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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

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 210 Watertown, MA	
(Address of principal executive offices)	**02472 (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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 9, 2024, the registrant had 14,734,479 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains statements that are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies, our ability to fund our working capital requirements, our financial performance and our ability to effectively manage our anticipated growth, our ability to obtain additional funding for our operations, and other risks and uncertainties, including those listed under the section titled "Risk Factors" in this Quarterly Report regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including, any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward looking statements in this Quarterly Report on Form 10-Q ("Quarterly Report") may include, for example, statements about:

- the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and related preparatory work and the period during which the results of the trials will become available, as well as our research and development programs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our strategies, prospects, plans, expectations or objectives of management for our future operations;
- our progress, scope or timing of the development of our product candidates;
- our expectations surrounding the potential safety, efficacy, and regulatory and clinical progress of TX45 and any other product candidates, and our anticipated milestones and timing therefor;
- the benefits that may be derived from any of our future products or the commercial or market opportunity with respect to any of our future products;
- our ability to identify and develop additional product candidates using our GEODe ™ platform;
- our ability to protect our intellectual property rights;
- our ability to enroll patients in clinical trials, to timely and successfully complete those trials and to receive necessary regulatory approvals;
- the expected timing of filings with regulatory authorities for any product candidates that we develop;
- our expectations regarding the potential market size and the rate and degree of market acceptance for any current or future product candidates that we develop; and
- our ability to receive any milestone or royalty payments under our collaboration and license agreements.

These forward-looking statements are based on our management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions and are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the section titled "Risk Factors" under Part II, Item 1A below, and under similar captions in our periodic reports filed with the SEC from time to time. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Quarterly Report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report to conform these statements to new information, actual results or changes in our expectations, except as required by law.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

TECTONIC THERAPEUTIC, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(unaudited)

	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 185,124	$ 28,769
Prepaid expenses and other current assets	2,264	2,115
Total current assets	187,388	30,884
Property, equipment and improvements, net	2,639	3,122
Finance right-of-use assets, net	1,208	1,437
Operating right-of-use assets	2,075	2,669
Deferred offering costs	—	669
Restricted cash	587	587
Other assets	13	31
Total assets	$ 193,910	$ 39,399
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,090	$ 409
Accrued expenses and other current liabilities	20,009	8,141
SAFE liabilities	—	30,515
Operating lease liability - current portion	1,428	1,348
Finance lease liability - current portion	474	475
Total current liabilities	26,001	40,888
Operating lease liability - net of current portion	905	1,644
Finance lease liability - net of current portion	637	876
Total liabilities	27,543	43,408
Commitments and contingencies (Note 7)		
Convertible preferred stock (Series A-1, A-2, A-3 and A-4), $0.0001 par value; 6,825,483 shares authorized as of December 31, 2023; 6,825,483 shares issued and outstanding as of December 31, 2023; aggregate liquidation preference of $87,459 as of December 31, 2023	—	80,627
Stockholders' Equity (Deficit):		
Common stock, $0.0001 par value; 150,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 14,734,323 and 2,634,246 shares issued and outstanding as of June 30, 2024 and December 31, 2023	2	—
Additional paid-in capital	284,922	5,979
Accumulated other comprehensive loss	(61)	(11)
Accumulated deficit	(118,496)	(90,604)
Total stockholders' equity (deficit)	166,367	(84,636)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 193,910	$ 39,399

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

TECTONIC THERAPEUTIC, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 7,074	$ 8,766	$ 17,892	$ 21,751
General and administrative	4,347	1,865	6,497	3,411
Total operating expenses	11,421	10,631	24,389	25,162
Loss from operations	(11,421)	(10,631)	(24,389)	(25,162)
Other (expense) income, net:				
Change in fair value of SAFE liabilities	(1,535)	—	(3,610)	—
Interest income	318	224	574	352
Interest expense	(28)	(40)	(59)	(82)
Other expense	(5)	(8)	(408)	(8)
Total other (expense) income, net	(1,250)	176	(3,503)	262
Net loss	(12,671)	(10,455)	(27,892)	(24,900)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.34)	$ (8.51)	$ (12.97)	$ (20.60)
Weighted-average common shares outstanding, basic and diluted	2,919,872	1,228,778	2,150,160	1,208,447
Other comprehensive loss:				
Foreign currency translation adjustment	(8)	—	(50)	—
Comprehensive loss	$ (12,679)	$ (10,455)	$ (27,942)	$ (24,900)

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

TECTONIC THERAPEUTIC, INC.

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

(In thousands, except share and per share amounts)

(unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances as of January 1, 2024	6,825,483	$ 80,627	2,634,246	$ —	$ 5,979	$ (11)	$ (90,604)	$ (84,636)
Retroactive application of reverse recapitalization	(3,177,808)	—	(1,226,452)	—	—	—	—	—
Adjusted balance, beginning of period	3,647,675	80,627	1,407,794	—	5,979	(11)	(90,604)	(84,636)
Exercise of stock options	—	—	1,535	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	321	—	—	321
Foreign currency translation adjustment	—	—	—	—	—	(42)	—	(42)
Net loss	—	—	—	—	—	—	(15,221)	(15,221)
Balances as of March 31, 2024	3,647,675	$ 80,627	1,409,329	$ —	$ 6,304	$ (53)	$ (105,825)	$ (99,574)
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
Exercise of stock options	—	—	265,165	—	644	—	—	644
Stock-based compensation expense	—	—	—	—	403	—	—	403
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 subscription agreement, net of offering costs of $2,000	—	—	4,163,606	1	94,600	—	—	94,601
Issuance of common stock upon the Merger	—	—	3,777,709	1	78,156	—	—	78,157
Transaction costs in connection with the Merger	—	—	—	—	(9,937)	—	—	(9,937)
Foreign currency translation adjustment	—	—	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	—	—	(12,671)	(12,671)
Balances as of June 30, 2024	—	$ —	14,734,323	$ 2	$284,922	$ (61)	$ (118,496)	$ 166,367

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances as of January 1, 2023	6,825,483	$ 80,627	2,525,771	$ —	$ 2,127	$ —	$ (47,781)	$ (45,654)
Retroactive application of reverse recapitalization	(3,177,808)	—	(1,175,948)	—	—	—	—	—
Adjusted balance, beginning of period	3,647,675	80,627	1,349,823	—	2,127	—	(47,781)	(45,654)
Exercise of stock options	—	—	686	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	275	—	—	275
Net loss	—	—	—	—	—	—	(14,445)	(14,445)
Balances as of March 31, 2023	3,647,675	$ 80,627	1,350,509	$ —	$ 2,403	$ —	$ (62,226)	$ (59,823)
Stock-based compensation expense	—	—	—	—	277	—	—	277
Net loss	—	—	—	—	—	—	(10,455)	(10,455)
Balances as of June 30, 2023	3,647,675	$ 80,627	1,350,509	$ —	$ 2,680	$ —	$ (72,681)	$ (70,001)

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

TECTONIC THERAPEUTIC, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (27,892)	$(24,900)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	713	734
Stock-based compensation expense	724	552
Non-cash lease expense	595	549
Change in fair value of SAFE liabilities	3,610	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(252)	(479)
Other non-current assets	422	(14)
Accounts payable	(70)	1,706
Accrued expenses and other current liabilities	153	1,645
Operating lease liabilities	(658)	(336)
Net cash used in operating activities	(22,655)	(20,543)
Cash flows from investing activities:		
Purchase of property, equipment and improvements	—	(222)
Net cash used in investing activities	—	(222)
Cash flows from financing activities:		
Proceeds from the Subscription Agreement, net of offering costs of $ 2,000	94,600	—
Cash acquired in connection with the Merger	85,230	—
Payment for Merger transaction costs	(1,168)	—
Proceeds from exercise of common stock options	648	1
Repayment of finance lease obligations	(240)	(270)
Net cash provided by (used in) financing activities	179,070	(269)
Effect of exchange rate changes on cash and cash equivalents	(60)	—
Net increase (decrease) in cash and cash equivalents and restricted cash	156,355	(21,034)
Cash and cash equivalents and restricted cash as of beginning of period	29,356	36,553
Cash and cash equivalents and restricted cash as of end of period	$185,711	$ 15,519
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$185,124	$ 14,932
Restricted cash	587	587
Total cash, cash equivalents and restricted cash	$185,711	$ 15,519
Supplemental disclosure of non-cash financing activities:		
Merger transaction costs included in accounts payable and accrued expenses and other current liabilities	$ 8,769	$ —
Conversion of SAFEs to Common Stock	$ 34,125	$ —
Conversion of Convertible Preferred Stock to Common Stock	$ 80,627	$ —
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 59	$ 82

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

TECTONIC THERAPEUTIC, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

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"). The Company focuses on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality of life. The Company's corporate headquarters are in Watertown, Massachusetts.

Reverse Merger and Pre-Merger Financing Transaction

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 is being 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.

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 an exchange ratio of 0.53 (the "Exchange Ratio"), as defined in the Merger Agreement, 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.

Each outstanding and unexercised option to purchase shares of Legacy Tectonic's common stock immediately prior to closing was assumed by AVROBIO and was converted into an option to purchase shares of AVROBIO common stock, with necessary adjustments to the number of shares and exercise price to reflect the Exchange Ratio. All of Legacy Tectonic's restricted common stock outstanding and unvested immediately prior to the closing that was assumed by AVROBIO in the Merger remains unvested to the same extent and is subject to the same repurchase option, risk of forfeiture or other condition under any applicable restricted stock purchase agreement.

Legacy Tectonic stockholders received approximately 10,956,614 shares of AVROBIO common stock in connection with the Merger, including 6,901 shares of AVROBIO common stock subject to vesting terms, based on the number of shares of Legacy Tectonic common stock outstanding immediately prior to the Merger, including restricted stock, the number of shares of common stock issued to investors participating in the Subscription Agreements (as defined below) and SAFEs, and Legacy Tectonic convertible preferred stock outstanding immediately prior to the Merger, which was converted into shares of Legacy Tectonic common stock on a one-for-one basis immediately prior to the closing of the Merger.

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") subject to and in accordance with the terms and conditions of the CVR Agreement, representing the contractual right to receive a pro rata portion of any net proceeds, if any, as a resulting from a disposition of certain AVROBIO intellectual property (including a license of AVROBIO's pre-closing assets as defined in the CVR Agreement) after the closing and prior to the 18-month anniversary of the closing, received within a 10-year period following the closing; provided that no contingent payment will be payable to any holder of the CVRs until such time as the then-outstanding and undistributed proceeds exceeds $0.4 million in the aggregate. As of June 30, 2024, no proceeds have been received under the CVR Agreement. As of June 30, 2024 there is no liability recorded in connection with the CVR Agreement.

Concurrently with the closing of the Merger, certain investors of Legacy Tectonic completed the purchase of 7,790,889 shares of Legacy Tectonic common stock pursuant to that certain Subscription Agreement dated January 30, 2024 (the "Subscription Agreement") at a purchase price of approximately $12.40 per share for an aggregate purchase price of approximately $96.6 million. Shares of Legacy Tectonic common stock issued pursuant to the Subscription Agreements were converted into 4,163,606 shares of AVROBIO common stock at the closing of the Merger based on the Exchange Ratio, pursuant to the Merger Agreement.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance reporting capabilities.

