UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38537

TECTONIC THERAPEUTIC, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**81-0710585**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
490 Arsenal Way, Suite 200	
Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (339) 666-3320

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	TECX	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market LLC on June 30, 2025, was $232.0 million.

As of February 16, 2026, the registrant had 18,776,626 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2026 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2025.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report on Form 10-K are statements that could be deemed forward-looking statements reflecting the current beliefs and expectations of management with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. These statements are often identified by the use of words such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "if," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "until," "will," "would," and similar expressions or variations. Forward-looking statements in this Annual Report on Form 10-K 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, TX2100 and any other product candidates, and our anticipated milestones and timing therefor;
- the benefits that may be derived from any of our future products, if approved, or the commercial or market opportunity with respect to any of our future products, if approved;
- 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.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in "Risk Factors" and elsewhere in this Annual Report on Form 10-K as well as our other filings made with the Securities and Exchange Commission ("SEC"). Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

TRADEMARKS

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 Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K 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.

PART I

Item 1. Business.

The business and the industry in which Tectonic Therapeutic, Inc. (inclusive of its consolidated subsidiaries, "Tectonic," the "Company," "we," "us," or "our") operates is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by Tectonic.

Overview

We are a clinical-stage 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™ (GPCRs Engineered for Optimal Discovery) with the aim of addressing these challenges and enabling 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, and where new medicines have the potential to improve patients' quality of life.

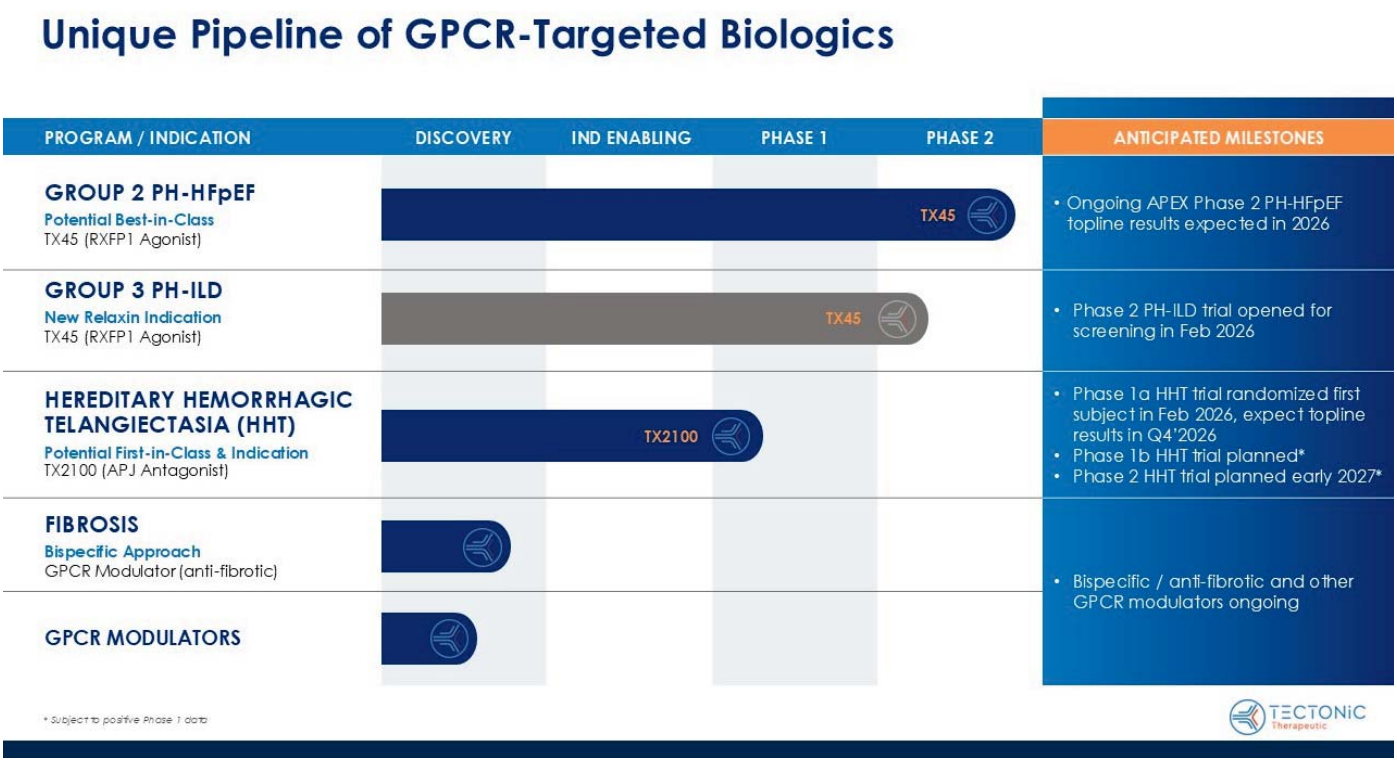
GPCRs are receptor molecules found on the surface of cells that act as sensors for various extracellular stimuli to enable communication between cells and their environment. These molecules regulate diverse aspects of human biology, including blood pressure, glucose metabolism, neuronal signaling, and immune surveillance. There are over 800 human genes encoding GPCRs, underscoring the extent to which human biology has relied on this molecular system for physiological control. The breadth of effects controlled by GPCRs is 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 in order 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 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 in 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.

Our Development and Pipeline Programs

The following chart summarizes our development programs and other pipeline programs. In 2026, we expect topline results from our ongoing TX45 APEX Phase 2 clinical trial in Group 2 PH-HFpEF patients as well as topline results from our TX2100 Phase 1a clinical trial in healthy volunteers.



TX45: Our Fc-Relaxin Fusion Molecule for the Treatment of Group 2 PH-HFpEF and Group 3 PH-ILD

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 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. Scientists have 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 targeting Fc-relaxin has been challenging, primarily because of relaxin's very short half-life.

We believe TX45's pharmacological profile, which is 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 PH-HFpEF, as the initial disease in which to interrogate the therapeutic potential of relaxin. We hypothesize that 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. Our clinical trials are ongoing to confirm this hypothesis.

Group 2 PH is a subtype of PH that develops secondary to left heart disease ("LHD"). This is a common, chronic, life-threatening condition with complex causality for which there are presently no FDA-approved medications. PH-HFpEF is characterized by declining cardiac function, fibrotic tissue remodeling in the heart, and in some patients, fibrotic remodeling in the pulmonary vasculature. We have elected to prioritize development of TX45 in PH-HFpEF because of the high unmet medical need in this population and the specific physiological actions of relaxin that suggest it could address the key pathophysiology of the disease. 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 ongoing to evaluate the hypothesis that relaxin could provide efficacy in patients with PH-HFpEF. Beyond PH-HFpEF, we believe there are

additional areas where TX45 could provide benefit, such as PH with heart failure with reduced ejection fraction ("PH-HFrEF"), as well as diseases resulting in chronic deterioration of lung and/or kidney function due to vasoconstriction and fibrotic remodeling.

TX45 may also provide benefit in Group 3 PH that is associated with interstitial lung disease ("PH-ILD"). ILDs include a range of pulmonary disorders, each with varying degrees of interstitial inflammation, fibrosis, or both. When ILD is complicated by PH, patients have more severe symptoms, reduced exercise capacity, an increased need for oxygen supplementation, and a significant worsening in overall prognosis. While many PAH-specific medications failed to show benefit in PH-ILD, more recent data supported the use of inhaled treprostinils (Tyvaso, Yutrepia), which are rapidly becoming the standard of care for this disorder. Inhaled treprostinils are not curative of PH-ILD and additional therapies are needed for this disorder. A clinical trial is planned to evaluate whether TX45 is beneficial in PH-ILD.

TX45 Clinical Results and Development Plans

Completed Phase 1a Single Ascending Dose Trial (TX000045-001)

TX000045-001 was a randomized, placebo-controlled, double-blind single ascending dose trial in healthy volunteers, which was completed in the third quarter of 2024. In September 2024, we announced favorable results from this trial evaluating safety, tolerability, and pharmacokinetic ("PK") and pharmacodynamic ("PD") properties for TX45. In this trial, TX45 was well-tolerated after single intravenous ("IV") doses ranging from 0.3 mg/kg to 3 mg/kg and subcutaneous ("SC") doses ranging from 150 mg to 600 mg.

The PK profile revealed dose-proportional kinetics and a half-life of 14–20 days. The PD response of TX45 on renal plasma flow ("RPF") was assessed at multiple time points post dose for all dose cohorts. From these PK/PD measurements, we developed a robust exposure-response Emax model to enable dose selection for our Phase 2 trial. We found the Emax effect of TX45 on RPF to be a 33% increase, consistent with the reported effect of other relaxin compounds, such as serelaxin.

Based on our exposure-response model, we selected TX45 doses for our Phase 2 trial as follows: 300 mg SC every four weeks, predicted to provide steady-state trough exposure of approximately 2.6 μg/mL and near-maximal effect on RPF at trough, and 300 mg SC every two weeks, predicted to provide a trough exposure of approximately 8.7 μg/mL with maximal pharmacodynamic effects throughout the dosing interval. There was no evidence of immunogenicity or anti-drug antibodies in this Phase 1a trial. This data was used to develop the exposure-response model that enabled dose selection for the APEX Phase 2 clinical trial.

Completed Phase 1b Trial (TX000045-002)

TX000045-002 was an open-label, single-dose Phase 1b trial in patients with PH associated with heart failure, designed to evaluate the safety, tolerability, and acute hemodynamic effects of TX45, as assessed by right heart catheterization ("RHC").

Part A of this trial enrolled 19 patients with PH-HFpEF, including both combined pre- and post-capillary pulmonary hypertension ("CpcPH") and isolated post-capillary pulmonary hypertension ("IpcPH"). The doses of TX45 administered were 0.3 mg/kg IV, 1 mg/kg IV, and 3 mg/kg IV. The trial evaluated safety and tolerability, as well as changes from baseline in hemodynamic parameters including pulmonary capillary wedge pressure ("PCWP"), pulmonary vascular resistance ("PVR"), mean pulmonary arterial pressure ("mPAP"), cardiac output ("CO"), systemic vascular resistance ("SVR"), and additional hemodynamic measures. Notably, exposures over the first eight hours after dosing were anticipated to be within the therapeutic range for all doses tested; therefore, it was prespecified that efficacy analyses would pool patient data across doses.

In May 2025, we announced the complete results from Part A, confirming the tolerability and hemodynamic effects of TX45 previously reported in the interim data in January 2025. TX45 was well-tolerated in subjects with PH-HFpEF, with no serious or severe adverse events. In the overall study population, TX45 achieved a 19.0% reduction in PCWP, an endpoint reported to correlate with exercise capacity, morbidity, and mortality in patients with heart failure, and an 18.5% improvement in CO. In the subpopulation with CpcPH, who have an elevated PVR and more severe disease, TX45 demonstrated >30% reduction in PVR, which, along with PCWP, correlates with exercise capacity and mortality in this patient population.

In October 2025, we announced topline results from Part B of the Phase 1b hemodynamic clinical trial of TX45 in subjects with Group 2 PH in heart failure with reduced ejection fraction ("HFrEF"). Part B had a similar design as Phase 1b Part A, assessing hemodynamic effects of TX45 in subjects with PH-HFrEF. Based on the topline results, TX45 was well-tolerated, with no serious or severe adverse events. In the overall study population, TX45 achieved a 29.2% reduction in PCWP and a 17.3% improvement in CO. In the subpopulation with CpcPH, who have elevated PVR and more severe disease, TX45 demonstrated a 19.7% reduction in PVR in patients with a PVR ≥3 Wood Units ("WU") and a 10.3% reduction in patients with a PVR ≥2 WU.

Ongoing Phase 2 Proof-of-Concept ("POC"), Randomized, Placebo-Controlled, Double-Blind Trial in PH-HFpEF (TX000045-003 – APEX Trial)

Our ongoing Phase 2 APEX trial in patients with PH-HFpEF, enriched for CpcPH, is a global, 24-week, placebo-controlled study designed to evaluate the safety and efficacy of TX45 administered SC. Patients are being randomized to receive TX45 or placebo for the duration of the trial, with two TX45 dosing regimens: 300 mg SC every two weeks or 300 mg SC once monthly. The first subject was dosed in October 2024.

Prior to dosing, RHC is performed to determine baseline hemodynamics. After 24 weeks of treatment, patients undergo a second RHC. The primary endpoint is change from baseline in PVR in patients with CpcPH, with approximately 70% of subjects expected to meet this enrichment criterion. The key secondary endpoint is change from baseline in PCWP in all subjects. Additional endpoints include change from baseline in six-minute walk distance ("6MWD"), Kansas City Cardiomyopathy Questionnaire ("KCCQ") score, CO, mPAP, SVR, stroke volume, and biomarkers such as N-terminal pro b-type natriuretic peptide ("NT-proBNP"). Changes in relevant echocardiographic endpoints will also be explored.

We currently expect to enroll approximately 180 subjects and report topline results in 2026. This trial is designed to evaluate efficacy in both the enriched CpcPH population and the broader PH-HFpEF population. An independent data management committee reviewed unblinded data when 40% of total study patient years exposure had accrued. The independent committee reviewed safety labs, adverse events as well as right heart catheterization data and recommended no changes to the trial.

Group 2 PH-HFpEF Anticipated Pivotal Development Pathway

Subject to Phase 2 results and feedback from an End-of-Phase 2 ("EOP2") 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, along with a long-term, open-label extension trial for safety evaluation. Based on historical precedent across multiple PH subtypes and pre-IND consultation with the FDA regarding requirements for approval in Group 2 PH with HFpEF, we believe that achieving a clinically significant change in a functional endpoint, such as 6MWD, could be sufficient for approval. Secondary endpoints may include change from baseline to week 24 in KCCQ-12 score, percentage of subjects improving in WHO functional class, time to first occurrence of a clinical worsening event or death, and changes in relevant echocardiographic and biomarker endpoints such as NT-proBNP. At this time, assessment of TX45's impact on long-term cardiovascular outcomes such as hospital and death is not anticipated to be required for approval. Commercialization in the United States and other countries will be contingent on regulatory approval and confirmation that studies were conducted according to accepted guidance and demonstrate a positive benefit-risk profile.

Planned Phase 2 Open-Label, Repeat Dose Trial in Group 3 PH-ILD

In February 2026, the first site was activated and opened for screening in the 16-week, open-label, repeat dose, Phase 2 clinical trial to evaluate TX45's safety and hemodynamic effects in up to 25 subjects with pulmonary hypertension associated with interstitial lung disease ("PH-ILD"), classified as Group 3 pulmonary hypertension. PH-ILD is an orphan disease with limited treatment options and a high mortality rate.

We believe TX45's mechanism is well suited to PH-ILD's disease pathophysiology because of its pulmonary vasodilation, anti-inflammatory, remodeling, and anti-fibrotic activity. In patients with PH-ILD, elevation in pulmonary vascular resistance ("PVR") and mPAP have been associated with increased mortality. In the Phase 1b trial in Group 2 PH patients, both CpcPH HFpEF and CpcPH HFrEF patients treated with TX45 had meaningful reductions in mPAP and PVR as well as improvements in other hemodynamic endpoints. Hence we will test whether the benefits on pulmonary hemodynamics observed in Group 2 PH patients will also be observed in Group 3 PH-ILD patients. The TX45 PH-ILD Phase 2 trial will initiate a dose of 300 mg TX45 administered SC every four weeks, with the primary efficacy endpoint being change from baseline in PVR at Week 16.

