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): April 17, 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 April 17, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the publication of two articles in the *American Journal of Transplantation* demonstrating that the Company's TNX-1500 (Fc-modified anti-CD40L humanized monoclonal antibody [mAb]) product candidate in development for the prevention of organ transplant rejection showed activity in preventing organ rejection and was well tolerated in non-human primates. (the "Articles"). 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 April 17, 2023, the Company announced the publication of the Articles by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital in collaboration with the Company. The data involve studies of TNX-1500, the molecular target of which is CD40-ligand (CD40L), also known as CD154, T-BAM or 5c8 antigen. The Articles include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates, as well as having a favorable safety profile, as neither non-human primate nor human platelet activation were observed *in-vitro* when exposed to TNX-1500-sCD40L immune complexes. The therapeutic effects of TNX-1500 to consistently inhibit rejection of mismatched kidney allografts were not associated with infectious or thromboembolic complications, suggesting that clinical studies are warranted to evaluate TNX-1500 for transplant indications. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate models of cardiac and kidney allograft model without clinical thrombosis. The studies found that TNX-1500 retains activity to prevent rejection and preserve graft function. The Company expects to start a first-in-human Phase 1 study in the second quarter of 2023 of TNX-1500 for prophylaxis of organ rejection in adult patients receiving a kidney transplant.

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 April 17, 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: April 17, 2023

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

Exhibit 99-01

Tonix Pharmaceuticals Announces Two Publications of Data in *American Journal of Transplantation* Showing TNX-1500 (anti-CD40L mAb) Prolongs Nonhuman Primate Renal and Heart Allograft Survival

Research Directed by Faculty of the Center for Transplantation Sciences, Massachusetts General Hospital

CHATHAM, N.J., April 17, 2023 (GLOBE NEWSWIRE) – T onix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced the on-line publication of two papers[1,2] in the *American Journal of Transplantation* by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital (MGH) in collaboration with Tonix Pharmaceuticals. The data involve studies of Tonix's TNX-1500 (Fc-modified anti-CD40L humanized monoclonal antibody [mAb]) product candidate in development for the prevention of organ transplant rejection. The molecular target of TNX-1500 is CD40-ligand (CD40L), which is also known as CD154, T-BAM or 5c8 antigen. The publications include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate models of cardiac and kidney allograft model without clinical thrombosis.

"There remains a significant need for new treatments with improved activity and tolerability to prevent organ transplant rejection," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "To date, there has not been a humanized anti-CD40L antibody that can effectively prevent transplant rejections with an acceptable level of tolerability. TNX-1500 is a third generation anti-CD40L mAb that has been designed by protein engineering to decrease FcγRII binding and to reduce the potential for thrombosis. The animal studies found that TNX-1500 retains activity to prevent rejection and preserve graft function. Tonix expects to start a first-in-human Phase 1 study in the second quarter of 2023 of TNX-1500 for prophylaxis of organ rejection in adult patients receiving a kidney transplant."

Tatsuo Kawai, M.D., Ph.D., A. Benedict Cosimi Chair in Transplant Surgery, MGH and Professor of Surgery, Harvard Medical School (HMS) and senior author of the kidney transplant publication, said, "The blockade of the CD40L-CD40 pathway with anti-CD40L mAbs has been the most promising immunomodulatory approach to prevent allograft rejection. However, long-term graft and patient survival following transplantation of kidneys and other solid organs are constrained by side effects of the existing medications. Our data demonstrate a favorable safety profile associated with TNX-1500, since neither non-human primate nor human platelet activation were observed *in-vitro* when exposed to TNX-1500-sCD40L immune complexes. The therapeutic effects of TNX-1500 to consistently inhibit rejection of mismatched kidney allografts were not associated with infectious or thromboembolic complications, suggesting that clinical studies are warranted to evaluate TNX-1500 for transplant indications."

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 and senior author of the heart transplant paper said, "Anti-CD40L therapy has a unique activity in controlling the immune response to organ transplants. There remains a significant need for new treatments with improved activity and tolerability to prevent or treat organ transplant rejection. Anti-CD40L has shown great promise to facilitate transplant tolerance in multiple preclinical transplant models. A safe, effective anti-CD40L also has potential to enable use of genetically modified or humanized pig organs to treat humans with advanced organ failure or diabetes, an emerging field known as xenotransplantation."

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), a small molecule 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 of tianeptine 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 second 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 second 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, a class of broad-spectrum small molecule oral antivirals.

*All of Tonix's product candidates are investigational new drugs or biologics and none has been approved for any indication.

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

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.

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