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): May 4, 2023

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 May 4, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") cleared an Investigational New Drug ("IND") application to support a Phase 1 clinical trial of the Company's TNX-1500 (anti-CD40L monoclonal antibody [mAb]) product candidate for the prevention of organ rejection in patients receiving a kidney transplant. 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 May 4, 2023, the Company announced that the FDA cleared an IND application to support a Phase 1 clinical trial of TNX-1500 for the prevention of organ rejection in patients receiving a kidney transplant. The Company expects to initiate enrollment in the Phase 1 study in the third quarter of 2023. The Company's primary focus of early development will be allotransplantation in which the donor organ comes from another human, with potential development of TNX-1500 for xenograft transplantation in which the donor organ comes from a genetically engineered pig, as well as additional indications. The IND application for TNX-1500 was supported by preclinical allotransplantation studies conducted at Massachusetts General Hospital ("MGH"), led by principal investigators Tatsuo Kawai, MD, Professor of Surgery, Harvard Medical School, and Richard Pierson, MD, Professor of Surgery at MGH and director of the Center for Transplantation Science.

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, dated May 4, 2023
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: May 4, 2023

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

Exhibit 99.01

Tonix Pharmaceuticals Announces IND Clearance for TNX-1500 (anti-CD40L mAb) for the Prevention of Organ Rejection in Patients Receiving a Kidney Transplant

Multiple Additional Indications Possible, Including Autoimmune Diseases: Pipeline within a Product

Published Non-Human Primate Studies Show TNX-1500 Prolongs Renal and Heart Allograft Survival

Phase 1 Clinical Trial of TNX-1500 Expected to Start Third Quarter 2023

CHATHAM, N.J., May 4, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application to support a Phase 1 clinical trial with TNX-1500 (anti-CD40L monoclonal antibody [mAb]). The first indication Tonix is seeking for TNX-1500 is the prevention of organ rejection in patients receiving a kidney transplant. The Company expects to initiate enrollment in the Phase 1 study in the third quarter of 2023.

The IND application for TNX-1500 was supported by preclinical allotransplantation studies conducted at the Massachusetts General Hospital (MGH), led by principal investigators Tatsuo Kawai, MD, PhD, A. Benedict Cosimi Chair in Transplant Surgery, MGH and Professor of Surgery, Harvard Medical School (HMS), and Richard N. Pierson III, M.D., scientific director of the Center for Transplantation Sciences in the Department of Surgery at MGH and Professor of Surgery at HMS.

“This is an important milestone as we advance TNX-1500 into clinical development,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Despite advancements in the field of solid organ transplantation, there remains a significant need for new treatments with improved activity and tolerability to prevent organ transplant rejection. Our primary focus of early development will be allotransplantation in which the donor organ comes from another human. However, in the longer term we hope to develop TNX-1500 for xenograft transplantation in which the donor organ comes from a genetically engineered pig.”

Dr. Lederman continued, “We view TNX-1500 as a pipeline within a product, because of its potential to treat a number of autoimmune diseases. Anti-CD40L mAbs have demonstrated activity and tolerability in autoimmune diseases like systemic lupus erythematosus and Sjögren’s Syndrome. An anti-CD40L mAb is also in development for multiple sclerosis. CD40L is a member of the TNFα super gene family. Other TNFα super gene members have been the targets of successful mAb therapeutics: TNFα and RANKL for autoimmune diseases and osteoporosis, respectively. Still other TNFα super gene family members are targeted by mAbs in development including TNF-like ligand 1A (TL1A) and CD30L for ulcerative colitis and Ox40L for atopic dermatitis.”

TNX-1500 is a third generation anti-CD40L mAb that has been designed by protein engineering to decrease FcγRIIA binding and to therefore reduce the potential for thrombosis. Preclinical studies in non-human primates demonstrated that TNX-1500 showed activity in preventing allograft organ rejection and was well tolerated[1,2].

About TNX-1500

TNX-1500 (Fc-modified anti-CD40L mAb) is a humanized monoclonal antibody that interacts with the CD40-ligand (CD40L), which is also known as CD154. TNX-1500 is being developed for the prevention of allograft and xenograft rejection, for the treatment of autoimmune diseases and for the prevention of graft-versus-host disease (GvHD) after hematopoietic stem cell transplantation (HCT). A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Two articles have recently published in the *American Journal of Transplantation* that demonstrate TNX-1500 prolongs non-human primate renal and heart allograft survival[1,2].

[1]Lassiter, G., et al. (2023). TNX-1500, a crystallizable fragment–modified anti-CD154 antibody, prolongs non-human primate renal allograft survival.*American Journal of Transplantation*. April 3, 2023. https://doi.org/10.1016/j.ajt.2023.03.022

[2]Miura, S., et al. (2023) TNX-1500, a crystallizable fragment–modified anti-CD154 antibody, prolongs non-human primate cardiac allograft survival.*American Journal of Transplantation*. April 6, 2023. https://doi.org/10.1016/j.ajt.2023.03.025

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix’s portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’s CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the third quarter of 2023. Tonix’s rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix’s immunology portfolio includes 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 and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Tonix’s infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the second half of 2023. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

**All of Tonix's product candidates are investigational new drugs (IND) or biologics and have not been approved for any indication. TNX-801, TNX-2900, TNX-3900 and TNX-4000 are in pre-IND stage of development and have not been approved for any indication.*

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; delays and uncertainties caused by the global COVID-19 pandemic; 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Maddie Stabinski (media)
Russo Partners
Madeline.Stabinski@russopartnersllc.com
(212) 845-4273

Peter Vozzo (investors)
ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505