TX2100: Our APJ VHH-Fc fusion antagonist antibody for Hereditary Hemorrhagic Telangiectasia

Our second product candidate, TX2100, is a VHH-Fc fusion antagonist antibody that binds to the APJ receptor (also known as the apelin receptor; APLNR), a GPCR that mediates signaling by the pro-angiogenic peptide hormone apelin. TX2100 is under development as a potential treatment for hereditary hemorrhagic telangiectasia ("HHT"), the second-most common genetic bleeding disorder affecting an estimated 75,000 people in the United States. In HHT, abnormal blood vessel formations result in telangiectasias and arteriovenous malformations ("AVMs"), which are prone to spontaneous and severe bleeding that can be life-threatening. There are currently no approved therapies for HHT.

TX2100 is a VHH-Fc fusion antagonist antibody that binds to APJ. The Fc portion of TX2100 was modified to reduce Fc receptor activation and increase neonatal Fc receptor ("FcRn") binding, extending the molecule's half-life. Mutations in BMP9, BMP10, Endoglin, ALK1, and SMAD4 proteins, all members of a common signaling pathway, have been identified in HHT patients. Preclinical studies show that knockout or inhibition of these pathway members increases expression of factors driving angiogenesis and abnormal blood vessel formation, recapitulating the clinical situation. In HHT animal models, apelin has been reported to be upregulated and associated with an angiogenic gene expression signature. By blocking APJ signaling, we anticipate the potential for decreased bleeding resulting from abnormal angiogenesis.

APJ represents a differentiated approach for the treatment of HHT. APJ is a selective anti-angiogenic target that is primarily expressed in endothelial cells and is generally quiescent under normal physiological conditions, but is upregulated during pathologic angiogenesis, including in HHT preclinical models. TX2100 is designed as a selective APJ antagonist intended to inhibit disease-associated angiogenic signaling with the goal of providing a more favorable safety profile compared to less selective anti-angiogenic approaches.

Anti-angiogenic agents have demonstrated activity in HHT preclinical models and in patients, and APJ antagonism has shown activity in multiple HHT preclinical models, supporting the continued development of TX2100 for this indication.

TX2100 Preclinical Pharmacology

A rodent surrogate of TX2100 demonstrated reductions in AVM formation, bleeding, and anemia across the neonatal anti-BMP9/10 immunoblocked model and the more severe, adult inducible ALK1 knockout mouse model of HHT, supporting disease-modifying activity through APJ antagonism. TX2100 was further evaluated in non-human primates in IND-enabling GLP toxicology studies, including a 13-week repeat-dose study. In these studies, TX2100 was well tolerated at doses up to 100 mg/kg/week, with no treatment-related or target-related toxicities identified and no effects observed on cardiovascular, respiratory, neurological, renal, metabolic, or hematologic parameters. A formulation supporting subcutaneous dosing has been established, and drug substance and drug product manufacturing under Good Manufacturing Practice have been completed to support initiation of a Phase 1a clinical trial.

TX2100 Clinical Results and Development Plans

In February 2026, we randomized the first subject in the Phase 1a healthy volunteer clinical trial for TX2100, which is a randomized, placebo-controlled, double-blind ascending-dose trial in healthy volunteers. Primary endpoints include safety and tolerability, with secondary endpoints evaluating PK. Assuming adequate safety and PK are established, we plan to initiate Phase 2 efficacy trials, including a randomized, placebo-controlled, double-blind, proof-of-concept trial in moderate to severe HHT patients with frequent epistaxis and anemia in early 2027. The goal of the trial will be to evaluate improvement in epistaxis, anemia, hematological support, and other HHT endpoints. We are also planning a Phase 1b clinical trial to explore the safety and efficacy (epistaxis, anemia, and hematological support) of TX2100 in patients with severe HHT.

GPCR Modulator Bispecific for Fibrosis

Our third development program is aimed at discovering and developing a potential therapy for fibrotic diseases and employs a bispecific format for the construction of a molecule with a differentiated mechanism of action. The strategy leverages two targets-one with previous human POC and one novel target. Both targets are expressed on overlapping cell types with complementary and non-overlapping modes of action that could simultaneously enhance the therapeutic potential over modulating either target alone.

Anticipated Milestones

Over the next few years, we anticipate that several significant milestones could be achieved for our lead assets, TX45 and TX2100. This includes topline results from our TX45 APEX Phase 2 clinical trial in patients with PH-HFpEF expected in 2026, topline results from our TX2100 Phase 1a clinical trial expected in the fourth quarter of 2026, the potential initiation of a TX2100 Phase 1b clinical trial in patients with severe HHT, and plans to initiate a TX2100 Phase 2 clinical trial in patients with moderate to severe HHT in early 2027.

GEODe™ Platform

The GEODe™ platform is our proprietary technology for discovering biologic drugs targeted to GPCRs. The original components of GEODe™, including first-generation yeast library designs and initial yeast display selection protocols, were developed at Harvard Medical School. At that time, protocols were established to detergent-solubilize GPCRs and enable initial Fab (fragment antigen-binding) and VHH (variable domain of heavy-chain-only antibody) library selections.

Over the last several years, we have enhanced all aspects of GEODe™, including second and third-generation yeast library designs, optimized GPCR engineering strategies, and refined yeast display protocols tailored for GPCR antibody discovery. These modifications have improved the success rate of selection campaigns, producing molecules with higher affinity, potency, and superior biophysical properties compared to earlier hits.

To date, only 12% of the more than 800 human GPCRs have been translated into targets for approved therapeutics, with biologics representing only three of those approvals. GPCRs remain challenging targets for biologics due to their dynamic structures, variable expression in the plasma membrane, and difficulty maintaining functional conformations outside their native lipid microenvironment. Most approved GPCR-targeted drugs are small molecules, largely confined to six subfamilies with small-

molecule natural ligands. Maintaining target engagement and selectivity for small molecules is challenging, particularly for receptors with larger, more complex binding sites or overlapping ligands.
GEODe™ was specifically developed to address these challenges through:

- GPCR protein engineering strategies that stabilize pharmacologically relevant receptor conformations, increase cell surface expression, and enable large-scale purification and formulation in the correct conformation for naïve antibody selection;
- An optimized yeast display platform with highly diverse Fab and VHH libraries designed specifically for GPCRs; and
- Structure-guided protein engineering strategies to identify optimal GPCR-targeted biologics.

Our team has continually refined the platform to improve the quality of molecules emerging from naïve selections and affinity maturation. Enhancements include improved receptor designs, updated naive and affinity maturation libraries, and advanced yeast display selection protocols. In addition, GEODe™ integrates components to optimize GPCR expression, purification, and stabilization, paired with our protein engineering and structural biology capabilities. While current libraries and selection strategies are producing GPCR-targeted antibodies, we continue to evolve the platform, which we believe will yield even better outcomes in the future.

Collaboration, License and Services Agreements

Harvard Option and License Agreement

In July 2020, Legacy Tectonic (as defined below) 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 Legacy Tectonic 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, Legacy Tectonic 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. As consideration for the License Agreement, we paid Harvard a one-time license fee of $170,000 and issued 227,486 shares of common stock with a fair market value of $0.4 million.

We are 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 we generate 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 we generate from know-how enabled product licenses ("Know-How Enabled Products") and (3) a percentage between 10-20% of all non-royalty income received by us 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 at 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.

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 us 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 us 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.

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.

Our patent portfolio includes three patent families relating to Fc-relaxin fusion protein compositions (including TX45) and methods of use thereof, consisting of two granted U.S. patents, three pending U.S. non-provisional applications, and approximately 40 pending foreign applications. Specifically, we have exclusively in-licensed one patent family from the President and Fellows of Harvard College and wholly own two patent families, relating to Fc-relaxin fusion protein compositions (including TX45) and methods of use thereof. The in-licensed patent family consists of one pending U.S. non-provisional patent application, and approximately 10 pending foreign applications, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than May 2041. The first wholly owned patent family consists of one granted U.S. patent, one pending U.S. non-provisional patent application, and approximately 10 pending foreign applications, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than November 2042, and the second wholly owned patent family consists of one granted U.S. patent, one pending U.S. non-provisional patent application, and approximately 20 pending foreign applications, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than May 2044.

Our patent portfolio also includes a wholly owned patent family relating to apelin receptor binding polypeptides (including TX2100) and methods of use thereof, consisting of one pending U.S. non-provisional application, one pending international (Patent Cooperation Treaty) application, and one pending foreign application, with any patent issuing from these applications having an expected 20-year expiry date of not earlier than August 2045.

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 enforceabilitya of the patent.

Furthermore, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our 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 agreement 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 Our 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 candidates. We currently rely and expect to continue to rely for the foreseeable future, on third-party contract development and manufacturing organizations ("CDMOs") 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 CDMOs to conduct manufacturing activities in compliance with Current Good Manufacturing Practices ("CGMPs") requirements. We have assembled a team of experienced employees and consultants to provide the necessary technical, quality and regulatory oversight over its CDMOs. Currently, we contract with several third-party manufacturers, including WuXi Biologics, to provide biologics development and manufacturing services for our product candidates. In the future, we may engage additional third-party manufacturers to support any clinical trials for TX45 and TX2100 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 our 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 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 or small molecule agonists of relaxin including AstraZeneca, who is currently conducting a Phase 2b trial. To our knowledge, at this time, AstraZeneca is pursuing the Chronic Heart Failure population i.e. both HFpEF and HFrEF with their small molecule relaxin. In the HHT space, Vaderis, Terremoto, and Atavistik has been pursuing development of small molecule AKT inhibitors, Diagonal Therapeutics has been pursuing agonist antibodies, and Alnylam Pharmaceuticals has been pursuing an RNAi reducing plasminogen 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. We are not aware of any competitors targeting APJ.

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 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 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 ensure 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.

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". The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is 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. 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 for 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 (such as physician assistants and nurse 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.

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 Education 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. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In addition to pricing regulations, reforms of regulatory approval frameworks may adversely affect our pricing strategy. The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services ("HHS"), the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

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.

We expect that additional state, federal, and foreign healthcare reform measures will be adopted in the future.

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. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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. In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 ("CTR"), which entered into application on January 31, 2022 repealing and replacing the previous Clinical Trials Directive 2001/20/EC. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. The CTR is intended to harmonize and streamline clinical trial authorizations, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the Regulation, which is directly applicable in all Member States, introduces a streamlined application procedure through a single-entry point, the "EU portal", the Clinical Trials Information System; a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference Member State selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across Member States. This assessment is then submitted to the competent authorities of all concerned Member States in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and Ethics Committees in each concerned Member State. Individual Member States retain the power to authorize the conduct of clinical trials on their territory.

European Union drug review and approval

In the EU, medicinal products can only be commercialized after a related marketing authorization ("MA"), has been granted. To obtain an MA for a product in the EU, an applicant must submit a Marketing Authorization Application ("MAA"), either under a centralized procedure administered by the European Medicines Agency ("EMA"), or one of the procedures administered by the competent authorities of EU Member States (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid throughout the European Economic Area (which is comprised of the 27 EU Member States plus Iceland, Liechtenstein and Norway). Pursuant to

Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs"), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use ("CHMP"), conducts the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures – Human, or CMDh, for review. The subsequent decision of the European Commission is binding on all EU Member States.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU Member States of the MA of a medicinal product by the competent authorities of other EU Member States. The holder of a national MA may submit an application to the competent authority of an EU Member State requesting that this authority recognize the MA delivered by the competent authority of another EU Member State.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU Member State in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU Member States may decide on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing EU Member State within three years after authorization ceases to be valid (the so-called sunset clause).

Accelerated and Alternative Marketing Authorization Mechanisms

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME"), scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the EMA's Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies, are appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

A “conditional” MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted “under exceptional circumstances” where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan (“PIP”), agreed with the EMA’s Pediatric Committee (“PDCO”). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and 10 years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator’s data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU’s regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Orphan Designation

In the EU, Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the

benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Regulation (EC) No 847/2000 sets out further provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product. An application for the designation of a medicinal product as an orphan medicinal product must be submitted at any stage of development of the medicinal product but before filing of an MAA. An MA for an orphan medicinal product may only include indications designated as orphan. For non-orphan indications treated with the same active pharmaceutical ingredient, a separate marketing authorization has to be sought.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Authorization Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU Member States. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk- minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

Other EU Compliance Requirements

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

Much like the Anti-Kickback Statute prohibition in the United States, described above, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and

health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, 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.

Payments made to physicians and other health care professionals in certain EU Member States must be publicly disclosed. Moreover, agreements with health care professionals may require prior notification or approval by the health care professional's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment

Pricing, Coverage and Reimbursement

In the EU, pricing and reimbursement schemes vary widely from country to country. For example, some EU Member States may restrict the range of products for which their national health insurance systems provide reimbursement. Other countries may control the prices of medicinal products for human use or allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations.

In addition, EU Member States often require the completion of additional health technology assessments that compare the cost-effectiveness of a particular product candidate to currently available therapies. This Health Technology Assessment ("HTA") process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. At the EU level, on January 12, 2025, Regulation No 2021/2282 on Health Technology Assessment ("HTA Regulation"), entered into application through a phased implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The HTA Regulation is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. The Regulation establishes a framework for EU‑level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU‑level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

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 December 31, 2025, we had 60 full-time employees, 48 of whom were primarily engaged in research and development activities, and 26 of our employees had an M.D. or Ph.D. degree. None of our employees are 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.

Corporate Information

Our common stock is listed on The Nasdaq Global Market under the symbol "TECX".

We were incorporated under the laws of the State of Delaware in November 2015. Legacy Tectonic was incorporated under the laws of the State of Delaware in June 2019. Following the Merger (as defined below) with Tectonic Operating Company, Inc. (formerly Tectonic Therapeutic, Inc.) on June 20, 2024, we changed our name from AVROBIO, Inc. to Tectonic Therapeutic, Inc.

Our principal executive office is located at 490 Arsenal Way, Suite 200, Watertown, Massachusetts 02472, and our telephone number is (339) 666-3320.

Available Information

Our website is www.tectonictx.com. We may use our website to comply with disclosure obligations under Regulation FD. Therefore, investors should monitor our website in addition to following its press releases, filings with the SEC, public conference calls, and webcasts. The contents of our website are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

Investing in the Company's common stock involves a high degree of risk. Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Annual Report on Form 10-K and in other documents that were filed and will be filed with the SEC, in evaluating the Company and its business. Additional risks and uncertainties not presently known to or that are currently seen as immaterial may also harm Company's business. If any of these risks occur, business, growth prospects, operating results and financial condition could be materially and adversely affected, the trading price of the Company's common stock could decline, and investors could lose part or all of their investment.

Risk Factor Summary

The risk factors summarized below could materially and adversely affect our business, financial condition, operating results and prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock including the following:

- 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, TX2100 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 on and expect to rely on in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture TX45, TX2100 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.

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 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 clinical 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 years ended December 31, 2025 and 2024, we reported a net loss of $74.2 million and $58.0 million, respectively. As of December 31, 2025, we had an accumulated deficit of $222.7 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 candidates, TX45 and TX2100, 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 candidates TX45 and TX2100;
- 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, we have financed our operations primarily through the sale and issuance of common stock, convertible preferred stock, convertible promissory notes and the issuance of SAFEs. We expect our expenses to increase in connection with our ongoing

activities, particularly as we continue our Phase 2 clinical trials of TX45, including the Phase 2 PH-ILD clinical trial, pursue manufacturing and clinical activities for our HHT product candidate, TX2100, and initiate health authority and/or IND enabling safety studies 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.

As of December 31, 2025, we had $253.8 million in cash and cash equivalents. Although we believe that our available cash and cash equivalents will be sufficient to fund our planned operations for at least 12 months following the date of our consolidated financial statements included in this Annual Report on Form 10-K, this belief is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Future capital requirements for TX45, TX2100 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 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 preclinical 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 or royalty 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 in the Middle East, current international trade and regulatory environment uncertainty 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 our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity, debt or royalty 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.

