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 12, 2025

Tenax Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34600**	**26-2593535**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Glen Lennox Drive, Suite 300
Chapel Hill, North Carolina 27517
(Address of principal executive offices) (Zip Code)

919-855-2100
(Registrant's telephone number, including area code)

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	TENX	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 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 12, 2025, Tenax Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2025. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 2.02 (including Exhibit 99.1) 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

Exhibit No.	**Description**
99.1	Press release dated November 12, 2025.
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.

Date: November 12, 2025

Tenax Therapeutics, Inc.

By: /s/ Christopher T. Giordano
Christopher T. Giordano
President and Chief Executive Officer

Tenax Therapeutics Reports Third Quarter 2025 Financial Results and Provides Corporate Update

Phase 3 LEVEL Study Ongoing, Enrollment Completion (230 Patients) Expected in First Half of 2026, with Topline Data Expected in Second Half of 2026

On Track to Initiate Second Phase 3 Study, LEVEL-2, in 2025

Tenax to Host Virtual KOL Call Tomorrow, Thursday, November 13, 2025 at 4:30 p.m. ET

CHAPEL HILL, N.C., November 12, 2025 (GLOBE NEWSWIRE) -- Tenax Therapeutics, Inc. (Nasdaq: TENX) ("Tenax" or "Tenax Therapeutics" or the "Company"), a Phase 3, development-stage pharmaceutical company using clinical insights to develop novel cardiopulmonary therapies, today reported financial results for the quarter ended September 30, 2025 and provided an update on its recent corporate progress.

"We continued to advance our lead program, TNX-103, in patients with PH-HFpEF and remain on track to enroll 230 patients in the ongoing Phase 3 LEVEL study in the first half of 2026, and initiate the global LEVEL-2 study this year," said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. "PH- HFpEF is a debilitating, often fatal disease and the most common form of pulmonary hypertension, yet no drugs are approved for this indication. We look forward to our upcoming virtual KOL call with some of the leading minds in this field, who intend to discuss the physiology of PH-HFpEF, the strategy for using levosimendan to aleviate symptoms and improve exercise ability, and how this product is differentiated from other efforts to develop medicines for Group 2 PH patients."

Recent Corporate and Clinical Highlights

- In September 2025, the European Patent Office (EPO) notified Tenax of its Intention to Grant the Company's patent application titled "LEVOSIMENDAN FOR TREATING PULMONARY HYPERTENSION WITH HEART FAILURE WITH PRESERVED EJECTION FRACTION (PH-HFpEF)," which will provide intellectual property (IP) protection for the treatment of PH-HFpEF with TNX-103 (oral levosimendan), TNX-102 (subcutaneous levosimendan), TNX-101 (IV levosimendan), and transdermal levosimendan, as well as the active metabolites of levosimendan (OR1896 and OR1855). The patent will also expressly provide protection in Europe for a wide range of doses of levosimendan, as well as for use of levosimendan in combination with various cardiovascular drugs, in PH-HFpEF. This new patent, once granted, will have a patent term until December 2040, and it may qualify for European patent supplementary protection certificates (SPC) that would extend the period of patent protection beyond 2040.

- Enrollment in the Phase 3 LEVEL study of TNX-103 in PH-HFpEF is progressing well, with high rates of study and therapy continuation through both the blinded and open-label extension stages. Tenax expects to enroll 230 patients in the first half of 2026. LEVEL is being conducted in the United States and Canada.
- Tenax remains on track to initiate a second registrational Phase 3 study of TNX-103, LEVEL-2, in patients with PH-HFpEF this year. LEVEL-2 will have a global footprint. To date, over 160 investigative sites new to the program, across 15 countries, have been qualified for the LEVEL-2 study.

Virtual KOL Call On Treatment Landscape for PH-HFpEF and Phase 3 TNX-103 Programs

The Company will host a conference call and webcast on Thursday, November 13, 2025, at 4:30 p.m. ET to discuss the clinical development landscape for PH-HFpEF and the ongoing late-stage development program for TNX-103. Members of Tenax's management team will be joined on the call by recognized key opinion leaders in cardiovascular medicine. To participate in the conference call, please dial one of the following numbers and ask to join the Tenax Therapeutics call:

- +1-877-317-6789 for callers in the United States
- +1-412-317-6789 for international callers

The live and archived webcast of the call will be accessible on the Company's investor relations webpage.

Third Quarter 2025 Financial Results

Cash position: Tenax Therapeutics reported cash and cash equivalents of $99.4 million as of September 30, 2025. Tenax expects its cash and cash equivalents to fund the Company through 2027.

Research and development (R&D): R&D expenses for the third quarter of 2025 were $10.3 million, compared to $3.1 million for the third quarter of 2024. The increase was primarily attributable to increased clinical development costs associated with our ongoing Phase 3 LEVEL study and our second global Phase 3 study, LEVEL-2, for which we are conducting start-up activities in

anticipation of patient enrollment. Additionally, our R&D employee headcount increased during 2025, resulting in an increase in personnel costs compared to the same quarter in 2024. Our R&D expenses for the third quarter of 2025 includes $1.1 million of non- cash stock-based compensation expense, representing an increase of $1.1 million compared to the same period in 2024.

