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 20, 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 20, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it selected two contract manufacturing organizations, one of which is Almac Pharma Services, as dual supply sources for the potential launch and commercialization of the Company's Tonmya™ (cyclobenzaprine HCl sublingual tablets) product candidate in the U.S. 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 20, 2024, the Company announced that it selected two contract manufacturing organizations, one of which is Almac Pharma Services, as dual supply sources for the potential launch and commercialization of Tonmya™ in the U.S.

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 20, 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 20, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Selection of Two Contract Manufacturing Organizations for the Launch and Commercial Manufacture of Tonmya™ for the Management of Fibromyalgia

Tonmya™ is a potential new first-line, centrally acting non-opioid analgesic for the management of fibromyalgia, supported by positive results from two Phase 3 studies

New Drug Application (NDA) submission to the FDA planned for second half of 2024

CHATHAM, N.J., March 20, 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 it has selected two contract manufacturing organizations (CMOs), one of which is Almac Pharma Services, a member of the privately owned- Almac Group, as dual supply sources for the potential launch and commercialization of Tonmya™ (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablets) in the U.S.

"Dual sourcing is a critical element for the successful commercial launch and supply chain management of a product," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We are excited to advance our first internally developed program toward NDA submission and to work with two well-established CMOs for commercial supply and potential launch of Tonmya."

"Having supported the development and clinical trial supply of this drug, we're thrilled to be continuing our partnership with Tonix to support the commercial launch and ongoing supply of this important new non-opioid analgesic to patients with fibromyalgia, a chronic debilitating disease." said Mark English, VP Operations, Almac Pharma Services.

Tonmya is a centrally acting, non-opioid medication. As previously announced, Tonix's second positive Phase 3 study, RESILIENT, 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 (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. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies, and no new safety signals were observed.

Tonix plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration in the second half of 2024 for Tonmya for the management of fibromyalgia.

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

TNX-102 SL is a tablet containing 2.8 mg cyclobenzaprine HCl that will be administered sublingually once daily at bedtime for the first 2 weeks, titrating subsequently to 2 tablets (5.6 mg total per day) at bedtime, as tolerated, for chronic, long-term use. The sublingual tablet is formulated using a patented Protectic™ eutectic formulation including a basifying agent for transmucosal absorption with rapid systemic exposure pharmacokinetic properties suitable for bedtime administration. The eutectic properties enhance the stability with a predicted shelf life of greater than 48 months, at room temperature conditions. The planned commercial distribution will be a 14, 60 and 90 count tablet bottles allowing for titration, flexible and three-month chronic supply. Tonmya is a centrally acting, non-opioid, non-addictive, bedtime medication. 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. 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 (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

About Almac Pharma Services

Tailormade pharmaceutical development and commercial solutions

With over 50 years' experience, Almac Pharma Services is a world leading outsourcing partner to the global pharmaceutical and biotechnology industry.

Employing over 1,600 highly skilled individuals across 4 locations in Europe and the US, the company provides tailored, quality-led and timely solutions from early and late phase pharmaceutical development, clinical and commercial drug product manufacture, product launch through to commercial packaging and global distribution.

On March 6, 2024, the company announced the completion of a custom-built, high-volume facility that significantly increases commercial manufacturing and packaging of sachet drug product presentations forming part of the Group's ongoing global expansion investment now totaling over £400 million.

To keep up to date with latest news, follow us on LinkedIn or visit our website.

About Almac Group

The Almac Group is an established contract development and manufacturing organisation providing an extensive range of integrated services across the drug development lifecycle to the pharmaceutical and biotech sectors globally. Its innovative services range from R&D, biomarker discovery development and commercialisation, API manufacture, analytical services, formulation development, clinical trial supply, IRT (IVRS/IWRS) through to commercial-scale manufacture.

The international company is a privately owned organisation which has grown organically, now employing 7,200 highly skilled personnel across 18 facilities including Europe, the USA and Asia.

To keep up to date with latest news, follow us on X and LinkedIn or visit almacgroup.com.

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.

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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