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): March 7, 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 March 7, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the publication of a research paper entitled, "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," in the journal Psychiatry Research (the "Paper"). 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 March 7, 2024, the Company announced the publication of the Paper, which found that bedtime treatment of the Company's TNX-102 SL product candidate is well-tolerated and showed nominal improvement in PTSD severity and sleep quality measures in the first four weeks in miliary-related posttraumatic stress disorder ("PTSD"). The Company believes these findings suggest a potential role for short-term bedtime TNX-102 SL treatment in the immediate aftermath of traumatic events, and that bedtime TNX-102 SL has short-term activity on improving PTSD symptom severity and sleep quality in military-related PTSD.

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 March 7, 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: March 7, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Publication in *Psychiatry Research* Showing Activity of Bedtime TNX-102 SL on PTSD Symptoms and Sleep Quality in Military-Related PTSD at Four Weeks of Therapy

Data support evaluation of the effects of two weeks of TNX-102 SL therapy on severity of acute stress reaction (ASR) and frequency of acute stress disorder (ASD) and PTSD after civilian motor vehicle collision in upcoming U.S. DoD-Funded Phase 2 investigator-initiated OASIS trial

Nominal improvement in PTSD severity and measures of sleep quality at Week 4 in the HONOR study support development of bedtime TNX-102 SL therapy in the immediate aftermath of trauma

TNX-102 SL (Tonmya™) is also in late-stage development for the management of fibromyalgia for which NDA preparation is ongoing

CHATHAM, N.J., March 7, 2024 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the publication of a research paper in the Journal *Psychiatry Research*. The article titled, "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," by Parmenter, et al. found that bedtime TNX-102 SL* treatment is well-tolerated and showed nominal improvement in PTSD severity and sleep quality measures in the first four weeks in miliary-related posttraumatic stress disorder (PTSD).[1] The Company believes these findings suggest a potential role for short-term bedtime TNX-102 SL treatment in the immediate aftermath of traumatic events.

The data support the U.S. Department of Defense (DoD)-funded Phase 2 investigator-initiated OASIS trial to evaluate bedtime TNX-102 SL[2] in reducing the severity of acute stress reaction (ASR) and the frequency of acute stress disorder (ASD) and PTSD. The IND supporting the OASIS trial was recently cleared,[3] and the trial is expected to begin enrolling in the second quarter. The trial is sponsored by The University of North Carolina Institute for Trauma Recovery and supported by a $3 million grant from DoD. In the OASIS study, 14 days of bedtime TNX-102 SL 5.6 mg will be tested in the immediate aftermath of motor vehicle collision. The study will test the potential for TNX-102 SL treatment initiated within 24 hours of index trauma to target trauma-related sleep disturbance and other ASR symptoms to facilitate recovery from ASR and to prevent PTSD.

"There is an urgent need for interventions to reduce rates of ASD and PTSD in the immediate aftermath of trauma,"[4] said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We believe the results in the published paper suggest that bedtime TNX-102 SL has short-term activity on improving PTSD symptom severity and sleep quality in military-related PTSD. Poor sleep after trauma is a risk factor for progressing from ASD to PTSD. Therefore, poor sleep is not only a symptom of ASR, ASD and PTSD, but also a potential target of therapy."

Dr. Gregory Sullivan, Chief Medical Officer of Tonix said, "Sleep disturbances are known to play a critical role in the development and maintenance of PTSD. The upcoming OASIS trial will test a 14-day short-course of bedtime TNX-102 SL therapy beginning within 24 hours of index trauma for effects on ASR symptoms and incidence of PTSD development. We are excited to test bedtime TNX-102 SL in the immediate aftermath of trauma to learn whether drug intervention reorients the trajectory of posttraumatic pathology from acute trauma to early recovery in the first few weeks."

About TNX-102 SL (also known as Tonmya™ for the management of fibromyalgia)