The Company's proprietary GEODe™ platform is currently in development. There can be no assurance that current and future research and development activities will be successfully completed, that adequate protection for owned intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

Liquidity and Going Concern

As of June 30, 2024, the Company had an accumulated deficit of $ 118.5 million and has incurred losses and negative cash flows from operations since inception, including a net loss of $12.7 million and $27.9 million for the three and six months ended June 30, 2024, respectively. To date, the Company has financed its operations primarily through the issuance of common stock, convertible preferred stock, convertible promissory notes and Simple Agreements for Future Equity ("SAFEs"). The Company has devoted substantially all of its financial resources and efforts to business planning, conducting research and development, recruiting management and technical staff, and raising capital. Management expects that the Company's operating losses and negative cash flows will continue for the foreseeable future as it continues to develop its product candidates.

As the Company continues to develop its proprietary platform and potential product candidates, it will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. It may never achieve profitability, and unless and until it does, it will continue to need to raise additional capital to fund its operations. Management believes that its current cash on hand, which includes the proceeds related to the Merger and Subscription Agreements, is sufficient to fund the Company's planned operations for at least one year from the date of issuance of these unaudited condensed consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

During the six months ended June 30, 2024, there were no significant changes to the Company's significant accounting policies as described in the Company's audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with GAAP and the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to GAAP, as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). In the opinion of the Company, the accompanying unaudited condensed consolidated financial statements contain all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of its financial position and its results of operations, changes in convertible preferred stock and stockholders' equity (deficit) and cash flows. The information as of December 31, 2023 included in the unaudited interim condensed consolidated balance sheets was derived from audited annual consolidated financial statements but does not contain all of the footnote disclosures from the audited annual consolidated financial statements.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited annual consolidated financial statements as of and for the years ended December 31, 2023 and 2022.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include the contract research accruals, stock-based compensation expense, the fair value of the Company's common stock, the income tax valuation allowance, and the fair value determination of the SAFEs. Management's estimates are based on historical experience and various other assumptions that it believes are reasonable under the circumstances. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB, or other standard setting bodies and are adopted by the Company as of the specified effective dates. Unless otherwise discussed, the impact of recently issued standards that are not yet effective are not anticipated to have a material impact on the Company's condensed consolidated financial statements upon adoption.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting* (Topic 280) ("ASU 2023-07"), which enhances the segment disclosure requirements for public entities on an annual and interim basis. Under ASU 2023-07, public entities will be required to disclose significant segment expenses that are regularly provided to the chief operating decision maker ("CODM") and included within each reported measure of segment profit or loss. Additionally, current annual disclosures about a reportable segment's profit or loss and assets will be required on an interim basis. Entities will also be required to disclose information about the CODM's title and position at the Company along with an explanation of how the CODM uses the reported measures of segment profit or loss in their assessment of segment performance and deciding whether how to allocate resources. Finally, ASU 2023-07 requires all segment disclosures for public entities that have only a single reportable segment. The amendments in ASU 2023-07 are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-07 on its condensed consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes* (Topic 740) ("ASU 2023-09"), which enhances the income tax disclosure requirements for public entities on an annual basis. Under ASU 2023-09, public entities will be required to disclose in their rate reconciliation, on an annual basis, both percentages and amounts in their reporting currency for certain categories in a tabular format, with accompanying qualitative disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, and early adoption is permitted. The Company is currently evaluating the impact of ASU 2023-09 on its condensed consolidated financial statements.

3. MERGER

As described in Note 1, the Company completed its previously announced 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 non-operating assets. Under such reverse recapitalization accounting, the assets and liabilities of AVROBIO were recorded at their fair value in AVROBIO's financial statements 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 condensed 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 obtained 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 $9.9 million, of which $8.2 million was recorded within accrued expenses and other current liabilities on the condensed consolidated balance sheet, $0.6 million was recorded within accounts payable on the condensed consolidated balance sheet and $1.2 million was paid in cash as of June 30, 2024. This amount was recorded as a reduction to additional paid-in capital in the condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the three and six months ended June 30, 2024.

With respect to the CVRs issued in connection with the Merger, the Company believes that any receipt of payments resulting from an AVROBIO disposition of AVROBIO's pre-closing assets described in the CVR Agreement are highly susceptible to factors outside the Company's influence that are not expected to be resolved within the timeline outlined in the CVR Agreement, if at all. In particular, these amounts are primarily influenced by the actions and judgments of third parties and the buyers of such assets and are based on the buyers of such assets progressing the specific platform and intellectual property and early stage of research and development programs. If the Company were to record a receivable for such contingent payments, it would also record a corresponding liability. As of June 30, 2024, no receivables or liabilities were recorded on the condensed consolidated balance sheet relating to such contingent payments.

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 (in thousands):

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$100,442	$ —	$ —	$100,442
	$100,442	$ —	$ —	$100,442

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$27,278	$ —	$ —	$27,278
Liabilities:	$27,278	$ —	$ —	$27,278
SAFE liabilities	$ —	$ —	$30,515	$30,515
	$ —	$ —	$30,515	$30,515

As of June 30, 2024 and December 31, 2023, the Company's cash equivalents, which were invested in money market funds, were valued based on Level 1 inputs.

There were no transfers between the Level 1, Level 2 or Level 3 categories during the six months ended June 30, 2024 and 2023.

SAFE Liabilities

From October through December 2023, Legacy Tectonic entered into multiple SAFE agreements with certain existing investors and received $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 SAFEs 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.

The following table presents activity for the SAFE liabilities that were measured at fair value using significant unobservable Level 3 inputs during the six months ended June 30, 2024 and the year ended December 31, 2023 (in thousands):

	SAFE Liabilities
Balance as of January 1, 2023	$ —
Initial fair value recognition	31,515
Loss on issuance	255
Fair value adjustments	(1,255)
Balance as of December 31, 2023	30,515
Fair value adjustments	3,610
Conversion	(34,125)
Balance as of June 30, 2024	$ —

5. PROPERTY, EQUIPMENT AND IMPROVEMENTS, NET

Property, equipment and improvements, net is comprised of the following (in thousands):

	June 30, 2024	December 31, 2023
Laboratory equipment	$ 4,554	$ 4,510
Furniture and office equipment	244	244
Computer equipment	198	161
Construction in progress	—	38
Leasehold improvements	25	25
	5,021	4,978
Less: accumulated depreciation	(2,382)	(1,856)
Property and equipment, net	$ 2,639	$ 3,122

Depreciation expense was $0.3 million and $0.2 million during the three months ended June 30, 2024 and 2023, respectively, and $0.5 million during each of the six months ended June 30, 2024 and 2023, which was recorded as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
General and administrative	$ 5	$ 4	$ 9	$ 8
Research and development	259	242	517	468
	$ 264	$ 246	$ 526	$ 476

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 30, 2024	December 31, 2023
Accrued Tectonic transaction costs	$ 8,215	$ —
Accrued AVROBIO transaction costs	2,821	—
Employee compensation related costs	2,755	2,840
Accrued offering costs related to the Subscription Agreement	2,000	—
Accrued professional fees	1,607	1,798
Accrued contract research organization fees	985	2,298
Accrued contract development and manufacturing organization fees	649	660
Accrued office and laboratory costs	91	211
Other current liabilities	886	334
	$20,009	$ 8,141

7. COMMITMENTS AND CONTINGENCIES

Leases

The Company's commitments under its operating and finance leases are described in Note 8.

Harvard Agreement

In July 2020, Legacy 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 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. Management concluded that the acquisition of patents and materials received under the License Agreement represents an asset acquisition of an in-progress research and development asset without future alternative use; therefore, any consideration paid was expensed.

As consideration for the License Agreement, Legacy Tectonic agreed to pay Harvard a non-refundable license fee, consisting of a cash payment due in three equal annual installments, in total amounting to $170,000 and 227,486 shares of common stock. The installments became due on July 2, 2022 ("First Payment Due Date") and the first and second anniversaries of the First Payment Due Date. The first payment of $56,666 was paid in July 2022. The common stock issued to Harvard had a fair value of $ 0.4 million. Both the cash payment and the issuance of shares were expensed to research and development during the year ended December 31, 2022. The second payment of $56,666 was made in July 2023. The remaining installment amount of $ 56,668 is due in July 2024.

The Company also will be responsible for payment of (1) annual maintenance fees ranging from the low five digits to the low six digits during the term of the License Agreement (through the first commercial sale of a royalty-bearing product); (2) royalty payments as a percentage in the low single digits of the annual net sales that the Company generates from products that utilize the license technology ("Licensed Products") and royalty payments as a percentage in the low single digits of the annual net sales that the Company generates from know-how enabled product licenses ("Know-How Enabled Products") and (3) a percentage between 10-20% of all non-royalty income received by the Company under sublicenses, strategic partnerships and know-how enabled product licenses that utilize the license technology. Subsequent to the first commercial sale of a royalty-bearing product, annual maintenance fees will increase to a low six digits for the remainder of the term of the License Agreement. The royalty term from sales of Licensed Products will terminate on a country-by-country and product-by-product basis on the earlier of (i) the expiration of the patent rights covering the product, expected to be no earlier than May 2041, and (ii) the termination of the License Agreement.

The royalty term from sales of Know-How Enabled Products will terminate on the earlier of (i) ten years after the first commercial sale of the first Know-How Enabled Product and (ii) twelve years after the first commercial sale of the first Licensed Product. There was $0.1 million due to Harvard as of June 30, 2024. During the three months ended June 30, 2024 and 2023, the Company paid less than $0.1 million and $ 0.1 million, respectively, and during the six months ended June 30, 2024 and 2023, the Company paid $ 0.1 million and $0.2 million, respectively, to Harvard.

Alloy Therapeutics License Agreement

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

During the three months ended June 30, 2024 and 2023, the Company paid $ 0 and $0.1 million to ATX, respectively, and during the six months ended June 30, 2024 and 2023, the Company paid $0.1 million and $ 0.1 million to ATX, respectively.

Adimab Agreement

On May 1, 2023, Legacy Tectonic entered into a discovery agreement with Adimab, LLC ("Adimab"), an antibody discovery company, whereby Legacy Tectonic and Adimab are collaborating on human antibody discovery in accordance with an agreed upon research program. Legacy Tectonic paid an upfront technology access fee totaling $20,000 upon execution of the agreement.

The Company also will be responsible for payment of (1) quarterly funding equal to 100% of the actual full-time employee ("FTE") expended by Adimab in the performance of its obligations in accordance with the agreed upon research program at an annual rate of $0.4 million per FTE (subject to annual consumer price index increases) per the agreement, (2) delivery fees equal to $ 0.1 million upon both Adimab's initial delivery of sequences or physical materials and completion pursuant to the research program (initial and completion fees payable once per target for a total of up to $0.4 million), (3) a non-creditable, non-refundable fee of $0.5 million upon the exercise of an option to obtain the licenses and assignments for information discovered during the research program, (4) development milestone payments for the movement of certain product candidates thought clinical trials, which range in the low seven digits, and (5) royalty payments based on the annual net sales that the Company generates from products that utilize Adimab technology. The Company has the right to terminate the agreement if certain criteria are met. As of June 30, 2024, the Company recorded $0.1 million of costs associated with the FTEs in accrued expenses and other current liabilities and $0 of discovery delivery fees in accounts payable.