We currently have an effective shelf registration statement on Form S-3 filed with the SEC, which we may use to offer from time to time any combination of debt securities, common stock, preferred stock and warrants up to an aggregate amount of $400 million. Of this amount, we have the ability to sell up to $100 million of additional shares of our common stock to the public through an "at the market offering" pursuant to a sales agreement that we entered into with TD Securities (USA) LLC on July 7, 2025. Any shares of common stock issued in the "at the market offering" will result in dilution to our existing stockholders.

If we raise additional capital through future collaborations, strategic alliances, or third-party licensing arrangements, we may have to relinquish certain valuable rights to our 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 early in our development efforts. If we are unable to advance TX45, TX2100 or any of our other product candidates through clinical development, obtain regulatory approval and ultimately commercialize TX45, TX2100 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 candidates, TX45 and TX2100, 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 a Phase 2 clinical trials and TX2100 has just entered a Phase 1a clinical trial.

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, TX2100, and any future product candidates we develop, which may never occur. TX45, TX2100 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 Phase 1 and Phase 2 clinical trials. 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, TX2100 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 completed the Phase 1a trial in normal healthy volunteers and Phase 1b in patients with Group 2 Pulmonary Hypertension associated with HFrEF and HFpEF for TX45. We may experience delays in our ongoing clinical trials or preclinical studies. Additionally, 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. Furthermore, our product candidate TX2100 has just entered Phase 1a. 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, TX2100 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 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 or positive ethics committee opinions;
- 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;
- failure or approval of competing product candidates currently under investigation for the treatment of similar diseases or conditions, or competing clinical trials for similar product candidates, similar mechanisms of action or targeting patient populations meeting our patient eligibility criteria;
- 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 or ethics committees 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, TX2100 and any other future product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our biologic products, including TX45 and TX2100, 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. For example, during clinical development our product candidates may fail to meet the expected shelf-life due to unforeseen stability or other technical issues at suppliers, which would prevent or delay or limit the scope of clinical development, regulatory approval, and commercialization. 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, TX2100 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 our 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, TX2100 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 or comparable foreign regulatory 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 product candidate TX45 has been generally well tolerated in its preclinical studies, the Phase 1a healthy volunteer trial and our Phase 1b trial in patients with Group 2 PH to date, the results from future preclinical studies and clinical trials, including any of our other product candidates, may identify safety concerns or other undesirable properties of our product candidates.

The results of our ongoing Phase 2 clinical trials of TX45 and/or our ongoing Phase 1a trial of TX2100 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, vary or suspend 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 or a comparable foreign plan;
- 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 our 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 trial sites in Eastern Europe for the Phase 2 TX45 trials, including active sites in the Ukraine, with their proximity to the conflict between Russia and the Ukraine;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards ("IRBs") and positive ethics committee opinions or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in reaching agreement on acceptable terms with clinical trial sites on clinical budgets and/or clinical trial agreements;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- 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 our 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 our 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. In July 2024, we received clearance from the FDA for our IND application for our TX45 program. In January 2026, we received clearance from Australia to commence the Phase 1a study with TX2100. 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 a Phase 1a clinical trial for TX2100 and Phase 2 clinical trials for TX45, 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, such as TX2100, 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 our 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 our product candidates. Even if we believe the data collected from clinical trials of our 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 the United States, Eastern Europe, the European Union, Australia, and New Zealand 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. Similar requirements and considerations apply abroad. 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 our 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 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 our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Similar risks apply abroad as foreign regulatory authorities have comparable authority. 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 or comparable foreign regulatory authorities 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 and foreign regulatory authorities 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. Comparable rules apply in foreign countries. In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics (SmPC), which may require approval by the competent national authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

The holder of a BLA or a foreign marketing authorization 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 our 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 our 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. For instance, the regulatory landscape related to clinical trials in the EU evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR introduces, among other changes, a centralized application system, coordinated review procedures, expanded reporting and increased transparency obligations. The CTR foresaw a three-year transition period that ended on January 30, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a provisional agreement on a comprehensive overhaul of EU pharmaceutical legislation (the “Pharma Package”). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package - comprised of a new directive and regulation to replace existing legislation – aims to modernize the EU framework. The provisional agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year; reshape the incentives regime for orphan medicinal products; and expand the Bolar exemption. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates.

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

We are currently developing TX45 initially for the treatment of Group 2 Pulmonary Hypertension (“PH”) in HFpEF, and for the treatment of PH-ILD, which we anticipate will be regulated as a biological product. Once Phase 1 is complete we anticipate developing TX2100 for HHT 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, our 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 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 our portfolio, 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 our product candidates or misread trends in the biotechnology industry, in particular for our lead product candidates TX45 TX2100, 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.

In the EU, the European Commission grants orphan designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan designation application. Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (3) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan medicinal product designation entitles an applicant to incentives such as fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. The period of market exclusivity is ten years during which the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity may be extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product.

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, TX2100 or any other product candidate, our ability to generate revenues from any such products will depend on our 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 our 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, Group 3 PH-ILD, and Hereditary Hemorrhagic Telangiectasia ("HHT") disorders. Although there are no other companies who have commercialized therapies for Group 2 PH or HHT, there are many other companies, including large biotechnology and pharmaceutical companies, that are developing therapies for these therapeutic areas. For example, Merck and Tenax Therapeutics for the treatment of Group 2 PH and Diagonal Therapeutics, Atavistik, Terremoto, Vaderis Therapeutics and Alnylam Pharmaceuticals for the treatment of HHT. For PH-ILD, United Therapeutics and Liquidia have commercialized therapies, while Insmed, Gossamar, Pulmovant, Halo Biosciences and Foresee Pharmaceuticals are developing therapies for PH-ILD. In addition, in January 2025, Eli Lilly terminated its Phase 2 trial of volenrelaxin, and in February 2026 AstraZenca announced its Phase 2 clinical trial with AZD3427 for Group 2 PH was discontinued due to efficacy, which has affected investor perception of relaxin product candidates in general.

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 our 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 our 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, TX2100 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, TX2100 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, 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 and amendments to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services ("HHS"), the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Such reforms could have an adverse effect on anticipated revenue from TX45, TX2100 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. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In the EU, Regulation (EU) 2021/2282 on Health Technology Assessment, entered into application on January 12, 2025, through a phrased implementation. The Regulation intended to increase cooperation among EU Member States in assessing clinical aspects of health technologies, including new medicinal products. The Regulation establishes a framework for joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The Regulation permits EU member states to use common HTA tools, methodologies and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Each EU member state will, however, remain exclusively competent for assessing non-clinical aspects, such as economic, ethical, and social considerations, and for 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 our 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 (including layoffs) may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, many staff members from the FDA and other agencies have recently been laid off. If a prolonged government shutdown or disruption continues or occurs in the future, 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 and/or disruptions could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our 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 and foreign 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; 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 our 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.

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, because our key manufacturer and supplier for TX45 is located in China. For example, trade tensions between the United States and China have been escalating in recent years. The U.S. government has indicated its intent to adopt a new approach to trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements. For example, in April 2025, the U.S. government announced a new universal baseline tariff of 10%, plus additional country-specific tariffs for select trading partners, on all U.S. imports. The ultimate impact of any tariffs will depend on various factors, including how long such tariffs remain in place, the ultimate levels and application of such tariffs and the extent to which other countries impose retaliatory tariffs. In addition, these newly proposed and imposed tariffs have resulted in threatened and actual retaliatory tariffs against U.S. goods. 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, on December 18, 2025, President Trump signed the National Defense Authorization Act for Fiscal Year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. Government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern" ("BCC"), entering into, extending, or renewing government contracts with an entity that directly or indirectly uses biotechnology equipment or services from a BCC in performance of a federal contract, and issuing grants or loans to entities to purchase, obtain, or use biotechnology equipment or services produced or provided by a BCC. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List. In addition, the U.S. Government has the ability to designate entities as BCCs through a separate designation process. There is a "safe harbor" provision providing that the restrictions do not apply to equipment or services that were formerly but are no longer provided by a BCC, as well as a "grandfathering" provision providing that the prohibitions do not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. It is unclear whether the grandfathering provision would apply to entities designated as BCCs due to their inclusion on the 1260H List. The guidance to be issued by the Office of Management and Budget regarding implementation of the BIOSECURE Act may provide further clarity on this point. The BIOSECURE Act, and any other similar laws that may be passed, could 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.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States. For example, WuXi Biologics manufactured TX45 for use in our Phase 1a, Phase 1b and Phase 2 clinical trials. We currently have a sole source relationship with WuXi Biologics for our supply of TX45.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report.

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 contract development and manufacturing organizations (“CDMOs”) 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 or TX2100 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 CDMOs 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 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, 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 expectations 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, TX2100 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. For example, the U.S. Department of Health and Human Services, or HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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, and methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. 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. In addition, we cannot guarantee that patent applications or patents that we initially believe to be owned by the company will not be encumbered by third party ownership or other third party rights that may not have been evident to us at the time of preparation or filing. For instance, such rights could arise from the intellectual contributions of company employees who were previously employed by third parties, such as universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors, or from the intellectual contributions of company consultants, advisors, or independent contractors with current or previous relationships with such third parties. Therefore, these patents and applications may not be prepared, filed, prosecuted or enforced in a manner consistent with the best interests of our business. Furthermore, licenses from such third parties may be required or desirable but may not be available on reasonable terms, or at all.

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 our 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 our patents that cover our products.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening 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 actions 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 patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in the future and whether patent expiration dates may be impacted. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which has and will continue to significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, it is still developing its case law, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds or cells that are similar to the biological compositions of our product candidates but that are not covered by the claims of our 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 our 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 our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to our own;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the 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 our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates 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 including Harvard. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

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 licenses with a third party, we could lose license rights that are important to our business.

We are a party to license agreements pursuant to which we in-license key patents 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 our 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 , including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information 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 our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary 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 intellectual property 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;
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time; and
- 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, TX2100 or another one of our product candidates is approved by the FDA, certain third parties may seek to enforce their patents 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 our 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 our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. 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 and TX2100. 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. In addition, we have used and continue to use consultants, advisors, and/or independent contractors with relationships with third parties, including institutions and/or other companies. We try to ensure that our employees, consultants, advisors, and/or independent contractors have the right to assign to us intellectual property generated during their engagement with us, and that they do not use the proprietary information or know-how of others in their work for us. Although no claims against us are currently pending, there is no guarantee that in the future we may not be subject to claims that we or our employees, consultants, advisors, 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, or improperly assign intellectual property rights to us. 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 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 our 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 related to 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.

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 or have exclusively in-licensed pending patent applications that relate to our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2041 through 2045, 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 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 its 2023 decision in *Amgen v. Sanofi*, the Supreme Court held that a functionally-claimed genus was invalid for failing to comply with the enablement requirement; 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 our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could

provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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. 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.

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. 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.

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 on and expect to rely on in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture TX45, TX2100 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 contract development and manufacturing organizations (“CDMO”), including WuXi Biologics (Hong Kong) Limited (“WuXi Biologics”), to manufacture TX45 for use in our Phase 2 clinical trial. We currently have a sole source relationship with WuXi Biologics for our supply of TX45. If there should be any disruption in such supply arrangement or the supply arrangement with our CDMO for TX2100, including any adverse events affecting our sole supplier for TX45, 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 partners 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 CDMO facility that supports our supply of TX45 and TX 2100 and reviews and approves all TX45 and TX2100 CGMP-related documentation. We also have quality agreements with our CDMOs that document 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 our CDMOs 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 CDMOs, 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 CDMOs 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 health 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, on December 18, 2025, President Trump signed the National Defense Authorization Act for Fiscal Year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. Government from procuring or obtaining biotechnology equipment or services produced or provided by a "biotechnology company of concern" ("BCC"), entering into, extending, or renewing government contracts with an entity that directly or indirectly uses biotechnology equipment or services from a BCC in performance of a federal contract, and issuing grants or loans to entities to purchase, obtain, or use biotechnology equipment or services produced or provided by a BCC. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List. In addition, the U.S. Government has the ability to designate entities as BCCs through a separate designation process. There is a "safe harbor" provision providing that the restrictions do not apply to equipment or services that were formerly but are no longer provided by a BCC, as well as a "grandfathering" provision providing that the prohibitions do not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. It is unclear whether the grandfathering provision would apply to entities designated as BCCs due to their inclusion on the 1260H List. The guidance to be issued by the Office of Management and Budget regarding implementation of the BIOSECURE Act may provide further clarity on this point. In addition to the BIOSECURE Act, any additional U.S. executive action, legislative action, or potential sanctions with China could materially impact our work with WuXi Biologics. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. 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 CDMO 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 CDMO 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 CDMO 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 our 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 our 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 our preclinical or clinical protocols, regulatory requirements or for other reasons, our 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 our 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 or a comparable foreign regulatory authority 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 or a comparable foreign regulatory authority. 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 our 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 our product candidates;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- 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 Quarterly Report also apply to the activities of our 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 preclinical 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 preclinical 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 our preclinical 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 preclinical programs and successfully develop our preclinical 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.

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

Our operations, and those of our CROs, CDMOs 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-related 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 are 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 CDMOs, service providers, our current and potential future partners or other third parties with whom we work fail or suffer security breaches, we could experience adverse consequences, including but not limited to material disruptions to our business operations and product development programs, 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 with whom we work process certain of that information on our behalf.

Our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities that 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 with whom we work, 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 conduct our clinical trials.

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 our 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 our 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 our 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. Also, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

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. In the future we may be required to or 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 require us to implement and maintain certain 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 our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. 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, whether due to a loss of our trade secrets or other proprietary information or similar disruptions. 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. 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 applicable federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under applicable laws and regulations that protect the privacy and security of personal information.

Likewise, we rely on third parties for the manufacture of TX45 and TX2100, 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 relevant 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, and the third parties with whom we work, 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, and the third parties with whom we work 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 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, including personal information from clinical trial participants and other individuals located in the EEA, the United Kingdom (the "UK"), or Switzerland 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 have in the past and may continue to adopt similarly stringent 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. 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 that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services if we become subject to these 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 and other state privacy laws contain an exemption for certain personal information processed in connection with clinical trials, , these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. 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.

For example, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in certain transactions or agreements with certain third parties in the future.

We are bound by contractual obligations and our efforts to comply with such obligations may not be successful. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading 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 individuals' 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 have in the past and may in the future necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on our 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 with whom we work) 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 our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

We are subject to U.S. and certain foreign anti-corruption laws and regulations, export and import controls, sanctions and embargoes. We could face liability and other serious consequences for violations which can harm our business.

We are subject to anti-corruption laws and regulations, including the Foreign Corrupt Practices Act of 1977, as amended (the FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other state and national anti-bribery laws in the countries in which we may conduct activities in the future. Anti-corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors and other third-party collaborators from offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly through third parties, to any person in the public or private sector to obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We may engage third parties to sell our products or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals outside the United States. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions.

There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or those of our affiliates, will comply with all applicable anti-corruption, export and import control, and sanctions laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

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.

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 December 31, 2025, we had U.S. federal net operating loss carryforwards of $453.3 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 Internal Revenue Code of 1986, 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.

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 our 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 CDMOs 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 CDMOs 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 our 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 CDMOs 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 Quarterly Report 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 previously filed lawsuits, which were subsequently dismissed, relating to the Merger; however, additional lawsuits could be filed.

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). 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 (as defined below). 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. Following the issuance of the Supplemental Disclosures, each of the Merger Actions was voluntarily dismissed and each of the Demands were withdrawn.

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 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 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 our 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 our operations or continued development of our 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;
- 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 selling stockholders, in the public market or otherwise, could cause the market price for our securities to decline, even though selling stockholders would still realize a profit on sales at lower prices. Resales of the securities offered 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, 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 selling stockholders acquired securities at prices that are significantly less than the current trading price of our common stock. Accordingly, certain 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, 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 connection with a private placement we completed in February 2025, we filed a resale shelf registration statement covering the resale of up to an aggregate of 3,689,465 shares of our common stock. Given the substantial number of shares available for resale, the sale of shares by such stockholders, or the perception in the market that the 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.

