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 5, 2026

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 5, 2026, Tenax Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2026. 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 5, 2026.
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 5, 2026

Tenax Therapeutics, Inc.

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

Tenax Therapeutics Reports Third Quarter 2026 Financial Results and Provides Corporate Update

Completed Statistical Analyses of LEVEL Yielded a Predictive Enrichment Strategy Being Applied in Amended LEVEL-2 Protocol

Company Has Been Granted a Type C Meeting with the FDA

CHAPEL HILL, N.C., November 5, 2026 (GLOBE NEWSWIRE) — Tenax Therapeutics, Inc. (Nasdaq: TENX) ("Tenax" or "Tenax Therapeutics" or the "Company") today reported financial results for the quarter ended September 30, 2026 and provided an update on recent corporate progress.

On August 10, 2026, Tenax announced that LEVEL, the first Phase 3 clinical trial of oral levosimendan in patients with pulmonary hypertension associated with heart failure with preserved ejection fraction (PH-HFpEF), did not achieve its primary or key secondary objectives, but did demonstrate evidence of beneficial biological effects on predefined cardiac biomarker and pulmonary hemodynamic measures in the overall population. Clinically meaningful improvements were observed in cardiac wall stress as measured by NT-proBNP (49% reduction, nominal $p<0.0001$) and in right ventricular systolic pressure (RVSP), an echocardiographic measure of pulmonary arterial pressure (reduction of 3.5 mmHg, nominal $p=0.0045$). Subgroup analyses identified a meaningful beneficial treatment effect in patients with the most advanced disease, defined by their limitation in exercise capacity, hemodynamic elevation in central venous pressure (CVP), pulmonary arterial pressure (PAP), and pulmonary capillary wedge pressure (PCWP), and elevated NT-proBNP levels. The treatment effect in the half of the LEVEL population with greater exercise impairment was manifested not only by clinically meaningful changes in 6-minute walk distance (6MWD), but also by greater improvement in pulmonary hemodynamic measures than was observed overall.

According to Stuart Rich, Chief Medical Officer of Tenax Therapeutics, "NT-proBNP and measures of PAP such as RVSP are independent biomarkers used in everyday diagnosis and treatment of patients with all forms of heart failure and pulmonary hypertension. Decades of research link improvements in both markers to reductions in mortality in patients suffering from these diseases. We believe the combination of robust reductions in both NT-proBNP and PAP in the patients treated with levosimendan support the hypothesis that levosimendan will provide meaningful chronic clinical effectiveness."

On August 29, 2026, in a Late-Breaking Clinical Science session at the European Society of Cardiology (ESC) Congress, Professor Sanjiv Shah of Northwestern University Feinberg School of Medicine, who serves as LEVEL's Principal Investigator, reviewed in more detail a prespecified analysis of the LEVEL population: in patients who walked less than the trial median of 333 meters at baseline, the levosimendan group demonstrated a 26.3 meter improvement in 6MWD as compared to the placebo group, a strong drug-treatment benefit in a more characteristic PH-HFpEF population. In this group of more symptomatic patients who demonstrated impressive exercise improvement, the observed RVSP reduction was greater than in the overall trial population (4.9 mmHg reduction, nominal $p=0.009$).

On October 8, 2026, the Company disclosed the completion of a multivariable analysis of LEVEL results that identified baseline characteristics as predictors of enhanced treatment response, described a predictive enrichment strategy for LEVEL-2 resulting from this analysis, and announced a temporary pause on LEVEL-2 enrollment while a protocol amendment is implemented at each site to ensure the population recruited for the trial meets these requirements. The enrichment criteria for LEVEL-2 were derived from a post hoc predictive enrichment analysis of the LEVEL data using a statistical methodology that estimates individual-level treatment effects using arm-specific regression models and then applies classification trees to identify baseline characteristics that distinguish treatment-responsive from non-responsive patients.