During the three months ended June 30, 2024 and 2023, the Company paid $ 0.2 million and less than $0.1 million to Adimab, respectively. During the six months ended June 30, 2024 and 2023, the Company paid $0.3 million and less than $0.1 million to Adimab, respectively.

Indemnification Agreements

In accordance with the Company's amended and restated certificate of incorporation ("ARCOI") and certain indemnification agreements, the Company indemnifies certain officers and directors for specified events or occurrences, subject to certain limits, in which the officer or director is or was serving at the Company's request in such capacity.

The Company enters into certain types of contracts that contingently requires it to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which it must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship with the Company, (ii) contracts under which it must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the its products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on future business, operating results or financial condition. It is not possible to estimate the maximum amount potentially payable under these contracts since there is no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

As of June 30, 2024 and December 31, 2023, the Company did not have any liabilities or other commitments related to indemnification claims.

Litigation

In the normal course of operations, the Company may become involved in various legal proceedings. As of June 30, 2024 and December 31, 2023, 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 condensed consolidated financial statements.

8. LEASES

Legacy Tectonic has entered into operating leases for office and laboratory facilities and financing leases for laboratory equipment used in research and development activities. The remaining lease terms for its leases range from approximately two months to approximately 3.5 years. These leases often include options to extend the term of the lease. When it is reasonably certain that the option will be exercised, the impact of the renewal term is included in the lease term for purposes of determining total future lease payments and measuring the ROU asset and lease liability. The Company is not reasonably certain to exercise any available renewal options, which are therefore excluded from the measurement of leases. The Company applies the short-term lease policy election for its real estate and equipment leases, which allows it to exclude from recognition leases with an original term of twelve months or less.

In November 2020, Legacy Tectonic executed a facilities lease agreement to occupy 18,768 square feet of office and laboratory space, that was subsequently amended on April 21, 2022. The lease requires the Company to pay fixed base rent, which is included in the measurement of the lease, as well as its proportionate share of the facilities operating expenses which are treated as variable lease costs based on the Company's election to combine lease and associated non-lease components and are excluded from the measurement of the lease. The lease expires on January 31, 2026, and contains a five-year renewal option exercisable by the Company which is not included in the measurement of the lease.

The following table sets forth information about lease costs for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Finance lease cost				
Amortization of ROU assets	$ 115	$ 124	$ 230	$ 258
Interest on lease liabilities	28	39	59	81
Operating lease cost	351	351	702	702
Short-term lease cost	185	198	360	348
Variable lease cost	198	195	448	401
Total lease costs	$ 877	$ 907	$ 1,799	$ 1,790

The following table sets forth information about the Company's leases for the six months ended June 30, 2024 and 2023 (in thousands):

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities		
Finance leases - financing cash flows	$ 240	$ 270
Finance leases - operating cash flows	59	81
Operating leases - operating cash flows	765	489
Weighted-average remaining lease terms (in years)		
Finance leases	2.75	3.73
Operating leases	1.59	2.59
Weighted-average discount rate		
Finance leases	9.69%	9.58%
Operating leases	8.25%	8.25%

The following table presents the maturity of the Company's finance and operating lease liabilities for as of ended June 30, 2024 (in thousands):

Year ended December 31,	Finance Leases	Operating Leases
2024 (remaining)	$ 284	$ 769
2025	552	1,580
2026	363	132
2027	44	—
2028	—	—
Thereafter	—	—
Total lease payments	1,243	2,481
Less: interest	(132)	(148)
Total lease liabilities	$ 1,111	$ 2,333

9. STOCKHOLDERS' EQUITY

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 "Preferred Stock").

Prior to the completion of the Merger, Legacy Tectonic classified the Preferred Stock outside of permanent equity as the shares had redemption features that were not entirely within the control of Legacy Tectonic.

Upon the closing of the Merger, all outstanding shares of the Preferred Stock were converted into 3,647,675 shares of common stock. No shares of the Preferred Stock were outstanding as of June 30, 2024.

Preferred Stock

Subsequent to consummation of the Merger, the Company authorized the issuance of 10,000,000 shares of new undesignated preferred stock, however no such shares were issued or outstanding as of June 30, 2024.

Common Stock

As of June 30, 2024 and as a result of the Merger, the Company's ARCOI authorized the Company to issue 150,000,000 shares of voting common stock of $0.0001 par value common stock, of which 14,734,323 shares were issued and outstanding. 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 June 30, 2024, no dividends had been declared.

The Company has included in issued and outstanding common stock shares of restricted common stock granted by the Company. As of June 30, 2024, there were 14,734,323 shares of common stock issued and outstanding, of which 11,447 relate to shares of restricted common stock (see Note 10).

10. STOCK-BASED COMPENSATION

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 and its affiliates with the opportunity to receive grants of stock options, stock awards and equity awards. Since inception, Legacy Tectonic has only issued stock options.

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 terms of stock award agreements, including vesting requirements, are determined by the Company's Board of Directors and are subject to the provisions of the 2024 Plan. The term of each stock option shall be no more than ten years from the date of grant. Following the effectiveness of the 2024 Plan, no further grants will be made under the 2019 Plan; however, any outstanding equity awards granted under the 2019 Plan will continue to be governed by the terms of the 2019 Plan.

The 2024 Plan initially provided for the issuance of up to 1,938,799 shares of common stock (the "Initial Share Reserve"). Subject to any other adjustments as defined in the 2024 Plan, such aggregate number of shares of common stock will automatically increase on January 1st of each year for a period of ten years commencing on January 1, 2025 and ending on (and including) January 1, 2034, in an amount equal to 5% of the total number of shares of common stock issued and outstanding determined as of the day prior to such increase; provided, however that the board of directors may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares of common stock. The aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options is three multiplied by the Initial Share Reserve.

As of June 30, 2024, there were 1,063,999 shares available for issuance under the 2024 Plan.

2024 Employee Stock Purchase Plan

On June 20, 2024, the Company adopted the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective upon completion of the Merger. The maximum number of shares of common stock that may be issued under the 2024 ESPP will not exceed 147,343 shares (the "Initial ESPP Share Reserve"), plus the number of shares of common stock that are automatically added on January 1st of each year for a period of up to ten years commencing on January 1, 2025 and ending on (and including) January 1, 2034, in an amount equal to the lesser of (x) 1% of the total number of shares of common stock issued and outstanding determined as of the day prior to such increase and (y) a number of shares equal to three times the Initial ESPP Share Reserve. Notwithstanding the foregoing, the Board of Directors may act prior to the first day of any calendar year to provide that there will be no January 1st increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence. No offering periods under the 2024 ESPP had been initiated as of June 30, 2024. The option activity below reflects the reverse stock split and retroactive application of the exchange ratio as discussed in Note 1.

A summary of the stock option activity for the six months ended June 30, 2024 is as follows (in thousands except share and per share amounts):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance as of January 1, 2024	1,002,485	$ 3.11	8.2	$ 2,276
Granted	874,800	16.80		
Exercised	(266,705)	2.44		$ 3,743
Forfeited and expired	(31,922)	2.71		
Options assumed from AVROBIO upon Merger closing	365,428	89.92		
Balance as of June 30, 2024	1,944,086	$ 25.68	7.5	$ 9,830
Options vested and exercisable as of June 30, 2024	683,184	$ 49.36	3.8	$ 4,987
Options vested and expected to vest as of June 30, 2024	1,944,086	$ 25.68	7.5	$ 9,830

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2024 and 2023 was $13.95 and $2.51 per share, respectively. The total intrinsic value of options exercised during the three months ended June 30, 2024 and 2023 was $3.7 million and $0, respectively, and was $3.7 million and less than $0.1 million during the six months ended June 30, 2024 and 2023, respectively. Forfeitures of options are recorded as incurred.

Cash received from option exercises was $0.6 million for the three and six months ended June 30, 2024 and $ 0 and less than $0.1 million for the three and six months ended June 30, 2023, respectively .

The fair values of the options granted in the six months ended June 30, 2023 were estimated based on the Black-Scholes-Merton option pricing model, using the following assumptions:

	Six Months Ended June 30,	
	2024	2023
Fair value per share of underlying common stock	$16.80	$2.98
Expected term (in years)	6.25	5.93
Expected volatility	104.00%	111.05% - 111.21%
Risk-free interest rate	4.26%	3.65%
Expected dividend yield	0%	0%

Restricted Common Stock

Since 2019, Legacy Tectonic has granted restricted common stock to founders, employees and consultants. The purchase price of the restricted common stock is the estimated fair value on the grant date and the restricted stock is subject to various vesting schedules. Unvested restricted common stock are subject to repurchase rights held by the Company at the original issuance price in the event the restricted common stockholders' service to the Company is terminated either voluntarily or involuntarily. As of June 30, 2024, there were 11,447 shares of unvested restricted common stock, with a repurchase liability of less than $ 0.1 million, that is classified in accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheet.

The following table summarizes restricted stock activity:

	Number of Shares
Unvested restricted common stock as of January 1, 2024	18,968
Granted	—
Early exercise of options	6,859
Vested	(14,380)
Forfeited	—
Unvested restricted common stock as of June 30, 2024	11,447

The weighted-average grant date fair value of unvested restricted common stock and restricted common stock vested and forfeited for the six months ended June 30, 2024 and 2023 was immaterial.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense regarding its employees and nonemployees as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
General and administrative	$ 228	$ 175	$ 421	$ 349
Research and development	175	102	303	203
	$ 403	$ 277	$ 724	$ 552

The Company records compensation expense for options with service based vesting conditions on a straight-line basis over the vesting period. As of June 30, 2024, total compensation cost not yet recognized related to unvested stock options was $13.8 million, which is expected to be recognized over a weighted-average period of 3.4 years.

11. INCOME TAXES

During the three and six months ended June 30, 2024 and 2023, the Company recorded no income tax provision or benefit.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which primarily consist of net operating loss carryforwards. The Company has considered its history of cumulative net losses, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. As a result, as of June 30, 2024, the Company has maintained a full valuation allowance against its net deferred tax assets.

12. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss attributable to common stockholders	$ (12,671)	$ (10,455)	$ (27,892)	$ (24,900)
Denominator:				
Weighted-average common shares outstanding, basic and diluted	2,919,872	1,228,778	2,150,160	1,208,447
Net loss per share attributable to common stockholders, basic and diluted	$ (4.34)	$ (8.51)	$ (12.97)	$ (20.60)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. For the three and six months ended June 30, 2024 and 2023, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders for the period because including them would have had an anti-dilutive effect:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Convertible preferred stock (as converted to common stock)	—	3,647,675	—	3,647,675
Stock options to purchase common stock	1,944,086	852,667	1,944,086	852,667
Unvested restricted common stock	11,447	36,504	11,447	36,504
	1,955,533	4,536,846	1,955,533	4,536,846

13. RELATED PARTY TRANSACTIONS

Scientific Advisory Board Member

One of the Company's co-founders and former director is a member of the Company's Scientific Advisory Board ("SAB") and meets the criteria of a related party. The Company paid the SAB member fees in the amount of less than $0.1 million during the three months ended June 30, 2024 and 2023, respectively, and less than $0.1 million during the six months ended June 30, 2024 and 2023 for advisory services provided. There was less than $0.1 million and $0 due to this related party as of June 30, 2024 and December 31, 2023.

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. Additionally, both co-founders were members of the Board during the six months ended June 30, 2024 and one co-founder is a major shareholder in the Company. Core intellectual property utilized by the Company is licensed from Harvard in exchange for license fees, future milestones and royalties, and equity in the Company in the form of common stock.