In addition, common stock that is issued in connection with stock options and restricted stock units will also 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.

Based on the number of shares outstanding as of December 31, 2025, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 60% 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.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trial and development of therapeutic proteins and antibodies ("Information Systems and Data").

Our Information Technology ("IT") Department, led by our Vice President of IT, helps identify, assess and manage the Company's cybersecurity threats and risks. Our IT Department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and threat actors, conducting scans of the threat environment, evaluating and assessing threats reported to us, coordinating with law enforcement about certain threats as may be appropriate, conducting internal and external audits and conducting risk and threat assessments.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: our incident response plan, incident detection and response procedures, disaster recovery and business continuity plans, encryption of certain data, network security controls, data segmentation, access and physical security controls, asset management and disposal, monitoring of our systems, employee training, and maintaining cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, cybersecurity risk is addressed as a component of the Company's enterprise risk management program and the IT Department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example cybersecurity consultants and managed cybersecurity providers.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, and third parties associated with our clinical trial development, such as contract research organizations and contract manufacturing organizations.

We have vendor management processes to manage cybersecurity risks associated with our use of certain of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including if our information technology systems, or the information technology systems of our CROs, our CDMOs, service providers, our current and potential future partners or other third parties with whom we work 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.

Governance

Our Board of Directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Board of Directors' audit committee is responsible for overseeing Company's cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our VP of IT, who has over 25 years of IT experience and 10 years of cybersecurity management expertise.

Our VP of IT is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our Chief Financial Officer is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances. Management works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response plan includes reporting to the audit committee of the Board of Directors for certain cybersecurity incidents as appropriate.

The audit committee receives periodic reports our VP of IT concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also can request access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

Our corporate headquarters are currently located in Watertown, Massachusetts, where we lease approximately 33,000 square feet of research laboratory and office space under a lease that expires in 2029. We believe our current facilities are adequate to meet our present operational needs.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Our common stock is traded on the Nasdaq Global Market under the symbol "TECX". Public trading of our common stock began on June 21, 2024.

Holders of Common Stock

As of February 16, 2026, there were 30 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

Not applicable.

Purchases of Equity Securities by the Issuer

None.

Item 6. Reserved

Item 7. 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 in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that are based upon current expectations that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

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 subsibdiaries 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 clinical-stage 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.

Our lead product candidates are TX45, an Fc-relaxin fusion molecule that activates the RXFP1 receptor, the GPCR target of the hormone relaxin, and TX2100, a VHH-Fc fusion antagonist antibody that binds to the APJ receptor ("APLNR").

In September 2024, we announced favorable results from a Phase 1a clinical trial evaluating safety, tolerability and pharmacokinetic ("PK") and pharmacodynamic ("PD") properties for TX45. In this clinical trial, TX45 was well-tolerated with no drug-related severe adverse events, no observed immunogenicity and demonstrated a favorable PK/PD relationship. Renal plasma flow was measured in each patient at several time points as a PD marker. This data was used to develop an exposure-response model which enabled the selection of doses for the APEX Phase 2 clinical trial.

In May 2025, we announced the complete results from Part A of the Phase 1b hemodynamic clinical trial of TX45 in subjects with Group 2 Pulmonary Hypertension ("PH") in Heart Failure with Preserved Ejection Fraction ("HFpEF"), known as PH-HFpEF. Part A of the TX45 Phase 1b clinical trial was a single dose IV, open-label clinical trial evaluating the safety, tolerability and hemodynamic effects of TX45 over an 8-hour period in subjects with PH-HFpEF. The complete data from Part A confirmed the tolerability and hemodynamic effects of TX45 in subjects with PH-HFpEF previously reported in the interim data in January 2025. Based on the complete dataset, TX45 was well-tolerated in subjects with PH-HFpEF with no serious or severe adverse events. In the overall study population of the complete dataset, TX45 achieved a 19.0% reduction in pulmonary capillary wedge pressure ("PCWP"), an endpoint reported to correlate with exercise capacity, morbidity and mortality in patients with heart failure, and an 18.5% improvement in cardiac output. In the subpopulation with combined pre- and post-capillary pulmonary hypertension ("CpcPH") who have an elevated Pulmonary Vascular Resistance ("PVR") and more severe disease, TX45 demonstrated >30% reduction in PVR, which along with PCWP is correlated to exercise capacity and mortality in this patient population.

In October 2025, we announced the topline results from Part B of the Phase 1b hemodynamic clinical trial of TX45 in subjects with Group 2 PH in Heart Failure with Reduced Ejection Fraction ("PH-HFrEF"). Part B of the TX45 Phase 1b clinical trial had a similar design as the Phase 1b Part A, assessing hemodynamic effects of TX45 but was conducted in subjects with PH-HFrEF. Based on the topline results, TX45 was well-tolerated in subjects with PH-HFrEF with no serious or severe adverse events. In the overall study population, TX45 achieved a 29.2% reduction in PCWP, an endpoint reported to correlate with exercise capacity, morbidity and mortality in patients with heart failure, and a 17.3% improvement in cardiac output. In the subpopulation with CpcPH who have an elevated PVR and more severe disease, TX45 demonstrated a 19.7% reduction in PVR in patients with a PVR equal to or greater than 3 Wood Units and a 10.3% reduction in PVR in patients with a PVR equal to or greater than 2 Wood Units. PVR along with PCWP is correlated to exercise capacity and mortality in this patient population.

The ongoing APEX Phase 2 clinical trial is a global, 24-week, placebo-controlled trial designed to evaluate the safety and efficacy of TX45 administered subcutaneously ("SC") in subjects with PH-HFpEF, enriched for CpcPH. We dosed our first subject in the APEX Phase 2 clinical trial in October 2024. Subjects are being randomized to 300 mg SC (2 ml injection) once monthly of TX45, 300 mg SC once every other week of TX45, or placebo. Change from baseline in PVR in the PVR$\geq$3 population is the primary endpoint of the trial. The trial is designed to enrich patients with a PVR$\geq$3 aiming for 70% of patients enrolled. We expect topline results from the APEX clinical trial in 2026.

In February 2026, the first site was activated and opened for screening in the 16-week, open label, repeat dose, Phase 2 clinical trial to evaluate TX45's safety and hemodynamic effects in up to 25 subjects with PH associated with Interstitial Lung Disease ("ILD"), known as PH-ILD (Group 3 PH). PH-ILD is an orphan disease with limited treatment options and a high mortality rate. We believe TX45's mechanism is well suited to PH-ILD's disease pathophysiology because of its pulmonary vasodilation, anti-inflammatory, remodeling and anti-fibrotic activity. In patients with PH-ILD, elevation in PVR and mean pulmonary arterial pressure ("mPAP") has been associated with increased mortality. In the Phase 1b trial in both CpcPH-HFpEF and CpcPH-HFrEF, TX45 resulted in significant reductions in mPAP and PVR as well as improvements in other hemodynamic endpoints. The TX45 PH-ILD Phase 2 trial will initiate at a dose of TX45 300 mg every four weeks administered SC with a primary efficacy endpoint of change from baseline in PVR at Week 16.

Our lead product candidate, TX2100, is being evaluated for the treatment of Hereditary Hemorrhagic Telangiectasia ("HHT"), the second most common genetic bleeding disorder with no approved therapy. TX2100 is a VHH-Fc fusion antagonist antibody that binds to APJ (also known as the apelin receptor; APLNR), a GPCR that mediates signaling by the pro-angiogenic peptide hormone apelin. A rodent surrogate of TX2100 demonstrated reductions in arteriovenous malformation ("AVM") formation, bleeding, and anemia across the neonatal anti-BMP9/10 immunoblocked model and the more severe, adult inducible ALK1 knockout mouse model of HHT, supporting disease-modifying activity through APJ antagonism. TX2100 was further evaluated in non-human primates in IND-enabling GLP toxicology studies, including a 13-week repeat-dose study. In these studies, TX2100 was well tolerated at doses up to 100 mg/kg/week, with no treatment-related or target-related toxicities identified and no effects observed on cardiovascular, respiratory, neurological, renal, metabolic, or hematologic parameters. A formulation supporting subcutaneous dosing has been established, and drug substance and drug product manufacturing under Good Manufacturing Practice ("GMP") have been completed to support initiation of a Phase 1a clinical trial. In February 2026, we randomized the first subject in the Phase 1a healthy volunteer clinical trial for TX2100. We are also planning a Phase 1b clinical trial to explore the safety and efficacy (epistaxis, anemia, and hematological support) of TX2100 in patients with severe HHT. In addition, subject to positive Phase 1a results, we plan to initiate a Phase 2 clinical trial for TX2100 in early 2027.

Private Placement

In February 2025, we entered into a securities purchase agreement (the "Private Placement") pursuant to which we issued an aggregate of 3,689,465 shares of common stock, at a price of $50.00 per share to institutional accredited investors and $54.14 per share to individual accredited investors that are either an officer or director of the Company. The net proceeds from the Private Placement were approximately $173.1 million.

Merger with AVROBIO

On June 20, 2024, we completed our previously announced merger transaction in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 30, 2024 (the "Merger Agreement") with AVROBIO, Inc. ("AVROBIO"), pursuant to which Alpine Merger Subsidiary, Inc., a wholly owned subsidiary of AVROBIO, merged with and into the entity formerly known as Tectonic Therapeutic, Inc., now known as Tectonic Operating Company, Inc. ("Legacy Tectonic"), with Legacy Tectonic continuing as a wholly owned subsidiary of the surviving corporation of AVROBIO (the "Merger").

Components of our Results of Operations

Revenue

We have not generated any revenue since our inception and 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 if we enter collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements, 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 our product candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred in connection with our research activities, including discovery efforts and the preclinical and clinical development of our programs, product candidates, and platform. These expenses include:

- employee-related expenses, including salaries, bonuses, benefits and stock-based compensation, 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 fees paid to contract research organizations ("CROs");

- costs related to manufacturing materials for our preclinical studies and clinical trials, including fees paid to contract development and manufacturing organizations ("CDMOs");
- 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, utilities, and facility maintenance;
- costs related to compliance with regulatory requirements; and
- payments made under third-party licensing agreements.

We expense all research and development costs as 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. 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.

Costs that are deployed across multiple programs or platform activities and not directly attributable to any single program are recorded as platform development and unallocated research and development expenses, which include multi-program employee-related costs, cross-program licensing payments, laboratory supplies and related expenses, contract research, manufacturing and consulting services, facility-related and other expenses, including depreciation, and discovery efforts.

Research and development activities are central to our business. Later-stage clinical programs generally incur higher costs than early-stage programs due to the increased size and duration of trials. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of our product candidates due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We will continue to evaluate which product candidates to pursue and the allocation of funding based on preclinical and clinical results, regulatory developments, and commercial potential. We expect our research and development expenses to increase significantly as we advance our product candidates through clinical development and initiate additional clinical trials. Our future expenses may vary significantly each period based on factors such as:

- expenses incurred to conduct preclinical studies required to advance our product candidates into clinical development;
- per patient trial costs, based on the number of doses that patients receive;
- the number of patients who enroll in each trial;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the ability to manufacture our product candidates;

- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related costs, including salaries, bonuses, benefits and stock-based compensation, for our personnel in executive, finance and information technology, and other administrative functions. General and administrative expenses also include professional fees for legal, accounting, and consulting services, insurance costs, facilities and information technology expenses, investor relations and public company compliance costs, and other general corporate overhead. As a clinical-stage company, our general and administrative expenses are driven in part by the costs required to support our research and development activities and to operate as a public company.

Other Income (Expense)

Interest Income

Interest income primarily consists of interest earned on money market funds, which are included in cash and cash equivalents on the Consolidated Balance Sheet.

Loss on Issuance of SAFE Liabilities 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 Sheets at their fair value on the issuance dates. Until redemption on June 20, 2024, 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.

Income Tax Expense

During the year ended December 31, 2025, we recorded income tax expense of approximately $1.2 million related to the dissolution of our wholly owned Australian subsidiary, Tectonic Therapeutic Pty Ltd. This entity is being dissolved as part of a broader corporate initiative intended to streamline operations and reduce administrative costs. The dissolution triggered a taxable event under Australian tax law due to the deemed disposition of certain assets at fair market value. As a result, we recognized a tax liability based on the difference between the carrying amount of these assets for financial reporting purposes and their tax basis. The dissolution does not have a significant impact on our effective tax rate for the period, but it did result in a discrete item within the period. We do not expect material ongoing tax consequences from this dissolution.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Operating expenses:				
Research and development	$ 63,489	$ 41,364	$ 22,125	53%
General and administrative	20,547	16,651	3,896	23%
Total operating expenses	84,036	58,015	26,021	45%
Loss from operations	(84,036)	(58,015)	(26,021)	45%
Other income (expense):				
Interest income	11,297	4,261	7,036	165%
Interest expense	(63)	(107)	44	(41%)
Change in fair value of the SAFE liabilities	—	(3,610)	3,610	(100%)
Other expense	(119)	(511)	392	(77%)
Total other income, net	11,115	33	11,082	33,582%
Loss before income tax	(72,921)	(57,982)	(14,939)	26%
Income tax expense	(1,230)	—	(1,230)	100%
Net loss	$ (74,151)	$ (57,982)	$ (16,169)	28%

Research and Development Expenses

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Direct research and development expenses by program:				
TX45	$ 24,327	$ 15,324	$ 9,003	59%
TX2100	12,494	4,417	8,077	183%
Platform development and unallocated expenses:				
Employee-related expenses, including stock-based compensation	17,455	12,317	5,138	42%
Contract research, manufacturing and consulting services	1,163	1,159	4	0%
Laboratory supplies and related expenses	3,274	3,653	(379)	(10%)
Facility related and other expenses, including depreciation	4,776	4,494	282	6%
Total platform development and unallocated expenses	26,668	21,623	5,045	23%
Total research and development expenses	$ 63,489	$ 41,364	$ 22,125	53%

Total research and development expenses increased by $22.1 million for the year ended December 31, 2025 compared to the year ended December 31, 2024.

Direct research and development program expenses increased primarily due to advancement of our preclinical and clinical programs. TX45 expenses increased by $9.0 million, primarily attributable to CRO costs related to the ongoing Phase 2 clinical trial. TX2100 expenses increased by $8.1 million, as the program progressed further through discovery and development.

Platform development and unallocated expenses increased by $5.0 million, primarily driven by higher employee-related expenses. The increase in employee-related expenses was primarily due to an increase in stock-based compensation expense related to the ongoing issuance of equity awards and increase in the weighted-average fair value of the awards granted. In addition, we expanded our research and development team to support our programs, resulting in higher payroll and related costs.

General and Administrative Expenses

	Year Ended December 31,			
	2025	2024	$ Change	% Change
Employee-related expenses, including stock-based compensation	$ 11,550	$ 7,862	$ 3,688	47%
Professional and consulting expenses	7,371	7,009	362	5%
Facility related and other expenses, including depreciation	1,626	1,780	(154)	(9%)
Total general and administrative expenses	$ 20,547	$ 16,651	$ 3,896	23%

General and administrative expenses increased by $3.9 million for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to higher employee-related expenses, including stock-based compensation, which increased by $3.7 million. The increase in stock-based compensation expense was primarily attributable to the ongoing issuance of equity awards and increase in the weighted-average fair value of the awards granted.

We anticipate that our general and administrative expenses will continue to increase in the future as we continue to invest in infrastructure and personnel to support the advancement of our clinical programs and operation 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)

Interest Income

Interest income increased by $7.0 million for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily due to an increase in cash and cash equivalents as a result of the Merger and Private Placement.

Change in Fair Value of SAFE Liabilities

The SAFE liabilities loss of $3.6 million resulted from the remeasurement of the SAFE liabilities to fair value during the year ended December 31, 2024.

