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): February 27, 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 February 27, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced positive results from its clinical pharmacokinetic ("PK") bridging study of its Tonmya™ (also known as TNX-102 SL, cyclobenzaprine sublingual tablets) product candidate in healthy adult male and female ethnic Japanese and Chinese volunteers.

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 February 27, 2024, the Company announced positive results from its clinical PK bridging study of Tonmya in healthy adult male and female volunteers of documented Japanese and Chinese ancestry. The study characterized the PK profile and dose proportionality of Tonmya following administration in 10 healthy volunteers, and compared these findings to an existing PK dataset conducted under similar conditions in Caucasian volunteers. Results indicate that key PK parameters of cyclobenzaprine for Japanese, Chinese and Caucasian groups were similar, with geometric mean ratios falling within the 90% confidence interval, and that Tonmya was generally safe and well tolerated at doses up to 5.6 mg as single sublingual administrations. The Company expects these data to fulfill the requirements for a bridging study, and to support regulatory filings for clinical studies in Japan and China, where cyclobenzaprine is a new chemical entity. The Company intends to meet with the Pharmaceuticals and Medical Devices Agency and National Medical Products Administration to further the development of Tonmya in Japan and China, respectively.

The incidence of adverse events ("AEs") and investigational product-related AEs was low. No volunteers discontinued due to an AE and no clinically significant abnormal findings in laboratory parameters, electrocardiograms, or other safety assessments were noted during the study. No severe AEs and no deaths were reported during the study. The Company believes it can proceed with submitting an Investigational New Drug applications in Japan and China and begin clinical development of Tonmya to support a registration-enabling Phase 3 study in Asia.

The study was a randomized, single-dose, open-label, 2-way, crossover study design in ethnic Japanese (N=10) and Chinese (N=10) healthy male and female

volunteers. The primary objective of the study was to characterize the PK profile and dose proportionality of Tonmya following administration of 2.8 mg and 5.6 mg (one and two 2.8 mg tablets) under fasting conditions in the volunteers, and to retrospectively compare these PK data with existing data from a prior Phase 1 study in Caucasian volunteers dosed under the same conditions. Safety and tolerability were also assessed. A 2.8 mg or 5.6 mg tablet (2 X 2.8 mg) of Tonmya was administered sublingually in the morning under fasted conditions. As the similarity in PK profile between Japanese and Chinese volunteers was confirmed, the PK data from the two ethnic groups were pooled (n=20) for the comparison between Asian and Caucasian volunteers. The primary PK endpoints were the total amount of cyclobenzaprine and metabolite norcyclobenzaprine in the blood (expressed as the area under the curve (AUC_{0-T})) and maximum concentration (expressed as C_{max}).

The Company holds issued patents for market exclusivity rights of Tonmya expected to provide market exclusivity into 2034 in Japan, China, Hong Kong and Taiwan.

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 February 27, 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: February 27, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Positive Results from Clinical Pharmacokinetic Bridging Study of Tonmya™ to Support Development and Partnering in Japan and China

Tonix plans to File a Clinical Trial Notification (CTN) in Japan and Investigational New Drug (IND) application in China to support a registration-enabling Asian Phase 3 study without dosage adjustment based on U.S. registrational Phase 3 data

Tonmya's market exclusivity is supported by issued patents in Japan, China, Hong Kong and Taiwan; cyclobenzaprine is a new chemical entity in Japan and China

New Drug Application (NDA) submission to the U.S. FDA for the approval of Tonmya for the management of fibromyalgia planned for second half of 2024

CHATHAM, N.J., February 27, 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, announced positive results from its clinical pharmacokinetic (PK) bridging study of Tonmya™ (also known as TNX-102 SL, cyclobenzaprine HCl sublingual tablets) in healthy adult male and female ethnic Japanese and Chinese volunteers. Results indicate that key pharmacokinetic parameters of cyclobenzaprine are comparable in ethnic Japanese and Chinese volunteers to Caucasian volunteers from a prior PK study. Tonmya was generally well tolerated in the ethnic Japanese and Chinese healthy volunteers. The company expects these data to fulfill the requirement for a bridging study, and to support regulatory filings for clinical studies in Japan and China where cyclobenzaprine is a new chemical entity (NCE). Tonix holds issued patents for market exclusivity rights of Tonmya in Japan, China, Hong Kong and Taiwan.

