
**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 06, 2025

Tectonic Therapeutic, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38537
(Commission File Number)

81-0710585
(IRS Employer
Identification No.)

490 Arsenal Way
Suite 210
Watertown, Massachusetts
(Address of Principal Executive Offices)

02472
(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 Stock Market LLC

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 6, 2025, Tectonic Therapeutic, Inc. announced its financial results for the quarter ended September 30, 2025 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.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

- 99.1 [Press Release of Tectonic Therapeutic, Inc. dated November 6, 2025](#)
 - 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)
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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 6, 2025

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

Tectonic Therapeutic Announces Third Quarter 2025 Financial Results and Recent Business Highlights

- Positive topline data from Part B of the TX45 Phase 1b trial demonstrated improvements in both left heart function and pulmonary hemodynamics in patients with Group 2 Pulmonary Hypertension in Heart Failure with reduced Ejection Fraction (“PH-HFrEF”)
- Expect to initiate TX2100 Phase 1 clinical trial in healthy volunteers in Q1’2026 as a potential treatment for Hereditary Hemorrhagic Telangiectasia (“HHT”)
- TX45 PH-ILD Phase 2 clinical trial is planned to initiate in 2026 to evaluate TX45’s safety and hemodynamic effects in patients with Pulmonary Hypertension associated with Interstitial Lung Disease (“PH-ILD”, Group 3 PH) to expand the therapeutic breadth of TX45
- Ongoing TX45 APEX Phase 2 clinical trial in patients with Group 2 Pulmonary Hypertension in Heart Failure with preserved Ejection Fraction (“PH-HFpEF”) continues to enroll; topline results expected in 2026
- Cash and cash equivalents were \$268.4 million as of September 30, 2025, expected to provide cash runway into Q4’2028

WATERTOWN, Mass., November 6, 2025 (GLOBE NEWSWIRE) -- Tectonic Therapeutic, Inc. (NASDAQ: TECX) (“Tectonic”), 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 financial results for the third quarter ended September 30, 2025, and provided an overview of recent business highlights.

“Our team continued to advance our lead asset TX45 with the positive topline data from Part B of our Phase 1b study in patients with HFrEF. Following our recent presentation of the full Part A data set at the ESC Heart Failure 2025 Congress, the improvements demonstrated in both left heart function and pulmonary hemodynamics across both PH-HFrEF and PH-HFpEF populations suggest TX45 has the potential to be effective in a broad patient population,” said Alise Reicin, M.D., President and Chief Executive Officer of Tectonic. “Enrollment continues in our global APEX Phase 2 trial in PH-HFpEF, and we expect to report topline results from that study in 2026.”

Recent Business Highlights

- **Positive Topline Results from Part B of the TX45 Phase 1b Clinical Trial:** In October 2025, positive topline results from Part B of the TX45 Phase 1b clinical trial in 14 patients with PH-HFrEF were announced. TX45 was well tolerated in the overall study population and demonstrated a 29.2% reduction in pulmonary capillary wedge pressure (PCWP) and a 17.3% improvement in cardiac output. In the subpopulation with combined pre- and post-capillary pulmonary hypertension (“CpcPH”) who have an elevated pulmonary vascular resistance (PVR) and more severe disease, TX45 demonstrated a 19.7% reduction in PVR in patients with a $PVR \geq 3$ Wood Units and a 10.3% reduction in PVR in patients with a $PVR \geq 2$ Wood Units. PCWP and PVR are endpoints known to correlate with exercise capacity, morbidity and mortality in this patient population.

Upcoming Milestones

- **TX2100 GPCR Antagonist Phase 1 Clinical Trial Initiation for HHT Expected Q1’2026:** TX2100 is a GPCR targeting biotherapeutic being developed as a potential treatment for HHT, the second-most common genetic bleeding disorder. The in-life portion of the IND-enabling non-human primate GLP toxicology studies are now complete. We expect to initiate a Phase 1 clinical trial in healthy volunteers for TX2100 in Q1’2026.
- **TX45 Pulmonary Hypertension associated with Interstitial Lung Disease (“PH-ILD”) Phase 2 Clinical Trial Initiation Expected in 2026:** PH-ILD (Group 3 PH) is an orphan disease with limited treatment options and a high mortality rate. In 2026, Tectonic plans to initiate a 16-week, open label, repeat dose, Phase 2 clinical trial to evaluate TX45’s safety and hemodynamic effects in up to 25 patients with PH-ILD. The study is being initiated at a dose of TX45 300 mg every four weeks administered subcutaneously, with the primary efficacy endpoint being the change from baseline in PVR at Week 16. TX45 is designed to address key aspects of PH-ILD’s disease pathophysiology, including pulmonary vasodilation, anti-inflammatory, remodeling and anti-fibrotic activity.
- **Ongoing TX45 APEX Phase 2 Clinical Trial Results Expected in 2026:** The global, randomized, placebo-controlled 24-week APEX Phase 2 clinical trial is designed to evaluate the safety and efficacy of TX45 administered subcutaneously in patients with PH-HFpEF, enriched for CpcPH. The primary efficacy endpoint of the trial is the change from baseline in PVR in the CpcPH with $PVR \geq 3$ Wood Units population, and the trial aims to enroll 70% of patients in the enriched population of CpcPH with a $PVR \geq 3$. The clinical trial is now over 50% enrolled and topline results are expected in 2026.