“Analysis of the results of the LEVEL trial provides insights into those patients who exhibit a significant improvement in exercise tolerance. With treatment continuing for those randomized prior to October, we believe we have now taken the steps necessary to ensure our LEVEL-2 protocol population will be enriched with these more symptomatic patients,” said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. “In a LEVEL population with greater exercise limitation at baseline (i.e., lower 6MWD) and more pronounced echocardiographic evidence of volume overload causing their left heart disease, an improvement of 34 meters in 6MWD was observed after 12 weeks in this clinical trial. Our objective in LEVEL-2 is to enroll a population that conforms to this LEVEL subpopulation demonstrating significant treatment benefit on levosimendan, which made up more than 50% of patients in LEVEL, following the protocol amendment we are in the process of implementing.”

Mr. Giordano added, “We shared the topline LEVEL data with the Food and Drug Administration (“FDA” or the “Agency”) in mid-August, have updated the Agency on these hypothesis-generating observations from LEVEL and have been granted a Type C meeting to discuss the overall development of levosimendan in PH-HFpEF. We remain focused on our mission to bring the first approved therapy to these patients.”

Recent Corporate and Clinical Highlights

- In August 2026, Tenax announced topline results from the Phase 3 LEVEL clinical trial of TNX-103 (oral levosimendan) in patients with PH-HFpEF. LEVEL did not meet its primary endpoint of improvement in 6MWD versus placebo. However, in a prespecified analysis, patients with a baseline 6MWD below the trial median of 333 meters showed a 26.3-meter improvement compared to placebo (95% CI 6.0, 46.7; nominal p=0.0112).
    - In prespecified exploratory analyses in the overall trial population, treatment with TNX-103 resulted in a 49% greater reduction in NT-proBNP compared to placebo (nominal $p<0.0001$) and a 3.5 mmHg reduction in RVSP compared to placebo (nominal p=0.0045).
    - TNX-103 was generally safe and well tolerated, with serious adverse events and adjudicated clinical worsening events balanced across treatment groups.

- In August 2026, LEVEL results were presented by Sanjiv Shah, MD, Director of the HFpEF Program at Northwestern University Feinberg School of Medicine and LEVEL's Principal Investigator, in a Late-Breaking Clinical Science session at the ESC Congress 2026 in Munich, Germany.
    - Approximately 20 echocardiographic parameters improved with TNX-103 compared to placebo, and no significant arrhythmias were observed across the overall trial population.
    - With full statistical analysis now complete, the Company confirms TNX-103's biological effects include marked reductions in PAP and NT-proBNP, a biomarker reflecting increased cardiac wall stress.
- Based on multivariable analyses of LEVEL, Tenax has temporarily paused enrollment and is amending the protocol for LEVEL-2, its ongoing global Phase 3 clinical trial, to enrich for patients with either a baseline 6MWD of 100 to 300 meters, or a baseline 6MWD of 301 to 400 meters and a right atrial volume index (RAVI) of at least 25 mL/m².
    - In LEVEL patients meeting these criteria, TNX-103 showed a 34-meter improvement in 6MWD compared to placebo at Week 12 (95% CI 15, 53; nominal p=0.001).
    - Enrollment in LEVEL-2 has been temporarily paused while the amendment is implemented.
    - Tenax shared the topline LEVEL results with the FDA in mid-August and has been granted a Type C meeting to discuss the overall development of levosimendan in PH-HFpEF.
    - Tenax expects to publish the LEVEL-2 protocol design paper and to provide further updates on the development of levosimendan in the first quarter of 2027.

Third Quarter 2026 Financial Results

Cash position: Tenax Therapeutics reported cash and cash equivalents of $113.7 million as of September 30, 2026. The Company utilized $4.3 million in the third quarter of 2026 but has $16.2 million more cash and cash equivalents than on December 31, 2025. Tenax now expects its cash runway to fund operations through fiscal 2028, but its current operating plan is subject to change pending the outcome of its Type C meeting with the FDA.

