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): August 12, 2024

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 7.01 Regulation FD Disclosure.

On August 12, 2024, Tenax Therapeutics, Inc. (the "Company") issued a press release regarding the closing of its previously announced private placement for gross proceeds of approximately $100 million. The press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information in this Item 7.01 (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 August 12, 2024.

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: August 12, 2024

Tenax Therapeutics, Inc.

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

Tenax Therapeutics Announces Closing of $100 Million Private Placement and Plans to Accelerate the Oral Levosimendan Phase 3 Program

- *Funding supports advancement of oral levosimendan (TNX-103) Phase 3 development program, including completion of the ongoing LEVEL Study for the treatment of Pulmonary Hypertension Due to Heart Failure with Preserved Ejection Fraction (PH-HFpEF)*

- *Proceeds also will fund the initiation of a second Phase 3 study planned for 2025, shortening timeline to NDA submission; the protocol for this study will be submitted to FDA for comment*

CHAPEL HILL, N.C., Aug 12, 2024 (GLOBE NEWSWIRE) – Tenax Therapeutics, Inc. ("Tenax") (NASDAQ: TENX), a Phase 3, development-stage pharmaceutical company focused on developing and commercializing products that address cardiovascular and pulmonary diseases with high unmet medical need, announced the closing of a private placement by certain institutional and accredited healthcare investors, raising gross proceeds of approximately $100 million.

The oversubscribed private placement was led by new investor BVF Partners LP, with participation from other new investors, including Venrock Healthcare Capital Partners, Vivo Capital, Janus Henderson Investors, a large investment management firm, Vestal Point Capital, Velan Capital, ADAR1 Capital Management, LLC, Stonepine Capital Management, and Sphera Biotech.

"This transformational financing is a significant commitment by top-tier biotech investors who believe in levosimendan's potential to impact the lives of patients suffering from PH-HFpEF," said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. "The proceeds position us to accelerate our ongoing Phase 3 development program and shorten the time to NDA submission. We are now funded through completion of the ongoing Phase 3 LEVEL study, including its open label extension. This funding should also enable us to initiate all sites and advance enrollment in a second, global Phase 3 study. The Tenax team looks forward to completing the Phase 3 studies of oral levosimendan in treatment of PH-HFpEF patients, the only therapy shown to produce favorable hemodynamic changes and improve exercise tolerance in these patients."

The LEVEL study is designed to demonstrate the impact of daily oral levosimendan administration on exercise ability, as measured by the six-minute walk distance (6MWD) test, over a 12-week period. PH-HFpEF is a devastating disease that severely impacts patients' daily activity levels, and for which no therapies have been approved by the U.S. Food and Drug Administration.

"Participants in the HELP study showed an approximate 10% improvement of 29 meters in their six-minute walk distance over a six-week period, making levosimendan the first drug to show exercise improvement in any patients with HFpEF, with or without PH. In a subsequent open-label study, patients showed further improvement in exercise capacity when transitioned from weekly IV to oral daily therapy," said Stuart Rich, MD, Chief Medical Officer of Tenax Therapeutics. Several other clinical assessments also demonstrated benefit following the transition to oral therapy, currently being tested in the Phase 3 LEVEL study.

About the Private Placement

The Company's private placement was for an aggregate of 1,450,661 shares of its common stock, plus pre-funded warrants to purchase an aggregate of 31,882,671 shares of its common stock that include accompanying warrants to purchase an aggregate of 16,666,666 shares of its common stock (or, in lieu thereof, additional pre-funded warrants). The purchase price for each share of common stock and accompanying warrant was $3.00, with the accompanying warrant having an exercise price of $4.50 (provided, the purchase price for each pre-funded warrant and accompanying warrant is $2.99, with the pre-funded warrants having an exercise price of $0.01). The pre-funded warrants are exercisable at any time after their original issuance and will not expire. The accompanying warrants are immediately exercisable and expire upon the earlier of (i) 30 trading days following the date of the Company's initial public announcement of topline data from its Phase 3 LEVEL trial (LEVosimendan to Improve Exercise Limitation in PH-HFpEF Patients); (ii) upon the exercise of the holder's pre-funded warrant issued in the private placement, if such exercise is prior to the topline data announcement; and (iii) five years from the date of closing of the private placement.

Leerink Partners acted as the lead placement agent for the private placement and was joined by Guggenheim Securities and William Blair as joint placement agents. ROTH Capital Partners acted as financial advisor to the Company.

The securities issued were offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Regulation D promulgated thereunder and have not been registered under the Securities Act, or any state or other applicable jurisdictions' securities laws, and may not be offered or sold in the United States absent registration or an applicable exemption from the registration requirements of the Securities Act and applicable state or other jurisdictions' securities laws. Tenax Therapeutics has agreed to file a registration statement with the United States Securities and Exchange Commission (the "SEC") registering the resale of the shares of common stock issued in the private placement and the shares of common stock issuable upon the exercise of the pre-funded warrants and accompanying warrants issued in the private placement, no later than 30 days after the closing of the private placement.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction. Any offering of the securities under the resale registration statement will only be made by means of a prospectus.

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

Levosimendan is a unique, potassium ATP channel activator and calcium sensitizer that affects the heart and vascular system through multiple mechanisms of action. Initially discovered and developed by Orion Corporation in Finland, intravenous levosimendan has been granted market authorization in 60 countries outside the United States for use in hospitalized patients with acutely decompensated heart failure. Results of Tenax Therapeutics' Phase 2 HELP study of levosimendan in patients with pulmonary hypertension (PH) with heart failure with preserved ejection fraction (HFpEF) demonstrated that IV levosimendan produces potent dilation of the central and pulmonary venous circulations which translates into an improvement in exercise capacity, a discovery that is the basis of LEVEL, the Phase 3 investigation of Tenax Therapeutics' potential groundbreaking therapy. To date, no other drug therapy has improved exercise tolerance in patients with PH associated with HFpEF, "a growing epidemic with high morbidity and mortality and no treatment. The clear unmet need and lethal nature of PH-HFpEF must be met with novel solutions at all levels of therapeutic development" (AHA Scientific Advisory, "A Call to Action," 2022).

About Tenax Therapeutics

Tenax Therapeutics, Inc. is a Phase 3, development-stage pharmaceutical company focused on developing and commercializing products that address cardiovascular and pulmonary diseases with high unmet medical need. The Company owns global rights to develop and commercialize levosimendan, which it has prioritized in the near term. Tenax Therapeutics also may resume developing its unique oral formulation of imatinib. 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: the expected use of proceeds from our recent private placement; the expected cash runway with the net proceeds of our recent private placement, and risks associated with our cash needs; risks related to our business strategy, including the prioritization and development of product candidates; risks of our clinical trials, including, but not limited to, the timing, delays, costs, design, initiation, enrollment, and results of such trials; any delays in regulatory review and approval of product candidates in development; 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; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; our competitive position; intellectual property risks; risks related to our continued listing on Nasdaq; our ability to maintain our culture and recruit, integrate and retain qualified personnel and advisors, including on our Board of Directors; volatility and uncertainty in the global economy and financial markets in light of 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. Tenax Therapeutics assumes no obligation and does not intend to update these forward-looking statements except as required by law.

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