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): June 27, 2022

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 June 27, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the design of a new Phase 2 clinical trial of TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution) for the treatment of cocaine intoxication. 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 June 27, 2022, the Company issued a press release announcing the design of a new Phase 2 clinical trial of TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution) for the treatment of cocaine intoxication. The Company plans to submit the new protocol to the U.S. Food and Drug Administration. 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 standard of care alone for the treatment of signs and symptoms of acute cocaine intoxication in approximately 60 emergency department patients presenting with cocaine intoxication.

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 development of TNX-1300, 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 June 27, 2022
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: June 27, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Trial Design of New Phase 2 Clinical Study of TNX-1300 for Cocaine Intoxication

New Trial Design is Single-Blind, Placebo-Controlled, Potential Pivotal Study, Pending FDA Agreement

Expected to Include Women Based on Reproductive Toxicology Studies, Pending FDA Agreement

Planning to Include Patients Who Have Received Naloxone to Increase Enrollment

CHATHAM, N.J., June 27, 2022 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the design of a new Phase 2 clinical trial of TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution) for the treatment of cocaine intoxication. This new protocol has the potential to serve as a pivotal trial. TNX-1300 is a recombinant enzyme that efficiently degrades and metabolizes cocaine in cocaine users, as demonstrated in a prior Phase 2a randomized, double-blind, placebo-controlled clinical study, providing support of the use of TNX-1300 as a treatment for cocaine intoxication.[1] The Company plans to submit the new protocol to the U.S. Food and Drug Administration (FDA) .

A positive Phase 2a study of volunteer cocaine users in a controlled laboratory setting has been previously completed. TNX-1300 has been granted Breakthrough Therapy designation by the FDA. As a biologic and new molecular entity, TNX-1300 is eligible for 12 years of U.S. market exclusivity upon approval by the FDA, in addition to expected patent protection through 2029.

“The design of the new Phase 2 trial has the potential to serve as a pivotal trial,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “There are approximately 505,000 emergency room visits annually involving cocaine use, with approximately 61,000 of the visits involving detox services to treat cocaine overdose. In 2020, about 19,447 overdose deaths involving cocaine occurred in the U.S.[2] We believe that TNX-1300 has the potential to be a new treatment option for the substantial morbidity and mortality caused by cocaine intoxication.”

“The new study replaces the Phase 2 open-label trial with TNX-1300 for cocaine intoxication originally expected to start in the second quarter of 2022, which was designed to evaluate feasibility of enrollment,” said Gregory Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals. “We expect to be able to include women in this study, pending FDA agreement, since we have now completed the required reproductive toxicology studies in which no incidents of toxicity were observed. Additionally, we will now admit patients into the study who might have received naloxone due to the intoxication symptoms they are presenting. Based on our learnings from the feasibility study, excluding patients who had received naloxone at the time of intoxication was a hindrance to enrollment. Both of these changes in the new protocol should improve our ability to enroll appropriate patients in a more timely manner.”

Currently there is no specific pharmacotherapy indicated for cocaine intoxication, a state characterized by acute agitation, hyperthermia, tachycardia, arrhythmias, and hypertension, with the potential life-threatening sequalae of myocardial infarction, cerebrovascular accident, rhabdomyolysis, respiratory failure and seizures. Patients are currently managed only by supportive care for the adverse effects of cocaine overdose on the cardiovascular and central nervous systems. By targeting the cause rather than