For the six months ended June 30, 2024 and 2023, the Company paid Harvard $ 0.1 million and $0.2 million in cash considerations, respectively (see Note 7). Accounts payable to Harvard amounted to less than $0.1 million and $0.1 million as of June 30, 2024 and December 31, 2023, respectively.

SAFE Agreements

From October through December 2023, Legacy Tectonic entered into multiple SAFE agreements with certain existing investors and received $34.1 million representing the purchase amount. 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.

As discussed in Note 4, the SAFEs were redeemed for shares of Legacy Tectonic common stock in connection with the closing of the Merger.

14. 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. Highly compensated employees (as defined by the Plan) are not eligible to receive the Nonelective Contribution. The Company's contributions were $0.1 million during each of the three and six months ended June 30, 2024 and 2023 and were recorded as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
General and administrative	$ 10	$ 5	$ 16	$ 12
Research and development	70	47	114	116
	$ 80	$ 52	$ 130	$ 128

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report. In addition to historical information, the following discussion contains forward-looking statements. Our actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" in this Quarterly Report.

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

Overview

We are a 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™, with the aim of addressing these challenges to enable the discovery and development of GPCR-targeted biologic medicines that can modify the course of disease. We focus on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality or extend duration of life.

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

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

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

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

Since our inception in 2019, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio and conducting preclinical studies and clinical trials. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have funded our operations primarily with proceeds from sales of Series A-1, A-2, A-3, and A-4 convertible preferred stock (collectively, the "Preferred Stock"), proceeds received from the Merger (as defined below), proceeds from the issuance of common stock, proceeds from issuance of convertible promissory notes, which were all converted to convertible preferred stock in March 2021 and proceeds from issuance of Simple Agreements for Future Equity ("SAFEs") in October and December 2023. From inception through June 30, 2024, we have received $288.6 million in capital contributions from sales of Preferred Stock, issuance of convertible promissory notes, proceeds from issuance of SAFEs, proceeds from the Merger and proceeds from the issuance of common stock. As of June 30, 2024, we had $185.1 million in cash and cash equivalents. Based on our current operating plan, we believe that our existing cash and cash equivalents should be sufficient to fund our operations for at least the next twelve months following the issuance of our interim condensed consolidated financial statements.

Since inception, we have incurred significant operating losses. Our net losses were $12.7 million and $10.5 million for the three months ended June 30, 2024 and 2023, respectively, and $27.9 million and $24.9 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $118.5 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue our ongoing and planned research and clinical development of our lead product candidate TX45 and our other product candidates;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek to discover and develop additional product candidates and further expand our clinical product pipeline;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- continue to scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and eventual potential commercialization;
- establish sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- acquire or in-licenses other product candidates and technologies;
- hire additional clinical, quality control, regulatory and manufacturing personnel;
- add discovery, clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and

- incur additional legal, accounting, investor relations and other expenses associated with operating as a public company.

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

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

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

Recent Developments

Merger with AVROBIO

On January 30, 2024, Legacy Tectonic entered into the Agreement and Plan of Merger and Reorganization (“Merger Agreement”) with AVROBIO and Alpine Merger Subsidiary, Inc. (“Merger Sub”). Pursuant to the Merger Agreement and the satisfaction of the conditions described in the Merger Agreement, on June 20, 2024, Merger Sub merged with and into Legacy Tectonic, with Legacy Tectonic surviving as a wholly owned subsidiary of AVROBIO (the “Merger”). The Merger Agreement and the transactions contemplated therein were approved by the members of the AVROBIO board of directors and Legacy Tectonic board of directors. Subject to the terms and conditions of the Merger Agreement, at the effective time, (a) each outstanding share of Legacy Tectonic common stock (including shares of Legacy Tectonic common stock issued upon conversion of its preferred stock and the shares issued pursuant to that certain Subscription Agreement dated January 30, 2024, entered into among Legacy Tectonic and the investors party thereto (the “Subscription Agreement”) and conversion of the SAFEs into the right to receive a number of shares of AVROBIO common stock equal to the exchange ratio; and (b) each then outstanding Legacy Tectonic stock option that was outstanding and unexercised immediately prior to the effective time was assumed by AVROBIO, subject to the exchange ratio.

Immediately after the Merger, AVROBIO securityholders as of immediately prior to the Merger owned approximately 24.8% of the outstanding shares of our capital stock on a diluted basis. Immediately after the Merger, Legacy Tectonic securityholders owned approximately 38.5% of the outstanding shares of our capital stock on a diluted basis. Investors participating in the Subscription Agreement and the SAFEs owned approximately 27.1% and 9.6% of the outstanding shares of our capital stock, respectively, on a diluted basis.

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

Tectonic Subscription 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 approximately $12.40 per share for an aggregate purchase price of approximately $96.6 million. The shares of Legacy Tectonic common stock that were issued pursuant to the Subscription Agreement were converted into 4,163,606 shares of our common stock upon the closing of the Merger based on the exchange ratio, pursuant to the Merger Agreement.

Macroeconomic Considerations

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

Revenue

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

Operating Expenses

Research and Development

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

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

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

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

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

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical 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 anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly as we commence 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, including based on the number of doses that patients received;
- 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

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

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

Other (Expense) Income, Net

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 sheet at their fair value on the issuance dates. Until redemption, the SAFEs were measured at a fair value on a recurring basis, with subsequent changes in fair value recorded in other income and expenses on the consolidated statement of operations and comprehensive loss. We recorded a loss of $3.6 million resulting from the remeasurement of the SAFEs to fair value from March 31, 2024 to June 20, 2024.

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

Interest Income

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

Interest Expense

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

Other Expense

Other expense primarily consists of the difference between transactional currency and functional currency.

Income Taxes

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

Components of Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,			
	2024	2023	Change	%
	(in thousands)			
Operating expenses:				
Research and development	$ 7,074	$ 8,766	$(1,692)	(19)%
General and administrative	4,347	1,865	2,482	133
Total operating expenses	11,421	10,631	790	7
Loss from operations	(11,421)	(10,631)	(790)	7
Other (expense) income, net:				
Change in fair value of the SAFE liabilities	(1,535)	—	(1,535)	100
Interest income	318	224	94	42
Interest expense	(28)	(40)	12	(30)
Other expense	(5)	(8)	3	(38)%
Total other (expense) income, net	(1,250)	176	(1,426)	(810)
Net loss	$(12,671)	$(10,455)	$(2,216)	21%

Operating Expenses

Research and Development Expenses

	Three Months Ended June 30,			
	2024	2023	Change	%
	(in thousands)			
Direct research and development expenses by program:				
TX45	$ 2,460	$ 4,381	(1,921)	(44)%
Platform development, early-stage research and unallocated expenses:				
Personnel related (including share-based compensation)	2,763	2,873	(110)	(4)
External services	786	188	598	318
Facility, supplies and other	1,065	1,324	(259)	(20)
Total research and development expenses	$ 7,074	$ 8,766	$(1,692)	(19)%

Research and development expenses were $7.1 million for the three months ended June 30, 2024, as compared to $8.8 million for the three months ended June 30, 2023. The decrease of $1.7 million resulted from a reduction of $1.1 million in direct research and development costs from our CMO as a result of fewer batches of clinical trial supply produced during the three months ended June 30, 2024 as compared to the three months ended June 30, 2023 due to the completed production of drug substance for the TX45 program in 2023 for planned Phase 1 and Phase 2 studies and a reduction of $1.0 million in preclinical Contract Research Organization (“CRO”) research costs, partially offset by an increase of $0.3 million in clinical trial CRO costs. The decrease of $0.1 million in personnel related costs was primarily due to a reduction in salary and bonus expenses subsequent to the reduction in force that occurred during the three months ended March 31, 2024. The increase of $0.6 million in external services was primarily due to an increase in consulting and professional services to support the ongoing development activities. The decrease of $0.3 million in facility, supplies and other expenses was primarily due to the receipt of reimbursements during the three months ended June 30, 2024 for leasehold improvements made during the year ended December 31, 2023.

General and Administrative Expenses

	Three Months Ended June 30,			
	2024	2023	Change	%
	(in thousands)			
Personnel related (including share-based compensation)	$ 1,543	$ 1,013	$ 530	52%
Professional and consultant fees	2,475	420	2,055	489
Facility related and other	329	432	(103)	(24)
Total general and administrative expenses	$ 4,347	$ 1,865	$2,482	133%

General and administrative expenses were $4.3 million for the three months ended June 30, 2024 as compared to $1.9 million for the three months ended June 30, 2023. The increase of $2.5 million resulted from an increase of $0.5 million in personnel related costs and was primarily due to increases in employee compensation and bonus expense during the three months ended June 30, 2024 as well as recruiting costs incurred during the three months ended June 30, 2024. The increase of $2.1 million in professional and consultant fees was related to an increase in consulting and professional services fees to support Merger-related activities during the three months ended June 30, 2024.

Other (Expense) Income, Net

Change in Fair Value of SAFE Liabilities

The SAFE liabilities loss of $1.5 million resulted from the remeasurement of the SAFE liabilities to fair value during the three months ended June 30, 2024.

Interest Income

Interest income increased by $0.1 million for the three months ended June 30, 2024 compared to the three months ended June 30, 2023 due to an increase in interest rates between the three months ended June 30, 2023 and the three months ended June 30, 2024.

Interest Expense

Interest expense was consistent for the three months ended June 30, 2024 and 2023.

Other Expense

Other expense was consistent for the three months ended June 30, 2024 and 2023.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes Tectonic's results of operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,			
	2024	2023	Change	%
		(in thousands)		
Operating expenses:				
Research and development	$ 17,892	$ 21,751	$(3,859)	(18)%
General and administrative	6,497	3,411	3,086	90
Total operating expenses	24,389	25,162	(773)	(3)
Loss from operations	(24,389)	(25,162)	773	(3)
Other (expense) income, net:				
Change in fair value of the SAFE liabilities	(3,610)	—	(3,610)	—
Interest income	574	352	222	63
Interest expense	(59)	(82)	23	(28)
Other expense	(408)	(8)	(400)	5,000%
Total other (expense) income, net	(3,503)	262	(3,765)	(1,437)
Net loss	$(27,892)	$ (24,900)	$(2,992)	12%

Operating Expenses

Research and Development Expenses

	Six Months Ended June 30,			
	2024	2023	Change	%
		(in thousands)		
Direct research and development expenses by program:				
TX45	$ 8,169	$ 13,037	(4,868)	
Personnel related (including share-based compensation)	5,966	5,726	240	4
External services	1,570	461	1,109	241
Facility, supplies and other	2,187	2,527	(340)	(13)
Total research and development expenses	$17,892	$ 21,751	$(3,859)	(18)%

Research and development expenses were $17.9 million for the six months ended June 30, 2024, as compared to $21.8 million for the six months ended June 30, 2023. The decrease of $3.9 million resulted from a reduction of $6.2 million in direct research and development costs from our CMO as a result of fewer batches of clinical trial supply produced during the three months ended June 30, 2024 as compared to the three months ended June 30, 2023 due to the completed production of drug substance for the TX45 program in 2023 for planned Phase 1 and Phase 2 studies, a reduction of $0.7 million in preclinical CRO research costs and a $0.6 million reduction in lab supplies and lab services costs, partially offset by an increase of $2.6 million in clinical trial CRO costs. The increase of $0.2 million in personnel related costs was primarily due to severance and related costs incurred as a result of a reduction in force that occurred during the six months ended June 30, 2024. The increase of $1.1 million in external services was primarily due to an increase in consulting and professional services to support the ongoing development activities. The decrease of $0.3 million in facility, supplies and other expenses was primarily due to the receipt of reimbursements during the six months ended June 30, 2024 for leasehold improvements made during the year ended December 31, 2023.

