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): November 07, 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 November 7, 2024, Tectonic Therapeutic, Inc. announced its financial results for the three and nine months ended September 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.

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 November 7, 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: November 7, 2024

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

Exhibit 99.1

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

- Patient enrollment in the Phase 1b hemodynamic trial remains ahead of expectation, with topline results now expected in late Q1'2025 or early Q2'2025
- First subject dosed with TX000045 ("TX45") in APEX Phase 2 clinical trial in early October, with topline results expected in 2026
- Development Candidate TX002100 ("TX2100") selected for second program targeting patients with Hereditary Hemorrhagic Telangiectasia (HHT)
- Cash and cash equivalents were $159.1 million as of September 30, 2024, expected to provide cash runway into mid-2027

WATERTOWN, MA, November 7, 2024 (GLOBE NEWSWIRE) -- 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 third quarter ending September 30, 2024, and provided an overview of recent business highlights.

"During the third quarter we continued to make excellent progress advancing our novel pipeline. We initiated the APEX Phase 2 clinical trial and continued better than expected enrollment in our Phase 1b hemodynamic, proof of concept clinical trial for TX45," commented Alise Reicin, M.D., President and Chief Executive Officer of Tectonic. "Additionally, today we are announcing the selection of TX2100 as our development candidate for Tectonic's second program targeting HHT, and we are looking forward to discussing our Phase 1a trial results for TX45 this month at the American Heart Association followed by topline results for the Phase 1b trial expected in late Q1'2025 or early Q2'2025."

Recent Business Highlights

- **First Subject Dosed TX45 in APEX Phase 2 Trial in Early October 2024**: Tectonic dosed its first subject in its global, 24-week APEX Phase 2 clinical trial in early October. The trial is a placebo-controlled study designed to evaluate the safety and efficacy of Tectonic's lead program, TX45 administered subcutaneously (SC) in subjects with PH-HFpEF. Subjects will be randomized to 300 mg SC (2 ml injection) once monthly of TX45, 300 mg SC once every other week of TX45, or placebo. Topline trial results from the APEX trial are expected in 2026.
- **Favorable Phase 1a Topline Trial Results for TX45 Announced in September 2024**: In September, Tectonic announced favorable Phase 1a safety, tolerability and pharmacokinetic (PK) and pharmacodynamic (PD) results for TX45. TX45 was well-tolerated with no observed immunogenicity and demonstrated a favorable PK/PD relationship which was used to identify doses for the ongoing APEX Phase 2 clinical trial.
- **Development Candidate TX2100 Selected for HHT Program**: Tectonic has identified TX2100 as its development candidate for the treatment of HHT, the second most common genetic bleeding disorder with no approved therapy. TX2100 is a VHH-Fc fusion antagonist antibody that binds to an undisclosed GPCR target ("GPCR3") which plays a key role in pathogenic angiogenesis. A rodent surrogate of TX2100 demonstrated reduced arteriovenous malformation development and bleeding in an animal model of HHT. A 4-week non-human primate dose-range study with a functionally equivalent precursor to TX2100 showed no treatment-related toxicity observed at doses up to 100 mg/kg. Tectonic expects to initiate a Phase 1 clinical trial for TX2100 in Q4'2025 or Q1'2026 following the conclusion of favorable IND enabling studies.

Upcoming Milestones

- **Phase 1a Clinical Trial Results at AHA**: The TX45 Phase 1a poster titled "The tolerability, safety, pharmacokinetics, and pharmacodynamics of TX000045, a long-acting Fc-relaxin fusion protein after single doses in healthy volunteers" will be presented at the American Heart Association (AHA) Scientific Sessions on November 16th from 3-4pm EST.
- **Ongoing Phase 1b Hemodynamic Clinical Trial Results Expected Late Q1'2025 or Early Q2'2025**: The TX45 Phase 1b hemodynamic clinical trial evaluating single doses of TX45 in subjects with PH-HFpEF continues to enroll ahead of plan, with topline trial results expected in late Q1'2025 or early Q2'2025.
- **Ongoing APEX Phase 2 Clinical Trial Results Expected in 2026**: The global, 24-week APEX Phase 2 clinical trial, a placebo-controlled study designed to evaluate the safety and efficacy of TX45 administered subcutaneously in subjects with PH-HFpEF remains on track, with topline trial results expected in 2026.

