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 20, 2024

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 August 20, 2024, the Company announced that the first patient was dosed in the Phase 2, single-blind, placebo-controlled, proof of concept trial of its TNX-1300 (double-mutant cocaine esterase 200 mg, *i.v.* solution) product candidate for the treatment of acute cocaine intoxication in the emergency department (the "CATALYST Study"). 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 August 20, 2024, the Company announced that the first patient was dosed in the CATALYST Study. The primary endpoint of the CATALYST Study is reduction of systolic blood pressure associated with acute cocaine intoxication identified at study baseline comparing TNX-1300 to placebo with standard of care after 60 minutes. Multiple secondary endpoints will be measured, including reduction of circulating cocaine and levels of its metabolites at multiple post-baseline timepoints.

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, August 20, 2024
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: August 20, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Announces First Patient Enrolled in Phase 2 CATALYST Study of TNX-1300 for the Treatment of Cocaine Intoxication

CATALYST is a Phase 2 single-blind, placebo-controlled, proof-of-concept study in patients presenting to the emergency department

More than 27,569 individuals in the U.S. died from drug overdose deaths involving cocaine in 2022; there is currently no FDA-approved product for cocaine intoxication

Topline results are expected in the first half of 2025

CHATHAM, N.J., August 20, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the first patient has been dosed in the Phase 2, single-blind, placebo-controlled, proof of concept trial of TNX-1300 (double-mutant cocaine esterase 200 mg, *i.v.* solution) for the treatment of acute cocaine intoxication in the emergency department (ED). TNX-1300 is a recombinant enzyme that rapidly and efficiently degrades and metabolizes cocaine in cocaine users, as demonstrated in a prior Phase 2a randomized, double-blind, placebo-controlled, laboratory-based clinical study, providing support for the use of TNX-1300 as a treatment for life-threatening cocaine intoxication.[1]

Tonix has been awarded a Cooperative Agreement Grant from National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), to support development of TNX-1300 for the treatment of cocaine intoxication. In addition, TNX-1300 has been granted Breakthrough Therapy designation by the U.S Food and Drug Administration (FDA).

“Cocaine abuse and dependence are major problems in the U.S. However, there is currently no FDA-approved treatment indicated for cocaine intoxication, a life-threatening state characterized by acute symptoms including agitation, hyperthermia, tachycardia, arrhythmias, hypertensive crisis, myocardial infarction, stroke, and seizures,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “In 2022, the number of overdose deaths involving cocaine reached 27,569 individuals.[2] With approximately 505,000 emergency room visits annually involving cocaine use and approximately 61,000 of the visits involving detox services to treat cocaine overdose,[3,4] we believe TNX-1300 has the potential to help address the morbidity and mortality caused by cocaine intoxication. By targeting the cause rather than the symptoms of cocaine intoxication, TNX-1300 may offer significant advantages to the current standard of care for cocaine overdose.”

The Phase 2 trial is a single-blind, open-label, placebo-controlled, randomized study comparing the safety of a single 200 mg dose of TNX-1300 to placebo injection plus standard of care alone for the treatment of signs and symptoms of acute cocaine intoxication. The study is being conducted in the EDs of six academic medical centers in the U.S. It will include approximately 60 subjects presenting to the ED with cocaine intoxication. During the treatment period, subjects randomized to receive TNX-1300 will receive a single *i.v.* injection of TNX-1300 administered over two minutes or less; whereas subjects randomized to receive standard of care alone will receive a single *i.v.* saline injection over two minutes or less. For both study arms, signs and symptoms of cocaine intoxication will be assessed at pre-determined time points after treatment. After randomization, blood samples will be drawn at specific time points to assess the pharmacokinetics of TNX-1300 and levels of cocaine and its metabolites in the plasma. The primary endpoint of the study is reduction of systolic blood pressure associated with acute cocaine intoxication identified at study baseline comparing TNX-1300 to placebo with standard of care after 60 minutes. A variety of secondary endpoints will be measured, including reduction of circulating cocaine and levels of its metabolites at multiple post-baseline timepoints.

