

**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): September 29, 2026

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
(I.R.S. Employer
Identification No.)

**490 Arsenal Way, Suite 200
Watertown, Massachusetts**
(Address of principal executive offices)

02472
(Zip Code)

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

Not applicable
(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	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 8.01 Other Events.

On September 29, 2026, Tectonic Therapeutic, Inc. issued a press release titled “Tectonic Therapeutic Announces Favorable Phase 1 Safety, Tolerability and PK Results for TX2100, a Novel Approach for the Treatment of Hereditary Hemorrhagic Telangiectasia (HHT)”. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and, other than the quotes contained therein, is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated September 29, 2026.
104	Cover Page Interactive Data File (the cover page XBRL tags are 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.

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

Dated: September 29, 2026

Tectonic Therapeutic Announces Favorable Phase 1 Safety, Tolerability and PK Results for TX2100, a Novel Approach for the Treatment of Hereditary Hemorrhagic Telangiectasia (HHT)

- U.S. FDA has granted Fast Track designation for TX2100 in HHT and cleared the Investigational New Drug (IND) application for the TX2100 Phase 1b clinical trial in HHT patients in the U.S.
- TX2100 Phase 1a clinical trial topline results demonstrated single ascending doses of TX2100 were generally safe and well-tolerated in healthy adult volunteers
- Company plans to initiate an open-label TX2100 Phase 1b clinical trial in patients with hematologic-support dependent HHT by year-end 2026, and initiate a Phase 2 clinical trial in parallel in patients with moderate-to-severe HHT in early 2027

WATERTOWN, Mass., Sept. 29, 2026 (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 favorable topline results from its Phase 1a clinical trial evaluating TX2100, an investigational VHH-Fc fusion antagonist antibody targeting the APJ (apelin) receptor, in healthy adult volunteers. The clinical trial was designed to support the advancement of clinical development for TX2100 as a potential treatment for Hereditary Hemorrhagic Telangiectasia (HHT), a rare, inherited vascular disorder with no currently approved therapies. The Company also announced that the U.S. Food and Drug Administration (FDA) granted TX2100 Fast Track Designation for HHT. In addition, the FDA recently cleared the Company’s Investigational New Drug (IND) application to conduct the upcoming TX2100 Phase 1b clinical trial in the U.S. in patients with HHT.

“We are very excited about our TX2100 clinical program as a potential first-in-class, selective anti-angiogenic therapy for HHT, a disease with no approved treatments,” said Alise Reicin, M.D., President and Chief Executive Officer of Tectonic Therapeutic. “We are proceeding into clinical trials in HHT patients with a clear rationale: a differentiated mechanism, supportive preclinical data, and the favorable safety profile observed in the Phase 1a single ascending dose clinical trial. We look forward to evaluating TX2100 in patients living with HHT in our Phase 1b and Phase 2 trials, which are planned to advance in parallel in the months ahead.”

The TX2100 Phase 1a clinical trial met its primary objectives, including the following:

- Single ascending doses of TX2100, administered intravenously and subcutaneously, were generally safe and well-tolerated across all six planned dose cohorts.
- Treatment-emergent adverse events (TEAEs) were mild or moderate and transient. There were no deaths, serious adverse events (SAEs) or severe TEAEs at any dose. No clinically significant changes were observed in vital signs, laboratory assessments or electrocardiograms. Anti-drug antibody (ADA) results are pending.
- Pharmacokinetic (PK) results reflected target-mediated drug disposition (TMDD) at low concentrations, confirming TX2100’s high affinity binding to the APJ receptor and clearance through this mechanism, which is consistent with potent target engagement.

- Dose selection for the upcoming Phase 1b and Phase 2 clinical trials is being informed by two independent methods: exposures associated with high receptor occupancy inferred from the observed TMDD in the Phase 1a clinical trial, and target exposure levels shown to drive activity in nonclinical models of HHT. These two methods converged on a consistent target exposure range, supporting the approach to dose selection.
- The observed PK results support exploration of once weekly and every other week subcutaneous dosing regimens in future clinical trials.

Detailed results from the TX2100 Phase 1a clinical trial, including safety, tolerability, PK and ADA results will be presented at the CureHHT 16th HHT International Scientific Conference, taking place October 12-16, 2026.

Marcella K. Ruddy, M.D., Chief Medical Officer of Tectonic Therapeutic commented, “Today’s topline safety results in healthy volunteers are consistent with TX2100’s preclinical results, including toxicology studies that demonstrated no dose limiting toxicities with wide safety margins. We selected our target exposures using two independent methods that pointed to the same range, which gives us confidence in our approach. Data from the ongoing Part B multiple-dose cohort of the Phase 1a trial will further confirm the dose-exposure relationship and dose selection for Phase 2.”