General and Administrative Expenses

	Six Months Ended June 30,			
	2024	2023	Change	%
		(in thousands)		
Personnel related (including share-based compensation)	$2,789	$ 2,028	$ 761	38%
Professional and consultant fees	2,774	794	1,980	249
Facility related and other	934	589	345	59
Total general and administrative expenses	$6,497	$ 3,411	$3,086	90%

General and administrative expenses were $6.5 million for the six months ended June 30, 2024 as compared to $3.4 million for the six months ended June 30, 2023. The increase of $3.1 million resulted from an increase of $0.8 million in personnel related costs and was primarily due to severance and costs incurred as a result of a reduction in force that occurred during the six months ended June 30, 2024, increases in employee compensation and bonus expense during the six months ended June 30, 2024 as well as recruiting costs incurred during the six months ended June 30, 2024. The increase of $2.0 million in professional and consultant fees was related to an increase in consulting and professional services fees to support Merger-related activities during the six months ended June 30, 2024. The increase of $0.3 million in facility related costs and other expenses was due to increased costs incurred related to operating as a public company following the closing of the Merger in addition to travel expenses incurred during the six months ended June 30, 2024.

Other (Expense) Income, Net

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 six months ended June 30, 2024.

Interest Income

Interest income increased by $0.2 million for the six months ended June 30, 2024 compared to the six months ended June 30, 2023 due to an increase in interest rates between the six months ended June 30, 2023 and the six months ended June 30, 2024.

Interest Expense

Interest expense was consistent for the six months ended June 30, 2024 and 2023.

Other Expense

Other expense increased by $0.4 million for the six months ended June 30, 2024 compared to the six months ended June 30, 2023 due to the reversal of an Australian research and development tax credit claim during the six months ended June 30, 2024.

Liquidity and Capital Resources

Sources of Liquidity

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

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have funded our operations primarily through proceeds from sales of preferred stock and common stock, proceeds from issuance of convertible promissory notes, proceeds from issuance of SAFEs and proceeds received from the Merger. From inception through June 30, 2024, we had received $288.6 million in capital contributions from sales of Preferred Stock, issuances of convertible promissory notes, proceeds from issuance of SAFEs, proceeds from the Merger and proceeds from the sale of pursuant to the Subscription Agreement. As of June 30, 2024, we had $185.1 million in cash and cash equivalents and an accumulated deficit shares of $118.5 million. We believe that our cash, cash equivalents, and marketable securities will be sufficient to fund our anticipated operating and capital expenditure requirements at least into mid-2027. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Cash Flows

The following table shows a summary of our cash flows for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (22,655)	$(20,543)
Net cash used in investing activities	—	(222)
Net cash provided by (used in) financing activities	179,070	(269)
Effect of exchange rate changes on cash and cash equivalents	(60)	—
Net increase (decrease) in cash, cash equivalents and restricted cash	$156,355	$(21,034)

Operating Activities

During the six months ended June 30, 2024, operating activities used $22.7 million of cash, primarily resulting from a net loss of $27.9 million and changes in our operating assets and liabilities of $0.4 million, offset by non-cash charges of $5.6 million. Non-cash charges primarily consisted of $3.6 million change in fair value of the SAFE liabilities, $0.7 million in depreciation and amortization expense, $0.7 million in stock-based compensation expense, and $0.6 million in non-cash lease expense. Net cash used by changes in our operating assets and liabilities consisted primarily of a $0.7 million decrease in operating lease liabilities, a $0.3 million increase in prepaid expenses and other current assets and a $0.1 million decrease in accounts payable, partially offset by a $0.4 million decrease in other non-current assets and a $0.2 million increase in accrued expenses and other current liabilities. The decrease in operating lease liabilities was primarily due to the lease payments made during the six months ended June 30, 2024. The increase in prepaid expenses and other current assets and accrued expenses and other current liabilities and decrease in accounts payable was primarily due to the Merger-related activities. The decrease in other non-current assets was due to a reassessment of the tax benefit amount related to the reversal of an Australian research and development tax credit claim.

During the six months ended June 30, 2023, operating activities used $20.5 million of cash, primarily resulting from a net loss of $24.9 million, offset by non-cash charges of $1.8 million and changes in our operating assets and liabilities of $2.5 million. Non-cash charges primarily consisted of $0.7 million in depreciation and amortization expense, $0.6 million in stock-based compensation expense, and $0.5 million in non-cash lease expense. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $1.6 million increase in accrued expenses and other current liabilities and a $1.7 million increase in accounts payable, partially offset by a $0.5 million increase in prepaid expenses and other current assets and a $0.3 million decrease in operating lease liabilities. The increase in accrued expenses and other current liabilities and increase in accounts payable were primarily due to the timing of vendor and research partner payments and invoicing. The increase in prepaid expenses and other current assets is due to prepayments of material costs and insurance and license fees. The decrease in operating lease liabilities was primarily due to the lease payments made during the six months ended June 30, 2023.

Investing Activities

During the six months ended June 30, 2024 and 2023, net cash used in investing activities was $0 and $0.2 million, respectively. The change in net cash used in investing activities during the six months ended June 30, 2023 was due to purchases of property, equipment, and improvements.

Financing Activities

During the six months ended June 30, 2024 and 2023, net cash provided by and used in financing activities was $179.1 million and $0.3 million, respectively. Net cash provided by financing activities during the six months ended June 30, 2024 was primarily due to $94.6 in net proceeds after offering costs from the sale of shares pursuant to the Subscription Agreement, $85.2 million in gross proceeds before net cash deductions from the Merger and $0.6 million in proceeds from the exercise of stock options, partially offset by $1.2 million of payments of Merger transaction costs and $0.2 million in payments on our financing lease liability. Net cash used in financing activities during the six months ended June 30, 2023 was primarily due to $0.3 million of repayment of finance lease obligations.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates including our lead product candidate TX45. In addition, if we obtain marketing approval for TX45 or any of our other product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with 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, together with the net proceeds from the Merger and the sale of securities pursuant to the Subscription Agreement, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of product discovery, preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidate;
- our ability to 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; and
- the costs of operating as a publicly traded company; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates; and
- the macroeconomic environment, including inflation and interest rates.

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

Going Concern

We evaluated certain adverse conditions and events that raise substantial doubt about our ability to continue as a going concern within twelve months after the date that the accompanying unaudited condensed consolidated financial statements were issued or available to be issued. We have funded our operations primarily with proceeds from the sale of common stock, preferred stock, issuance of convertible promissory notes, issuance of SAFEs and proceeds received at the closing of the Merger. We also have incurred significant recurring losses, including net losses of $12.7 million and $10.5 million for the three months ended June 30, 2024 and 2023, respectively, and $27.9 million and $24.9 million for the six months ended June 30, 2024 and 2023, respectively. In addition, we used $22.7 million and $20.5 million in operations for the six months ended June 30, 2024 and 2023, respectively. Our management believes that our current cash on hand is sufficient to fund our planned operations for at least one year from the date of issuance of these unaudited condensed consolidated financial statements.

Contractual Obligations & Commitments

Lease

The following is our contractual obligations and commitments as of June 30, 2024:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Finance Leases	$ 284	$ 915	$ 44	$ —	$1,243
Operating Leases	769	1,712	—	—	2,481
Total	$ 1,053	$ 2,627	$ 44	$ —	$3,724

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

Harvard Agreement

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

As partial consideration for the Harvard License Agreement, we agreed to pay Harvard a one-time license fee of $170,000, with such fee to be paid in equal installments over three years. In July 2022, we paid Harvard $56,666 and in July 2023 we paid Harvard $56,666. The final installment of $56,668 under the Harvard License Agreement is due in July 2024. As partial consideration for the Harvard License Agreement, we entered into a subscription agreement with Harvard in July 2022, pursuant to which Harvard was granted 227,486 shares of our common stock with a fair market value in the mid six digits.

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

For a more detailed description of this agreement, see Note 7 to the interim condensed consolidated financial statements included elsewhere in this Quarterly Report.

Alloy Therapeutics License Agreement

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

During the six months ended June 30, 2024 and 2023, we paid $0.1 million and $0.1 million to ATX, respectively.

Adimab Agreement

On May 1, 2023, we entered into a discovery agreement with Adimab, LLC (“Adimab”), an antibody discovery company, whereby we and Adimab are collaborating on human antibody discovery in accordance with an agreed upon research program. Legacy Tectonic paid an upfront technology access fee totaling $20,000 upon execution of the Adimab agreement during the year ended December 31, 2023.

We also will be responsible for payment of: (1) quarterly funding equal to 100% of the actual full-time employee (“FTE”) expended by Adimab in the performance of its obligations in accordance with the agreed upon research program at an annual rate of $0.4 million per FTE (subject to annual consumer price index increases) per the agreement, (2) delivery fees equal to $0.1 million upon both Adimab’s initial delivery of sequences or physical materials and completion pursuant to the research program (initial and completion fees payable once per target for a total of up to $0.4 million), (3) the option, with a non-creditable, non-refundable option exercise fee of $0.5 million, to obtain the licenses and assignments for information discovered during the research program (4) development milestone payments for the movement of certain product candidates thought clinical trials, which range in the low seven digits and (5) royalty payments based on the annual net sales that we generate from products that utilize Adimab technology. We have the right to terminate the agreement if certain criteria are met. During the three months ended June 30, 2024 and 2023, we paid $0.2 million and less than $0.1 million to Adimab, respectively. During the six months ended June 30, 2024 and 2023, we paid $0.3 million and less than $0.1 million to Adimab, respectively.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our interim condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these interim condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities at the date of the interim condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. We base our estimates on historical experience, known trends and events, and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities recorded expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Actual results may differ from these estimates.

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

Prepaid and Accrued Research and Development Expenses

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

Share-Based Compensation

We measure stock options granted to employees and non-employees based on their fair value on the date of the grant using the Black-Scholes-Merton ("BSM") option pricing model. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award for employees. Compensation expense for awards to non-employee with service-based vesting conditions is recognized in the same manner as if we had paid cash in exchange for the goods or services, which is generally the over the vesting period of the award. We use the straight-line method to recognize the expense of awards with service-based vesting conditions. We account for forfeitures of stock options as they occur.

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

Prior to being publicly-traded, we estimated the grant date fair value of our common stock using an appropriate valuation methodology, in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*. Each valuation methodology included estimates and assumptions that required our judgment. These estimates and assumptions included a number of objective and subjective factors, including external market conditions, guideline public company information, the prices at which we sold convertible preferred stock to third parties in arms' length transactions, the rights and preferences of securities senior to our common stock at the time and the likelihood of achieving a liquidity event such as an initial public offering or sale. Significant changes to the assumptions used in the valuations could result in different fair values at each valuation date.