Overview of Financial and Operating Results

- **Cash Position:** As of September 30, 2025, cash and cash equivalents were \$268.4 million, compared to \$287.4 million as of June 30, 2025. Tectonic anticipates that, based on current operating assumptions, its current cash and cash equivalents will provide a cash runway into Q4'2028, including through the Phase 2 readout for TX45 in PH-HFpEF and PH-ILD, and the progression of TX2100 for HHT into clinical development.
- **Research and Development Expenses:** Research and development expenses were \$16.9 million for the three months ended September 30, 2025, as compared to \$14.3 million for the three months ended September 30, 2024. The increase was primarily the result of the discovery, development and manufacturing of TX2100 and employee-related expenses due to an increase in non-cash, stock-based compensation expense.
- **General and Administrative Expenses:** General and administrative expenses were \$5.0 million for the three months ended September 30, 2025, as compared to \$5.3 million for the three months ended September 30, 2024.
- **Net Loss:** For the three months ended September 30, 2025, the Company had a net loss of \$19.0 million compared to a net loss of \$17.7 million for the three months ended September 30, 2024.

About Group 2 Pulmonary Hypertension in HFpEF

The World Health Organization has defined 5 groups of PH. Tectonic's initial focus has been on the Group 2 subtype, a condition that develops due to left-sided heart disease, specifically 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. PH-HFpEF is further segmented based on pulmonary hemodynamics into Isolated post-capillary PH ("IpcPH") and Combined pre- and post-capillary PH ("CpcPH"). CpcPH is more severe, accounts for about one third to one half of the 1.4 million PH-HFpEF patients in the U.S. and is characterized by additional, abnormal changes to the pulmonary vasculature, leading to an increase in Pulmonary Vascular Resistance ("PVR"). 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 Group 3 Pulmonary Hypertension and PH-ILD

The World Health Organization has defined 5 groups of PH. Group 3 is PH due to chronic lung disease. Tectonic is focused on a Group 3 subtype, called PH-ILD where PH develops in patients who have ILD. ILD is a group of rare conditions causing inflammation and scarring in the lungs. It is believed that a combination of factors leads to the formation of PH-ILD, including lung fibrosis, chronic hypoxia, vascular remodeling and other factors that lead to worsening exercise capacity. PH-ILD has worse survival than ILD without PH. There are currently two approved treatments for PH-ILD, both of which contain the active ingredient treprostinil administered via nebulizer or dry powder inhaler.

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

TX45 is an Fc-relaxin fusion protein with optimized pharmacokinetics and biophysical properties that activates the RXFP1 receptor, the G-protein coupled receptor target of the hormone relaxin. Relaxin is an endogenous protein, expressed at low levels in both men and women that is a pulmonary and systemic vasodilator with lusitropic, anti-fibrotic and anti-inflammatory activity. 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.

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 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 us on 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 and Group 2 PH-HFrEF and its planned Phase 2 clinical trial for TX45 in PH-ILD; the Company's planned initiation of a Phase 1 clinical trial for TX2100; 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 6, 2025, 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,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	\$ 16,927	\$ 14,317	\$ 47,148	\$ 32,208
General and administrative	4,963	5,320	15,372	11,816
Total operating expenses	<u>21,890</u>	<u>19,637</u>	<u>62,520</u>	<u>44,024</u>
Loss from operations	(21,890)	(19,637)	(62,520)	(44,024)
Other income (expense), net:				
Change in fair value of SAFE liabilities	—	—	—	(3,610)
Interest income	2,900	1,952	8,733	2,526
Interest expense	(14)	(25)	(51)	(85)
Other expense	(31)	(7)	(111)	(416)
Total other income (expense), net	<u>2,855</u>	<u>1,920</u>	<u>8,571</u>	<u>(1,585)</u>
Loss before income tax	(19,035)	(17,717)	(53,949)	(45,609)
Income tax expense	—	—	(976)	—
Net loss	<u>(19,035)</u>	<u>(17,717)</u>	<u>(54,925)</u>	<u>(45,609)</u>
Other comprehensive loss:				
Foreign currency translation adjustment	(26)	(16)	(84)	(66)
Comprehensive loss	<u>\$ (19,061)</u>	<u>\$ (17,733)</u>	<u>\$ (55,009)</u>	<u>\$ (45,675)</u>
Net loss per share, basic and diluted	<u>\$ (1.02)</u>	<u>\$ (1.20)</u>	<u>\$ (3.02)</u>	<u>\$ (7.16)</u>
Weighted-average common shares outstanding, basic and diluted	<u>18,712,767</u>	<u>14,729,018</u>	<u>18,189,185</u>	<u>6,373,717</u>

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

	<u>September 30, 2025</u>		<u>December 31, 2024</u>
Cash and cash equivalents	\$ 268,435	\$	141,239
Working capital*	263,868		135,247
Total assets	277,001		152,905
Total stockholders' equity	267,528		140,776

*Working capital is defined as current assets less current liabilities