Income Tax Expense

Income tax expense of approximately $1.2 million was recorded during the year ended December 31, 2025, related to the dissolution of Tectonic Therapeutic Pty Ltd.

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 CROs and CDMOs 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 have never generated any revenue from product sales. We have funded our operations primarily through the sale and issuance of common stock, convertible equity instruments, and the Merger. In February 2025, we sold shares of our common stock under the Private Placement in exchange for net proceeds of approximately $173.1 million. We currently have an effective shelf registration statement on Form S-3 filed with the SEC, which we may use to offer from time to time any combination of common stock, preferred stock, debt securities, and warrants up to an aggregate amount of $400 million. Of this amount, we have the ability to sell up to $100 million of additional shares of our common stock to the public through an at the market offering ("ATM"). During the year ended December 31, 2025, we did not sell any shares under the ATM program. As of December 31, 2025, the full $100 million remained available for issuance under the ATM program.

As of December 31, 2025, we had $253.8 million in cash and cash equivalents and an accumulated deficit of $222.7 million. Based on our current business plans, management believes that our cash, cash equivalents and marketable securities on hand at December 31, 2025 are sufficient to meet our operating requirements for at least the next 12 months from the issuance of the consolidated financial statements included in this Annual Report on Form 10-K. However, our estimates are based on assumptions that may prove to be incorrect, and we could exhaust our capital resources sooner than expected. We may require additional funding to support our research programs, clinical development, and general operations. There can be no assurance that additional financing, whether through public or private equity, debt, collaborations, or licensing arrangements, will be available on acceptable terms, or at all.

Cash Flows

The following table shows a summary of our cash flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (60,078)	$ (59,080)
Net cash used in investing activities	(138)	(156)
Net cash provided by financing activities	173,355	171,714
Effect of exchange rate changes on cash and cash equivalents	(95)	(8)
Net increase in cash, cash equivalents and restricted cash	$ 113,044	$ 112,470

Operating Activities

Net cash used in operating activities was $60.1 million for the year ended December 31, 2025. Cash used in operations was primarily used to fund our operations in developing our product candidates, resulting in a net loss of $74.2 million, partially offset by non-cash charges of $14.1 million. Changes in operating assets and liabilities, including the timing of vendor payments and lease repayments, had a minimal net effect of $0.1 million on cash used in operating activities.

Net cash used in operating activities was $59.1 million for the year ended December 31, 2024. Cash used in operating activities was primarily used to fund our operations to develop our product candidates resulting in a net loss of $58.0 million and $10.3 million of changes in operating assets and liabilities related to accrued expenses, timing of vendor payments and lease repayments offset by non-cash charges of $9.2 million.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2025 and 2024 was nominal and related to the purchase and sale of property and equipment.

Financing Activities

Net cash provided by financing activities was $173.4 million for the year ended December 31, 2025, primarily due to net proceeds of $173.1 million from the sale of shares pursuant to the Private Placement and $1.2 million in proceeds from the exercise of stock options.

Net cash provided by financing activities was $171.7 million for the year ended December 31, 2024, primarily due to net proceeds of $94.6 million from the sale of shares pursuant to the Subscription Agreement, $76.0 million of net cash acquired in connection with the Merger, and $1.6 million in proceeds from the exercise of stock options.

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 candidates TX45 and TX2100. In addition, if we obtain marketing approval for TX45, TX2100 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 our 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 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 access sufficient additional capital on a timely basis and on favorable terms;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development;
- 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;
- the costs of operating as a publicly traded company;
- 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 our 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 streams, 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 ourselves.

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.

Contractual Obligations & Commitments

We have entered into license agreements under which we are obligated to make specified milestone and royalty payments. The payment obligations under these agreements are contingent upon future events, such as our achievement of specified development, regulatory, and sales milestones, or generating product sales. Generally, the timing or likelihood of achieving these milestones or generating future product sales are not determinable. For further details regarding our significant contracts, and the commitments and contractual obligations contained within each contract, please refer to Note 11, *License Agreements*, and Note 12, *Commitments and Contingencies*, and to our consolidated financial statements included in this Annual Report on Form 10-K, which is incorporated herein by reference.

We have lease obligations for certain laboratory equipment and office and laboratory space under non-cancelable operating and finance leases. In September 2025, we entered into a non-cancelable operating lease for office and laboratory space in Watertown, Massachusetts. As of December 31, 2025, this lease had not commenced; accordingly, no right-of-use asset or lease liability has been recorded on the Consolidated Balance Sheet. The lease will be recognized upon commencement in January 2026, at which time a right-of-use asset and corresponding lease liability will be recorded based on the present value of lease payments over the lease term.

The leases, including the Watertown lease, expire at various times through 2029. Minimum lease payments under these agreements are $2.5 million in 2026, $1.9 million in 2027, $2.0 million in 2028, and $0.2 million in 2029. These amounts reflect enforceable obligations under non-cancelable contracts and do not include commitments that can be terminated without significant penalty.

In addition, we enter into agreements in the normal course of business with vendors for preclinical research studies, clinical trials and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and are generally cancelable upon written notice. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of the 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 in our 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, liabilities and 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 Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, to our financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses, primarily related to services performed by third parties such as CROs and CDMOs. 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 judgments and estimates of our research and development expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time, which includes corroboration of these estimates with the service providers. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust accrued expenses or prepaid expenses accordingly, which impact research and development expenses. Changes in these estimates that result in material changes to our accrued costs could materially affect our results of operations. To date, we have not experienced any material adjustments to our prior estimates of prepaid and accrued research and development expenses.

Stock-Based Compensation Expense

We recognize stock-based compensation expense for employee and non-employee equity awards, including stock options and restricted stock units, over the requisite service period in accordance with ASC 718. Stock options are measured at fair value on the grant date using the Black-Scholes option pricing model, which requires assumptions regarding expected volatility, expected term, risk-free interest rates, and expected dividend yield. The grant date fair value of our common stock is based on the closing quoted market price of our common stock as reported by the NASDAQ Global Market on the date of grant. Stock-based compensation is recorded in either research and development expense or general and administrative expenses depending on the roles of the recipients.

Recent Accounting Pronouncements

Recent accounting pronouncements are addressed in Note 2, Summary of Significant Accounting Policies and Basis of Presentation, in the Notes to the Consolidated Financial Statements included herein.

Smaller Reporting Company Status

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 Annual Report on Form 10-K and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information otherwise required under this Item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K beginning on page F-1. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control—Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Attestation Report of the Registered Public Accounting Firm

Our independent registered public accounting firm is not required to issue an attestation report on the internal control over financial reporting because we are a non-accelerated filer and a "smaller reporting company".

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d‑15(f) under the Exchange Act) during the three months ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2025, the following directors of the Company adopted a "Rule 10b5-1 trading arrangement" as the term is defined in Item 408(a) of Regulation S-K, all of which were entered into during an open trading window in accordance with the Company's Insider Trading Policy and all of which were intended to satisfy Rule 10b5-1(c):

- On November 14, 2025, Peter McNamara, a member of our Board of Directors, adopted a Rule 10b5-1 trading plan that provides for the sale of up to 35,102 shares of common stock from the exercise of vested stock options. The plan will expire on December 14, 2026 subject to early termination for specified events set forth in the plan.

Except as set forth above, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K during the three months ended December 31, 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

We have adopted a written Code of Business Conduct and Ethics (the "Code of Conduct") applicable to all of our employees, executive officers and directors, including our principal executive officer, principal financial officer and principal accounting officer. A current copy of the Code of Conduct is available on the Investors section of our website, https://investors.tectonictx.com, under "Investors / Corporate Governance." We intend to disclose on our website any amendments to, or waivers from, our Code of Conduct that are required to be disclosed pursuant to SEC rules. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be a part of this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial Statement Schedules.

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

(3) Exhibits.

Exhibit Number	Description
2.1**	Agreement and Plan of Merger and Reorganization, dated as of January 30, 2024, by and among AVROBIO, Alpine Merger Subsidiary, Inc. and Tectonic Therapeutic Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on January 30, 2024).
3.14**	Fourth Amended and Restated Certificate of Incorporation as amended through June 20, 2024 (incorporated by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38537) filed with the Securities and Exchange Commission on August 14, 2024).
3.2**	Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 25, 2018).
4.1**	Description of Capital Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Annual Report on Form 10-K (File No. 001-3857) filed with the SEC on March 20, 2025).
10.1**	Contingent Value Rights Agreement dated June 20, 2024, by and between Tectonic Therapeutic, Inc. and Computershare Trust Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 20, 2024).
10.2**	Form of Indemnification Agreement between Tectonic Therapeutic, Inc. and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 20, 2024).
10.3**	2019 Equity Incentive Plan of Tectonic Therapeutic, Inc., and form of award agreements thereunder (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-4 (File No. 333-277048) filed with the Securities and Exchange Commission on February 14, 2024).
10.4*	Non-Employee Director Compensation Policy of Tectonic Therapeutic, Inc.
10.5**	2024 Equity Incentive Plan of Tectonic Therapeutic, Inc.(incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 20, 2024).
10.6**	Forms of Option Grant Notice, Option Agreement and Notice of Exercise under Tectonic Therapeutic, Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 20, 2024).
10.7**	2024 Employee Stock Purchase Plan of Tectonic Therapeutic, Inc. (incorporated by reference to Exhibit 10.8 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 20, 2024).

10.8**	Amended and Restated Employment Agreement, dated as of June 20, 2024, by and between Tectonic Therapeutic, Inc. and Alise Reicin, M.D. (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on June 20, 2024).
10.09**	License Agreement, dated February 10, 2022, by and between Tectonic Therapeutic, Inc. and President and Fellows of Harvard College (incorporated by reference to Exhibit 10.35 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-4 (File No. 333-277048) filed with the Securities and Exchange Commission on March 26, 2024).
10.10**	Master Contract Services Agreement, dated February 16, 2022, by and between Tectonic Therapeutic, Inc. and ITR LABORATORIES CANADA INC. (incorporated by reference to Exhibit 10.38 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-4(File No. 333-277048) filed with the Securities and Exchange Commission on March 26, 2024).
10.11**	Master Clinical Contract Services Agreement, dated March 6, 2023, by and between Tectonic Therapeutic, Inc. and Novotech (Australia) Pty Limited CAN (incorporated by reference to Exhibit 10.40 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-4 (File No. 333-277048) filed with the Securities and Exchange Commission on March 26, 2024)
10.12**	Offer Letter dated June 16, 2021, by and between Tectonic Therapeutic, Inc. and Marcella Ruddy (incorporated by reference to Exhibit 10.43 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-4 (File No. 333-277048) filed with the Securities and Exchange Commission on April 15, 2024).
10.13**	Offer Letter dated May 28, 2024, by and between Tectonic Therapeutic, Inc. and Daniel Lochner (incorporated by reference to Exhibit 10.17 to the Registrants Annual Report on Form 10-K (File No. 001-38537) filed with the Securities and Exchange Commission on March 20, 2025)
10.14**	Form of Severance Plan and Form of Participation Agreement of Tectonic Therapeutic, Inc. (incorporated as reference to Exhibit 10.47 to the Registrant's Amendment No. 2 to the Registration Statement on Form S-4 filed on April 15, 2024 (File No. 333-277048) and incorporated herein by reference).
10.15**	Form of Securities Purchase Agreement, dated as of February 3, 2025, by and among Tectonic Therapeutic, Inc. and the purchasers thereunder (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on February 3, 2025).
10.16**	Form of Registration Rights Agreement, dated as of February 3, 2025, by and among Tectonic Therapeutic, Inc. and the signatories thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-38537) filed with the Securities and Exchange Commission on February 3, 2025)
19.1**	Insider Trading Policy of Tectonic Therapeutic, Inc. (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38537) filed with the Securities and Exchange Commission on March 20, 2025).
21.1*	List of Subsidiaries.
23.1*	Consent of independent registered public accounting firm, Deloitte & Touche LLP
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

97.1**	Incentive Compensation Recoupment Policy of Tectonic Therapeutic, Inc.(incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10K (File No. 001-38537) filed with the Securities and Exchange Commission on March 20, 2025).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as Inline XBRL document and contained in Exhibit 101)

* Filed herewith.

** Filed previously.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

TECTONIC THERAPEUTIC, INC.

Date: February 26, 2026

By: /s/ Alise Reicin, M.D.
Alise Reicin, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 26, 2026

By: /s/ Daniel Lochner
Daniel Lochner
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Alise Reicin and Daniel Lochner, and each of them, as true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for them and in their 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 other documents in connection therewith, with the Securities and Exchange Commission, and generally to do all such things in their names and behalf in their capacities as officers and directors to enable Tectonic Therapeutic, Inc. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Signature	Title	Date
/s/ Alise Reicin Alise Reicin	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 26, 2026
/s/ Daniel Lochner Daniel Lochner	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 26, 2026
/s/ Terrance McGuire Terrance McGuire	Director	February 26, 2026
/s/ Stefan Vitorovic Stefan Vitorovic	Director	February 26, 2026
/s/ Timothy A. Springer Timothy A. Springer	Director	February 26, 2026
/s/ Praveen Tipirneni Praveen Tipirneni	Director	February 26, 2026
s/ Phillip B. Donenberg Phillip B. Donenberg	Director	February 26, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the 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, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (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, 2025 and 2024, 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.

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 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.

Accrued and prepaid contract research and development and manufacturing expenses — Refer to Notes 2 and 6 to the financial statements

Critical Audit Matter Description

As disclosed in Note 2 to the financial statements, the Company records accrued and prepaid research and development and manufacturing expenses for third-party contract research organizations (“CROs”) and contract development and manufacturing organizations (“CDMOs”). Estimates of expenses incurred are determined by reviewing information provided to the Company by its service providers and through discussions with both internal personnel and external service providers as to the status of specific tasks within arrangements. Expenses incurred in excess of amounts invoiced are recorded as accrued expenses. Payments made in excess of costs incurred are recorded as prepaid expenses.

We identified auditing the estimates of the progress to completion of specific tasks performed by CROs and CDMOs as a critical audit matter due to (i) the level of judgment required by management and the volume of such estimates made by management and (ii) the degree of auditor judgment, subjectivity, and increased extent of effort in performing procedures to evaluate the reasonableness of management’s estimates of progress to completion.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to accrued and prepaid research and development expenses and manufacturing expenses included the following, among others:

- We tested the design and implementation of controls over the estimation of accrued and prepaid research and development and manufacturing expenses.
- For a sample of contracts with service providers performing research and development and manufacturing activities, we performed the following:
    - Evaluated the appropriateness of the method used by management to develop its estimates of progress to completion of specific tasks.
    - Tested the completeness and accuracy of the underlying data used in the estimates of progress to completion through inspection of the terms of contracts and statements of work between the Company and its service providers and testing of actual billed expenses under the contracts.
    - Performed corroborating inquiries with Company personnel responsible for overseeing the activities performed by the Company's CROs and CDMOs, which may include the service providers' estimate of completed tasks or progress of completion of certain tasks within the arrangement.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 26, 2026

We have served as the Company's auditor since 2022.