Recent Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our primary exposure to market risk is to market risk related to interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of June 30, 2024, we had cash and cash equivalents of $185.1 million, which consisted of cash and money market funds. As of June 30, 2024, we had a finance lease liability and an operating lease liability of $1.1 million and $2.3 million, respectively. Interest income and expenses are sensitive to changes in the general level of interest rates. However, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of our investment portfolio.

Inflation Risk

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2024, the end of the period covered by this Quarterly Report. Based on the evaluation of our disclosure controls and procedures as of June 30, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

On June 20, 2024, we completed the Merger. Other than any changes relating to the integration of internal controls in connection with the Merger, there were no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Prior to the closing of the merger between AVROBIO and Tectonic Therapeutic, Inc. on June 20, 2024, three actions were filed by purported stockholders of AVROBIO in connection with the Merger. One action has been filed in the United States District Court for the Southern District of New York captioned *Garofalo v. Avrobio, Inc. et al.* , 24-cv-1493 (filed February 27, 2024), which was voluntarily dismissed without prejudice on June 13, 2024. Two actions have been filed in the Supreme Court of New York, captioned *Price v. Avrobio, Inc., et al.* , No. 652555/2024 (filed May 17, 2024) and *Keller v. Avrobio, Inc., et al.* , No. 652597/2024 (filed May 21, 2024). The foregoing actions are referred to as the "Merger Actions."

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

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

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

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.

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

Item 1A. Risk Factors.

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

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 or any future product candidates.
- Our clinical trials may fail to demonstrate substantial evidence of the safety, efficacy, purity and potency of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.
- If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.
- Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We currently rely and expect to rely in the future on the use of manufacturing suites in third-party facilities or on third parties to manufacture TX45 and any other product candidates, and we may rely on third parties to produce and process our products, if approved.
- Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers encounter difficulties in production.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.
- If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Risks Related to Our Financial Position and Cash Needs

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

We are a clinical-stage biotechnology company with a limited operating history. Since our inception in 2019, we have invested most of our resources in organizing and staffing our company, developing our technology and product candidates, building our intellectual property portfolio, conducting business planning, raising capital and providing general and administrative support for these operations. We also completed the Merger in June 2024 and have been operating under this structure for only a short time. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing drug products. We continue to incur significant research and 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 three months ended June 30, 2024 and 2023, we reported a net loss of $12.7 million and $10.5 million, respectively. As of June 30, 2024, we had an accumulated deficit of $118.5 million. We expect to continue to incur significant losses for the foreseeable future, and expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our lead product candidate, TX45, along with any future product candidates we may develop.

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

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our lead product candidate TX45;
- increase the amount of research and development activities to identify and develop product candidates using our proprietary discovery approach;
- make milestone, royalty or other payments under in-license or collaboration agreements;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- establish sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties;
- invest in or in-license other technologies; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we, our collaborators and any potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, producing biologics with contract manufacturing development organizations (“CDMOs”) in the United States and in other countries, obtaining marketing approval for product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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

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

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

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

- the progress, timing and completion of preclinical studies and clinical trials for our current or any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to disease outbreaks, epidemics and pandemics or other causes;
- the timing and amount of milestone and royalty payments we are required to make or are eligible to receive under our license agreements with President and Fellows of Harvard College (“Harvard”) and other license agreements, as applicable;
- the number of potential new product candidates we identify and decide to develop;
- the need for additional or expanded pre-clinical studies and clinical trials beyond those that we plan to conduct with respect to our current and future product candidates;
- the costs involved in growing the organization to the size needed to allow for the research, development and potential commercialization of our current or any future product candidates;
- the costs involved in filing patent applications, maintaining and enforcing patents or defending against infringement or other claims raised by third parties;
- the maintenance of our existing license and collaboration agreements and the entry into new license and collaboration agreements;
- the time and costs involved in obtaining regulatory approval for our product candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the effect of competing technological and market developments;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own;
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our product candidates, if approved; and
- market acceptance of any approved product candidates.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product or royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements.

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

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

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

If we raise additional capital through future collaborations, strategic alliances, or third-party licensing arrangements, 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 very early in our development efforts. If we are unable to advance TX45 or any of our other product candidates through clinical development, obtain regulatory approval and ultimately commercialize TX45 or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. We are early in our product candidate development efforts, as TX45 is still in Phase 1 clinical trials, and recently initiated a Phase 2 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 and any future product candidates we develop, which may never occur. TX45 and any future product candidates we develop will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions for specific indications for use, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales. The success of our current and future product candidates will depend on several factors, including the following:

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

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

All of our product candidates are in discovery, preclinical or 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 or any future product candidates.

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

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

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

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

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any period during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Our clinical trials may fail to demonstrate substantial evidence of the safety, efficacy, purity and potency of our product candidates or any future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

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

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with 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 and any future product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit our commercial potential.

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

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

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

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

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

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

Additionally, adverse developments in clinical trials of pharmaceutical and biopharmaceutical products conducted by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or to change the requirements for approval of any of our product candidates. For example, immunogenicity is a concern for all protein therapeutics in human clinical trials, and immunogenic reactions in patients in our trials may lead to adverse effects and/or impact exposure, which in turn may lead to protocol amendments, clinical holds, or other actions that delay or significantly impact the prospects for our product candidates.

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

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

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

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

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to 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 one of our trial sites in Moldova for the Phase 1b trial and its proximity to the conflict between Russia and the Ukraine;
- size and nature of the patient population and process for identifying patients;
- proximity and availability of clinical trial sites for prospective patients;
- eligibility and exclusion criteria for the trial;
- design of the clinical trial;
- safety profile, to date, of the product candidate under study;
- perceived risks and benefits of the product candidate under study;
- perceived risks and benefits of our approach;
- approval of competing product candidates currently under investigation for the treatment of similar diseases or conditions, or competing clinical trials for similar product candidates or targeting patient populations meeting our patient eligibility criteria;
- severity of the disease under investigation;
- degree of progression of the patient's disease at the time of enrollment;
- ability to obtain and maintain patient consent;
- risk that enrolled patients will drop out before completion of the trial;
- patient referral practices of physicians; and
- ability to adequately monitor patients during and after treatment.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

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

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, if any, and the company in general. In addition, the information we choose to publicly disclose regarding a particular preclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in 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 but as the date of this report, studies are only being conducted in Australia, Moldova and the Netherlands. Conducting preclinical testing is a lengthy, time-consuming and expensive process and delays associated with product candidates for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. While we are currently conducting Phase 1a, Phase 1b and the recently initiated Phase 2 clinical trials for TX45, including some trials which may be outside of the United States, we cannot be certain of the timely completion or outcome of our preclinical testing and studies for our other product candidates and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and foreign clinical trials will ultimately support the further development of our other product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin.

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

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

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

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

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

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability including, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling.

The holder of a BLA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of 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.

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

We are developing TX45 initially for the treatment of Group 2 Pulmonary Hypertension ("PH") in HFpEF, 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 must, and have in the past decided to, prioritize development of certain product candidates over other potential product candidates. These decisions may prove to have been wrong and may adversely affect our ability to develop our own programs, our attractiveness as a commercial partner and may ultimately have an impact on our commercial success.

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

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

If we are successful in obtaining marketing approval from applicable regulatory authorities for TX45 or any other product candidate, our ability to generate revenues from any such products will depend on 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 with HFpEF and Hereditary Hemorrhagic Telangiectasia ("HHT") disorders. Although there are no other companies who have commercialized therapies for the same therapeutic areas that our product candidates target, there are many other companies, including large biotechnology and pharmaceutical companies, that are developing therapies for the same therapeutic areas. For example, AstraZeneca and Tenax Therapeutics for the treatment of Group 2 PH and Diagonal Therapeutics and Vaderis Therapeutics for the treatment of HHT.

Also, treatments that could potentially be of use across all HFpEF patients, such as are currently being developed by Lilly and others, could also benefit the Group 2 PH subgroup of the HFpEF population and thus represent competition for us in this segment as well.

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and/or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the “individual mandate.”

On June 17, 2021, the Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

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

Additionally, on August 16, 2022, President Biden signed the Inflation Reduction Act (the "IRA"), into law, which among other things, (1) directs the Department of Health and Human Services (the "HHS"), to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA includes certain exemptions to the price negotiation program, including a limited exemption for products with orphan drug designation. This exemption applies only to products with one orphan drug designation that is (i) for a rare disease or condition and (ii) is approved for indication(s) for such rare disease or condition. By limiting price negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for our product candidates in multiple indications. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug pricing negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for TX45 and any potential future product candidates, which would adversely affect our business.

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

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

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

In many countries outside the United States, government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government-mandated price cuts, limitations on coverage of target population and introduction of volume caps.

Many countries implement health technology assessment (“HTA”), procedures that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, Regulation (EU) 2021/2282 on Health Technology Assessment, which will become effective on January 12, 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for 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 may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue 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 anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing; federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and state and foreign laws that govern the privacy and security and other processing of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, damages, fines, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of 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, as well as the effects of disease outbreaks, epidemics and pandemics.

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

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

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

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

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

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

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meets 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 expects or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

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

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

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

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign health authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs of research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product candidates, their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing 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. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The strength of patents in the biotechnology field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents are successfully issued, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around its claims. If the breadth or strength of protection provided by the patent applications, we hold with respect to our product candidates is threatened, we could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in 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 patents that we have had issued that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy-Smith America Invents Act ("America Invents Act"), enacted in 2013, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and our implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

- others may be able to make or use compounds 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 us or our licensors' patents, as the case may be, or parts of ours or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to our own;
- the laws of foreign countries may not protect ours or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around 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 license with a third party, we could lose license rights that are important to our business.

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

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by our licensor have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

If we are unable to protect the confidentiality of 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 and proprietary information, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to, or disclose, our technology.

Thus, we may not be able to meaningfully protect our proprietary information. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning 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 product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for its products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

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

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block 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. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses for the product candidates or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products or services.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at universities or other biopharmaceutical or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources.

Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

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

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing its compounds and pre-existing pharmaceutical compounds. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm 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 to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that its patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the foreign patent offices. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering products or technology similar to ours. Any such patent application may have priority over our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third-party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

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

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

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

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to its business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Also, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of 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.

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

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trade names or trademarks that incorporate variations of our unregistered trade names or trademarks. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected.

Risks Related to Our Reliance on Third Parties

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

We do not currently lease or own any facility that may be used as our clinical-scale manufacturing and processing facility and currently rely on a contract manufacturing organization ("CMO"), WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), to manufacture TX45 our product candidate used in our Phase 1a, Phase 1b and the recently initiated Phase 2 clinical trials. 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, including any adverse events affecting our sole supplier, Wuxi Biologics, it could have a negative effect on the clinical development of our product candidates and other operations while we work to identify and qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partner for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of a product candidate. We perform periodic audits of each CMO facility that supports our supply of TX45 and reviews and approves all TX45 cGMP-related documentation. We also have a quality agreement with WuXi Biologics that documents our mutual agreement on compliance with cGMPs and expectations on quality-required communications to us. Beyond this, we have no control over the ability of our CMO to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities and the associated Quality Management System for the manufacture of a product candidate or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially and adversely affect our ability to develop, obtain regulatory approval for or market such product candidate, if approved. Similarly, our failure, or the failure of our CMO, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of a product candidate or drug and harm our business and results of operations. In addition, we have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved.

