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): May 17, 2025

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)**	**(I.R.S. 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

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 May 17, 2025, the Company issued a press release titled "Tectonic Therapeutic Presents Complete Results for Positive Phase 1b Clinical Trial of TX45 in Patients with Group 2 Pulmonary Hypertension in HFpEF in Late-Breaking Presentation at ESC Heart Failure 2025." 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

Exhibit No.	Description
99.1	Press Release dated May 17, 2025.
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: May 19, 2025

Exhibit 99.1

Tectonic Therapeutic Presents Complete Results for Positive Phase 1b Clinical Trial of TX45 in Patients with Group 2 Pulmonary Hypertension in HFpEF in Late-Breaking Presentation at ESC Heart Failure 2025

- Data confirmed TX45's tolerability profile and improved left ventricular function and pulmonary hemodynamics in patients with Group 2 Pulmonary Hypertension in Heart Failure with preserved Ejection Fraction ("PH-HFpEF")
- In new echocardiographic analysis, TX45 treatment resulted in sustained hemodynamic effects for 29 days
- TX45 improved cardiac and pulmonary hemodynamics in PH-HFpEF patients across a range of left ventricular ejection fractions ("LVEF"), including LVEF≥ 50% and LVEF 41-49%

WATERTOWN, Mass., May 17, 2025 — Tectonic Therapeutic, Inc. (NASDAQ: TECX) ("Tectonic") today announced the complete results from Part A of the Phase 1b clinical trial of TX45 in patients with Group 2 Pulmonary Hypertension in Heart Failure with preserved Ejection Fraction ("PH-HFpEF"), which are being presented in a late-breaking, oral session at the European Society of Cardiology (ESC) Heart Failure 2025 Congress being held in Belgrade, Serbia. The results include the full cohort of 19 patients in Part A of the Phase 1b trial of TX45, Tectonic's lead asset and a long-acting relaxin therapy. Interim data for 16 patients in the Phase 1b trial was previously reported in a press release on January 30, 2025.

The complete data from Part A of the Phase 1b clinical trial confirmed the tolerability and hemodynamic effects of TX45 in patients with PH-HFpEF previously reported in the interim data. Based on the complete dataset in PH-HFpEF, a single intravenous dose of TX45 was well tolerated in patients with PH-HFpEF with no serious or severe adverse events. In the overall study population, TX45 achieved a 19.0% reduction in pulmonary capillary wedge pressure ("PCWP"), an endpoint known to correlate with exercise capacity, morbidity and mortality in patients with heart failure. 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 >30% reduction in PVR, which along with PCWP is correlated to exercise capacity and mortality in this patient population. The Phase 1b trial enrolled a patient population and evaluated hemodynamic endpoints which are similar to the ongoing APEX Phase 2 clinical trial (ClinicalTrials.gov NCT06616974). APEX is a 24-week clinical trial in PH-HFpEF with topline results expected in 2026.

New hemodynamic data reported today from the Phase 1b clinical trial include the following:

- Echocardiograms were evaluated at baseline and at Days 2, 15 and 29. Following the administration of TX45, sustained improvements in echocardiogram endpoints were observed consistent with improved hemodynamics. Increased tricuspid annular plane systolic excursion/systolic pulmonary artery pressure (TAPSE/SPAP), a marker of PVR, and right ventricular fractional area of change (RVFAC), a marker of right ventricular function, were observed on all days post treatment compared to baseline demonstrating a sustained effect for 29 days after single dose administration.

- In the clinical trial, hemodynamics were analyzed across a range of left ventricular ejection fractions ("LVEF"), including LVEF≥50% and LVEF 41-49%. Both subpopulations showed similar improvements in PCWP (19.7% and 18.4%, respectively) and cardiac output (18.3% and 18.7%, respectively), as well as improvement in pulmonary hemodynamics following administration of TX45.
- Cardiac output increased numerically more in response to TX45 in patients with higher baseline PVR, with 16.8% improvement in patients with baseline PVR<2 wood units, 20.5% with baseline PVR≥2 and 24.5% with baseline PVR≥3.

