SECURITIES & EXCHANGE COMMISSION EDGAR FILING

TENAX THERAPEUTICS, INC.

Form: 8-K

Date Filed: 2017-01-31

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): January 31, 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))

Item 8.01 Other Events.

On January 31, 2017, Tenax Therapeutics, Inc. issued a press release announcing top-line results from its Phase 3 LEVO-CTS trial. 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 January 31, 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.

Tenax Therapeutics, Inc.

Date: January 31, 2017

By: /s/ John Kelley
John Kelley
Chief Executive Officer

Exhibit Index

Exhibit No.	Description
Exhibit 99.1	Press Release dated January 31, 2017

>

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): January 31, 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))

Item 8.01 Other Events.

On January 31, 2017, Tenax Therapeutics, Inc. issued a press release announcing top-line results from its Phase 3 LEVO-CTS trial. 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 January 31, 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.

Tenax Therapeutics, Inc.

Date: January 31, 2017

By: /s/ John Kelley
John Kelley
Chief Executive Officer

Exhibit Index

Exhibit No.	Description
Exhibit 99.1	Press Release dated January 31, 2017

Exhibit 99.1

Tenax Therapeutics Announces Top-Line Results From Phase 3 LEVO-CTS Trial in Cardiac Surgery

– Study Did Not Achieve Statistically Significant Reductions in Dual or Quad Primary Endpoints –

– Study Met Two Secondary Endpoints with Statistically Significant Reduction in Incidence of LCOS and Use of Postoperative Secondary Inotropes –

Morrisville, NC, January 31, 2017 – Tenax Therapeutics, Inc. (NASDAQ: TENX), a specialty pharmaceutical company focused on identifying, developing and commercializing products for the critical care market, today announced top-line results from its Phase 3 LEVO-CTS trial. The study did not achieve statistically significant reductions in the dual endpoint of death or use of a mechanical assist device at 30 days, nor in the quad endpoint of death, myocardial infarction, need for dialysis, or use of a mechanical assist device at 30 days. However, the study demonstrated statistically significant reductions in two of three secondary endpoints including reduction in low cardiac output syndrome (LCOS) and a reduction in postoperative use of secondary inotropes. Patient visits for data on death through day 90 have not yet been completed. The Company has a meeting scheduled with the U.S. Food and Drug Administration (FDA) to review the preliminary trial data and discuss a path forward to bring this potentially lifesaving treatment to the benefit of patients undergoing serious cardiac surgery.

“We are disappointed and surprised by the top-line results from this trial, especially given the promising results from earlier published clinical trials. On the other hand, we are encouraged by the statistically significant reduction in incidence of LCOS and use of postoperative secondary inotropes, both of which we believe are clinically important. This is consistent with what we know about how this drug works. In addition, we continue to review the full data set, including the in-process data collection on all-cause mortality through day 90, and will share our complete findings at the upcoming American College of Cardiology (ACC) meeting in March,” said John Kelley, CEO of Tenax Therapeutics. “We thank our clinical collaborators and their patients who participated in this clinical trial with the hope of improving not only their own outcomes, but also the outcomes of future patients undergoing cardiac surgery.”

Analyses of the LEVO-CTS trial results are ongoing and will be presented on Sunday, March 19, 2017, at 8:00 am EDT during a late-breaking clinical trial session at the American College of Cardiology 66th Annual Scientific Session in Washington, D.C.

The full LEVO-CTS trial design was recently published by the study's investigators in the *American Heart Journal* in an article titled, "Levosimendan in Patients with Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery on Cardiopulmonary Bypass: Rationale and Study Design of the LEVO-CTS Trial."

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, Inc.

About Tenax Therapeutics

Tenax Therapeutics, Inc., is a specialty pharmaceutical company focused on identifying, developing and commercializing products for the critical care market. The Company owns the North American rights to develop and commercialize levosimendan, and the United States Food and Drug Administration (FDA) has granted Fast Track status for levosimendan for the reduction of morbidity and mortality in cardiac surgery patients at risk for developing Low Cardiac Output Syndrome (LCOS). 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-KT filed on March 14, 2016, its quarterly report on Form 10-Q filed on November 9, 2016 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.

Investor Contact
Will O'Connor
Stern Investor Relations, Inc.
will@sternir.com
212-362-1200

Tenax Therapeutics Announces Top-Line Results From Phase 3 LEVO-CTS Trial in Cardiac Surgery

– Study Did Not Achieve Statistically Significant Reductions in Dual or Quad Primary Endpoints –

– Study Met Two Secondary Endpoints with Statistically Significant Reduction in Incidence of LCOS and Use of Postoperative Secondary Inotropes –

Morrisville, NC, January 31, 2017 – Tenax Therapeutics, Inc. (NASDAQ: TENX), a specialty pharmaceutical company focused on identifying, developing and commercializing products for the critical care market, today announced top-line results from its Phase 3 LEVO-CTS trial. The study did not achieve statistically significant reductions in the dual endpoint of death or use of a mechanical assist device at 30 days, nor in the quad endpoint of death, myocardial infarction, need for dialysis, or use of a mechanical assist device at 30 days. However, the study demonstrated statistically significant reductions in two of three secondary endpoints including reduction in low cardiac output syndrome (LCOS) and a reduction in postoperative use of secondary inotropes. Patient visits for data on death through day 90 have not yet been completed. The Company has a meeting scheduled with the U.S. Food and Drug Administration (FDA) to review the preliminary trial data and discuss a path forward to bring this potentially lifesaving treatment to the benefit of patients undergoing serious cardiac surgery.

“We are disappointed and surprised by the top-line results from this trial, especially given the promising results from earlier published clinical trials. On the other hand, we are encouraged by the statistically significant reduction in incidence of LCOS and use of postoperative secondary inotropes, both of which we believe are clinically important. This is consistent with what we know about how this drug works. In addition, we continue to review the full data set, including the in-process data collection on all-cause mortality through day 90, and will share our complete findings at the upcoming American College of Cardiology (ACC) meeting in March,” said John Kelley, CEO of Tenax Therapeutics. “We thank our clinical collaborators and their patients who participated in this clinical trial with the hope of improving not only their own outcomes, but also the outcomes of future patients undergoing cardiac surgery.”

Analyses of the LEVO-CTS trial results are ongoing and will be presented on Sunday, March 19, 2017, at 8:00 am EDT during a late-breaking clinical trial session at the American College of Cardiology 66th Annual Scientific Session in Washington, D.C.

The full LEVO-CTS trial design was recently published by the study's investigators in the *American Heart Journal* in an article titled, "Levosimendan in Patients with Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery on Cardiopulmonary Bypass: Rationale and Study Design of the LEVO-CTS Trial."

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, Inc.

About Tenax Therapeutics

Tenax Therapeutics, Inc., is a specialty pharmaceutical company focused on identifying, developing and commercializing products for the critical care market. The Company owns the North American rights to develop and commercialize levosimendan, and the United States Food and Drug Administration (FDA) has granted Fast Track status for levosimendan for the reduction of morbidity and mortality in cardiac surgery patients at risk for developing Low Cardiac Output Syndrome (LCOS). 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-KT filed on March 14, 2016, its quarterly report on Form 10-Q filed on November 9, 2016 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.

Investor Contact
Will O'Connor
Stern Investor Relations, Inc.
will@sternir.com
212-362-1200