

**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 5, 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 March 5, 2024, Tonix Pharmaceuticals Holding Corp. (the “Company”) announced the results of modeling key human pharmacokinetic (“PK”) properties for its TNX-1500 (Fc-modified humanized anti-CD40L monoclonal antibody, or mAb) product candidate from animal studies.

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 5, 2024, the Company announced the results of modeling key human PK properties for TNX-1500 from animal studies. Modeling studies from animal PK data predict a half-life of approximately three weeks for TNX-1500 in humans, which supports monthly dosing. This PK analysis, together with TNX-1500’s activity and tolerability in animals, suggests that the protein engineering of TNX-1500’s Fc region has achieved its design goals. The company expects the results of the Phase 1 PK and pharmacodynamic trial in the third quarter of 2024.

The PK study was conducted in six healthy cynomolgus monkeys at 30, 100 and 300 mg/kg and revealed linear PK across those doses, consistent with an antibody with no target mediated drug disposition. The half-life of TNX-1500 in cynomolgus monkeys is approximately 14 days. Human half-life prediction for TNX-1500 was based on allometric scaling for mAbs with linear PK. Clearance in cynomolgus animals was 6.24 mL/day (26.6% C.V.) and the predicted clearance in humans was 141 mL/day (C.V. 22.9%). The predicted human half-life for TNX 1500 is 23.8 days (range of 18.3 to 27.6 days) which supports monthly dosing.

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	Description.
	No.	
	99.01	Press Release, dated March 5, 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 5, 2024

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

Tonix Pharmaceuticals Announces Translation of Preclinical Pharmacokinetic Parameters of TNX-1500 (Fc-modified humanized anti-CD40L mAb) Supports Monthly *i.v.* Dosing in Humans

TNX-1500, a third generation anti-CD40L mAb, was Fc-modified to preserve the activity and bioavailability of first generation mAbs while addressing their thrombosis risk

Sanofi projects its Fc-modified humanized anti-CD40L mAb frexalimab will exceed €5B per year in peak sales¹ based on Phase 2 multiple sclerosis data recently published in the New England Journal of Medicine²

Topline results of TNX-1500 Phase 1 trial expected in the third quarter of 2024; clinical stage completed last month

TNX-1500 has multiple potential indications including solid organ and bone marrow transplantation and the treatment of autoimmune diseases: potential 'pipeline in a product'

CHATHAM, N.J., March 5, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the results of modeling key human pharmacokinetic (PK) properties for TNX-1500 (Fc-modified humanized anti-CD40L monoclonal antibody, or mAb)* from animal studies. TNX-1500 is in development for the prevention of rejection in solid organ and bone marrow transplantation and for the treatment of autoimmune disorders.

“For more than 30 years, anti-CD40L therapy has shown promise in transplantation and the treatment of autoimmunity, but first-generation humanized mAbs were associated with an increased risk of thrombosis and second-generation agents had poor PK properties or reduced activity,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Preclinical studies in non-human primates have shown that TNX-1500 maintains the activity of first generation mAbs, with reduced risk of thrombotic complications.³⁻⁵ Today we are announcing that modeling studies from animal PK data³, predict that a half-life of approximately three weeks for TNX-1500 in humans^{6,7}, which supports monthly dosing. This PK analysis together with TNX-1500’s activity and tolerability in animals, suggests that the protein engineering of TNX-1500’s Fc region has achieved its design goals.”