Moreover, our CMO may experience manufacturing difficulties due to resource constraints, governmental restrictions or as a result of labor disputes or unstable political environments. Supply chain issues, including those resulting from the COVID-19 pandemic and the ongoing military conflict between Russia and Ukraine, may affect our third-party vendors and cause delays. Furthermore, since we have engaged WuXi Biologics, a manufacturer located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments or political unrest or unstable economic conditions in China. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, loans, and grants to entities that use equipment or services from certain Chinese biotechnology companies and would authorize the U.S. government to name other Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. For example, in the event that we need to transfer from WuXi Biologics, which is our sole manufacturing source for TX45, we anticipate that the complexity of the manufacturing process may materially impact the amount of time it would take to secure a replacement manufacturer. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to supply product candidates, including TX45, in a timely manner or within budget. If any CMO on which we will rely fails to manufacture quantities of a product candidate at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition, cash flows, and prospects could be materially and adversely affected. In addition, our CMO and/or distribution partners are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and our CMO may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our products.

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators, contracted laboratories and third-party CROs, to conduct our preclinical studies and clinical trials in accordance with applicable regulatory requirements, to validate our assays and to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good laboratory practices ("GLPs"), as applicable, and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible, reproducible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these GLPs and GCPs through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators or any of our CROs or contracted laboratories fail to comply with applicable GLPs and GCPs, the clinical data generated in 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 concludes that the financial relationship may have affected the interpretation of the preclinical study or clinical trial, the integrity of the data generated at the applicable preclinical study or clinical trial site may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing our clinical-stage product candidate or any future product candidates.

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

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into additional strategic collaborations in the future when strategically attractive, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for 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 pre-clinical programs and successfully develop our product candidates requires access to animal research models sufficient to assess safety and in some cases to establish the rationale for therapeutic use. Failure to access or a significant delay in accessing animal research models that meet our needs or that fulfil regulatory requirements may materially adversely affect our ability to advance our pre-clinical programs and successfully develop our product candidates and this could result in significant harm to our business. During the COVID-19 pandemic, researchers and CROs experienced significant limitations in their access to animal research models, specifically including a sharp reduction in the availability of NHPs originating from breeding farms in Southeast Asia and limited access to the generation of genetically-modified rodent models used in efficacy evaluations. If we are unable to obtain NHPs in sufficient quantities and in a timely manner to meet the needs of our pre-clinical research programs, if the price of NHPs that are available increases significantly, or if our suppliers are unable to ship the NHPs in their possession that are reserved for them, our ability to advance our pre-clinical programs and successfully develop our pre-clinical candidates may be materially adversely affected or significantly delayed.

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

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

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

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

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

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

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

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the current and future use of a product candidate in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims may be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to 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.

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

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

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

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

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

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

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

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") and the Swiss Federal Data Protection Act (collectively, "European Data Protection Laws") impose strict requirements for processing personal information, including relating to transfer of personal information to countries like the United States. European Data Protection Laws and other relevant laws govern patient confidentiality and storage of personal health data, and may apply to our processing of personal information from clinical trial participants and other individuals located in the EEA, the United Kingdom (the "UK"), or Switzerland and, if TX45 or any potential future product candidates are approved, our possible commercialization of those products in the EEA, the UK, or Switzerland (as applicable).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of December 31, 2023, we had U.S. federal net operating loss carryforwards of approximately $43.6 million. The amount of net operating loss carryforwards that we are permitted to deduct is limited to 80% of taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, our U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Code, if we have undergone or undergo an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in our equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law.

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

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

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

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

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect 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 CMOs and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any CMOs and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at third-party facilities. We could also incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding 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 CMOs and suppliers we engage will also be subject to these and other environmental, health and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

As a public company, we incur significant legal, accounting and other expenses that Legacy Tectonic did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costlier. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

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

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. We currently qualify as a “smaller reporting company,” as such term is defined in Rule 12b-2 under the Exchange Act, which allows the us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this 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 have filed lawsuits relating to the Merger and 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), which was voluntarily dismissed without prejudice on June 13, 2024. Two actions have been filed in the Supreme Court of New York, captioned *Price v. Avrobio, Inc., et al.* , No. 652555/2024 (filed May 17, 2024) and *Keller v. Avrobio, Inc., et al.* , No. 652597/2024 (filed May 21, 2024). The foregoing actions are referred to as the "Merger Actions."

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

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

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

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

Pursuant to the Subscription Agreement, we filed a resale shelf registration statement covering the resale of up to an aggregate of 2,969,583 shares of our common stock, which was declared effective on July 30, 2024. The common stock being offered for resale pursuant to the resale shelf registration statement by the selling stockholders would represent approximately 20.2% of our outstanding common stock as of August 9, 2024. 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, certain of our shares are subject to lock-up agreements between AVROBIO and Legacy Tectonic. Following the expiration of these lock-up agreements, the relevant stockholders will not be restricted from selling shares our common stock held by them, other than by applicable securities laws. Stockholders not subject to these lock-up agreements will not be restricted from selling shares of our common stock held by them, other than by applicable securities laws. In addition, shares of common stock that are subject to outstanding options or will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after any legal or contractual restrictions on resale lapse, the trading price of our common stock could decline.

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

Based on the number of shares outstanding as of June 30, 2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 47.4% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of or based on a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (3) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless AVROBIO consents in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principal executive offices are located in Watertown, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporation by Reference			
		Form	File No	Exhibit	Filing Date
3.1*	Fourth Amended and Restated Certificate of Incorporation, as amended through June 20, 2024.				
3.2	Amended and Restated Bylaws, as currently in effect.	8-K	001-38537	3.2	6/25/2018
10.1	Contingent Value Rights Agreement dated June 20, 2024, by and between Tectonic Therapeutic, Inc. and Computershare Trust Company, LLC.	8-K	001-38537	10.1	6/20/2024
10.2	Form of Indemnification Agreement between Tectonic Therapeutic, Inc. and each of its directors and executive officers.	8-K	001-38537	10.2	6/20/2024
10.3#	2019 Equity Incentive Plan of Tectonic Therapeutic, Inc., and form of award agreements thereunder.	S-4	333-277048	10.43	2/14/2024

Exhibit Number	Description	Incorporation by Reference			
		Form	File No	Exhibit	Filing Date
10.4#	Tectonic Therapeutic, Inc. 2024 Equity Incentive Plan.	8-K	001-38537	10.6	6/20/2024
10.5#	Forms of Option Grant Notice, Option Agreement and Notice of Exercise under Tectonic Therapeutic, Inc. 2024 Equity Incentive Plan.	8-K	001-38537	10.7	6/20/2024
10.6#	Tectonic Therapeutic, Inc. 2024 Employee Stock Purchase Plan.	8-K	001-38537	10.8	6/20/2024
10.7#	Amended and Restated Employment Agreement, dated as of June 20, 2024, by and between Tectonic Therapeutic, Inc. and Alise Reicin, M.D.	8-K	001-38537	10.4	6/20/2024
10.8#	Form of Severance Plan and Form of Participation Agreement of Tectonic Therapeutic, Inc.	S-4	333-277048	10.47	4/15/2024
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 and Principal Financial Officer, Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document				
101.SCH*	XBRL Taxonomy Extension Schema Document with Embedded Linkbase Documents				
104*	Cover page formatted as Inline XBRL and contained in Exhibit 101				

* Filed herewith.
\# Indicates a management contract or any compensatory plan, contract or arrangement.
^ This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing by the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

TECTONIC THERAPEUTIC, INC.

Date: August 14, 2024

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

Date: August 14, 2024

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

Exhibit 3.1

CERTIFICATE OF AMENDMENT
TO THE
FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
AVROBIO, INC.

AVROBIO, Inc. (the "Corporation"), a corporation organized and existing under the laws of the State of Delaware, does hereby certify as follows:

1. That the Fourth Amended and Restated Certificate of Incorporation of the Corporation that was filed with the Secretary of State of Delaware on June 25, 2018 (the "Amended and Restated Certificate") is hereby amended to add the following paragraph after the first paragraph of Article IV thereof to provide the following:

Upon this Certificate of Amendment becoming effective (the "Effective Time") pursuant to the DGCL, each twelve (12) shares of the Common Stock issued and outstanding and held of record by each stockholder of the Corporation or issued and held by the Corporation in treasury immediately prior to the Effective Time shall automatically without further action on the part of the Corporation or any holder of such Common Stock, be combined into one (1) validly issued, fully paid and nonassessable share of Common Stock, subject to the treatment of fractional share interests as described below (the "Reverse Stock Split"). No fractional shares shall be issued as a result of the Reverse Stock Split. Instead, if upon aggregating all of the shares of Common Stock held by a record holder immediately following the Reverse Stock Split such holder would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split, the Corporation shall pay in cash (without interest) to each such holder an amount equal to the product of such resulting fractional interest in one share of Common Stock multiplied by the closing trading price on The Nasdaq Stock Market LLC of a share of Common Stock on the last trading day immediately prior to the date on which the Effective Time occurs (with such price proportionately adjusted to give effect to the Reverse Stock Split). Each holder of record of a certificate or certificates representing one or more shares of Common Stock pre-Reverse Stock Split shall be entitled to receive as soon as practicable following the Effective Time, upon surrender of such certificate or certificates, a certificate or certificates representing the whole number of shares of Common Stock post-Reverse Stock Split to which such holder shall be entitled pursuant to the Reverse Stock Split as well as cash in lieu of any fractional shares of Common Stock to which such holder may be entitled. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Effective Time of the Reverse Stock Split upon the surrender thereof).

2. That the foregoing amendment was duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware.

3. That the foregoing amendment shall become effective at 4:00 p.m. eastern on June 20, 2024.

IN WITNESS WHEREOF, this Certificate of Amendment to the Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this Corporation on this 20th day of June, 2024.

AVROBIO, INC.

By: /s/ Erik Ostrowski
Erik Ostrowski
President, Interim Chief Executive Officer,
Chief Financial Officer and Treasurer

CERTIFICATE OF AMENDMENT
TO THE
FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
AVROBIO, INC.

AVROBIO, Inc. (the "Corporation"), a corporation organized and existing under the laws of the State of Delaware, does hereby certify as follows:

1. That the Fourth Amended and Restated Certificate of Incorporation of the Corporation that was filed with the Secretary of State of Delaware on June 25, 2018 (the "Amended and Restated Certificate") is hereby amended to add a new Article X thereto to read in its entirety as follows:

ARTICLE X

An Officer of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of his or her fiduciary duty as an Officer, except for liability (a) for any breach of the Officer's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) for any transaction from which the Officer derived an improper personal benefit or (d) in any action by or in the right of the Corporation. If the DGCL is amended after the effective date of this Certificate to authorize corporate action further eliminating or limiting the personal liability of Officers, then the liability of an Officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. For purposes of this Article X, "Officer" shall have the meaning set forth in Section 102(b)(7) of the DGCL.

Any amendment, repeal or modification of this Article X by either of (i) the stockholders of the Corporation or (ii) an amendment to the DGCL, or the adoption of any provision of this Certificate inconsistent with this Article X, shall not adversely affect any right or protection existing at the time of such amendment, repeal, modification or adoption with respect to any acts or omissions occurring before such amendment, repeal, modification or adoption of a person serving as an Officer at the time of such amendment, repeal, modification or adoption. Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article X.