Tectonic plans to advance TX2100 into two clinical trials in HHT in the upcoming months: an open-label Phase 1b clinical trial in patients with hematologic-support dependent HHT, with endpoints exploring an improvement in need for iron and red blood cell support, as well as an improvement in hematologic parameters, and a placebo-controlled Phase 2 clinical trial in moderate-to-severe HHT patients, with endpoints expected to include epistaxis, hemoglobin, hematologic support, and other endpoints relevant to HHT. Phase 1b and Phase 2 trials are planned to run in parallel, with the Phase 1b anticipated to initiate by year-end 2026 and the Phase 2 trial anticipated to initiate in early 2027.

The clinical program for TX2100 has achieved recent regulatory milestones with the U.S. FDA. In August 2026, the FDA cleared the Company’s IND application for TX2100 for the treatment of HHT, enabling Tectonic to conduct the planned open label Phase 1b clinical trial in patients with HHT in the U.S. In September 2026, the FDA granted TX2100 Fast Track Designation for the treatment of HHT. Fast Track Designation is an FDA process designed to facilitate the development and expedite the review of investigational treatments intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

About the Phase 1a clinical trial with TX2100

The Phase 1a clinical trial is a randomized, double-blind, placebo-controlled, single ascending dose (SAD), first-in-human trial conducted at CMAX Clinical Research in Adelaide, South Australia (ANZCTR registration: ACTRN12626000242325). The trial enrolled 48 healthy adult volunteers (men and women of non-childbearing potential, ages 18–55) across six sequential dose cohorts of eight participants each, randomized 3:1 to receive a single dose of TX2100 or matching placebo, administered via intravenous (IV) infusion or subcutaneous (SC) injection: Cohort A, 0.1 mg/kg IV; Cohort B, 0.3 mg/kg IV; Cohort C, 100 mg SC; Cohort D, 1 mg/kg IV; Cohort E, 300 mg SC; Cohort F, 600 mg SC. The primary objectives of the trial were to characterize the safety and tolerability of TX2100, assessed by the incidence of adverse events (AEs) and serious adverse events (SAEs), and clinically significant changes in safety laboratory parameters, 12-lead ECGs, and vital signs. The key secondary objective was to characterize the pharmacokinetic profile of TX2100; immunogenicity was also assessed.

Following the completion of Part A of the TX2100 Phase 1a clinical trial, Tectonic is conducting Part B of the trial which is a multiple dose cohort and has completed enrollment. Part B is evaluating six healthy volunteers in an open-label design who will be dosed with 600 mg SC on Day 1, followed by 200 mg SC dose on Day 8 and 200 mg SC dose on Day 15.

About TX2100, a VHH-Fc fusion antagonist antibody

TX2100, is a VHH-Fc fusion antagonist antibody that binds to the APJ receptor (also known as the apelin receptor; APLNR), a GPCR that mediates signaling by the pro-angiogenic peptide hormone apelin. APJ represents a differentiated approach for the potential treatment of HHT. APJ is a selective anti-angiogenic target that is primarily expressed in endothelial cells and is generally quiescent under normal physiological conditions, but is upregulated during pathologic angiogenesis, including in HHT preclinical models. TX2100 is designed as a selective APJ antagonist intended to inhibit disease-associated angiogenic signaling with the goal of providing a more favorable safety profile compared to less selective anti-angiogenic approaches. Anti-angiogenic agents have demonstrated activity in HHT preclinical models and in patients, and APJ antagonism has shown activity in multiple HHT preclinical models, supporting development of TX2100 for this indication.

About Hereditary Hemorrhagic Telangiectasia (HHT)

HHT is a rare, inherited vascular disorder affecting an estimated 75,000 people in the United States. HHT is the second most common inherited bleeding disorder and a disease for which there are currently no approved therapies. It is characterized by fragile, abnormal blood vessels that lead to recurrent bleeding, which can reduce quality of life, result in emergency room visits and hospitalizations, as well as chronic anemia requiring frequent iron infusions and/or blood transfusions. Many patients with HHT also develop arteriovenous malformations (AVMs) in vital organs such as the lungs, brain, and liver that, if left untreated, are at risk of rupturing and can result in serious and potentially life-threatening complications including lung or brain hemorrhage, stroke, heart failure, or death. Despite being a rare disease and the second most common inherited bleeding disorder, there are currently no approved therapies.

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 <https://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 potential of TX2100, including its potential future benefit to patients, the Company’s plan with respect to TX2100, including the design, objectives, initiation, timing, progress and results of current and future clinical trials of TX2100, including the ongoing Phase 1a clinical trial for TX2100 and the planned Phase 1b and Phase 2 clinical trials for TX2100; the Company’s expectations regarding the presentation of full clinical data from the Phase 1a clinical trial; and the Company’s business strategies, plans and prospects. 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 and ongoing global conflicts, 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 for the quarter ended June 30, 2026 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.

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