TECTONIC THERAPEUTIC, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 253,798	$ 141,239
Prepaid expenses and other current assets	2,974	5,618
Restricted cash	587	—
Total current assets	257,359	146,857
Property and equipment, net	1,185	2,151
Finance right-of-use assets, net	495	919
Operating right-of-use assets	874	2,235
Restricted cash	485	587
Other assets	640	156
Total assets	$ 261,038	$ 152,905
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,093	$ 976
Accrued expenses and other current liabilities	7,340	7,850
Finance lease liability	344	489
Operating lease liability	889	2,295
Total current liabilities	9,666	11,610
Operating lease liability, non-current	—	132
Finance lease liability, non-current	43	387
Total liabilities	9,709	12,129
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2025 and December 31, 2024; no shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 18,738,249 and 14,856,309 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	2	2
Additional paid-in capital	474,160	289,351
Accumulated other comprehensive (loss) income	(96)	9
Accumulated deficit	(222,737)	(148,586)
Total stockholders' equity	251,329	140,776
Total liabilities and stockholders' equity	$ 261,038	$ 152,905

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 data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 63,489	$ 41,364
General and administrative	20,547	16,651
Total operating expenses	84,036	58,015
Loss from operations	(84,036)	(58,015)
Other income (expense):		
Interest income	11,297	4,261
Interest expense	(63)	(107)
Change in fair value of SAFE liabilities	—	(3,610)
Other expense	(119)	(511)
Total other income, net	11,115	33
Loss before income tax	(72,921)	(57,982)
Income tax expense	(1,230)	—
Net loss	(74,151)	(57,982)
Other comprehensive loss:		
Foreign currency translation adjustment	(105)	9
Comprehensive loss	$ (74,256)	$ (57,973)
Net loss per share, basic and diluted	$ (4.05)	$ (6.83)
Weighted-average common shares outstanding, basic and diluted	18,322,533	8,490,171

The accompanying notes are an integral part of these Consolidated Financial Statements.

TECTONIC THERAPEUTIC, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance as of January 1, 2024	3,647,675	$ 80,627	1,407,753	$ —	$ 5,979	$ (11)	$ (90,604)	$ (84,636)
Conversion of Convertible Preferred Stock into common stock in connection with the Merger	(3,647,675)	(80,627)	3,647,675	—	80,627	—	—	80,627
Issuance of common stock upon exercise of stock options	—	—	388,727	—	1,624	—	—	1,624
Issuance of common stock upon vesting of restricted common stock	—	—	—	—	15	—	—	15
Issuance of common stock to related party investors upon redemption of the SAFEs	—	—	1,470,839	—	34,125	—	—	34,125
Issuance of common stock under the Subscription Agreement, net of offering costs of $2,000	—	—	4,163,606	1	94,600	—	—	94,601
Issuance of common stock upon the Merger, net of transaction costs of $9,300	—	—	3,777,709	1	68,890	—	—	68,891
Stock-based compensation expense	—	—	—	—	3,491	—	—	3,491
Foreign currency translation adjustment	—	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	—	(57,982)	(57,982)
Balance as of December 31, 2024	—	$ —	14,856,309	$ 2	$ 289,351	$ 9	$ (148,586)	$ 140,776
Issuance of common stock upon exercise of stock options	—	—	185,773	—	1,231	—	—	1,231
Issuance of common stock in connection with the private placement, net of offering costs of $11,928	—	—	3,689,465	—	173,098	—	—	173,098
Issuance of common stock upon vesting of restricted stock units, net	—	—	6,702	—	(17)	—	—	(17)
Stock-based compensation expense	—	—	—	—	10,497	—	—	10,497
Foreign currency translation adjustment	—	—	—	—	—	(105)	—	(105)
Net loss	—	—	—	—	—	—	(74,151)	(74,151)
Balance as of December 31, 2025	—	$ —	18,738,249	$ 2	$ 474,160	$ (96)	$ (222,737)	$ 251,329

The accompanying notes are an integral part of these Consolidated Financial Statements.

TECTONIC THERAPEUTIC, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (74,151)	$ (57,982)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,375	1,645
Stock-based compensation expense	10,497	3,491
Loss on sale of property and equipment	153	—
Reduction in the carrying amount of the operating right-of-use assets	2,118	434
Change in fair value of SAFE liabilities	—	3,610
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	2,644	(3,194)
Other non-current assets	17	544
Accounts payable	116	(1,421)
Accrued expenses and other current liabilities	(552)	(5,642)
Operating lease liabilities	(2,295)	(565)
Net cash used in operating activities	(60,078)	(59,080)
Cash flows from investing activities:		
Purchase of property and equipment	(208)	(156)
Proceeds from the sale of property and equipment	70	—
Net cash used in investing activities	(138)	(156)
Cash flows from financing activities:		
Proceeds from the Private Placement, net of offering costs of $11,928	173,098	—
Proceeds from the Subscription Agreement, net of offering costs of $2,000	—	94,600
Cash acquired in connection with the Merger, net of transaction costs of $9,300	—	75,965
Proceeds from exercise of stock options	1,231	1,624
Payments for employee taxes related to net share settlement of equity awards	(17)	—
Payment of deferred offering costs	(468)	—
Repayment of finance lease obligations	(489)	(475)
Net cash provided by financing activities	173,355	171,714
Effect of exchange rate changes on cash and cash equivalents	(95)	(8)
Net increase in cash and cash equivalents and restricted cash	113,044	112,470
Cash and cash equivalents and restricted cash as of beginning of period	141,826	29,356
Cash and cash equivalents and restricted cash as of end of period	$ 254,870	$ 141,826
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 253,798	$ 141,239
Restricted cash	1,072	587
Total cash, cash equivalents and restricted cash	$ 254,870	$ 141,826
Supplemental Cash Flow Information:		
Deferred offering costs included in accrued expenses and other liabilities	$ 35	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 757	$ —
Conversion of SAFEs to Common Stock	$ —	$ 34,125
Conversion of Convertible Preferred Stock to Common Stock	$ —	$ 80,627

The accompanying notes are an integral part of these Consolidated Financial Statements.

TECTONIC THERAPEUTIC, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(in thousands, except share and per share data)

1. NATURE OF BUSINESS

Description of the Business

Tectonic Therapeutic, Inc. (formerly AVROBIO, Inc.) (the "Company" or "Tectonic") is a clinical-stage 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), Tectonic 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. Tectonic 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.

Merger

On June 20, 2024, the Company completed its previously announced merger transaction in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 30, 2024 (the "Merger Agreement") with AVROBIO, Inc. ("AVROBIO"), pursuant to which Alpine Merger Subsidiary, Inc., a wholly owned subsidiary of AVROBIO, merged with and into the entity formerly known as Tectonic Therapeutic, Inc., now known as Tectonic Operating Company, Inc. ("Legacy Tectonic"), with Legacy Tectonic continuing as a wholly owned subsidiary of the surviving corporation of AVROBIO (the "Merger"). The Merger was accounted for as a reverse recapitalization in accordance with generally accepted accounting principles in the United States of America ("GAAP"), with AVROBIO treated as the acquired company for financial reporting purposes, and Legacy Tectonic treated as the accounting acquirer. Accordingly, the historical financial statements prior to the Merger reflect those of Legacy Tectonic.

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 preclinical 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 Capital Resources

Since inception, the Company has incurred recurring losses and negative cash flows from operations and expects such losses to continue in the future as it conducts research and development activities and continues to develop its product candidates. The Company generated net losses of $74.2 million and $58.0 million for the years ended December 31, 2025 and 2024, respectively and had an accumulated deficit of $222.7 million as of December 31, 2025. The Company has financed its operations primarily through the sale and issuance of common stock, convertible equity instruments, and the Merger. In February 2025, the Company sold shares of its common stock under a securities purchase agreement in exchange for net proceeds of approximately $173.1 million. 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. The Company also has an effective shelf registration statement on Form S-3 filed with the SEC, which may be used to offer from time to time any combination of common stock, preferred stock, debt securities, and warrants up to an aggregate amount of $400 million. Of this amount, the Company has the ability to sell up to $100 million of additional shares of common stock to the public through an at the market offering ("ATM"). During the year ended December 31, 2025, the Company did not sell any shares under the ATM program. As of December 31, 2025, the full $100 million remained available for issuance under the ATM program.

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 had cash and cash equivalents of $253.8 million as of December 31, 2025. In accordance with 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 these consolidated financial statements are issued.

The Company believes that its existing cash and cash equivalents will be sufficient to allow the Company to fund operations beyond twelve months from the date of issuance of these consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance refers to U.S. GAAP as codified in the Accounting Standards Codification ("ASC") and as amended by Accounting Standards Updates ("ASUs") issued by the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The Company consolidates the financial statements of its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Reverse Stock Split and Exchange Ratio

Upon the closing of the Merger, each outstanding share of Legacy Tectonic'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 of 0.53, after giving effect to the 1-for-12 reverse stock split of AVROBIO common stock that was effected on June 20, 2024. The exchange ratio was retroactively applied to all outstanding common shares, convertible preferred shares, stock options and restricted stock for all periods presented.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. These estimates are based on historical experience and other assumptions that the Company believes are reasonable under the circumstances. Revisions to estimates are recorded in the period in which the change becomes known.

Significant estimates include the valuation of stock-based awards, prepaid and accrued research and development activities, and income taxes. Actual results may differ from these estimates, and such differences could be material to the Company's financial position and results of operations.

Foreign Currency

The operations of each of the Company's subsidiaries are measured in the currency of the primary economic environment in which the subsidiary operates (the "functional currency"). Assets and liabilities of foreign subsidiaries whose functional currency is the local currency are translated into U.S. dollars using period-end exchange rates. Income and expense items are translated at the average exchange rate in effect during each fiscal month. Translation adjustments resulting from the remeasurement of foreign subsidiary financial statements are included as a component of Accumulated Other Comprehensive Loss in the Consolidated Balance Sheets. Gains and losses from foreign currency transactions are included in Other Income (Expense), Net in the Consolidated Statements of Operations and Comprehensive Loss.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is made available for evaluation by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is its chief executive officer, who reviews financial information on a consolidated basis for the purpose of making operating decisions, assessing financial performance, and allocating resources. The Company manages and evaluates its operations on a consolidated basis and has one reportable segment. The CODM primarily evaluates the Company's performance based on net loss and reviews significant expense categories at the consolidated level. Segment assets are not separately monitored, as the CODM focuses on cash and expense impact. Refer to Note 16, *Segment Information*, for additional disclosures regarding the Company's single reportable segment, including segment net loss and significant expense categories.

Summary of Significant Accounting Policies

Cash, Cash Equivalents, Restricted Cash, and Concentration of Credit Risk

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash and cash equivalents consisted of cash on deposit with banks denominated in U.S. dollars and investments in money market funds.

Restricted cash represents cash held to support letters of credit related to certain operating leases and is classified within other current or non-current assets on the Consolidated Balance Sheets based on the expected timing of release.

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the Consolidated Balance Sheets that total the same such amounts shown in the Consolidated Statements of Cash Flows:

	December 31,	
	2025	2024
Cash and cash equivalents	$ 253,798	$ 141,239
Restricted cash	1,072	587
Cash, cash equivalents and restricted cash	254,870	141,826

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and restricted cash. The Company maintains its cash, cash equivalents, and restricted cash with multiple accredited financial institutions. Deposits held with these institutions may exceed federally insured limits. The Company has not experienced any losses related to these accounts and does not believe it is exposed to significant credit risk beyond the normal risks associated with commercial banking relationships.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally ranging from three to five years, depending on the nature of the asset. Leasehold improvements are amortized over the shorter of the asset's estimated useful life or the remaining lease term.

Construction-in-progress reflects amounts incurred for property and equipment that have not yet been placed in service and, accordingly, are not depreciated or amortized until the related assets are ready for their intended use.

Expenditures for major renewals and improvements that extend the useful life of an asset or increase its functionality are capitalized when they meet the Company's capitalization criteria. Routine maintenance and minor repairs that do not extend the useful life of an asset are expensed as incurred.

Upon retirement or disposal of property and equipment, the cost of the asset and the related accumulated depreciation are removed from the accounts, and any resulting gain or loss is included in operating expenses in the Consolidated Statements of Operations and Comprehensive Loss.

Long-Lived Assets

The Company reviews long-lived assets, which consist primarily of property and equipment, for impairment in accordance with ASC 360, *Property, Plant, and Equipment*. Long-lived assets are evaluated for recoverability whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. Asset groups are determined at the lowest level for which identifiable cash flows are largely independent.

Recoverability is assessed by comparing the carrying amount of the asset group to the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset group. If the carrying amount exceeds the undiscounted cash flows, an impairment loss is recognized and measured as the amount by which the carrying amount exceeds the asset group's fair value. Fair value is determined using valuation techniques consistent with ASC 820, *Fair Value Measurement*, which may include market and income approaches, as appropriate.

Changes in estimates of useful lives or residual values are accounted for prospectively and result in adjustments to depreciation or amortization expense over the remaining useful lives of the related assets.

No impairment losses were recognized during the years ended December 31, 2025 and 2024.

Fair Value Measurements

The Company measures certain financial instruments at fair value on a recurring basis. Fair value is defined as the price that would be received to sell 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 at the measurement date. Fair value is a market-based measurement and is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company's financial instruments measured at fair value consist solely of cash equivalents, which are valued using quoted prices in active markets. Accordingly, these instruments are classified within Level 1 of the fair value hierarchy. The Company does not have any financial instruments classified within Level 2 or Level 3 of the fair value hierarchy.

A three-level fair value hierarchy has been established to prioritize the inputs used in measuring fair value as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or valuations with significant inputs that are observable, either directly or indirectly.

Level 3 — Valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are classified in their entirety within the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

Leases

The Company accounts for leases in accordance with ASC Topic 842, *Leases* ("ASC 842"). The Company's leases primarily consist of real estate and laboratory equipment. At lease inception, the Company determines whether an arrangement contains a lease and classifies it as either an operating or finance lease. The Company's operating and finance lease assets are included in right-of-use assets, net, and the current and non-current portions of the lease liabilities are included in lease liabilities and lease liabilities, non-current, respectively, on the Consolidated Balance Sheets. Right-of-use assets and lease liabilities are initially measured at the present value of future lease payments over the lease term, including fixed payments and certain in-substance fixed payments. Right-of-use assets are based on the corresponding lease liability, adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. Variable lease payments that do not depend on an index or rate are excluded from the measurement of lease liabilities and are recognized as expense as incurred.

The Company does not account for renewals or early terminations unless it is reasonably certain that such options will be exercised at lease commencement. Lease modifications are accounted for in accordance with ASC 842 when the modification results in a separate contract or a remeasurement of the existing lease. The Company has elected the practical expedient to account for lease and non-lease components as a single lease component for both operating and finance leases.

Operating lease expense is recognized on a straight-line basis over the lease term. Finance lease right-of-use assets are amortized on a straight-line basis over the shorter of the lease term or the estimated useful life of the leased asset. The discount rate used to calculate the present value of lease liabilities is either the rate explicitly stated in the lease for finance leases or the Company's incremental borrowing rate at the lease commencement date. The incremental borrowing rate is estimated to approximate the interest rate on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located. In determining the incremental borrowing rate, the Company considers factors including its credit rating, interest rates for similar debt instruments of entities with comparable credit ratings, the lease term, and the currency in which the lease is denominated.

The Company has elected the practical expedient to not recognize leases with a lease term of twelve months or less ("short-term leases") on the balance sheet. Lease payments for such short-term leases are recognized as expense on a straight-line basis over the lease term.

Refer to Note 10, *Leases*, for additional information.

Research and Development Expenses

The Company expenses research and development costs as incurred in accordance with ASC 730, Research and Development. These costs primarily support discovery activities and the development of the Company's product candidates and technology platform, including preclinical and clinical development of its development programs. Expenses include fees paid to third parties and contract research organizations ("CROs"), costs to manufacture materials for studies and trials, including payments to contract development and manufacturing organizations ("CDMOs"), and employee-related costs such as salaries, bonuses, benefits, and stock-based compensation. The Company also includes facilities-related costs, depreciation, and other direct or allocated expenses for rent, maintenance, and utilities, as well as licensing and license maintenance fees under agreements with no alternative future use and costs incurred to meet regulatory requirements.

The Company accrues expenses for research and development activities performed by third parties based on the level of services performed, the progress of studies (including the phase or completion of events), and contracted costs. Estimated costs of research and development provided but not yet invoiced are recorded in accrued expenses and other current liabilities on the Consolidated Balance Sheets. Accruals are adjusted as actual timing of services or levels of effort differ from estimates. Payments made to third parties in advance of the related services are recorded as prepaid expenses until the services are rendered. The Company estimates the period over which such services will be performed based on the terms of the agreements and the level of effort expected in each period.

