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): May 30, 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 May 30, 2024, the Company announced data from two poster presentations (the "Posters") at the American Society of Clinical Psychopharmacology ("ASCP") Annual Meeting being held May 28-31, 2024. 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 May 30, 2024, the Company announced data from the Posters at the ASCP. The Poster titled, "*Effect of Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) on Pain, Sleep, Fatigue, and Cognition in Fibromyalgia-Type Long COVID: Results of a Double-Blind Randomized Proof-of-Concept Phase 2 Study*," included data demonstrating that the Company's TNX-102 SL product candidate had an effect size of 0.5 in improving fatigue and showed consistent activity across secondary measures of sleep quality, cognitive function, disability and Patient Global Impression of Change, but did not meet the primary endpoint of multi-site pain reduction at Week 14.

In the Poster titled, "*Optimizing Acute Stress Reaction (ASR) Interventions with TNX-102 SL* (Sublingual Cyclobenzaprine HCl) – The OASIS Trial: Sustaining Civilian Performance Post-Trauma by Reduction of ASR and Prevention of ASD/PTSD*," TNX-102 SL will be evaluated for the reduction in severity of acute stress reaction ("ASR") and the frequency of acute stress disorder and posttraumatic stress disorder in civilians after a motor vehicle collision.

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 May 30, 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: May 30, 2024

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

EXHIBIT 99.01

Tonix Pharmaceuticals Announces Two Poster Presentations of TNX-102 SL (Sublingual Cyclobenzaprine HCl) at the ASCP Annual Meeting

In the Phase 2 PREVAIL trial in fibromyalgia-type Long COVID, bedtime TNX-102 SL resulted in a signal in fatigue, sleep and cognitive function

Phase 2, investigator-initiated OASIS trial is designed to examine the safety and efficacy of TNX-102 SL in treating Acute Stress Disorder (ASD) after motor vehicle collision

First patient in OASIS expected to enroll in second quarter 2024

CHATHAM, N.J., May 30, 2024 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced two poster presentations at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting being held May 28-31, 2024 in Miami Beach, Fla. A copy of the presentations are available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com.

In the poster presentation titled, "*Effect of Bedtime Sublingual Cyclobenzaprine (TNX-102 SL) on Pain, Sleep, Fatigue, and Cognition in Fibromyalgia-Type Long COVID: Results of a Double-Blind Randomized Proof-of-Concept Phase 2 Study*," TNX-102 SL showed a robust effect size of 0.5 in improving fatigue and showed consistent activity across secondary measures of sleep quality, cognitive function, disability and Patient Global Impression of Change, but did not meet the primary endpoint of multi-site pain reduction at Week 14. Prior to the trial, Tonix had pre-specified that any effect size greater than 0.2 would be considered of interest for further study and, even given a substantial placebo response in pain magnitude measurements, key endpoints such as sleep quality diary (ES = 0.23), PROMIS Sleep Disturbance (ES = 0.32), PROMIS Fatigue (ES = 0.50), PROMIS Cognitive Function (ES = 0.21), the Insomnia Severity Index (ES = 0.24) and the Sheehan Disability Scale (ES = 0.26) all matched the criterion for further evaluation. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies and no new safety signals observed.

"These results further support the growing evidence that for most Long COVID patients, symptoms are at least partly driven by central nervous system mechanisms rather than persistent exposure to the SARS-CoV-2 virus," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "While Tonix is preparing for submission of a New Drug Application (NDA) for TNX-102 SL for the management of fibromyalgia (branded "Tonmya"), we believe that these results demonstrate it may also be effective in managing pain and aiding in sleep quality for patients with fibromyalgia-type Long COVID, further indicating that for many patients Long COVID should be viewed in the context of a chronic overlapping pain condition like fibromyalgia or chronic fatigue syndrome/myalgic encephalomyelitis framework."

In the poster presentation titled, "*Optimizing Acute Stress Reaction (ASR) Interventions with TNX-102 SL* (Sublingual Cyclobenzaprine HCl) – The OASIS Trial: Sustaining Civilian Performance Post-Trauma by Reduction of ASR and Prevention of ASD/PTSD*," TNX-102 SL will be evaluated for the reduction in severity of acute stress reaction (ASR) and the frequency of acute stress disorder (ASD) and posttraumatic stress disorder (PTSD) in civilians after a motor vehicle collision. To reduce the persistence of ASR symptoms and the rate and severity of ASD and PTSD, it may be critical to intervene in the immediate aftermath of trauma. Currently, there are no medications available at or near the point of care to treat patients suffering from acute trauma and support long-term health. Previous trials of TNX-102 SL showed that it reduced military PTSD symptoms in as early as two weeks with favorable tolerability. The first participant for the OASIS trial is expected to enroll in the second quarter of 2024.

"Previous trials of TNX-102 SL in PTSD suggested activity on sleep and stress related symptoms in the first several weeks of treatment,[1],[2] said Dr. Lederman. "The study is motivated by the observation that the symptoms of ASR and PTSD are similar and by the hypothesis that TNX-102 SL's effect on sleep quality may reduce ASR symptoms, possibly providing military personnel, veterans, and civilians with a new treatment option that, when administered in the early aftermath of a traumatic event, improves recovery, job performance, and quality of life."

TNX-102 SL is a centrally acting, non-opioid medication, and, under the trade name Tonmya™, Tonix remains on track to submit an NDA to the U.S. Food and Drug Administration (FDA) in the second half of 2024 for the management of fibromyalgia. Tonix has scheduled a Type B pre-NDA meeting with FDA for the second quarter of 2024.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for Tonmya[1], a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction as well as fibromyalgia-type Long COVID. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic 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 and infectious disease. 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.

[1]Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

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

1. *Sullivan GM, et al. Randomized clinical trial of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related PTSD and the role of sleep quality in treatment response. Psychiatry Res. 2021 Jul;301:113974.*
2. *Parmenter ME, et al. A phase 3, randomized, placebo-controlled, trial to evaluate the efficacy and safety of bedtime sublingual cyclobenzaprine (TNX-102 SL) in military-related posttraumatic stress disorder. Psychiatry Res. 2024 (In Press). https://doi.org/10.1016/j.psychres.2024.115764*

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.

Investor Contact

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

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

Media Contact

Katie Dodge
LaVoieHealthScience
kdodge@lavoiehealthscience.com
(978) 360-3151