SECURITIES & EXCHANGE COMMISSION EDGAR FILING

TENAX THERAPEUTICS, INC.

Form: 8-K

Date Filed: 2017-07-28

Corporate Issuer CIK: 34956

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): July 28, 2017

Tenax Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34600**	**26-2593535**
(State or other jurisdiction of incorporation)	(CommissionFile Number)	(IRS EmployerIdentification No.)

ONE Copley Parkway, Suite 490
Morrisville, NC 27560
(Address of principal executive offices) (Zip Code)

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

N/A
(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))

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 July 28, 2017, Tenax Therapeutics, Inc. issued a press release providing a regulatory update following discussions with the U.S. Food and Drug Administration (FDA) and Health Canada regarding a regulatory path forward for levosimendan. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
Exhibit 99.1	Press Release dated July 28, 2017

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: July 28, 2017

Tenax Therapeutics, Inc.

By: /s/ Michael Jebsen

Michael Jebsen

Interim Chief Executive Officer and Chief Financial Officer

Exhibit Index

Exhibit No.	Description
Exhibit 99.1	Press Release dated July 28, 2017

Tenax Therapeutics Provides Regulatory Update on Levosimendan

Morrisville, NC, July 28, 2017 – Tenax Therapeutics, Inc. (NASDAQ: TENX), a specialty pharmaceutical company focused on identifying, developing and commercializing products for the critical care market, today provides a regulatory update following discussions with the U.S. Food and Drug Administration (FDA) and Health Canada regarding a regulatory path forward for levosimendan.

In May 2017, the Company participated in a pre-NDA meeting with the FDA to discuss the possibility of submitting an NDA for levosimendan in two indications: treatment of patients undergoing coronary artery bypass grafting (CABG) to reduce the risk of low cardiac output syndrome (LCOS) and treatment of patients with acute decompensated heart failure (ADHF) for improvement in symptoms. After a review of further analyses, the FDA has requested an additional clinical trial. Given the size and scope of such a trial, the Company is reviewing clinical, regulatory and financial options with regard to the levosimendan program in the U.S. and Canada.

The Company's Board of Directors is continuing its review of strategic alternatives with the assistance of their financial advisors at Ladenburg Thalmann & Co. Inc. Strategic alternatives under review include, but are not limited to a merger, a business combination, a strategic investment into the Company, or a purchase, license or other acquisition of assets. This process may not result in any transaction and the Company does not intend to disclose additional details unless and until it has entered into a specific transaction.

About Levosimendan

Levosimendan is a calcium sensitizer that works through a unique triple mechanism of action. It initially was developed for intravenous use in hospitalized patients with acutely decompensated heart failure. It was discovered and developed by Orion Pharma, Orion Corporation of Espoo Finland, and is currently approved in over 60 countries for this indication and not available in the United States. Tenax Therapeutics acquired the North American rights to develop and commercialize levosimendan from Phyxius Pharma.

About Tenax Therapeutics

Tenax Therapeutics, Inc., is a specialty pharmaceutical company focused on identifying, developing and commercializing products for the critical care market. For more information, visit www.tenaxthera.com.

Caution Regarding Forward-Looking Statements

This news release contains certain forward-looking statements by the company that involve risks and uncertainties and reflect the company’s judgment as of the date of this release. The forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to matters beyond the company's control that could lead to delays in the clinical study, delays in new product introductions and customer acceptance of these new products, and other risks and uncertainties as described in the company’s filings with the Securities and Exchange Commission, including in its transition report on Form 10-K filed on March 16, 2017, its quarterly report on Form 10-Q filed on May 10, 2017 as well as its other filings with the SEC. The company disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. Statements in this press release regarding management’s future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

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