

**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): July 25, 2024

**TONIX PHARMACEUTICALS HOLDING CORP.**

(Exact name of registrant as specified in its charter)

Nevada  
(State or Other Jurisdiction of Incorporation)

001-36019  
(Commission File Number)

26-1434750  
(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 July 25, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") granted Fast Track designation to its Tonmya™ (cyclobenzaprine HCl sublingual tablets) product candidate for the management of fibromyalgia. 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 July 25, 2024, the Company announced that the FDA granted Fast Track designation to Tonmya for the management of fibromyalgia. The Company plans to request Priority Review designation for Tonmya for the treatment of fibromyalgia.

*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 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 statements 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 the Company operates 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 Current Report on Form 8-K. 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)	<b>Exhibit No.</b>	<b>Description.</b>
	<u>99.01</u> 104	Press Release of the Company, July 25, 2024 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: July 25, 2024

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

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## Tonix Pharmaceuticals Granted Fast Track Designation by FDA for Tonmya™ for Fibromyalgia

*Fast Track is designed to expedite FDA review of important new drugs to treat serious conditions and fill an unmet medical need*

*Fast Track designation for Tonmya recognizes fibromyalgia as a serious condition impacting more than 10 million U.S. adults*

*NDA submission on track for second half 2024*

*Tonmya has the potential to be the first new drug for treating fibromyalgia in more than 15 years*

CHATHAM, N.J., July 25, 2024 (GLOBE NEWSWIRE) – 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 U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia. Tonmya is a non-opioid, centrally-acting analgesic drug under development for treating fibromyalgia, which is a common chronic pain condition affecting mostly women. The designation validates that fibromyalgia is a serious condition and that Tonmya has the potential to address this unmet medical need. Tonix previously announced alignment with the FDA regarding the content of its proposed NDA submission, following completion of the Company's pre-NDA meetings. The Company reaffirms its guidance to submit the NDA for Tonmya to the FDA in the second half of 2024.

“The FDA’s decision to grant Tonmya Fast Track designation supports our goal of bringing this well tolerated, non-opioid analgesic treatment option to the market in 2025,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “The designation underscores the importance of addressing the unmet needs of fibromyalgia patients, who report dissatisfaction with current treatment options. If approved by the FDA, we expect Tonmya to become the first new pharmacotherapy for fibromyalgia in over 15 years. The NDA being prepared supports Tonmya’s potential position as a first line therapy for fibromyalgia, indicated for long-term daily use at bedtime.”

The FDA’s Fast Track process is designed to facilitate development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially bring important new medicines to patients sooner. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development. Tonix plans to request Priority Review designation, and if granted, FDA may accelerate the review of the NDA. For more information on Fast Track designation, please visit the FDA’s website at [www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track](http://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track).

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

Tonmya is a centrally acting, non-opioid, analgesic investigational drug for bedtime use. 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, the second pivotal 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 six key secondary endpoints related to improving sleep quality, reducing fatigue and improving overall fibromyalgia symptoms and function (all  $p\leq 0.001$ ). RELIEF, the first statistically significant 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. In both pivotal studies, the most common treatment-emergent adverse event was tongue or mouth numbness at the administration site, which was temporally-related to dosing, self-limited, never rated as severe, and rarely led to study discontinuation (one participant in each study). Tonix has announced the results of two positive pre-NDA meetings and alignment with FDA on nonclinical, clinical pharmacology, clinical and CMC features of the NDA submission.

### About Fibromyalgia

Fibromyalgia is a common 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, non-restorative sleep, fatigue, and brain fog (or cognitive dysfunction). Other associated symptoms include mood disturbances, including anxiety and depression, headaches, and abdominal pain or cramps. 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.

### 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, 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. 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.

\*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’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.

**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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