of its common stock.

/s/ Ernst & Young LLP

Boston, Massachusetts
July 19, 2024

Exhibit 107

Calculation of Filing Fee Tables

S-1
(Form Type)

Tectonic Therapeutic, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Share(2)	Maximum Aggregate Offering Price(2)	Fee Rate	Amount of Registration Fee
Newly Registered Securities								
Fees to Be Paid	Equity	Common stock, $0.0001 par value per share	457(c)	2,969,583(1)	$16.77	$49,799,906.61	$0.00014760	$7,350.47
	Total Offering Amounts					$49,799,906.61		$7,350.47
	Total Fees Previously Paid							–
	Total Fee Offsets							–
	Net Fees Due							$7,350.47

(1) Represents the number of shares of common stock, par value $0.0001 per share ("Common Stock") of Tectonic Therapeutic, Inc. that will be offered for resale by the selling stockholders named in this registration statement (the "Registration Statement"). Pursuant to Rule 416(a) of the Securities Act of 1933, as amended (the "Securities Act"), the Registration Statement shall also cover any additional shares of Common Stock that become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without receipt of consideration that increases the number of outstanding shares of Common Stock.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(c) under the Securities Act, based on the average of the high and low sales price of the Common Stock as reported on the Nasdaq Global Market on July 12, 2024, a date within five business days prior to the filing of the Registration Statement.