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 11, 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 11, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the presentation of additional efficacy data from the Phase 3 RESILIENT study, the second positive Phase 3 study evaluating the Company's Tonmya (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablets) product candidate for the management of fibromyalgia, at the 6th International Congress on Controversies in Fibromyalgia. A copy of the press release that discusses this matter is filed as Exhibit 99.01 and hereto 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 11, 2024, the Company announced additional efficacy data from the Phase 3 RESILIENT study. The effect sizes of the five continuous key secondary outcomes measures of the study ranged from 0.3 to 0.5. The results demonstrated that Tonmya treatment resulted in an improvement in cognitive dysfunction, measured by the change in the Fibromyalgia Impact Questionnaire-Revised ("FIQ-R") memory item. The FIQ-R cognitive item showed nominal improvement in Tonmya-treated patients versus placebo-treated patients, with a p=0.001 and effect size of 0.31 (LS mean (SE) difference of −0.8 (0.23); nominal p=0.001; effect size 0.31, no correction for multiple comparisons, mixed model repeated measures analysis). The Company believes the activity of Tonmya on pain, sleep quality, fatigue and brain fog are indicative of broad-spectrum activity of Tonmya and suggests that Tonmya treats fibromyalgia at a syndromal level.

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, dated March 11, 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 11, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Improvement in "Brain Fog," in Fibromyalgia Patients Treated with Tonmya™ in RESILIENT, an NDA-Enabling Phase 3 Clinical Trial, at the 6th International Congress on Controversies in Fibromyalgia

Phase 3 RESILIENT study of Tonmya met its primary endpoint of daily pain reduction (p=0.00005) and achieved statistically significant improvement on all six key pre-specified secondary endpoints with effect sizes on sleep, fatigue, FIQ-R symptoms and FIQ-R function ranging from 0.3 to 0.5

Cognitive dysfunction, or "brain fog," nominally improved on FIQ-R memory item (p=0.001) where the patients rated their level of memory problems

NDA submission expected in the second half of 2024 following pre-NDA meeting with FDA scheduled for the second quarter of 2024

CHATHAM, N.J., March 11, 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 presentation of additional efficacy data from RESILIENT, the second positive Phase 3 study evaluating Tonmya (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia, at the 6th International Congress on Controversies in Fibromyalgia in Brussels, Belgium, March 7-8, 2024.

In presenting more detailed data from the RESILIENT study, Seth Lederman, M.D., President and Chief Executive Officer of Tonix, said, "We previously reported statistically significant and clinically meaningful results in all six key secondary endpoints related to improving sleep quality, reducing fatigue, and improving overall fibromyalgia symptoms and function. We now report that the effect sizes of the five continuous key secondary outcomes measures ranged from 0.3 to 0.5. The results also showed that Tonmya treatment resulted in an improvement in cognitive dysfunction, or 'brain fog', measured by the change in the Fibromyalgia Impact Questionnaire-Revised (FIQ-R) memory item. The FIQ-R cognitive item showed nominal improvement in Tonmya-treated patients vs placebo-treated patients with a p=0.001 and effect size of 0.31. Together, we believe the activity of Tonmya on pain, sleep quality, fatigue and brain fog are indicative of broad-spectrum activity of Tonmya and suggest that Tonmya treats fibromyalgia at a syndromal level."

As previously announced, RESILIENT met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo (p=0.00005) in participants with fibromyalgia. RELIEF, the first Phase 3 trial of Tonnya 5.6 mg in fibromyalgia, was completed in December 2020. It also met its pre-specified primary endpoint of daily pain reduction compared to placebo (p=0.010). Tonix plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2024 and has scheduled a pre-NDA meeting with FDA in the second quarter of 2024.

Tonmya was not associated with increases in systolic or diastolic blood pressure or body weight, nor were there any reported sexual side effects in the RESILIENT trial. In addition, when systematically investigated using the Changes in Sexual Functioning Questionnaire short form (CSFQ-14), women who received study drug had a higher CSFQ-14 total score relative to those who received placebo, which is consistent with improved sexual function.