General and administrative (G&A): G&A expenses for the third quarter of 2025 were $6.5 million, compared to $1.5 million for the third quarter of 2024. The increase is primarily due to increased non-cash stock-based compensation expense. Our G&A expenses for the third quarter of 2025 include $4.5 million of non-cash stock-based compensation expense, representing an increase of $4.5 million compared to the same period in 2024. Additionally, legal and professional fees increased during the third quarter of 2025 compared to the same period in 2024.

Net loss: Tenax Therapeutics reported a net loss of $15.8 million for the third quarter of 2025, compared to a net loss of $4.0 million for third quarter of 2024.

About Levosimendan (TNX-101, TNX-102, TNX-103)

Levosimendan is a novel, first-in-class K-ATP channel activator/calcium sensitizer currently being evaluated to treat pulmonary hypertension (PH) associated with heart failure with preserved ejection fraction (PH-HFpEF). Levosimendan was first developed for intravenous use in hospitalized patients with acutely decompensated heart failure, and it has received market authorization in 60 countries in this indication, although it is not available in the United States or Canada. Tenax's Phase 2 HELP study, including its open-label extension stage, demonstrated the potential of IV (TNX-101) and oral (TNX-103) levosimendan to bring durable improvements in exercise capacity and quality of life, as well as other clinical assessments, in patients with PH-HFpEF. TNX-103 (oral levosimendan) is currently being evaluated in LEVEL, a Phase 3, double-blind, randomized, placebo-controlled clinical trial in patients with PH-HFpEF.

About Tenax Therapeutics

Tenax Therapeutics, Inc. is a Phase 3, development-stage pharmaceutical company using clinical insights to develop novel cardiopulmonary therapies. The Company owns global rights to develop and commercialize levosimendan, which it is developing for the treatment of PH-HFpEF, the most prevalent form of pulmonary hypertension globally, for which no product has been approved to date. For more information, visit www.tenaxthera.com. Tenax Therapeutics' common stock is listed on The Nasdaq Stock Market LLC under the symbol "TENX".

Caution Regarding Forward-Looking Statements

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. These forward-looking statements may include information concerning possible or projected future business operations. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: risks of our clinical trials, including, but not limited to, the timing, delays, costs, design, location, initiation, enrollment, and results of such trials; intellectual property risks; any delays in regulatory review and approval of product candidates in development; risks related to our business strategy, including the prioritization and development of product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties, including Orion Corporation, our manufacturers and CROs; risks regarding the formulation, production, marketing, customer acceptance and clinical utility of our product candidates; the potential advantages of our product candidates; our competitive position; our ability to maintain our culture and recruit, integrate and retain qualified personnel and advisors, including on our Board of Directors; risks associated with our cash needs; volatility and uncertainty in the global economy and financial markets in light of unexpected changes in tariffs and the possibility of pandemics, global financial and geopolitical uncertainties, including in the Middle East and the Russian invasion of and war against the country of Ukraine; changes in legal, regulatory and legislative environments in the markets in which we operate, including any changes resulting from government shut downs, and the impact of these changes on our ability to obtain regulatory approval for our products; and other risks and uncertainties set forth from time to time in our SEC filings. Tenax Therapeutics assumes no obligation and does not intend to update these forward-looking statements except as required by law.

Contact:

Investor and Media:

Argot Partners
tenax@argotpartners.com

Tenax Theapeutics, Inc.
Consolidated Statements of Operations

	For the three months ended September 30,	For the nine months ended September 30,

	2025	2024	2025	2024
	(in thousands, except share and per share data)			
Operating expenses				
Research and development	$ 10,328	$ 3,112	$ 22,132	$ 8,115
General and administrative	6,478	1,507	17,804	4,084
Total operating expenses	16,806	4,619	39,936	12,199
	-	-		
Net operating loss	(16,806)	(4,619)	(39,936)	(12,199)
	-	-		
Interest income	1,017	665	2,901	887
Interest expense	-	(7)	-	(24)
Other income (expense), net	(15)	-	(24)	1
Net loss	$ (15,804)	$ (3,961)	$ (37,059)	$ (11,335)
Net loss per share, basic and diluted	$ (0.40)	$ (0.19)	$ (0.96)	$ (1.37)
Weighted average number of common shares and prefunded warrants outstanding, basic and diluted	39,741,404	21,161,143	38,644,395	8,282,118

Tenax Therapeutics, Inc.
Consolidated Balance Sheets

	September 30, 2025	December 31, 2024
ASSETS	(in thousands)	
Current assets		
Cash and cash equivalents	$ 99,369	$ 94,851
Prepaid expenses and other current assets	3,441	1,835
Total current assets	102,810	96,686
Total assets	$ 102,810	$ 96,686
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 5,608	$ 3,157
Accrued liabilities	991	1,536
Total current liabilities	6,599	4,693
Total liabilities	6,599	4,693
Commitments and contingencies		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares		
Series A Preferred stock, par value $0.0001, authorized 5,181,346 shares; issued and outstanding 210, as of September 30, 2025 and December 31, 2024	-	-
Common stock, par value $0.0001 per share; authorized 400,000,000 shares; issued and outstanding 5,907,233 as of September 30, 2025 and 3,420,906 as of December 31, 2024, respectively	1	-
Additional paid-in capital	448,124	406,848
Accumulated deficit	(351,914)	(314,855)
Total stockholders' equity	96,211	91,993
Total liabilities and stockholders' equity	$ 102,810	$ 96,686