PTSD: The Phase 3 HONOR study described in the published article was performed in military-related PTSD with the primary endpoint of improvement from baseline in Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) total score at Week 12 comparing TNX-102 SL 5.6 mg and placebo. The study did not reach statistical significance on the primary endpoint. While there was nominal improvement by the Week 4 visit on CAPS-5 (p=0.019), the improvement relative to placebo was not sustained at Weeks 8 and 12. The CAPS-5 "sleep disturbance" item also showed nominal improvement at Week 4 (p=0.002), as well as at Week 8 (p=0.026), but not thereafter. The PROMIS Sleep Disturbance T-score also showed early nominal improvement with TNX-102 SL 5.6 mg at Week 4 (p=0.015). It is also notable that when the primary endpoint was analyzed for responder rate, defined as ≥50% improvement on CAPS-5 total score at Week 4, 38.4% of those on TNX-102 SL were responders versus 24.4% on placebo (p=0.019). TNX-102 SL was well-tolerated and the adverse events reported were similar to those seen in prior TNX-102 SL studies. There were three participants with serious adverse events (SAEs) reported during the study: two in the placebo group and one in the active group. None were deemed related to study drug. Administration site reactions were similar in profile to prior studies with TNX-102 SL, with oral numbness (hypoaesthesia) at the highest rate. These oral sensory adverse events (AE), oral numbness, oral tingling, and tongue discomfort were temporally-related to dosing and were rated as mild and transient (<60 min) in the majority of cases. No new safety signals were observed.

In addition to the Phase 3 HONOR study described in the published article[1], Tonix has also studied TNX-102 SL in a Phase 2 ('AtEase') trial in military PTSD[5] and in a Phase 3 ('RECOVERY') trial in civilian PTSD.[6] Both studies were performed with the primary endpoint of CAPS-5 improvement at Week 12. AtEase compared bedtime TNX-102 SL at two doses (2.8 mg & 5.6 mg) and placebo. RECOVERY compared TNX-102 SL 5.6 mg and placebo. Neither study reached statistical significance on the primary endpoint.

Fibromyalgia: TNX-102 SL has shown positive results in two Phase 3 clinical trials for the management of fibromyalgia. Tonix plans to submit a New Drug Application to the U.S. Food and Drug Administration in the second half of 2024 under the 505(b)(2) regulatory pathway for Tonmya for the management of fibromyalgia.

Formulation Technology and Patents: TNX-102 SL is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride which is designed for daily administration at bedtime with a proposed mechanism of improving sleep quality in fibromyalgia. TNX-102 SL provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. As a multifunctional agent with potent binding and antagonist activities at the 5-HT2A-serotonergic, α1-adrenergic, H1-histaminergic, and M1-muscarinic cholinergic receptors, TNX-102 SL is in development as a daily bedtime treatment for fibromyalgia. TNX-102 SL is also in development for fibromyalgia-type Long COVID (formally known as post-acute sequelae of COVID-19 [PASC]), alcohol use disorder, and agitation in Alzheimer's disease. The United States Patent and Trademark Office (USPTO) issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary TNX-102 SL composition. These patents are expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034/2035. In addition, Tonix has pending but not issued U.S. patent applications directed to the transmucosal absorption of cyclobenzaprine HCl, with U.S. market exclusivity expected until 2033, for treating depressive symptoms in fibromyalgia, with U.S. market exclusivity expected until 2032, and for treating pain in fibromyalgia with U.S. market exclusivity expected until 2041.

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*TNX-102 SL has not been approved for any indication; name conditionally approved by FDA as Tonmya™ for the management of fibromyalgia

1. Parmenter ME, et al. *Psychiatry Research*. 2024. 334: 115764. https://doi.org/10.1016/j.psychres.2024.115764.

2. Tonix Press Release – September 27, 2023. “Tonix Pharmaceuticals Announces Department of Defense Grant to Support the University of North Carolina’s Proposed Investigator Sponsored OASIS Trial of TNX-102 SL for Treatment of Acute Stress Reaction, Acute Stress Disorder, and Posttraumatic Stress Disorder”. https://bit.ly/3T1LyIl

3. Tonix Press Release – Feb 12, 2024. “Tonix Pharmaceuticals Announces FDA IND Clearance for DoD Funded Trial of TNX-102 SL for the Reduction of Acute Stress Reaction and Prevention of PTSD” https://bit.ly/3TiQOsj.

4. Schnurr, PP et al. Annals of Internal Medicine. 2024: www.acpjournals.org/doi/10.7326/M23-2757.

5. Sullivan GM, et al. *Psychiatry Res*. 2021. 301:113974. https://doi.org/10.1016/j.psychres.2021.113974.

6. Tonix Press Release – December 21, 2020, “Tonix Pharmaceuticals Reports Topline Results from Phase 3 RECOVERY Study of TNX-102 SL in PTSD and Outlines Future Development Plans” https://bit.ly/3uOgUu8

Tonix Pharmaceuticals Holding Corp.*

Tonix is a 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, a product candidate for which two positive 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 with 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.

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, 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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