Overview of Financial and Operating Results

- **Cash Position**: As of September 30, 2024, cash and cash equivalents were $159.1 million, compared to $185.1 million as of June 30, 2024. Tectonic anticipates that its current cash and cash equivalents, 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 $14.3 million for the three months ended September 30, 2024, as compared to $8.1 million for the three months ended September 30, 2023. The increase was primarily the result of increased external contract research organization research costs related to the progression of the TX45 Phase 1b clinical trial and the initiation of the TX45 Phase 2 clinical trial, along with an increase in consulting and professional services to support the ongoing development activities of Tectonic's early stage drug candidates.
- **General and Administrative Expenses**: General and administrative expenses were $5.3 million for the three months ended September 30, 2024, as compared to $2.0 million for the three months ended September 30, 2023. The increase was primarily the result of increases in personnel-related costs as well as increases in professional and consulting fees to support merger-related activities.
- **Net Loss**: For the three months ended September 30, 2024, the Company had a net loss of $17.7 million compared to a net loss of $10.1 million for the three months ended September 30, 2023.

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

Tectonic's lead program, 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.

Tectonic is evaluating TX45 in an ongoing Phase 1b hemodynamic, proof-of-concept study and a Phase 2 clinical proof-of-concept study; both studies are being conducted in patients with PH-HFpEF.

About Group 2 Pulmonary Hypertension in HFpEF

The World Health Organization has defined five groups of PH. Tectonic is focused on the Group 2 subtype, a condition that develops due to left-sided heart disease, specifically pulmonary hypertension secondary to left heart failure with preserved ejection fraction (PH-HFpEF).

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 TX2100

TX2100 is a GPCR-targeting biotherapeutic that is being developed to treat HHT, the second most common genetic bleeding disorder. In HHT, loss-of-function mutations in the BMP9/10-Endoglin-ALK1-SMAD4 signaling pathway lead to increased expression of factors that promote abnormal blood vessel formation. The abnormal blood vessel formations found in HHT, also known as telangiectasias and arterio-venous malformations or "AVMs", are prone to spontaneous recurrent and severe bleeding episodes that can be life-threatening, yet there are no approved therapies to treat these patients. The target GPCR for TX2100 is a receptor for an angiogenic factor known to be upregulated in animal models of HHT. By blocking the signaling of this receptor, Tectonic anticipates it can reduce bleeding resulting from the abnormal blood vessel formation seen in HHT.

About Tectonic

Tectonic is a biotechnology company focused on the discovery and development of therapeutic proteins and antibodies that modulate the activity of G-protein coupled receptors (GPCRs). Leveraging its proprietary technology platform called GEODe™ (GPCRs Engineered for Optimal Discovery), Tectonic is focused on developing biologic medicines that overcome the existing challenges of GPCR-targeted drug discovery and harness the human body to modify the course of disease. Tectonic focuses on areas of significant unmet medical need, often where therapeutic options are poor or nonexistent, as these are areas where new medicines have the potential to improve patient quality of life. Tectonic is headquartered in Watertown, Massachusetts. For more information, please visit www.tectonictx.com and follow @TectonicTx on X 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 preclinical studies and clinical trials of Tectonic’s product candidates, including the ongoing Phase 1b and Phase 2 clinical trials for its lead program, TX45, in Group 2 PH-HFpEF; the proposed initiation of a Phase 1 clinical trial for its development candidate for a second program in HHT, including its preclinical studies and anticipated endpoints; 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 in the Middle East, 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 under the heading “Risk Factors” in Tectonic’s quarterly report on Form 10-Q filed with the SEC on November 7, 2024, and in other 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)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 14,317	$ 8,134	$ 32,208	$ 29,774
General and administrative	5,320	1,980	11,816	5,500
Total operating expenses	19,637	10,114	44,024	35,274
Loss from operations	(19,637)	(10,114)	(44,024)	(35,274)
Other income (expense), net:				
Change in fair value of SAFE liabilities	—	—	(3,610)	—
Interest income	1,952	97	2,526	448
Interest expense	(25)	(36)	(85)	(118)
Other expense	(7)	(1)	(416)	(10)
Total other income (expense), net	1,920	60	(1,585)	320
Net loss	(17,717)	(10,054)	(45,609)	(34,954)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.20)	$ (7.62)	$ (7.16)	$ (28.06)
Weighted-average common shares outstanding, basic and diluted	14,729,018	1,319,147	6,373,717	1,245,745
Other comprehensive loss:				
Foreign currency translation adjustment	(16)	—	(66)	—
Comprehensive loss	$ (17,733)	$ (10,054)	$ (45,675)	$ (34,954)

Tectonic Therapeutic, Inc.
Select Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 159,095	$ 28,769
Working capital*	145,278	(10,004)
Total assets	168,717	39,399
Total stockholders' equity (deficit)	150,361	(84,636)

*Working capital is defined as current assets less current liabilities