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

FORM 8-K

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

Date of Report (Date of earliest event reported): August 14, 2024

Tectonic Therapeutic, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38537**	**81-0710585**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

490 Arsenal Way
Suite 210
Watertown, Massachusetts **02472**
(Address of Principal Executive Offices) **(Zip Code)**

Registrant's Telephone Number, Including Area Code: (339) 666-3320

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

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

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

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

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

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

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

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

Emerging growth company ☐

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

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2024, Tectonic Therapeutic, Inc. announced its financial results for the quarter ended June 30, 2024 and provided a general business update. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press Release of Tectonic Therapeutic, Inc. dated August 14, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

TECTONIC THERAPEUTIC, INC.

Date: August 14, 2024

By: /s/ Daniel Lochner
Daniel Lochner
Chief Financial Officer

Exhibit 99.1

Tectonic Therapeutic Announces Second Quarter 2024 Financial Results and Recent Business Highlights

- TX45 advances into Phase 2 clinical trial for patients with Group 2 PH-HFpEF with first site activated and screening open in August 2024
- Received U.S. Investigational New Drug (IND) clearance for lead program, TX45 in July 2024
- Completed reverse merger with AVROBIO in June 2024, including concurrent private placement of $130.7 million
- Cash and cash equivalents were $185.1 million as of June 30, 2024, prior to the payment of accrued transaction and related expenses of approximately $14.4 million, are expected to provide cash runway into mid-2027

WATERTOWN, MA, August 14, 2024 (GLOBENEWSWIRE) — Tectonic Therapeutic, Inc. (NASDAQ: TECX) ("Tectonic", or "the Company"), 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), today announced its financial results for the second quarter ending June 30, 2024, and provided an overview of recent business highlights.

"The second quarter of 2024 was transformational for Tectonic as we transitioned from a private to a public company, completed a significant concurrent capital raise, and continued to advance TX45, our novel Fc-relaxin fusion protein," commented Alise Reicin, M.D., President and Chief Executive Officer of Tectonic. "Today, we announced the start of our global Phase 2 "APEX" clinical trial of TX45 for patients with Group 2 PH-HFpEF. Looking forward, this September, we expect to report topline results from our Phase 1a clinical trial evaluating single dose TX45 in healthy volunteers and dose the first subject in our Phase 2 clinical trial of TX45."

Recent Business Highlights

- **TX45 Phase 2 Clinical Trial Open for Screening**: This August, the Company activated the first clinical trial site for the global, 24-week Phase 2 clinical trial (named the APEX trial) evaluating TX45 administered subcutaneously in subjects with Group 2 Pulmonary Hypertension (PH) due to Heart Failure with Preserved Ejection Fraction (PH-HFpEF). PH-HFpEF is a serious condition estimated to affect over 600,000 people in the United States alone, currently with no approved therapies.
- **U.S. IND Clearance for TX45**: On July 30, 2024, the Company announced the U.S. Food and Drug Administration cleared its IND application for TX45.
- **Closed Reverse Merger with AVROBIO and Concurrent Financing**: On June 20, 2024, the Company announced the closing of its reverse merger with AVROBIO along with a concurrent private placement financing of $130.7 million.

- **Appointed New CFO**: On June 3, 2024, Tectonic appointed Dan Lochner, who has nearly 20 years of biotechnology experience, as the Company's Chief Financial Officer.

Upcoming Milestones

- **APEX Phase 2 Clinical Trial to Dose First Subject with TX45**: The Company expects to dose its first subject in its global, 24-week APEX Phase 2 clinical trial this September. The trial is a placebo-controlled study designed to evaluate the safety and efficacy of TX45 administered subcutaneously in subjects with PH-HFpEF. Topline trial results from this trial are expected in 2026.
- **Phase 1a Clinical Trial Results**: Topline results for the TX45 Phase 1a clinical trial in healthy volunteers are expected to be released this September, with detailed data to be subsequently presented at a scientific meeting.
- **Ongoing Phase 1b Hemodynamic Clinical Trial**: The TX45 Phase 1b hemodynamic clinical trial evaluating single doses of TX45 in subjects with PH-HFpEF continues to enroll as planned, with topline trial results from this trial are expected in mid-2025.
- **Selection of Development Candidate for Second Program**: The Company's second program is evaluating Hereditary Hemorrhagic Telangiectasia (HHT), the second-most common genetic bleeding disorder, representing a potential first-in-indication opportunity. The Company plans to select a development candidate in the second half of 2024 and anticipates initiating a Phase 1 clinical trial beginning in the fourth quarter of 2025 or the first quarter of 2026. HHT is the second most common genetic bleeding disorder, and it is estimated to affect approximately 70,000-75,000 people in the United States alone, with up to 10-20% of those patients expected to have severe disease.

Overview of Financial and Operating Results

- **Cash Position**: As of June 30, 2024, cash and cash equivalents were $185.1 million, compared to $18.7 million as of March 31, 2024. Tectonic anticipates that its current cash and cash equivalents as of the date hereof, will provide a cash runway into mid-2027, including through key Phase 1b and Phase 2 readouts for TX45, and the progression of the HHT program into clinical development.
- **Research and Development Expenses**: 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 was primarily due to a reduction in Contract Manufacturing Organization (CMO) costs as a result of fewer batches of clinical trial supply produced during the three months ended June 30, 2024 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 in preclinical Contract Research Organization ("CRO") costs. This was partially offset by an increase in consulting and professional services fees, as well as an increase in clinical CRO costs.