"We are enthusiastic about the potential of TX45 as a treatment for patients with Group 2 pulmonary hypertension. In particular, we are very encouraged that the echocardiographic analysis demonstrated sustained hemodynamic effects of TX45 out to 29 days," said Alise Reicin, M.D., President and Chief Executive Officer of Tectonic. "Additionally, the positive and consistent hemodynamic effects across a range of LVEF confirmed that TX45 is well positioned to address the full spectrum of PH-HFpEF patients. We look forward to the topline data from Part B of the Phase 1b study in another type of pulmonary hypertension patients, those with Heart Failure with reduced Ejection Fraction (HFrEF), expected in the second half of 2025."

Marcella K. Ruddy, M.D., Chief Medical Officer of Tectonic commented, "These results from the Phase 1b study show the promising therapeutic profile of TX45, offering patients a potential best-in-class therapy for Group 2 pulmonary hypertension, a disease with high morbidity, mortality and no approved treatments. Additionally, these data continue to support our hypothesis that TX45 may provide the greatest benefit to patients with CpcPH, based on data showing strong improvement in pulmonary hemodynamics and cardiac output relative to baseline PVR."

Highlights from complete Phase 1b Part A results

Within the cohort of 19 patients with PH-HFpEF enrolled in the Phase 1b open label clinical trial of TX45, 9 patients had CpcPH, as measured by PVR>2 Wood units. Hemodynamic measures evaluating left ventricular function included PCWP, Cardiac Output ("CO") and Stroke Volume ("SV"). Hemodynamic measures evaluating the pulmonary vasculature included PVR, Total Pulmonary Resistance ("TPR") and mean Pulmonary Artery Pressure ("mPAP").

Safety Results: TX45 was well tolerated with no serious or severe adverse events, discontinuations, infusion reactions or drug-related adverse events.

- There were no clinically significant changes in vital signs, physical exam or safety laboratory values.
- Transient asymptomatic decreases in blood pressure were observed over the first 24 hours after TX45 dosing.

Hemodynamic Results: TX45 administration resulted in meaningful improvement in both left ventricular function and pulmonary hemodynamics, representing a differentiated profile for TX45 compared to other PAH drugs that are pulmonary vasodilators but have not shown improvement in left ventricular function and have not shown efficacy in PH-HFpEF.

- TX45 achieved the following improvements in left ventricular function:
  - PCWP decreased 19.0% [95% CI, -26.1% to -11.9%].
  - CO increased 18.5% [95% CI, 10.2% to 26.9%].

- TX45 achieved the following improvements in pulmonary hemodynamics:
  - PVR decreased 32.0% [95% CI, -35.9% to -28.1%] and 35.5% (95%CI, -38.6% to -32.5%) in the subgroup of patients with baseline PVR≥2 and baseline PVR≥3, respectively.
  - TPR decreased 28.7% [95% CI, -34.1% to -22.1%] in the overall population.
  - Mean pulmonary artery pressure decreased 16.8% [95% CI, -20.8% to -12.8%] in the overall population.
- As a relaxin therapeutic, the differentiated mechanism of TX45 improved both left ventricular function and pulmonary hemodynamics, which most strongly matches the more severe pathophysiology of patients with CpcPH.

About the TX45 Phase 1b clinical trial in Group 2 pulmonary hypertension

The Phase 1b open label clinical trial is designed to evaluate the safety and hemodynamic effect of single doses of TX45 in patients with Group 2 pulmonary hypertension. Part A evaluated the effect of TX45 in PH-HFpEF and Part B will evaluate effects of TX45 in Pulmonary Hypertension in Heart Failure with reduced Ejection Fraction ("PH-HFrEF"). The design of the clinical trial is as follows: after obtaining informed consent, a right heart catheter, which is the gold standard for the measurement of cardiopulmonary hemodynamics, is inserted and baseline measurements are obtained, an intravenous dose of TX45 is administered, and hemodynamic effects are evaluated over 8 hours post dose. Participants are then followed for 45 days post dose for safety and exploratory biomarker endpoints. Part A of the trial has completed. Part B enrollment is ongoing with topline data expected in the second half of 2025.

About Group 2 Pulmonary Hypertension in HFpEF

The World Health Organization has defined 5 groups of pulmonary hypertension ("PH"). Tectonic is focused on the Group 2 subtype, a condition that develops due to left-sided heart disease, specifically Pulmonary Hypertension in 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. 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 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 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 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. 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 May 8, 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 LinkedIn.

Contacts:

Investors:

Dan Ferry
LifeSci Advisors
daniel@lifesciadvisors.com
(617) 430-7576

Media:

Kathryn Morris
The Yates Network
kathryn@theyatesnetwork.com
(914) 204-6412