Research and development (R&D): R&D expenses for the third quarter of 2026 were $12.1 million, compared to $10.3 million for the third quarter of 2025. The increase is primarily attributable to increased preclinical development costs and clinical costs associated with the Company's LEVEL and LEVEL-2 clinical trials.

Selling, General and administrative (SG&A): SG&A expenses for the third quarter of 2026 were $5.7 million, compared to $6.5 million for the third quarter of 2025. The decrease is primarily attributable to a decrease in stock-based compensation expense, partially offset by an increase in professional fees as well as salary and benefit costs.

Net loss: Tenax Therapeutics reported a net loss of $16.7 million for the third quarter of 2026, compared to a net loss of $15.8 million for the third quarter of 2025.

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. TNX-103 (oral levosimendan) is being evaluated in LEVEL-2, 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 our clinical trials and our 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, including that the Phase 3 LEVEL trial did not meet its primary endpoint of change in 6-minute walk distance (6MWD) in the overall enrolled population; the risk that, if LEVEL-2 fails or regulators require additional trials, we may be unable to continue development of TNX-103 and may need to pursue strategic alternatives; the risk that subgroup and post hoc analyses of LEVEL may not be confirmed in LEVEL-2 or accepted by regulators, physicians or investors, and that enriching enrollment in LEVEL-2 may slow enrollment, reduce the commercial opportunity for TNX-103 or result in narrower labeling; the pause in LEVEL-2 enrollment and the implementation of the LEVEL-2 protocol amendment; the outcome of our Type C meeting with the FDA, including the risk that the FDA may disagree with our revised development plan or the amended LEVEL-2 design or require additional trials or a larger or longer safety database; any delays in regulatory review and approval of product candidates in development; 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; risks related to our business strategy, including the

prioritization and development of product candidates; our competitive position; our ability to maintain our culture and recruit, integrate and retain qualified personnel and advisors, including our executives and on our Board of Directors, including following the LEVEL results and the decline in our stock price; risks associated with our cash needs, including the assumptions underlying our expected cash runway, and our ability to raise additional capital on acceptable terms, and the potential for any such financing to be highly dilutive; the outcome of securities litigation, derivative claims, or regulatory inquiries arising from the LEVEL results; intellectual property risks; 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, 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, including those described under “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2025 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2026. Tenax Therapeutics assumes no obligation and does not intend to update these forward-looking statements except as required by law.

Contact:

Investor and Media:

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Tenax Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Amounts in thousands, except share and per share data)

	September 30, 2026 (unaudited)	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 113,729	$ 97,565
Prepaid expenses	3,177	5,643
Other current assets	108	1,019
Total current assets	117,014	104,227
Total assets	$ 117,014	$ 104,227
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,570	$ 6,041
Accrued liabilities	1,785	1,115
Total current liabilities	8,355	7,156
Total liabilities	8,355	7,156
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, 2026 and December 31, 2025	—	—
Common stock, par value $0.0001 per share; authorized 400,000,000 shares; issued and outstanding 45,536,448 as of September 30, 2026 and 9,314,130 as of December 31, 2025, respectively	5	1
Additional paid-in capital	526,331	464,524
Accumulated deficit	(417,677)	(367,454)
Total stockholders' equity	108,659	97,071
Total liabilities and stockholders' equity	$ 117,014	$ 104,227

Tenax Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(Amounts in thousands, except share and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 12,068	$ 10,328	$ 36,457	$ 22,132
Selling, general and administrative	5,660	6,478	16,628	17,804
Total operating expenses	17,728	16,806	53,085	39,936
Net operating loss	(17,728)	(16,806)	(53,085)	(39,936)
Interest income	1,036	1,017	2,878	2,901
Other income (expense), net	(12)	(15)	(16)	(24)
Net loss	$ (16,704)	$ (15,804)	$ (50,223)	$ (37,059)
Net loss per share, basic and diluted	$ (0.31)	$ (0.40)	$ (1.01)	$ (0.96)
Weighted average number of common shares and prefunded warrants outstanding, basic and diluted	53,452,869	39,741,404	49,880,130	38,644,395