**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): December 3, 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 December 3, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the hiring of Bradley Raudabaugh, Vice President, Marketing, and Errol Gould, Ph.D. Vice President, Medical Affairs. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

The Company updated its investor presentation, which is used to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website and which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.02 hereto and incorporated herein by reference. The Company updated its TNX-102 SL and TNX-1500 product candidate presentations, which it intends to place on its website and which may contain nonpublic information. Copies of the product presentations are filed as Exhibits 99.03 and 99.04 hereto and incorporated herein by reference

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01, 99.02, 9903 and 99.04 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 December 3, 2024, the Company announced the expansion of its leadership team to support the launch of its TNX-102 SL product candidate for the management of fibromyalgia with the hiring of Mr. Raudabaugh, Vice President, Marketing, and Dr. Gould, Vice President, Medical Affairs.

The Company updated the timing (i) of enrollment for the TNX-102 SL OASIS study for the treatment of acute stress reaction and acute stress disorder, which is expected to commence in the first quarter of 2025; and (ii) a decision by the U.S. Food and Drug Administration on the New Drug Application ("NDA") for TNX-102 SL in August 2025, if the NDA is accepted for standard review in December 2024.

*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, December 3, 2024 |
| 99.02 | Corporate Presentation by the Company for December 2024 |
| 99.03 | TNX-102 Product Presentation |
| 99.04 | TNX-1500 Product Presentation |
| 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: December 3, 2024

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

**Exhibit 99.01**

**Tonix Pharmaceuticals Announces Expansion of Leadership Team with Two Strategic Hires**

*Tonix appoints two executives with decades of experience successfully launching and commercializing new CNS products*

*Bradley Raudabaugh, MBA, joins as Vice President, Marketing, bringing over 25 years of marketing, sales and product planning experience to Tonix*

*Errol Gould, Ph.D., joins Tonix as Vice President, Medical Affairs, with over 25 years of experience in R&D and medical affairs across a wide range of therapeutic areas, including fibromyalgia*

*New Drug Application (NDA) for TNX-102 SL for the management of fibromyalgia submitted to FDA in October 2024; NDA acceptance expected December 2024; Fast Track designation previously granted by FDA; FDA decision on approval expected 2025*

*If approved by FDA, TNX-102 SL would be the first member of a new class of analgesic drugs for fibromyalgia and the first new drug for treating fibromyalgia in more than 15 years*

CHATHAM, N.J., December 3, 2024 (GLOBE NEWSWIRE) – 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 expansion of its leadership team to support the launch of TNX-102 SL for the management of fibromyalgia. Bradley Raudabaugh, MBA, has been appointed Vice President, Marketing, and Errol Gould, Ph.D., has been appointed Vice President, Medical Affairs.

"We have further strengthened our leadership team with these two strategic hires as we continue to develop our commercial strategies and enhance the potential of our pipeline products. We look forward to leveraging their leadership capabilities and commercial experience as Tonix prepares for the launch of TNX-102 SL for the management of fibromyalgia," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Bradley's experience in spearheading successful product launches and his deep commercial insights provide us a crucial asset as we prepare to receive a decision from the U.S. Food and Drug Administration (FDA) for our TNX-102 SL NDA in 2025. Similarly, we believe Errol's experience from working with Tonix since March 2024 as a medical affairs consultant and his vast and well-rounded experience in the development of products in a variety of therapeutic areas will help us continue to build our reputation within the medical community."

Mr. Raudabaugh offers significant leadership experience in building and launching major brands. Most recently, he was the Vice President of Product Strategy at Axsome Therapeutics, where he led the strategic go-to-market planning across five products/indications in psychiatry and neurology. Earlier at Axsome, he led their first commercial launch with Auvelity for the treatment of major depressive disorder, and the integration of Sunosi upon acquisition for the treatment of excessive daytime sleepiness in patients with narcolepsy and sleep apnea. Prior to Axsome, Bradley has held roles of increasing responsibility across marketing, sales, and market access at Insmed, Amgen, Teva, and AstraZeneca. Mr. Raudabaugh holds a Master of Business Administration from the Olin Business School at Washington University in St. Louis and a Bachelor of Arts from Louisiana State University.

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"This is an exciting time to be joining Tonix as it prepares to receive an FDA decision on its NDA for TNX-102 SL for the management of fibromyalgia," said Mr. Raudabaugh. "I am ecstatic to work with the Tonix team. We have an opportunity to bring to patients and clinicians the first newly approved drug for fibromyalgia in more than 15 years."

Dr. Gould has over 25 years of experience in research and development and medical affairs across multiple therapeutic areas, including neurology, pain, and sleep, and worked with Tonix as a medical affairs consultant since March 2024. Since 2022, Dr. Gould has served as Head of Medical Affairs in a consultant role at Enalare Therapeutics, developing medical strategy, external messaging and publication plans for its novel respiratory stimulant candidate, ENA-001. Previously, he spent over eight years at Currax Pharmaceuticals, where he ultimately served as Head of Medical and Scientific Affairs. In this role, he led clinical and non-clinical research, developed U.S. and global medical affairs strategies and oversaw medical information for all marketed products. Earlier in his career, Dr. Gould had various medical affairs roles at Synchrony Healthcare Communications, Nuvo Research and Endo Pharmaceuticals. Dr. Gould began his career at GlaxoSmithKline as the Assistant Director in the Metabolism Therapeutic Area and later served on secondment as an Associate Product Manager for the Diabetes Franchise. Dr. Gould holds a Ph.D. in pharmacology from West Virginia University and a Bachelor of Science in biochemistry from the University of Massachusetts-Amherst. He also served as a Research Associate at Hahnemann University and as a Post-Doctoral Fellow/Research Associate at the University of Virginia.

"I look forward to partnering with the Tonix team and building upon the Company's successes to support TNX-102 SL as well as provide medical and strategic insight across the entire Tonix portfolio," said Dr. Gould.

**Tonix Pharmaceuticals Holding Corp.***

Tonix is a fully-integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to advance TNX-102 SL, a product candidate for the management of fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. We expect an FDA decision on the acceptance of the NDA for review and a PDUFA date in December 2024 and if accepted, a decision on NDA approval in August 2025 for standard review. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation and its development is supported by a grant from the U.S. National Institute of Drug Abuse and Addiction. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified 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, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. 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; their efficacy and safety have not been established 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 atwww.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, 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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**Indication and Usage**

Zembrace® SymTouch® (sumatriptan succinate) injection (Zembrace) and Tosymra® (sumatriptan) nasal spray are prescription medicines used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine. Zembrace and Tosymra are not used to prevent migraines. It is not known if Zembrace or Tosymra are safe and effective in children under 18 years of age.

**Important Safety Information**

**Zembrace and Tosymra can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:**

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Zembrace and Tosymra are not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace or Tosymra if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider for a list of these medicines if you are not sure.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the components of Zembrace or Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace and Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace and Tosymra may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- serotonin syndrome, a rare but serious problem that can happen in people using Zembrace or Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

**The most common side effects of Zembrace and Tosymra include:** pain and redness at injection site (Zembrance only); tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired; application site (nasal) reactions (Tosymra only) and throat irritation (Tosymra only).

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace and Tosymra. For more information, ask your provider.

This is the most important information to know about Zembrace and Tosymra but is not comprehensive. For more information, talk to your provider and read the **Patient Information** and **Instructions for Use**. You can also visit https://www.tonixpharma.com or call 1-888-869-7633.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.