Stock-Based Compensation Valuation and Expense

The Company measures all stock options and other stock-based awards granted to employees, non-employees, and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award, in accordance with ASC Topic 718, *Compensation – Stock Compensation* ("ASC 718") . Restricted stock units ("RSUs") are measured and recognized over the vesting period based on the quoted market price of the Company's common stock on the grant date.

The Company utilizes the Black-Scholes-Merton ("BSM") option pricing model to determine the estimated fair value of stock options granted to employees and non-employees, including directors. In addition to the fair value of the Company's common stock, the BSM model requires several key assumptions:

- 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 term in accordance with the simplified method, which is an average of the contractual term of the stock option and its vesting period.
- 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.
- Risk-Free Interest Rate—The risk-free interest rate is based on the implied yield currently available on U.S. Treasury issues with a term that is equal to the stock options' expected term at the grant date.
- Expected Dividend—The expected dividend yield is assumed to be zero as the Company has not declared or paid dividends to date and does not anticipate declaring dividends for the foreseeable future.

The Company accounts for forfeitures as they occur. 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, based on the employee or non-employee's functional role within the Company. See Note 8, *Equity Incentive Plans*, for additional information.

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with 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 consolidated financial statements. Under this method, the Company determined deferred tax assets and liabilities on the basis of the differences between the consolidated financial statements 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.

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. Refer to Note 13, *Income Taxes*, for further information.

Net Loss per Share

Basic and diluted net loss per common share is calculated in accordance with ASC 260, *Earnings per Share*, by dividing net loss by the weighted-average number of common shares outstanding during the period. Potentially dilutive securities, including stock options and restricted stock units, are excluded from the computation of diluted net loss per share because their effect would be anti-dilutive for all periods presented. Refer to Note 9, *Net Loss per Share*, for the detailed computation of basic and diluted net loss per share and information regarding the potentially dilutive securities excluded from the computation.

Comprehensive Loss

Comprehensive loss is determined in accordance with ASC 220, *Comprehensive Income*, and includes net loss and other changes in stockholders' equity resulting from transactions and economic events other than those with stockholders. For the Company, comprehensive loss consists of net loss plus foreign currency translation adjustments for all periods presented.

Recently Adopted Accounting Standards

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 adopted ASU 2023-09 during the year ended December 31, 2025. The adoption of this standard impacted the Company's disclosures but did not have a material impact on its consolidated financial statements, results of operations, or financial position.

Recently Issued Accounting Standards Not Yet Adopted

In January 2025, the FASB issued ASU No. 2025-01 to clarify the effective date of ASU No. 2024-03 *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures* (Subtopic 220-40) ("ASU 2024-03"), which requires disaggregated disclosure of certain income statement captions within the footnotes to the financial statements. ASU 2025-01 requires adoption of the amendments of ASU 2024-03 in annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270)* ("ASU 2025-11") to clarify the applicability of ASC 270 and improve the organization of the guidance. The ASU clarifies when an entity is subject to interim reporting requirements and establishes disclosure principles for material events occurring since the end of the most recent annual reporting period. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-12, *Improvements to Accounting Standards Codification* ("ASU 2025-12*"),* which addresses stakeholder suggestions and makes incremental improvements to U.S. GAAP. The amendments clarify guidance, correct errors, and make minor improvements to the Accounting Standards Codification. ASU 2025-12 is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. The Company is currently evaluating the impact of this standard on its financial statements and related disclosures.

3. MERGER

As described in Note 1, *Nature of the Business*, the Company completed its Merger with AVROBIO on June 20, 2024. The Merger was accounted for as a reverse recapitalization in accordance with GAAP, with Legacy Tectonic as the accounting acquirer of AVROBIO. At the effective time of the Merger, substantially all the assets of AVROBIO consisted of cash and cash equivalents, as well as other nominal assets. Under such reverse recapitalization accounting, the assets and liabilities of AVROBIO were recorded at their fair value at the effective time of the Merger, which approximated book value due to the short-term nature. No goodwill or intangible assets were recognized. Consequently, the consolidated financial statements of the Company reflect the historical operations of Legacy Tectonic for accounting purposes together with the issuance of shares to the former shareholders of AVROBIO, the legal acquirer, and a recapitalization of the equity of Legacy Tectonic, the accounting acquirer. The exchange ratio was retroactively applied to all outstanding common shares, convertible preferred shares, stock options and restricted stock of Legacy Tectonic.

As part of the recapitalization, Legacy Tectonic recognized the assets and liabilities listed below:

Cash and cash equivalents	$	85,230
Prepaid expenses and other current assets		319
Accounts payable		(1,988)
Accrued expenses and other current liabilities		(5,405)
Net assets acquired	$	78,156

The Company incurred transaction costs of $9.3 million which was recorded as a reduction to additional paid-in capital in the Consolidated Balance Sheet for the year ended December 31, 2024.

4. 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:

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 253,498	$ —	$ —	$ 253,498
Total assets	$ 253,498	$ —	$ —	$ 253,498

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 139,610	$ —	$ —	$ 139,610
Total assets	$ 139,610	$ —	$ —	$ 139,610

Money market funds are included in cash and cash equivalents on the Consolidated Balance Sheets and are measured at fair value on a recurring basis. These instruments are classified within Level 1 of the fair value hierarchy because they are valued using quoted prices in active markets for identical assets.

There were no transfers between the Level 1, Level 2 or Level 3 categories during the years ended December 31, 2025 and 2024.

The carrying amounts reflected in the Company's Consolidated Balance Sheets for prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair values, due to their short-term nature.

SAFE Liabilities

From October through December 2023, Legacy Tectonic entered into multiple SAFE agreements with certain existing investors and received proceeds of $34.1 million. Prior to redemption, 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 required 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.

Upon the closing of the Merger, the principal balance of the SAFE instruments was automatically redeemed for 2,752,216 shares of Legacy Tectonic common stock at the conversion price of $12.40 per share immediately prior to the Merger closing. As such the valuation inputs utilized to adjust the SAFE liability to fair value upon the closing of the Merger was $12.40. At closing, shares of Legacy Tectonic common stock issued pursuant to the redemption of Legacy Tectonic SAFEs were converted into 1,470,839 shares of AVROBIO common stock based on the Exchange Ratio, pursuant to the Merger Agreement. No level 3 instruments remain outstanding after the Merger.

The following table presents activity for the SAFE liabilities that were measured at fair value using significant unobservable Level 3 inputs during the year ended December 31, 2024:

	SAFE Liabilities
Balance as of January 1, 2024	30,515
Fair value adjustments	3,610
Redemption	(34,125)
Balance as of December 31, 2024	$ —

5. PROPERTY AND EQUIPMENT, NET

Property and equipment, net is comprised of the following:

	December 31, 2025	December 31, 2024
Laboratory equipment	$ 4,286	$ 4,590
Office equipment, furniture and fixtures	281	281
Leasehold improvements	25	25
	4,592	4,896
Less: accumulated depreciation	(3,407)	(2,745)
Property and equipment, net	$ 1,185	$ 2,151

Depreciation expense was $1.0 million and $1.2 million for the years ended December 31, 2025 and 2024, respectively, and is primarily attributable to research and development activities.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities is comprised of the following:

	December 31, 2025	December 31, 2024
Accrued compensation and related expenses	$ 4,110	$ 3,585
Accrued research and development expenses	2,301	2,787
Accrued other expenses	929	1,478
Total accrued expenses and other current liabilities	$ 7,340	$ 7,850

7. STOCKHOLDERS' EQUITY

Common Stock

The Company is authorized to issue 150,000,000 shares of common stock at a par value of $0.0001 per share. Holders of voting common stock are entitled to one vote per share. In addition, holders of voting common stock are entitled to receive dividends, if and when declared by the Company's Board of Directors. As of December 31, 2025, no dividends have been declared.

The Company reserved common stock for future issuance as follows:

	December 31, 2025	December 31, 2024
Outstanding options to purchase common stock	1,951,417	1,626,841
Unvested restricted stock units	262,184	25,612
Equity awards available for future issuance under the 2024 Equity Incentive Plan	925,367	976,082
Shares reserved for purchase under the 2024 Employee Stock Purchase Plan	295,906	147,343
Total	3,434,874	2,775,878

Preferred Stock

The Company is authorized to issue 10,000,000 shares of undesignated preferred stock at a par value of $0.0001 per share, however no such shares were issued or outstanding as of December 31, 2025.

Convertible Preferred Stock

Prior to the conversion upon the closing of the Merger, Legacy Tectonic issued Series A-1, A-2, A-3 and A-4 convertible preferred stock (the "Convertible Preferred Stock"). Upon the closing of the Merger, all outstanding shares of the Convertible Preferred Stock were converted into 3,647,675 shares of common stock. No shares of Convertible Preferred Stock are authorized for issuance as of December 31, 2025.

Changes in Capital Structure

In February 2025, the Company entered into a securities purchase agreement (the "Private Placement") pursuant to which the Company issued an aggregate of 3,689,465 shares of common stock, at a price of $50.00 per share to institutional accredited investors and $54.14 per share to individual accredited investors that are either an officer or director of the Company. The net proceeds from the Private Placement were approximately $173.1 million.

Upon the closing of the Merger as described in Note 3, *Merger*, all outstanding shares of convertible preferred stock were converted into an aggregate of 3,647,675 shares of the Company's common stock and $80.6 million of mezzanine equity was reclassified to common stock and additional paid-in capital. As of December 31, 2024, there were no shares of convertible preferred stock issued or outstanding.

Upon the closing of the Merger, the principal balance of the SAFE instruments was automatically redeemed for 2,752,216 shares of Legacy Tectonic common stock at the conversion price of $12.40 per share immediately prior to the Merger closing. At closing, shares of Legacy Tectonic common stock issued pursuant to the redemption of Legacy Tectonic SAFEs were converted into 1,470,839 shares of common stock based on the Exchange Ratio, pursuant to the Merger Agreement.

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 $12.40 per share for an aggregate purchase price of $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 common stock upon the closing of the Merger based on the exchange ratio, pursuant to the Merger Agreement.

8. EQUITY INCENTIVE PLANS

2019 Equity Incentive Plan

The Legacy Tectonic 2019 Equity Incentive Plan (the "2019 Plan") provides employees, consultants and advisors and non-employee members of the Board of Directors with the opportunity to receive grants of stock options, stock awards and equity awards. Following the effectiveness of the 2024 Equity Incentive Plan as described below, no further grants are to be made under the 2019 Plan; however, outstanding equity awards granted under the 2019 Plan continue to be governed by the terms of the 2019 Plan.

2024 Equity Incentive Plan

On June 20, 2024, the Company adopted the 2024 Equity Incentive Plan (the "2024 Plan") which became effective upon completion of the Merger. The 2024 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, consultants, and non-employee directors of the Company. The number of shares of common stock available for issuance under the 2024 Plan will automatically increase on January 1st of each year through January 1, 2034, in an amount equal to the lesser of (a) 5% of the total number of shares of common stock issued and outstanding determined as of the day prior to such increase, or (b) an amount determined by the Board of Directors. On January 1, 2026, the number of shares of common stock available for issuance under the 2024 Plan automatically increased by 936,912 shares.

2024 Employee Stock Purchase Plan

On June 20, 2024, the Company adopted the 2024 Employee Stock Purchase Plan (the "ESPP"), which became effective upon completion of the Merger. The number of shares of our common stock available for issuance under the ESPP will automatically increase on January 1st of each year through 2034, in an amount equal to the lesser of (a) 1% of the total number of shares of common stock issued and outstanding determined as of the day prior to such increase, (b) a number of shares qual to three times the initial share reserve , or (c) an amount determined by the Board of Directors. On January 1, 2026, the number of shares of common stock available for issuance under the ESPP increased by 187,382 shares. No offering periods under the ESPP have been initiated as of December 31, 2025.

Stock Options

Stock options granted to employees generally vest over a four-year period in multiple tranches and have a contractual term of ten years. Options granted to the Board of Directors generally vest over a one-year period.

The following table summarizes the stock option activity under the 2019 Plan and 2024 Plan for the year ended December 31, 2025:

	Outstanding Options			
	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2025	1,534,361	$ 12.49		
Options granted	559,873	35.21		
Options exercised	(114,558)	2.91		$ 3,240
Options forfeited and expired	(28,259)	14.27		
Outstanding as of December 31, 2025	1,951,417	$ 19.55	8.2	$ 12,532
Options vested and exercisable as of December 31, 2025	792,535	$ 13.45	7.5	$ 8,004
Options vested and expected to vest as of December 31, 2025	1,951,417	$ 19.55	8.2	$ 12,532

During the years ended December 31, 2025 and 2024, the Company granted options with a weighted-average grant-date fair value of $29.04 and $14.90 per share, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $3.2 million and $5.6 million, respectively.

The following table summarizes the stock option activity for the options that were assumed from AVROBIO upon the Merger closing for the year ended December 31, 2025:

	Outstanding Options		
	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding as of January 1, 2025	92,480	$ 22.69	
Options exercised	(71,215)	12.61	$ 2,099
Options forfeited and expired	(21,265)	56.44	
Outstanding as of December 31, 2025	—	$ —	$ —
Options vested and exercisable as of December 31, 2025	—	$ —	$ —
Options vested and expected to vest as of December 31, 2025	—	$ —	$ —

As of December 31, 2025, no unexercised or outstanding stock options related to the Merger remain.

Fair Value of Stock Options Granted

The Company utilizes the BSM option-pricing model to determine the fair value of stock options granted.

The following table summarizes the assumptions used for estimating the fair value of stock options granted under the BSM option-pricing model:

	Year Ended December 31,	
	2025	2024
Expected term (in years)	5.50 - 6.25	6.00 - 6.25
Expected volatility	102.6% - 103.7%	100.0% - 104.0%
Risk-free interest rate	3.76% - 4.43%	4.10% - 4.26%
Expected dividend yield	0%	0%

Restricted Stock Units

Restricted stock units (“RSUs”), which are granted to employees, generally vest over a three-year period. The value of an RSU award is based on the quoted market price of the Company's stock on the grant date. The shares underlying the RSUs are not issued until the RSUs vest. The following table summarizes the RSU activity for the year ended December 31, 2025:

	Outstanding RSUs	
	Number of Shares Underlying Outstanding Units	Weighted-Average Grant Date Fair Value per Unit
Outstanding as of January 1, 2025	25,612	$ 44.90
Restricted stock units granted	246,262	36.13
Restricted stock units vested	(7,561)	44.08
Restricted stock units forfeited	(2,129)	48.01
Outstanding as of December 31, 2025	262,184	$ 36.66
Unvested and expected to vest as of December 31, 2025	262,184	$ 36.66

During the years ended December 31, 2025 and 2024, the Company granted RSUs with a weighted-average grant date fair value of $36.13 and $44.62 per unit, respectively. The total fair value of RSUs vested during the year ended December 31, 2025 was $0.1 million. No RSUs vested during the year ended December 31, 2024.

Upon vesting of RSUs, the Company withholds shares with a fair value equal to the minimum statutory tax withholding requirements. During the year ended December 31, 2025, 859 shares were withheld for tax purposes. Shares withheld are accounted for as a reduction of additional paid-in capital within stockholders' equity.

