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): October 18, 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 October 18, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that a study published in the Journal*Nature* by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital ("MGH") in collaboration with eGenesis, Inc., a biotechnology company, utilized the Company's TNX-1500 (Fc-modified dimeric anti-CD40L monoclonal antibody) product candidate in development for the prevention of human kidney organ transplant rejection as part of an immune modulating regimen to prevent organ transplant rejection. 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 October 18, 2023, the Company announced that a study published in the Journal*Nature* by faculty at MGH in collaboration with eGenesis, Inc. utilized TNX-1500 as part of an immune modulating regimen to prevent organ transplant rejection. The research was conducted at MGH and led by Tatsuo Kawai, MD, Professor of Surgery, Harvard Medical School and the Center for Transplantation Science. Results of the study support the growing evidence that the protein engineering behind the invention of TNX-1500 resulted in a dimeric antibody that retains activity to prevent rejection and preserve graft function.

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 October 18, 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: October 18, 2023

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Publication of Data in the Journal *Nature* Involving TNX-1500 (Fc-modified dimeric anti-CD40L mAb) for the Prevention of Rejection in Kidney Xenotransplantation in Animal Models

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

TNX-1500 is Enrolling in a Phase 1 Clinical Trial

Tonix is Developing TNX-1500 for Prevention of Kidney Allograft Rejection as the First Indication: Multiple Other Indications, including Autoimmune Disorders, are Planned

CHATHAM, N.J., October 18, 2023 (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 that a study published in the Journal *Nature*[1] by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital (MGH) in collaboration with biotechnology company, eGenesis, utilized TNX-1500 (Fc-modified dimeric anti-CD40L monoclonal antibody [mAb]) as part of the immune modulating regimen to prevent organ transplant rejection. Tonix's TNX-1500 is in development for the prevention of human kidney organ transplant rejection. The molecular target of TNX-1500 is CD40-ligand (CD40L), which is also known as CD154.

TNX-1500 was invented and developed in-house by Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals, and colleagues. TNX-1500 is a third generation anti-CD40L monoclonal antibody that has been designed by protein engineering to decrease FcγRII binding and to reduce the potential for thrombosis. Preclinical studies in non-human primates demonstrated that TNX-1500 showed activity in preventing allograft and xenograft organ rejection and was well tolerated. The research in the *Nature* paper was conducted at MGH, led by principal investigator Tatsuo Kawai, M.D., Professor of Surgery, Harvard Medical School and the Center for Transplantation Science. A "News and Views" editorial[2] and a News[3] story appeared in the same issue of *Nature*.

The *Nature* article titled, "Design and testing of a humanized porcine donor for xenotransplantation" includes data that provide additional support for TNX-1500's activity in preventing pig xenograft organ rejection and for its tolerability in non-human primates. Because anti-CD40L treatment is widely recognized as critical to the success of xeno organ transplant, no animals were transplanted without anti-CD40L treatment. Four of the transplanted animals received prophylactic treatment with TNX-1500. The other animals were treated with a primate-adapted version of mAb 5c8, which is an earlier antibody that was also discovered by Dr. Lederman, when he was an assistant professor at Columbia University.[4] The primate-adapted 5c8 anti-CD40L mAb[5] has been provided to qualified researchers at a nominal charge for more than 20 years in an National Institute of Health (NIH)-funded program called the "Non-human Primate Reagent Resource Center" (NHPRRC).

"The animal study described in the *Nature* publication[1] supports the growing evidence that the protein engineering behind the invention of TNX-1500 resulted in a dimeric antibody that retains activity to prevent rejection and preserve graft function. These and other data[6,7] confirm the rationale for us to pursue development of TNX-1500 to prevent rejection in human transplantation," said Dr. Lederman. "We are currently enrolling in a Phase 1 trial with TNX-1500 in healthy volunteers to support the development of TNX-1500 for the prevention of allograft rejection. There remains a significant need for new treatments with improved activity and tolerability to prevent organ transplant rejection. We believe TNX-1500 has the potential for treating and preventing organ transplant rejection."