---

the symptoms of cocaine intoxication, the Company believes 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 standard of care alone for the treatment of signs and symptoms of acute cocaine intoxication in approximately 60 emergency department patients presenting with cocaine intoxication. During the treatment period, subjects assigned to receive TNX-1300 will receive a single IV injection of TNX-1300 administered over 2 minutes or less; whereas subjects assigned to receive standard of care alone will receive a single IV saline injection over 2 minutes or less. Both groups will be observed according to the site’s emergency department protocol. For both study arms, signs and symptoms of cocaine intoxication will be assessed at pre-determined time points after treatment (30 minutes and then at 60, 90, 120, 180, and 240 minutes). After randomization, blood samples will be drawn at specific time points. The primary endpoint of the study is reduction of systolic blood pressure associated with acute cocaine intoxication identified at study baseline comparing TNX-1300 and standard of care after 60 minutes. A variety of secondary endpoints will be measured, including reduction of circulating cocaine, cocaethylene and ecgonine methyl ester levels after at multiple post-baseline timepoints. Safety assessments will consist of incidence and severity of treatment-emergent adverse events, adverse events of special interest, 12-lead ECGs, and vital signs.

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 rDNA 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.[3] The gene encoding CocE was identified and the protein was extensively characterized.[3-6] CocE catalyzes the breakdown of cocaine into metabolite ecgonine methyl ester and benzoic acid. Wild-type CocE is unstable at 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[7]. In a Phase 2 study, 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 illegal recreational drug which is taken for its pleasurable effects and associated euphoria. 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 role in creating positive feeling. 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 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, preferably by ambulance in case cardiac arrest occurs during transit. There are approximately 505,000 emergency room visits for cocaine abuse each year in the U.S., of which 61,000 require detoxification services. According to the National Institute on Drug Abuse, in 2020 the number of

---

overdose death involving cocaine reached 19,447 individuals.[2] According to a recent report by the U.S. Centers for Disease Control and Prevention[7], among all 2019 U.S. drug overdose deaths, approximately nearly 1 in 5 involved cocaine. In 2019, Black Americans experienced the highest death rate for overdoses involving cocaine, at 10.7 per 100,000.[8]

References

[1] *Nasser AF, Fudala PJ, Zheng B, Liu Y, Heidbreder C. 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] *National Institute on Drug Abuse (NIDA) National Institute on Drug Abuse https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates; accessed June 19, 2022*

[3] *Bresler MM, Rosser SJ, Basran A, Bruce NC. Gene cloning and nucleotide sequencing and properties of a cocaine esterase from Rhodococcus sp. strain MB1. Appl Environ Microbiol. 2000. 66(3):904-8.*

[4] *Larsen NA, Turner JM, Stevens J, Rosser SJ, Basran A, Lerner RA, Bruce NC, Wilson IA. Crystal structure of a bacterial cocaine esterase. Nat Struct Biol. 2002. 9(1):17-21.*

[5] *Turner JM, Larsen NA, Basran A, Barbas CF 3rd, Bruce NC, Wilson IA, Lerner RA. Biochemical characterization and structural analysis of a highly proficient cocaine esterase. Biochemistry. 2002. 41(41):12297-307.*

[6] *Gao D, Narasimhan DL, Macdonald J, Brim R, Ko MC, Landry DW, Woods JH, Sunahara RK, Zhan CG. Thermostable variants of cocaine esterase for long-time protection against cocaine toxicity. Mol Pharmacol. 2009. 75(2):318-23.*

[7] https://www.cdc.gov/drugoverdose/deaths/other-drugs.html; accessed June 19, 2022

[8] *Kariisa M, Seth P, Scholl L, Wilson N, Davis NL. Drug overdose deaths involving cocaine and psychostimulants with abuse potential among racial and ethnic groups – United States, 2004-2019. Drug Alcohol Depend. 2021 Oct 1;227:109001. doi: 10.1016/j.drugalcdep.2021.109001. Epub 2021 Aug 28. PMID: 34492555.*

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the third quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is Phase 2 ready and has been granted Breakthrough Therapy Designation by the FDA. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the second half of 2022. Tonix's rare disease 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 portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second half of 2022. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human

---

monoclonal antibodies to treat COVID-19. Tonix's lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850, which are live virus vaccines

based on Tonix's recombinant pox live virus vector vaccine platform.

**All of Tonix's product 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; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Olipriya Das, Ph.D. (media)
Russo Partners
Olipriya.Das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)
Westwicke/ICR
peter.vozzo@westwicke.com
(443) 213-0505