This study characterized the PK profile and dose proportionality of Tonmya following administration in 20 healthy volunteers of documented Japanese or Chinese ancestry, and compared these findings to an existing PK dataset conducted under similar conditions in Caucasian volunteers.

"This bridging study is an important first step as we begin evaluating the potential for approval and marketing Tonmya in Japan and China. The results show a similar pharmacokinetic profile in ethnic Japanese and Chinese volunteers with a Caucasian comparator group," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "As a result, we believe that these data, with supporting results recently reported from the positive Phase 3 RESILIENT study, are the only clinical data needed to support regulatory filings in Japan and China."

Dr. Lederman continued, "With patents issued in Japan, China, Hong Kong and Taiwan expected to provide market exclusivity into 2034, we believe that Tonmya would be a welcome addition to the therapeutic options for fibromyalgia patients in East Asia and an attractive asset for the right development and commercialization partners in these markets. Cyclobenzaprine is an NCE in both of these countries. We plan to meet with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and China's National Medical Products Administration (NMPA) to seek agreement on the development of Tonmya in Japan and China, respectively."

About the Asia Bridging Study

The study was a randomized, single-dose, open-label, 2-way, crossover study design in ethnic Japanese (N=10) and Chinese (N=10) healthy male and female volunteers. The primary objective of the study was to characterize the PK profile and dose proportionality of Tonmya following administration of 2.8 mg and 5.6 mg (one and two 2.8 mg tablets) under fasting conditions in Japanese and Chinese volunteers, and to retrospectively compare these PK data with existing PK data of both cyclobenzaprine and norcyclobenzaprine from a prior Phase 1 study in Caucasian volunteers dosed under the same conditions. Safety and tolerability were also assessed. A 2.8 mg or 5.6 mg dose (2 X 2.8 mg tablet) of Tonmya was administered sublingually in the morning under fasted conditions. Blood samples were collected pre-dose and up to 15 days post-dose for analyte measurements, with a 28-day washout between periods. The primary PK endpoints were the total amount of cyclobenzaprine and metabolite norcyclobenzaprine in the blood (expressed as the area under the curve (AUC_{0-T})) and maximum concentration (expressed as C_{max}).

Study Results

Pharmacokinetics

Ethnic Japanese and Chinese volunteers were considered comparable on PK parameters for cyclobenzaprine following a 2.8 mg and 5.6 mg dose of Tonmya, and dose proportionality was demonstrated in both samples. Given that the similarity in PK profile between Japanese and Chinese volunteers was confirmed, the PK data from the two ethnic groups were pooled for the comparison between Asian (n=20) and Caucasian (n=16) volunteers. The PK parameters of cyclobenzaprine for Japanese, Chinese, and Caucasian groups were similar, with geometric mean ratios falling within the 90% confidence interval.

Safety

- Tonmya was shown to be safe and well-tolerated at doses up to 5.6 mg as single sublingual administrations in healthy adult Japanese and Chinese volunteers.
- The incidence of adverse events (AEs) and investigational product-related AEs was low. No volunteer discontinued due to an AE.
- No clinically significant abnormal findings in laboratory parameters, ECGs, or other safety assessments were noted during the study. No severe AEs and no deaths were reported during the study.

Issued Patents in Japan, China, Hong Kong and Taiwan

EUTECTIC FORMULATIONS	**Country**	**Patent Number**	**Expected Expiry**
	China	ZL 201480024011.1	03/14/2034
	China	ZL201910263541.6	03/14/2034
	Hong Kong	HK1218727	03/14/2034
	Japan	6310542	03/14/2034
	Taiwan R.O.C.	I661825	03/14/2034

TRANSMUCOSAL ABSORPTION	Japan	6259452	06/14/2033
	Taiwan R.O.C.	I590820	06/14/2033
	Taiwan R.O.C.	I683660	06/14/2033
	Taiwan R.O.C.	I642429	06/14/2033
	Hong Kong	1209361	06/14/2033

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.

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

*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.

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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