2. That the foregoing amendment was duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware.

3. That the foregoing amendment shall become effective at 4:01 p.m. eastern on June 20, 2024.

IN WITNESS WHEREOF, this Certificate of Amendment to the Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this Corporation on this 20th day of June, 2024.

AVROBIO, INC.

By: /s/ Erik Ostrowski
Erik Ostrowski
President, Interim Chief Executive Officer,
Chief Financial Officer and Treasurer

CERTIFICATE OF AMENDMENT OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF
AVROBIO, INC.

Pursuant to Section 242
of the General Corporation Law of the State of Delaware

AVROBIO, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), certifies that:

1. Article I of the Fourth Amended and Restated Certificate of Incorporation of the Corporation, as currently in effect, is hereby amended and restated in its entirety to read as follows:

"The name of the Corporation is Tectonic Therapeutic, Inc."

2. The foregoing amendment has been duly adopted in accordance with Section 242 of the Delaware General Corporation Law by the board of directors of the Corporation.

3. The foregoing amendment shall become effective at 4:03 p.m. eastern on June 20, 2024.

IN WITNESS WHEREOF, this Certificate of Amendment has been signed by an authorized officer of the Corporation on June 20, 2024.

AVROBIO, INC.

By: /s/ Erik Ostrowski
Erik Ostrowski
President, Interim Chief Executive Officer,
Chief Financial Officer and Treasurer

FOURTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
AVROBIO, INC.

AVROBIO, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is AVROBIO, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was November 17, 2015 under the name AvroBio, Inc.

2. This Fourth Amended and Restated Certificate of Incorporation (the "Certificate") amends, restates and integrates the provisions of the Third Amended and Restated Certificate of Incorporation that was filed with the Secretary of State of the State of Delaware on January 19, 2018 (the "Existing Certificate"), and was duly adopted in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL").

3. The text of the Existing Certificate is hereby amended and restated in its entirety to provide as herein set forth in full.

ARTICLE I

The name of the Corporation is AVROBIO, Inc.

ARTICLE II

The address of the Corporation's registered office in the State of Delaware is 251 Little Falls Drive, in the City of Wilmington, County of New Castle, 19808. The name of its registered agent at such address is Corporation Service Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

CAPITAL STOCK

The total number of shares of capital stock which the Corporation shall have authority to issue is One Hundred Sixty Million (160,000,000), of which (i) One Hundred Fifty Million (150,000,000) shares shall be a class designated as common stock, par value $0.0001 per share (the "Common Stock"), and (ii) Ten Million (10,000,000) shares shall be a class designated as undesignated preferred stock, par value $0.0001 per share (the "Undesignated Preferred Stock").

Except as otherwise provided in any certificate of designations of any series of Undesignated Preferred Stock, the number of authorized shares of the class of Common Stock or Undesignated Preferred Stock may from time to time be increased or decreased (but not below the number of shares of such class outstanding) by the affirmative vote of the holders of a majority in voting power of the outstanding shares of capital stock of the Corporation irrespective of the provisions of Section 242(b)(2) of the DGCL.

The powers, preferences and rights of, and the qualifications, limitations and restrictions upon, each class or series of stock shall be determined in accordance with, or as set forth below in, this Article IV.

A. COMMON STOCK

Subject to all the rights, powers and preferences of the Undesignated Preferred Stock and except as provided by law or in this Certificate (or in any certificate of designations of any series of Undesignated Preferred Stock):

(a) the holders of the Common Stock shall have the exclusive right to vote for the election of directors of the Corporation (the "Directors") and on all other matters requiring stockholder action, each outstanding share entitling the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate (or on any amendment to a certificate of designations of any series of Undesignated Preferred Stock) that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of Undesignated Preferred Stock if the holders of such affected series of Undesignated Preferred Stock are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to this Certificate (or pursuant to a certificate of designations of any series of Undesignated Preferred Stock) or pursuant to the DGCL;

(b) dividends may be declared and paid or set apart for payment upon the Common Stock out of any assets or funds of the Corporation legally available for the payment of dividends, but only when and as declared by the Board of Directors or any authorized committee thereof; and

(c) upon the voluntary or involuntary liquidation, dissolution or winding up of the Corporation, the net assets of the Corporation shall be distributed pro rata to the holders of the Common Stock.

B. UNDESIGNATED PREFERRED STOCK

The Board of Directors or any authorized committee thereof is expressly authorized, to the fullest extent permitted by law, to provide by resolution or resolutions for, out of the unissued shares of Undesignated Preferred Stock, the issuance of the shares of Undesignated Preferred Stock in one or more series of such stock, and by filing a certificate of designations pursuant to applicable law of the State of Delaware, to establish or change from time to time the number of shares of each such series, and to fix the designations, powers, including voting powers, full or limited, or no voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof.

ARTICLE V

STOCKHOLDER ACTION

1. Action without Meeting. Any action required or permitted to be taken by the stockholders of the Corporation at any annual or special meeting of stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders and may not be taken or effected by a written consent of stockholders in lieu thereof. Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article V, Section 1.

2. Special Meetings. Except as otherwise required by statute and subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock, special meetings of the stockholders of the Corporation may be called only by the Board of Directors acting pursuant to a resolution approved by the affirmative vote of a majority of the Directors then in office, and special meetings of stockholders may not be called by any other person or persons. Only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders of the Corporation.

Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article V, Section 2.

ARTICLE VI

DIRECTORS

1. General. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors except as otherwise provided herein or required by law.

2. Election of Directors. Election of Directors need not be by written ballot unless the By-laws of the Corporation (the "By-laws") shall so provide.

3. Number of Directors; Term of Office. The number of Directors of the Corporation shall be fixed solely and exclusively by resolution duly adopted from time to time by the Board of Directors. The Directors, other than those who may be elected by the holders of any series of Undesignated Preferred Stock, shall be classified, with respect to the term for which they severally hold office, into three classes. The initial Class I Directors of the Corporation shall be Christopher Paige, Scott Requadt and Joshua Resnick; the initial Class II Directors of the Corporation shall be Ian Clark and Annalisa Jenkins; and the initial Class III Directors of the Corporation shall be Bruce Booth, Phillip Donenberg and Geoff MacKay. The initial Class I Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2019, the initial Class II Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2020, and the initial Class III Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2021. At each annual meeting of stockholders, Directors elected to succeed those Directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. Notwithstanding the foregoing, the Directors elected to each class shall hold office until their successors are duly elected and qualified or until their earlier resignation, death or removal.

Notwithstanding the foregoing, whenever, pursuant to the provisions of Article IV of this Certificate, the holders of any one or more series of Undesignated Preferred Stock shall have the right, voting separately as a series or together with holders of other such series, to elect Directors at an annual or special meeting of stockholders, the election, term of office, filling of vacancies and other features of such directorships shall be governed by the terms of this Certificate and any certificate of designations applicable to such series.

Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article VI, Section 3.

4. Vacancies. Subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock to elect Directors and to fill vacancies in the Board of Directors relating thereto, any and all vacancies in the Board of Directors, however occurring, including, without limitation, by reason of an increase in the size of the Board of Directors, or the death, resignation, disqualification or removal of a Director, shall be filled solely and exclusively by the affirmative vote of a majority of the remaining Directors then in office, even if less than a quorum of the Board of Directors, and not by the stockholders. Any Director appointed in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of Directors in which the new directorship was created or the vacancy occurred and until such Director's successor shall have been duly elected and qualified or until his or her earlier resignation, death or removal. Subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock to elect Directors, when the number of Directors is increased or decreased, the Board of Directors shall, subject to Article VI.3 hereof, determine the class or classes to which the increased or decreased number of Directors shall be apportioned; provided, however, that no decrease in the number of Directors shall shorten the term of any incumbent Director. In the event of a vacancy in the Board of Directors, the remaining Directors, except as otherwise provided by law, shall exercise the powers of the full Board of Directors until the vacancy is filled.

5. Removal. Subject to the rights, if any, of any series of Undesignated Preferred Stock to elect Directors and to remove any Director whom the holders of any such series have the right to elect, any Director (including persons elected by Directors to fill vacancies in the Board of Directors) may be removed from office (i) only with cause and (ii) only by the affirmative vote of the holders of two thirds (2/3) of the outstanding shares of capital stock then entitled to vote at an election of Directors. At least forty-five (45) days prior to any annual or special meeting of stockholders at which it is proposed that any Director be removed from office, written notice of such proposed removal and the alleged grounds thereof shall be sent to the Director whose removal will be considered at the meeting.

Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article VI, Section 5.

ARTICLE VII

LIMITATION OF LIABILITY

A Director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a Director, except for liability (a) for any breach of the Director's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) under Section 174 of the DGCL or (d) for any transaction from which the Director derived an improper personal benefit. If the DGCL is amended after the effective date of this Certificate to authorize corporate action further eliminating or limiting the personal liability of Directors, then the liability of a Director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Any amendment, repeal or modification of this Article VII by either of (i) the stockholders of the Corporation or (ii) an amendment to the DGCL, shall not adversely affect any right or protection existing at the time of such amendment, repeal or modification with respect to any acts or omissions occurring before such amendment, repeal or modification of a person serving as a Director at the time of such amendment, repeal or modification.

Notwithstanding anything herein to the contrary, the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon, and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class, shall be required to amend or repeal any provision of this Article VII.

ARTICLE VIII

AMENDMENT OF BY-LAWS

1. Amendment by Directors. Except as otherwise provided by law, the By-laws of the Corporation may be amended or repealed by the Board of Directors by the affirmative vote of a majority of the Directors then in office.

2. Amendment by Stockholders. Except as otherwise provided therein, the By-laws of the Corporation may be amended or repealed at any annual meeting of stockholders, or special meeting of stockholders called for such purpose, by the affirmative vote of a majority of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class.

ARTICLE IX

AMENDMENT OF CERTIFICATE OF INCORPORATION

The Corporation reserves the right to amend or repeal this Certificate in the manner now or hereafter prescribed by statute and this Certificate, and all rights conferred upon stockholders herein are granted subject to this reservation. Except as otherwise required by this Certificate or by law, whenever any vote of the holders of capital stock of the Corporation is required to amend or repeal any provision of this Certificate, such amendment or repeal shall require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment or repeal, and the affirmative vote of the majority of the outstanding shares of each class entitled to vote thereon as a class, at a duly constituted meeting of stockholders called expressly for such purpose.

[End of Text]

THIS FOURTH AMENDED AND RESTATED CERTIFICATE OF INCORPORATION is executed as of this 25th day of June, 2018.

AVROBIO, INC.

By: /s/ Geoff MacKay
Geoff MacKay
President and Chief Executive Officer

Exhibit 31.1

CERTIFICATION

I, Alise Reicin, certify that:

1. I have reviewed this Form 10-Q of Tectonic Therapeutic, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

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

Exhibit 31.2

CERTIFICATION

I, Daniel Lochner, certify that:

1. I have reviewed this Form 10-Q of Tectonic Therapeutic, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in exchange act rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2024

/s/ Daniel Lochner
Daniel Lochner
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Alise Reicin, President and Chief Executive Officer of Tectonic Therapeutic, Inc. (the "Company"), and Daniel Lochner, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 14, 2024

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 14th day of August, 2024.

/s/ Alise Reicin, M.D.	/s/ Daniel Lochner
Alise Reicin, M.D. President and Chief Executive Officer	Daniel Lochner Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tectonic Therapeutic, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.