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 13, 2023

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 8.01 Other Events.

On November 13, 2023, Tenax Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has reviewed and cleared the Company's Investigational New Drug (IND) Application for TNX-103 (oral levosimendan) for the treatment of pulmonary hypertension with heart failure with preserved ejection fraction (PH-HFpEF), enabling the Company to launch its LEVEL trial, and initiate Phase 3 sites in the fourth quarter of 2023. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated November 13, 2023.
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 13, 2023

Tenax Therapeutics, Inc.

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

Tenax Therapeutics Announces FDA Clearance of IND for TNX-103 (oral levosimendan) for the Treatment of Pulmonary Hypertension with Heart Failure with Preserved Ejection Fraction (PH-HFpEF), Initiation of Phase 3 sites expected 2023

- *First Phase 3 study of TNX-103 in PH-HFpEF patients to start in 4Q 2023 (The LEVEL Study)*
- *FDA agreement that 6MWD will be the primary endpoint for both Phase 3 studies*
- *Phase 3 program designed to satisfy FDA's request for subject drug exposure of 300 patients for 6 months, 100 patients for 1 year (minimum requirements per ICH guidelines)*
- *No FDA requirement for a cardiovascular outcomes trial*
- *Oral levosimendan use in PH-HFpEF is protected by USPTO granted patent that will not expire until the end of 2040*
- *There are no FDA-approved treatments for PH-HFpEF, with an estimated prevalence of more than 2,000,000 patients in North America by 2030.*

CHAPEL HILL, N.C., November 13, 2023 (GLOBE NEWSWIRE) -- Tenax Therapeutics, Inc. (Nasdaq: TENX), a specialty pharmaceutical company focused on identifying, developing and commercializing products that address cardiovascular and pulmonary diseases with high unmet medical need, announced today that the U.S. Food and Drug Administration (FDA) has reviewed and cleared the Company's Investigational New Drug (IND) Application for TNX-103 (oral levosimendan) for the treatment of pulmonary hypertension with heart failure with preserved ejection fraction (PH-HFpEF), enabling Tenax to proceed with the first of two Phase 3 studies.

The LEVEL Study (**LEV**osimendan to Improve **E**xercise **L**imitation in PH-HFpEF Patients) is expected to launch in the fourth quarter of 2023.

"We could not be more pleased with the results of our collaborative, productive discussions with the FDA, which provide a clear path to starting LEVEL, including mutual alignment with respect to the primary efficacy endpoint and expected patient enrollment," said Chris Giordano, President and Chief Executive Officer of Tenax Therapeutics. "Importantly, Tenax will not be required to conduct a long-term, cardiovascular outcomes trial, which should significantly reduce our costs and time to registration for TNX-103. With no approved therapies currently available in the U.S., physicians, patients and regulators increasingly recognize the significant unmet need of patients who suffer from PH-HFpEF."

"Despite many therapeutic advancements across a wide spectrum of cardiovascular diseases, there are no FDA-approved treatments for PH-HFpEF, a condition impacting millions globally," said Sanjiv Shah, MD, Stone Professor and Director of the HFpEF Program at Northwestern University Feinberg School of Medicine, and Chair of the LEVEL Steering Committee. "I am pleased to be leading this important new trial investigating TNX-103, which is designed to help advance our understanding of how K+ATP activation may provide a new approach for reducing the high central and venous blood pressures frequently associated with PH-HFpEF."

"Based on its unique properties as a K+ ATP channel activator, coupled with the proof-of-concept data from the Phase 2 HELP study, TNX-103 has mechanistic potential to address the underlying pathophysiology of PH-HFpEF," said Stuart Rich, M.D., Chief Medical Officer of Tenax Therapeutics. "We expect oral levosimendan will provide consistent drug concentration levels, supporting improved efficacy, as observed in patients who transitioned from weekly IV to oral therapy following the HELP study."

Tenax Therapeutics and its CRO partner have already selected more than two-thirds of the research sites targeted to participate in the LEVEL Study, including many of the leading cardiovascular centers in the United States and Canada. Every investigative site that enrolled patients in the HELP Study has been invited to participate in LEVEL, and already 90% have agreed to take part.

About Levosimendan (TNX-101, TNX-102, and 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 is approved in 58 countries outside the United States for use in hospitalized patients with acutely decompensated heart failure. Tenax Therapeutics has North American rights to develop and commercialize IV (TNX-101), subcutaneous (TNX-102), and oral (TNX-103) formulations of levosimendan. Results of Tenax Therapeutics' Phase 2 HELP trial of levosimendan in patients with pulmonary hypertension (PH) and 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 forms the basis for 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 Imatinib (TNX-201)

Tenax Therapeutics is developing novel dosing and a unique formulation of imatinib mesylate, a kinase inhibitor that has received FDA's orphan designation (March 2020) for the treatment of pulmonary arterial hypertension (PAH). The IMPRES trial, a previous Phase 3 trial, demonstrated that oral imatinib may produce a markedly greater, and much more durable, treatment effect on exercise tolerance, than any other available PAH treatment, alone or in combination, based on the results observed in those patients who were maintained on the full imatinib dose for the majority of the trial. Despite the availability of several classes of pulmonary vasodilators, no existing treatment has been shown to halt progression or induce regression of the disease. Imatinib acts on underlying cellular proliferative pathways associated with PAH and has the potential to be approved as a disease modifying therapy for PAH.

About Tenax Therapeutics

Tenax Therapeutics, Inc. is a specialty pharmaceutical company focused on identifying, developing, and commercializing products that address cardiovascular and pulmonary diseases with high unmet medical need. The Company owns North American rights to develop and commercialize subcutaneous and oral formulations of levosimendan. Tenax Therapeutics also is developing a unique oral formulation of imatinib. For more information, visit www.tenaxthera.com. Tenax's 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. 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 related to our business strategy, including the prioritization 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; our ability to raise additional money to fund our operations for at least the next 12 months as a going concern; 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 COVID-19 pandemic or similar health epidemics and geopolitical uncertainties such as in 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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