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 22, 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 22, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it will deliver an oral presentation and present two 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 22, 2024, the Company announced that it will deliver an oral presentation and present two posters at the ASCP Annual Meeting. The oral presentation, entitled *Effects of Bedtime TNX-102 SL (Sublingual Cyclobenzaprine (CBP) HCl) on Mood and Anxiety Symptoms in Fibromyalgia: Results of the Phase 3 RESILIENT Trial*, will detail findings of studies of the Company's Tonmya® (TNX-102 SL, sublingual cyclobenzaprine HCl) product candidate in fibromyalgia. One poster, entitled *Effects of Bedtime TNX-102 SL (Sublingual Cyclobenzaprine (CBP) HCl) on Mood and Anxiety Symptoms in Fibromyalgia: Results of the Phase 3 RESILIENT Trial*, will describe the Phase 2 proof of concept study of TNX-102 SL in fibromyalgia-type Long COVID. The second poster, entitled *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*, will describe the upcoming investigator-initiated Phase 2 trial of TNX-102 SL in treating acute stress disorder and preventing posttraumatic stress disorder after motor vehicle collision, which will be conducted by University of North Carolina, the sponsor of the study.

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, May 22, 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 22, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals to Deliver an Oral Presentation and Present Two Posters at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting

Oral Presentation of Tonmya™ (TNX-102 SL) for Fibromyalgia; NDA preparation in progress

Posters Highlighting Other TNX-102 SL Programs In Clinical Development; Long COVID and Acute Stress Disorder

CHATHAM, N.J., May 22, 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 that the Company will deliver an oral presentation and present two posters at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting being held May 28-31, 2024 at the Loews Miami Beach Hotel in Miami Beach, Fla.

The oral presentation will detail findings of studies of Tonmya (TNX-102 SL, sublingual cyclobenzaprine HCl) in fibromyalgia. One poster will describe the Phase 2 proof of concept study of TNX-102 SL in fibromyalgia-type Long COVID. The second poster will describe the upcoming investigator-initiated Phase 2 trial of TNX-102 SL in treating acute stress disorder and preventing posttraumatic stress disorder after motor vehicle collision, which will be conducted by the University of North Carolina, the sponsor of the study.

TNX-102 SL is a centrally acting, non-opioid medication, which is trade named Tonmya™ for the management of fibromyalgia. As previously announced, the second statistically significant Phase 3 study of Tonmya, RESILIENT, met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo in participants with fibromyalgia (p=0.00005). Statistically significant and clinically meaningful results (p=0.001 or better) were also seen in all key secondary endpoints related to improving sleep quality, reducing fatigue, and improving overall fibromyalgia symptoms and function.

Tonix plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2024 for Tonmya for the management of fibromyalgia and has scheduled a Type B pre-NDA meeting with FDA for the second quarter of 2024.

Copies of the Company's presentation and posters will be available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com following the conference. Additional meeting information can be found on the ASCP website here.

Oral Presentation Details

Presenter:	Seth Lederman, M.D., Chief Executive Officer
Title:	Effects of Bedtime TNX-102 SL (Sublingual Cyclobenzaprine (CBP) HCl) on Mood and Anxiety Symptoms in Fibromyalgia: Results of the Phase 3 RESILIENT Trial
Date/Time:	May 29, 2024, 3:00 p.m. ET

Poster Presentation Details

Presenter:	Herbert Harris, M.D., Ph.D., Executive Vice President, Translational Medicine
Title:	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
Date/Time:	May 30, 2024, 12:30 p.m. ET
Presenter:	David Hsu, Ph.D., Senior Scientist
Title:	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
Date/Time:	May 30, 2024, 12:30 p.m. ET

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.

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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