Dr. Gregory Sullivan, Chief Medical Officer of Tonix Pharmaceuticals said, "These are important tolerability factors for fibromyalgia patients on long-term treatment with the three FDA-approved drugs, since weight gain and fatigue are associated with gabapentinoids, and negative sexual side effects, increased blood pressure and insomnia are associated with SNRIs."

Dr. Lederman added, "We believe that the data from our two positive Phase 3 studies, with clinically meaningful separation from placebo on pain, sleep disturbance, and fatigue, supports the conclusion that fibromyalgia may be successfully treated with Tonmya 5.6 mg, and may provide the opportunity for Tonix to launch the first FDA-approved drug for fibromyalgia in more than a decade. We are excited to bring forward a new first-line treatment to fibromyalgia patients that offers broad symptom relief with favorable tolerability attributes for chronic use and adherence, which provides hope for the 6-12 million affected adults in the U.S."

Dr. Sullivan added, "We believe that these broad-spectrum efficacy results will be important to fibromyalgia patients who struggle not only with pain, but also multiple other symptoms. We also believe the favorable tolerability and side effect profiles will be important to patients and doctors managing this debilitating condition on a long-term basis."

About the Phase 3 RESILIENT Study

The RESILIENT study is a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy and safety of Tonmya (cyclobenzaprine HCl sublingual tablets) in the management of fibromyalgia. The two-arm trial randomized 457 participants in the U.S. across 33 sites. The first two weeks of treatment consist of a run-in period in which participants start on Tonmya 2.8 mg (1 tablet) or placebo. Thereafter, all participants increase their dose to Tonmya 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for the remaining 12 weeks. The primary endpoint is the daily diary pain severity score change (Tonmya 5.6 mg vs. placebo) from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation. The results showed that Tonmya treatment resulted in an improvement in cognitive dysfunction or 'brain fog' measured by the change in the FIQ-R memory item. The FIQ-R cognition item showed improvement in Tonmya treated patients vs placebo treated patients (LS mean (SE) difference of −0.8 (0.23); nominal p=0.001; effect size 0.31, no correction for multiple comparisons, mixed model repeated measures analysis). The Cohen's d effect sizes (ESs) of the five continuous key secondary outcomes measures were: Fibromyalgia Impact Questionnaire-Revised (FIQ-R) – Symptoms domain ES = 0.44, FIQ-R-Function ES =0.30, PROMIS sleep disturbance ES =0.50, PROMIS Fatigue ES = 0.37 and Dairy Sleep quality rating ES = 0.32. The most common adverse events were local administration site reactions that were transient and self-limited.

For more information, see ClinicalTrials.gov Identifier: NCT05273749.

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 6 million to 12 million adults in the U.S., the majority of whom are women. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled. Physicians and

patients report common dissatisfaction with currently marketed products.

About Tonmya* (also known as TNX-102 SL)

Tonmya is a centrally acting, non-opioid, non-addictive, bedtime medication. The tablet is a patented sublingual formulation of cyclobenzaprine hydrochloride developed for the management of fibromyalgia. In December 2023, the company announced highly statistically significant and clinically meaningful topline results in RESILIENT, a second positive Phase 3 clinical trial of Tonmya for the management of fibromyalgia. In the study, Tonmya met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo (p=0.00005) in participants with fibromyalgia. Statistically significant and clinically meaningful results were also seen in all key secondary endpoints related to improving sleep quality, reducing fatigue and improving overall fibromyalgia symptoms and function. RELIEF, the first positive Phase 3 trial of Tonmya in fibromyalgia, was completed in December 2020. It met its pre-specified primary endpoint of daily pain reduction compared to placebo (p=0.010) and showed activity in key secondary endpoints.

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

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.

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 at www.tonixpharma.com

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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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