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): October 31, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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 (see General Instruction A.2. below):

☐ 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	TNXP	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 October 31, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced topline results from the Phase 2 UPLIFT study of its TNX-601 ER (tianeptine hemioxalate extended-release tablets) product candidate in patients with major depressive disorder ("MDD"). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On October 31, 2023, the Company announced topline results from the Phase 2 proof-of-concept double-blind, randomized, multi-center, placebo-controlled UPLIFT study of TNX-601 ER in patients with MDD. The primary efficacy endpoint of change from baseline in depression severity, as measured by the Montgomery-Åsberg Depression Rating Scale ("MADRS") total score, did not achieve clinical or statistical significance. Efficacy was assessed using the MADRS to measure any potential change in patients' depression severity from baseline. Based on the results, the Company is discontinuing development of TNX-601 ER. In the study, TNX-601 was generally well-tolerated with a favorable safety profile. There was one serious adverse event ("SAE") experienced in the placebo group, and two SAEs in the active treatment group deemed possibly related to study drug, both of which resolved without sequelae.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate,” “potential,” “predict,” “project,” “should,” “would” and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company’s filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press release of the Company, dated October 31, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: October 31, 2023

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Announces Topline Results from Phase 2 Proof-of-Concept Study of TNX-601 ER for the Treatment of Major Depressive Disorder

The study did not achieve statistical significance on the primary endpoint

Tonix is discontinuing development of TNX-601 ER based on the efficacy results of this study

Tonix expects topline data results in December 2023 for its Phase 2 study of TNX-1900 in chronic migraine and Phase 3 study of TNX-102 SL in fibromyalgia

CHATHAM, N.J., October 31, 2023 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced topline results from the Phase 2 proof-of-concept double-blind, randomized, multi-center, placebo-controlled UPLIFT study of TNX-601 ER* (tianeptine hemioxalate extended-release tablets) in patients with major depressive disorder (MDD). The primary efficacy endpoint of change from baseline in depression severity, as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS) total score, did not achieve clinical or statistical significance.

“Based on these efficacy results, we are discontinuing development of TNX-601 ER. We look forward to topline results from our Phase 2 study of TNX-1900 in chronic migraine in early December and topline results from our Phase 3 potential NDA-enabling study of TNX-102 SL in fibromyalgia in late December,” said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. “We would like to thank the patients, their families, and all the investigators and researchers who participated in the Phase 2 UPLIFT study.”

In the Phase 2 UPLIFT study, TNX-601 ER was orally administered as monotherapy once a day to 132 patients who, upon entering the study, met a DSM-5 diagnosis of moderate-to-severe depression with a duration for the current major depressive episode of at least 12 weeks. Efficacy was assessed using the MADRS to measure any potential change in patients’ depression severity from baseline. In the study, TNX-601 ER was generally well-tolerated with a favorable safety profile. There was one serious adverse event (SAE) experienced in the placebo group, and two SAEs in the active treatment group deemed possibly related to study drug, both of which resolved without sequelae.

About the Phase 2 UPLIFT Study

The Phase 2 proof-of-concept UPLIFT study, TNX-TI-M201, is a double-blind, randomized, multicenter, placebo-controlled study to evaluate the efficacy and safety of TNX-601 ER taken orally once-daily for 6 weeks for the treatment of moderate-to-severe MDD. It is a parallel design study with a TNX-601 ER 39.4 mg arm and a placebo arm. A total of 132 participants were randomized in a 1:1 ratio into the two arms across approximately 27 U.S. sites, enrolling adult patients 18-65 years old with a DSM-5 diagnosis of MDD and a duration for the current major depressive episode of at least 12 weeks. The primary efficacy endpoint is mean change from baseline in the MADRS total score at Week 6. Key secondary efficacy endpoints include the Clinical Global Impression - Severity Scale (CGI-S) and the Sheehan Disability Scale (SDS).

For more information, see ClinicalTrials.gov Identifier: NCT05686408.

About Major Depressive Disorder (Depression)

According to the National Institute of Mental Health, an estimated 21 million adults in the U.S. in 2020 experienced at least one major depressive episode [1], with highest prevalence among individuals aged 18-25 at a rate of 17.0%. For approximately 2.5 million adults in the U.S., adjunctive therapies are necessary for depression treatment.[2,3] Depression is a condition characterized by symptoms such as a depressed mood or loss of interest or pleasure in daily activities most of the time for two weeks or more, accompanied by appetite changes, sleep disturbances, motor restlessness or retardation, loss of energy, feelings of worthlessness or excessive guilt, poor concentration, and suicidal thoughts and behaviors. These symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. The majority of people who suffer from depression do not respond adequately to initial antidepressant therapy.[4]

[1] Data Courtesy of SAMHSA on Past Year Prevalence of Major Depressive Episode Among U.S. Adults 2020. Retrieved from http://www.nimh.nih.gov/health/statistics/major-depression.shtml

[2] IMS NSP, NPA, NDTI MAT-24-month data through Aug 2017.

[3] Kubitz N, et al. PLoS One 2013, 8 (10), e76882.

[4] Rush AJ, et al. Am J. Psychiatry 2007, 163 (11), 1905-1917.

About TNX-601 ER

TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a novel oral formulation of tianeptine designed for once-daily daytime dosing in development as a candidate for the treatment of MDD. Tianeptine sodium (amorphous) immediate release (dosed 3 times daily) was first marketed for depression in France in 1989 and has been available for decades in Europe, Russia, Asia, and Latin America for the treatment of depression. Tianeptine sodium has an established safety profile from decades of use in these jurisdictions. Currently no tianeptine-containing product is approved in the U.S. and no extended-release tianeptine product is approved in any jurisdiction. Tonix discovered a novel oxalate salt of tianeptine that may provide improved stability, consistency, and manufacturability compared to known salt forms of tianeptine.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix’s development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’s CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, having completed enrollment of a potentially confirmatory Phase 3 study in the third quarter of 2023, with topline data expected in late December 2023. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition, and topline results were reported in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), is in development as a preventive treatment in chronic migraine, and enrollment has completed in a Phase 2 proof-of-concept study with topline data expected in early December 2023. TNX-1900 is also being studied in binge eating disorder, pediatric obesity and social anxiety disorder by

academic collaborators under investigator-initiated INDs. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the fourth quarter of 2023. Tonix's rare disease development portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology development portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases, including TNX-1800, in development as a vaccine to protect against COVID-19 . The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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