Stock-Based Compensation Expense

The following table is a summary of stock-based compensation expense recognized by function:

	Year Ended December 31,	
	2025	2024
General and administrative	$ 6,003	$ 2,309
Research and development	4,494	1,182
Total stock-based compensation expense	$ 10,497	$ 3,491

The following table summarizes the unrecognized compensation expense and the weighted-average remaining period over which it is expected to be recognized, by type of award:

	As of December 31, 2025	
	Unamortized Expense	Weighted Average Remaining Recognition Period (Years)
Stock options	21,445	2.5
RSUs	7,163	2.3

Modification of Certain Stock Options

In July 2024, the Company entered into a separation agreement with the Company's Chief Operating Officer (the "Former Executive"). As part of the termination of employment, the Former Executive served as an advisor to the Company through March 31, 2025 ("Consulting Period") on an as needed basis. Pursuant to the separation agreement, certain modifications to the Former Executive's vested and non-vested stock option awards were executed including continued vesting of options during the Consulting Period and the extension of the post-termination exercise period of certain stock option awards. The services performed during the Consulting Period do not qualify as substantive services under ASC 718, *Compensation—Stock Compensation*; therefore, the continued vesting of these awards represents a modification to the original award. During the year ended December 31, 2024, the Company recorded the incremental stock-based compensation expense of $0.4 million for the modification of the stock options of the Former Executive. This amount is included in general and administrative expenses on the Consolidated Statement of Operations and Comprehensive Loss.

9. NET LOSS PER SHARE

The following table summarizes the computation of basic and diluted net loss per share:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (74,151)	$ (57,982)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	18,322,533	8,490,171
Net loss per share, basic and diluted	$ (4.05)	$ (6.83)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	As of December 31,	
	2025	2024
Options to purchase common stock	1,951,417	1,626,841
Unvested restricted stock units	262,184	25,612
Total	2,213,601	1,652,453

10. LEASES

The Company has lease obligations, including amounts due on leases of certain laboratory equipment and office and laboratory space under the terms of non-cancelable operating and finance leases.

Office and Laboratory Facilities Lease

In November 2020, the Company executed a facilities lease agreement to occupy approximately 19,000 square feet of office and laboratory space, which 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, consistent with the Company's current facilities plan noted below, will not be renewed. Operating lease cost is allocated between research and development and general and administrative expenses based on the usage of the leased facilities. The Company recognizes variable lease costs for operating leases, including its proportionate share of facilities operating expenses. These costs are excluded from the measurement of the lease liability. The reported lease term excludes the Company's renewal options under its office and laboratory lease agreements, as the Company does not consider it reasonably certain to exercise the options.

The Company also has a limited operating lease arrangement for laboratory space that provides the right to use designated research premises through December 31, 2026. The Company initially entered into the lease in December 2023 for a one-year term. The lease term has subsequently been extended pursuant to amendments executed in the ordinary course of business, including an amendment entered into in December 2025 that extended the term through December 31, 2026. The Company has recognized a corresponding right-of-use asset and lease liability of $0.8 million on its Consolidated Balance Sheet related to this arrangement. The lease requires the Company to pay fixed base rent, which is included in the measurement of the lease liability.

Laboratory Equipment Leases

The Company has entered into various financing leases for laboratory equipment used in research and development activities.

Future Lease Commencements

In September 2025, the Company entered into a non-cancelable operating lease for office and laboratory space in Watertown, Massachusetts. The total future minimum lease payments under this agreement are approximately $5.3 million over the lease term of three years. As of December 31, 2025, the lease has not yet commenced, and therefore no right-of-use asset or lease liability has been recognized on the Company's Consolidated Balance Sheet. The lease will be recorded on the balance sheet upon commencement in January 2026, at which time the Company will recognize a right-of-use asset and corresponding lease liability based on the present value of lease payments over the lease term.

The following table summarizes the components of lease costs for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Operating lease cost:		
Fixed lease cost	$ 2,220	$ 1,608
Finance lease cost:		
Amortization of right-of-use assets	424	448
Interest on lease liabilities	63	107
Short-term lease costs	-	545
Variable lease costs	1,008	911
Total lease cost	$ 3,715	$ 3,619

The following table summarizes the lease assumptions for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
	2025	2024
Weighted-average remaining lease terms in years		
Operating leases	0.86	1.06
Finance leases	1.03	2.26
Weighted-average discount rate		
Operating leases	15.50%	8.49%
Finance leases	10.08%	9.76%

Future commitments due under these lease agreements as of December 31, 2025 are as follows:

Year ended December 31,	Operating Leases	Finance Leases	Total
2026	948	363	1,311
2027	—	44	44
Thereafter	—	—	—
Total undiscounted cash flows	948	407	1,355
Less: interest	(59)	(20)	(79)
Total lease liabilities	$ 889	$ 387	$ 1,276
Less: current portion	(889)	(344)	(1,233)
Lease liabilities	$ —	$ 43	$ 43

Future minimum lease payments of $5.3 million related to a lease entered into in September 2025 that had not commenced as of December 31, 2025 are excluded from the maturity table above, as no lease liability had been recognized as of that date.

11. LICENSE AGREEMENTS

Harvard Agreement

In July 2020, Tectonic 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 Tectonic 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, Tectonic 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. The Company paid Harvard a one-time license fee and issued shares of common stock as consideration for the License Agreement.

The Company is 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) milestone payments payable upon regulatory approval and the achievement of specified clinical and commercial milestones for licensed products or know-how enabled products; (3) 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 (4) 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. The Company incurred expense of $0.1 million and $0.4 million related to the License Agreement during the years ended December 31, 2025 and 2024, respectively.

12. COMMITMENTS AND CONTINGENCIES

Commitments

The Company enters into contractual agreements with various suppliers in the normal course of its business. All contracts are terminable, with varying provisions regarding termination. If a contract with a specific vendor were to be terminated, the Company would only be obligated for the products or services that the Company had received through the time of termination.

The Company is also party to lease commitments, as described in Note 10, *Leases*, and milestone, royalty and maintenance based commitments, as described in Note 11, *License Agreements.*

Contingencies

In connection with the Merger, the Company 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 closing received a contractual contingent value right ("CVR") representing the contractual right to receive a pro rata portion of any net proceeds, if any, resulting from the disposition of certain AVROBIO intellectual property after the closing, subject to the terms of the CVR Agreement. The CVR Agreement expired 18 months following the closing of the Merger and is no longer in effect. No AVROBIO intellectual property was sold or otherwise disposed of, and, as a result, no payments were made or are due under the agreement. The Company did not record any receivables or liabilities related to the CVRs on the Consolidated Balance Sheets as of December 31, 2025 and 2024.

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. There are no matters pending that the Company currently believes are reasonably possible or probable of having a material impact to the Company's financial position, results of operations, or statements of cash flows.

In the normal course of operations, the Company may become involved in various legal proceedings. As of December 31, 2025 and 2024, the Company has not recorded accruals for probable losses related to any existing or pending litigation as the Company's management has determined that there are no matters where a potential loss is probable and reasonably estimable. The Company does not believe that any existing or pending claims would have a material impact on the Company's consolidated financial statements.

13. INCOME TAXES

The components of net (loss) income before income tax expense are as follows:

	Year Ended December 31,	
	2025	2024
Domestic	$ (73,150)	$ (55,483)
Foreign	229	(2,499)
Loss before income tax	$ (72,921)	$ (57,982)

The components of the provision for income taxes are as follows:

	Year Ended December 31,	
	2025	2024
Current expense (benefit):		
Federal	$ —	$ —
State	45	—
Foreign	1,185	—
Total current expense (benefit):	1,230	—
Deferred expense (benefit):		
Federal	14,931	13,004
State	4,127	3,181
Foreign	(380)	741
Deferred tax benefit	18,678	16,926
Less change in valuation allowance	(18,678)	(16,926)
Total income tax expense (benefit)	$ 1,230	$ —

The reconciliation of the Company's statutory tax rate and effective tax rate is as follows:

	Year Ended December 31,			
	2025		2024	
	Amount	Percent	Amount	Percent
Pretax loss	$ (72,921)	-	$ (57,982)	-
U.S. Federal statutory income tax rate	(15,313)	21.0%	(12,176)	21.0%
State and local income taxes, net of federal benefit[(a)]	45	(0.1)%	-	—%
Foreign tax effects:				
Australia-tax on sale of commercialization rights	1,185	(1.6)%	693	(1.2)%
Australia-other	(37)	0.1%	-	—%
Other foreign jurisdictions	(12)	—%	(168)	0.3%
Tax credits:				
Federal R&D credit	(1,418)	1.9%	(1,247)	2.2%
Change in valuation allowance	14,931	(20.4)%	13,004	(22.5)%
Nontaxable or nondeductible items:				
SAFE liability loss	-	—%	968	(1.7)%
Equity-based compensation	1,442	(2.0)%	(727)	1.3%
Other	407	(0.6)%	(347)	0.6%
Effective income tax rate	$ 1,230	(1.7)%	$ -	—%

(a) State taxes in Massachusetts make up the majority (greater than 50 percent) of the tax effect in this category.

The components of the Company’s net deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2025	2024
Deferred tax assets		
Net operating loss carryforward	$ 123,867	$ 109,392
Research credits	15,755	13,946
Accruals & other	913	863
Capitalized research and development expenses	43,829	40,742
Stock-based compensation	1,750	2,112
Amortization	3,167	3,555
Lease liability	240	660
Total deferred tax assets	189,521	171,270
Valuation allowance	(188,891)	(170,177)
Net deferred tax assets	$ 630	$ 1,093
Deferred tax liabilities		
Depreciation	$ (394)	$ (485)
Right of use asset	(236)	(608)
Total deferred tax liabilities	(630)	(1,093)
Net deferred tax assets (liabilities)	$ —	$ —

As of December 31, 2025, the Company had $453.3 million of U.S. federal net operating loss carryforwards, all of which have an unlimited carryforward period. As of December 31, 2025, the Company had $123.7 million of state net operating loss carryforwards, which begin to expire at various dates from 2038 through 2045. As of December 31, 2025, the Company had $8.0 million of foreign net operating loss carryforwards, which is comprised of $7.6 million in Australia that have an unlimited carryforward period and $0.4 million in Canada that begin to expire in 2044.

As of December 31, 2025, the Company had $11.9 million of U.S. federal research and development tax credits that begin to expire in 2039. As of December 31, 2025, the Company had $4.9 million of state research and development tax credits that begin to expire at various dates from 2034 through 2040.

The future realization of the tax benefits from existing temporary differences and tax attributes ultimately depends on the existence of sufficient taxable income. The Company assesses the realizability of its deferred tax assets at each balance sheet date. In assessing the realization of its deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The Company considers the projected future taxable income, expected reversal of existing deferred tax liabilities, and tax planning strategies in making this assessment. After consideration of all available evidence, both positive and negative, the Company determined that it is not more likely than not that its net deferred tax assets will be realized in the foreseeable future. As a result, the Company increased its valuation allowance by $18.7 million as of December 31, 2025.

The future realization of the Company's net operating loss carryforwards and other tax attributes may also be limited by the change in ownership rules under the U.S. Internal Revenue Code Section 382. Under Section 382, if a corporation undergoes an ownership change (as defined), the corporation’s ability to utilize its net operating loss carryforwards and other tax attributes to offset income may be limited. The Company has not completed a study to assess whether an ownership change has occurred or whether there have been multiple ownership changes.

The Company does not provide for U.S. Federal, state, and applicable foreign income and withholding taxes on the financial reporting basis over the tax basis of its foreign subsidiary investment because the Company has the intentions and ability to indefinitely reinvest the undistributed earnings of its foreign subsidiaries. As a result, deferred taxes have not been recorded for the outside basis differences in its foreign subsidiary as of December 31, 2025 to the extent such differences are expected to result in future taxable income upon repatriation. The Company reviews its ability and intentions to indefinitely reinvest its foreign earnings at each balance sheet.

The Company records uncertain tax positions as liabilities in accordance with ASC 740-10 and adjusts these liabilities when judgment changes as a result of the evaluation of new information not previously available. Since there is complexity in some of these uncertainties, the ultimate resolution may result in a payment that is materially different from the current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to income tax expense in the period in which new information is available. The calculation and assessment of the Company's income tax exposures generally involves the uncertainties in the application of complex tax laws and regulations for federal, state, and foreign jurisdictions. A tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon local tax examination including resolutions of any related appeals or litigation on the basis of the technical merits.

The Company files income tax returns in the US, Australia and Canada, which are the Company's major jurisdictions where it is subject to tax examination by local tax authorities. The Company is not currently under examination for income taxes, and is not aware of any issues

under review that could result in significant payments, accruals or material deviation from its tax positions. 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 local tax authorities to the extent utilized in a future period. The statute of limitations for the Company has expired for tax years prior to 2021.

The following summarizes the Company's income taxes paid (net of refunds received) for the years presented :

	Year Ended December 31,	
	2025	2024
Federal	$ —	$ —
State	45	—
Foreign	1,185	—
Total income tax paid, net	**$ 1,230**	**$ —**

The following summarizes the jurisdictions that exceeded 5% of the Company's total income taxes paid (net of refunds) for the years presented:

	Year Ended December 31,	
	2025	2024
Australia	$ 1,185	*

* Jurisdiction below the threshold for the period presented.

14. RELATED PARTY TRANSACTIONS

The Company enters into transactions with related parties in the ordinary course of business. Related parties include the Company's directors, executive officers, principal stockholders, and entities in which such individuals have a controlling financial interest.

Scientific Advisory Board Member

One of the Company's co-founders and former director is a member of the Company's Scientific Advisory Board and meets the criteria of a related party. For each of the years ended December 31, 2025 and 2024, the Company incurred expense of $0.1 million for advisory services provided. There were no amounts due to this related party as of December 31, 2025 or 2024.

License Agreement

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. Core intellectual property utilized by the Company is licensed from Harvard under the License Agreement described in Note 11, *License Agreements*.

The Company incurred expense of $0.1 million and $0.4 million related to the License Agreement during the years ended December 31, 2025 and 2024, respectively. No amounts were due to Harvard related to the License Agreement as of December 31, 2025 and 2024.

Private Placement

The Company issued shares in connection with the Private Placement at a price of $54.14 per share to accredited investors that are either an officer or director of the Company.

SAFE Agreements

From October through December 2023, Legacy Tectonic entered into multiple SAFE agreements with certain existing investors and received proceeds of $34.1 million. All investors were considered related parties of the Company. The SAFE agreements had no maturity date, bore no interest, and were redeemable by Legacy Tectonic upon the occurrence of a triggering event, including the Merger which qualified as a public listing transaction under the SAFE agreements. The SAFEs were redeemed for shares of Legacy Tectonic common stock in connection with the closing of the Merger. As of December 31, 2024, no related-party SAFEs were outstanding, and the Company had no further obligations under these agreements.

15. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) retirement plan (the "Plan") that covers eligible U.S. employees. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. The Company's funding policy is to contribute 3% ("Nonelective Contribution") of employees' eligible pay to the Plan. The Company recognized compensation expense related to the Plan of $0.4 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively.

16. SEGMENT INFORMATION

The Company operates in one operating segment, and therefore one reportable segment, focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of GPCRs. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

The determination of a single segment is consistent with the consolidated financial information regularly reviewed by the Chief Executive Officer, who serves as the CODM, in evaluating financial performance and allocating resources on a consolidated basis. The CODM primarily evaluates the Company's performance based on net loss and significant expense categories.

No segment asset information is presented because the CODM focuses on cash and expense impact; segment assets are monitored at the same level as the Consolidated Balance Sheet.

The following table presents the segment net loss and significant segment expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Employee-related expenses:		
Research and development employee-related expenses	$ 12,961	$ 11,135
General and administrative employee-related expenses	5,548	5,553
External research and development expenses:		
Research and preclinical expenses	7,001	8,477
Clinical and development expenses	23,798	15,380
Chemistry, manufacturing, and control expenses	10,052	3,570
Non-clinical science expenses	3,667	—
Non-employee-related general and administrative expenses	8,985	8,733
Other segment items[1]	2,139	5,134
Net loss	$ 74,151	$ 57,982

[1] Other segment expenses include expenses not captured in the primary employee-related, research and development, or general and administrative categories, such as stock-based compensation, depreciation and amortization, changes in the fair value of SAFE liabilities, income tax expense, interest income and interest expense.