Dr. Lederman continued, “Recently, positive clinical data have been reported by Sanofi, with its Fc-modified humanized anti-CD40L mAb frexalimab in treating relapsing multiple sclerosis with monthly *i.v.* or biweekly *s.c.* dosing regimens.² Based on its results in multiple sclerosis, Sanofi projects that frexalimab will exceed €5B per year in peak sales¹. TNX-1500 was designed to reduce binding to the Fc-receptor for IgG type 2a, or FcγR2a, which has been shown to play a role in the thrombosis associated with first-generation anti-CD40L mAbs, similar to frexalimab. In addition, Eledon Pharmaceuticals is in Phase 2 development for the prevention of rejection of kidney transplants with tegoprubart, a non-covalent dimer antibody with no heavy-light or heavy-heavy interchain disulfide bridges for the prevention of rejection of kidney transplants.”⁸

“Anti-CD40L therapy has multiple possible indications in addition to solid organ and bone marrow transplantation, including autoimmune diseases,” Dr. Lederman stated, “We look forward to the results of our Phase 1 PK and pharmacodynamic trial in the third quarter of 2024 and to advancing TNX-1500 as a promising candidate for prevention of organ and bone marrow transplant rejection and for treating autoimmune conditions.”

About the Translation of Human Pharmacokinetic Parameters from Animal Data

Results of a single dose PK study in animals were analyzed to predict human PK parameters. The PK study was conducted in six healthy cynomolgus monkeys at 30, 100 and 300 mg/kg and revealed linear PK across those doses, consistent with an antibody with no target mediated drug disposition.^{6,7} The half-life in cynomolgus monkeys is approximately 14 days. Human half-life prediction for TNX-1500 was based on allometric scaling for mAbs with linear PK.⁶ Clearance in cynomolgus animals was 6.24 ml/day (26.6% C.V.) and the predicted clearance in humans was 141 mL/day (C.V. 22.9%).^{6,7} The predicted human half-life for TNX 1500 is 23.8 days (range of 18.3 to 27.6 days) which supports monthly dosing.^{6,7}

About TNX-1500

TNX-1500 (Fc-modified humanized anti-CD40L mAb) is a humanized monoclonal antibody that binds and blocks the CD40-ligand (CD40L), also known as CD154. TNX-1500 is being developed for the prevention of allograft and xenograft rejection, for the prevention of graft-versus-host disease (GvHD) after hematopoietic stem cell transplantation (HCT) and for the treatment of autoimmune diseases. A first-in-human Phase 1 trial of TNX-1500 has completed the clinical phase. Topline results are expected in the third quarter of 2024. The primary objective of the Phase 1 trial is to assess the safety, tolerability, PK, and pharmacodynamics of intravenous (*i.v.*) TNX-1500. Eligible participants enrolled in the Phase 1 trial were distributed across three dosing cohorts (3 mg/kg, 10 mg/kg, and 30 mg/kg, respectively) and evaluated regularly over a 120-day period after dosing. The Phase 1 trial is intended to support dosing in a planned Phase 2 trial in kidney transplant recipients. Two published articles in the *American Journal of Transplantation* demonstrate TNX-1500 prevents rejection, prolongs survival and preserves graft function as a single agent or in combination with other drugs in non-human primate renal and heart allografts.^{3,4}

About anti-CD40L Therapeutics in Development

No anti-CD40L mAb has been approved in any jurisdiction. In addition to TNX-1500, frexalimab and tegoprubart, tn03 fusion protein dazodalibep is being developed by Amgen (formerly Horizon Therapeutics Public Limited Company) for the treatment of Sjögren's Syndrome.^{9,10} Dapirolizumab pegol, an anti-CD40L pegylated Fab, is being developed by UCB for the treatment of systemic lupus erythematosus.¹¹

*TNX-1500 is an investigational new biologic and is not approved for any indication

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<https://doi.org/10.1016/j.ajt.2023.03.022>

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<https://doi.org/10.1016/j.ajt.2023.03.025>
 5. Anand, R.P., et al *Nature*. 622, 393–401 (2023).
<https://doi.org/10.1038/s41586-023-06594-4>
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 7. Tonix Pharmaceuticals – Data on File
 8. Eledon press release. November 2, 2023.
<https://ir.eledon.com/news-releases/news-release-details/eledon-reports-updated-data-ongoing-phase-1b-trial-evaluating>
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 9. BioSpace. September 12, 2022.
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 10. BioSpace. January 18, 2023.
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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 Tonmya¹, 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.

¹Tonmya™ 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.

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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