Dr. Lederman added, "Our primary focus of early development will be allotransplantation in which the donor organ comes from a human volunteer or cadaver. However, long term we hope to develop TNX-1500 for xenograft transplantation in which the donor organ comes from genetically engineered pigs. Several lines of research indicate that anti-CD40L is required for long term xenograft acceptance. I believe it is unlikely for human xenotransplantation to proceed without CD40L blockade. In addition, anti-CD40L monoclonal antibodies have demonstrated efficacy in autoimmune diseases like systemic lupus erythematosus and Sjögren's Syndrome."

About TNX-1500

TNX-1500 (Fc-modified anti-CD40L mAb) is a humanized dimeric 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 including multiple sclerosis and for the prevention of graft-versus-host disease (GvHD) after hematopoietic stem cell transplantation (HCT). A Phase 1 study of TNX-1500 is currently enrolling. 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 disulfide-linked dimeric structure is similar to natural antibodies and in the case of anti-CD40L is believed to confer to TNX-1500 a higher avidity for cell-associated CD40L, relative to soluble CD40L. Two articles were recently published in the *American Journal of Transplantation* that demonstrate TNX-1500 prolongs nonhuman primate renal and heart allograft survival[6,7]. Other anti-CD40L mAbs are in development for treating systemic lupus erythematosus, Sjögren's syndrome and multiple sclerosis.[8-10] CD40-L is a member of the TNFα super gene family. Other members have been the targets of successful mAb: TNFα and RANKL for autoimmune diseases and osteoporosis, respectively. Other TNFα super gene family members are targeted by mAbs in development including, TNF-like ligand 1A (TL1A) and CD30L for ulcerative colitis.

1. Anand R.P., et al. *Nature.* 2023. 622, 393–401.
2. Mohiuddin M. *Nature*. News and Views. 2023. "Pig-to-primate organ transplants require genetic modifications of donor."
3. Kozlov M. Nature. New, 2023. "Monkey survives two years after gene-edited pig-kidney transplant."
4. Lederman S, et al. *J Exp Med.* 1992. 175(4):1091-101.
5. NHPRRC anti-CD154 clone 5C8H1D MassBiologics PR-1547
6. Lassiter G., et al. *Am. J. Transplant.* 2023. https://doi.org/10.1016/j.ajt.2023.03.022
7. Miura S., et al. *Am. J. Transplant*. 2023. https://doi.org/10.1016/j.ajt.2023.03.025
8. UCB Pipeline - https://www.ucb.com/our-science/pipeline
9. BioSpace. September 12, 2022 - https://www.biospace.com/article/releases/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-dazodalibep-for-the-treatment-of-sjoegren-s-syndrome-meets-primary-endpoint/
10. Business Wire. January 18, 2023 - https://www.businesswire.com/news/home/20230118005359/en/Horizon-Therapeutics-plc-Announces-Phase-2-Trial-Evaluating-Dazodalibep-for-the-Treatment-of-Sj%C3%B6gren%E2%80%99s-Syndrome-Meets-Primary-Endpoint-in-the-Second-Study-Population-Only-Phase-2-Trial-to-Meet-Primary-Endpoint-in-Both-Patient-Populations

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix's development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, having completed enrollment of a potentially confirmatory Phase 3 study in the third quarter of 2023, with topline data expected in late December 2023. TNX-

102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 proof-of-concept study has been completed, and topline results were reported in the third quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily oral formulation being developed as a treatment for major depressive disorder (MDD), that completed enrollment in a Phase 2 in the third quarter of 2023, with topline results expected in early November of 2023. TNX-4300 (estianeptine) is a single isomer version of TNX-601, a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer's disease and Parkinson's disease. Relative to tianeptine, estianeptine lacks activity on the mu-opioid receptor while maintaining activity and the ability to activate PPAR-β/δ and neuroplasticity in tissue culture. TNX-1900 (intranasal potentiated oxytocin), is in development as a preventive treatment in chronic migraine, and enrollment has completed in a Phase 2 proof-of-concept study with topline data expected in early December 2023. TNX-1900 is also being studied in binge eating disorder, pediatric obesity and social anxiety disorder by academic collaborators under investigator-initiated INDs. 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 fourth quarter of 2023. Tonix's rare disease development 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 development 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 rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

This press release and further information about Tonix can be found atwww.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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