- **General and Administrative Expenses**: 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 was primarily the result of increases in professional and consulting fees to support merger-related activities as well as increases in personnel related costs.
- **Other Expense, Net**: Other expense, net was $1.3 million for the three months ended June 30, 2024, as compared to $0.2 million of other income, net for the three months ended June 30, 2023. The $1.4 million change was primarily the result of a SAFE liabilities loss of $1.5 million due to a remeasurement of the SAFE liabilities to fair value during the three months ended June 30, 2024 as compared to the three months ended June 30, 2023.
- **Net Loss**: For the three months ended June 30, 2024, the Company had a net loss of $12.7 million, compared to a net loss of $10.5 million for the three months ended June 30, 2023.

About TX45, a long-acting Fc-relaxin fusion protein

Tectonic's lead program, TX000045 (TX45), is an Fc-relaxin fusion protein with optimized pharmacokinetics and biophysical properties 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.

TX45's pharmacological profile, with an extended half-life compared with native relaxin, is a direct result of applying Tectonic's protein engineering capabilities. It has the potential to address patients with Group 2 PH-HFpEF as the initial disease setting. Treatment with TX45 could potentially improve hemodynamics through effects on pulmonary and systemic vasodilation, cardiac diastolic dysfunction and potential remodeling in both the pulmonary vessels and the heart, which could translate into a clinically meaningful improvement in exercise capacity in these patients.

The Phase 1a clinical trial of TX45 in healthy volunteers was designed as a single ascending dose trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics (including renal blood flow) of TX45 administered intravenously (IV) (four doses ranging from 0.3 mg/kg to 10 mg/kg) and SC (three doses, 150 mg, 300 mg and 600 mg). Topline results are expected to be reported from this trial this September, followed by more detailed data at a later scientific meeting.

The Phase 1b clinical trial of TX45 in patients with Group 2 PH-HFpEF is a single dose, open-label trial to evaluate safety, tolerability and acute hemodynamic effects of IV administration of TX45, with study results expected in mid-2025. The trial will evaluate the change from baseline in pulmonary vascular resistance (PVR) as determined by right heart catheterization, as well as improvement in mean pulmonary artery pressure (mPAP), pulmonary capillary wedge pressure (PCWP), cardiac output, and systemic vascular resistance (SVR).

About Group 2 Pulmonary Hypertension in HFpEF

The World Health Organization has defined 5 groups of PH. Tectonic is focused on the Group 2 subtype, a condition that develops as a consequence of left-sided heart disease, specifically pulmonary hypertension secondary to left heart failure with preserved ejection fraction (PH-HFpEF). There are an estimated 6 million patients with heart failure in the United States, with HFpEF representing up to ~50% of heart failure cases. Tectonic estimates the combined Group 2 PH population with HFpEF at over 600,000.

In patients with PH-HFpEF, chronic heart failure leads to increased blood pressure in the pulmonary arteries, exerting severe strain on the right side of the heart, which adapts poorly to the increased pressure. This increased pulmonary pressure gradually causes worsening exercise capacity, shortness of breath and right-sided heart failure which can lead to death. Although several Group 1 PH (Pulmonary Arterial Hypertension, PAH) medications have been explored in Group 2 PH, to date, no medications have been approved for its treatment.

About Tectonic

Tectonic Therapeutic is a clinical-stage biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of G-protein coupled receptors (GPCRs). Leveraging its proprietary technology platform called GEODe™ (GPCRs Engineered for Optimal Discovery), Tectonic is focused on developing biologic medicines that overcome the existing challenges of GPCR-targeted drug discovery and harness the human body to modify the course of disease. Tectonic focuses on areas of significant unmet medical need, where therapeutic options are poor or nonexistent, and new medicines have the potential to improve patient quality of life. Tectonic is headquartered in Watertown, Massachusetts. For more information, please visit www.tectonictx.com and follow @TectonicTx on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. All statements in this press release other than statements of historical facts are “forward-looking statements”. These statements may be identified by words such as “aims”, “anticipates”, “believes”, “could”, “estimates”, “expects”, “forecasts”, “goal”, “intends”, “may”, “plans”, “possible”, “potential”, “seeks”, “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding: the design, objectives, initiation, timing, progress and results of current and future clinical trials of Tectonic’s product candidate, TX45, including the ongoing Phase 1a and Phase 1b clinical trial in Group 2 PH-HFpEF; the proposed initiation of the Phase 2 clinical trial of TX45 in Group 2 PH-HFpEF including anticipated clinical trial design and study endpoints; the anticipated market opportunity of TX45 to address the unmet needs of patients living with PH-HFpEF; the Company’s plans to select a development candidate for its second program in HHT and anticipated market opportunity; and the Company’s expected cash runway. These forward-

looking statements are based on Tectonic's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties that could cause Tectonic's clinical development programs, future results or performance to differ materially from those expressed or implied by the forward-looking statements. Many factors may cause differences between current expectations and actual results, including: the potential that success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate; the impacts of macroeconomic conditions, including the conflict in Ukraine and the conflict between Israel and Hamas, heightened inflation and uncertain credit and financial markets, on Tectonic's business, clinical trials and financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; Tectonic's ability to realize the benefits of its collaborations and license agreements; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; and unexpected litigation or other disputes. Other factors that may cause Tectonic's actual results to differ from those expressed or implied in the forward-looking statements in this press release are identified in the section titled "Risk Factors" in the final prospectus on Form 424(b)(3) filed by AVROBIO with the SEC on May 3, 2024, and in subsequent filings that Tectonic makes and will make with the SEC in the future. Tectonic expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law. For more information, please visit www.tectonictx.com and follow @TectonicTx on X (formerly Twitter) and LinkedIn.

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Tectonic Therapeutic, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)

	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 income (expense), 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)

Tectonic Therapeutic, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2024 (unaudited)	December 31, 2023
Cash and cash equivalents	$ 185,124	$ 28,769
Working capital	161,387	(10,004)
Total assets	193,910	39,399
Total stockholders' equity (deficit)	166,367	(84,636)