For more information, see ClinicalTrials.gov Identifier: NCT06045793

About TNX-1300

TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution) is being developed under an Investigational New Drug application (IND) for the treatment of cocaine intoxication. TNX-1300 is a recombinant protein enzyme produced through recombinant DNA technology in a non-disease-producing strain of *E. coli* bacteria. Cocaine esterase (CocE) was identified in bacteria (*Rhodococcus*) that uses cocaine as its sole source of carbon and nitrogen and that grows in soil surrounding coca plants.[5] The gene encoding CocE was identified and the protein was extensively characterized.[5-8] CocE catalyzes the breakdown of cocaine into metabolite ecgonine methyl ester and benzoic acid. Wild-type CocE is unstable at human body temperature, so targeted mutations were introduced in the CocE gene and resulted in the T172R/G173Q double-mutant CocE, which is active for approximately 6 hours at body temperature.[8] In a Phase 2 laboratory-based study in volunteers who use cocaine, TNX-1300, at 100 mg or 200 mg *i.v.* doses, was well tolerated and rapidly reduced cocaine effects after cocaine 50 mg *i.v.* challenge.[1]

About Cocaine Intoxication and Overdose

Cocaine is an illicit recreational drug which is taken for its pleasurable effects and associated euphoria. In 2022, over 5 million individuals in the U.S. reported current cocaine use, almost 2% of the population.[9] Pharmacologically, cocaine blocks the reuptake of the neurotransmitter dopamine from central nervous system synapses, resulting in the accumulation of dopamine within the synapse and an amplification of dopamine signaling and its capacity to produce euphoric mood states. With the continued use of cocaine, however, intense cocaine cravings occur resulting in a high potential for abuse and addiction (dependence), as well as the risk of acute cocaine intoxication. Cocaine intoxication refers to the deleterious effects on several body systems, especially those involving the cardiovascular system. Common symptoms of cocaine intoxication include tachyarrhythmias and elevated blood pressure, either of which can be life-threatening. As a result, individuals with known or suspected cocaine intoxication are sent immediately to the emergency department (ED), preferably by ambulance in case cardiac arrest occurs during transit. The standard of care for treating cocaine intoxication in the ED focuses on symptom management, preventing complications, and supporting cardiovascular, respiratory, and neurological function, e.g. benzodiazepines for agitation, seizures, and sympathetic overdrive; antihypertensives for extremely elevated blood pressure; aspirin and nitroglycerine for cardiac ischemia. There are approximately 505,000 emergency room visits for cocaine abuse each year in the U.S., of which 61,000 require detoxification services.[3,4] According to the National Institute on Drug Abuse, in 2022 the number of overdose death involving cocaine reached 27,569 individuals.[2] In 2019, Black Americans experienced the highest death rate for overdoses involving cocaine, at 10.7 per 100,000.[10]

References

[1] Nasser et al A randomized, double-blind, placebo-controlled trial of RBP-8000 in cocaine abusers: pharmacokinetic profile of rbp-8000 and cocaine and effects of RBP-8000 on cocaine-induced physiological effects. *J Addict Dis.* 2014;33(4):289-302.

[2] https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates; August 18, 2024

[3] Substance Mental Health Services Administration, Drug Abuse Warning Network, 2011: National Estimates of Drug- Related Emergency Department Visits. HHS Publication No. (SMA) 13-4760, DAWN Series D-39. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[4] Drug Abuse Warning Network, 2011: Selected Tables of National Estimates of Drug-Related Emergency Department Visits. Rockville, MD: Center for Behavioral Health Statistics and Quality, SAMHSA, 2013.

[5] Bresler, et al. Gene cloning and nucleotide sequencing and properties of a cocaine esterase from Rhodococcus sp. strain MB1.*Appl Environ Microbiol.* 2000. 66(3):904-8.

[6] Larsen, et al. Crystal structure of a bacterial cocaine esterase. *Nat Struct Biol.* 2002. 9(1):17-21.

[7] Turner, et al. Biochemical characterization and structural analysis of a highly proficient cocaine esterase. *Biochemistry.* 2002. 41(41):12297-307.

[8] Gao, et al. Thermostable variants of cocaine esterase for long-time protection against cocaine toxicity.*Mol Pharmacol.* 2009. 75(2):318-23.

[9] https://www.cdc.gov/drugoverdose/deaths/other-drugs.html; accessed August 18, 2024

[10] Kariisa, et al. Drug overdose deaths involving cocaine and psychostimulants with abuse potential among racial and ethnic groups – United States, 2004-2019*Drug Alcohol Depend.* 2021. 1;227:109001.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders, and its priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of 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. Tonix also has product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years in an Other Transaction Agreement (OTA) to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD, instrumental in progressing this development. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found atwww.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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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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