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): August 16, 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 August 16, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the initiation of a Phase 1, single ascending dose escalation study of TNX-1500 (Fc-modified humanized anti-CD40L monoclonal antibody or mAb) in healthy volunteers. 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, as amended (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, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On August 16, 2023, the Company announced the initiation of a Phase 1, single ascending dose escalation study of TNX-1500 (Fc-modified humanized anti-CD40L monoclonal antibody or mAb) in healthy volunteers. The primary objectives of the study are to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous (IV) TNX-1500.

TNX-1500 is in development for the prevention of kidney transplant rejection and other potential transplant and autoimmune disorder indications. Recent animal studies indicate that TNX-1500 prevents organ rejection and preserves graft function either as a single agent or in combination with other drugs. Eligible participants enrolled in the Phase 1 study will be evaluated regularly over a 120-day period after dosing. Target enrollment is 36 participants. Initiation of this first-in-human study is intended to support dosing in a planned Phase 2 trial in kidney transplant recipients. The Company believes TNX-1500 has the potential to prevent organ transplant rejection and improve long-term graft survival with reduced long-term toxicity burden compared to current immunosuppressive regimens. In addition, TNX-1500 has the potential to address multiple indications, including a number of autoimmune diseases.

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 and Section 21E of the

Exchange Act 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 August 16, 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: August 16, 2023

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

Exhibit 99.01

Tonix Pharmaceuticals Initiates Phase 1 Trial of TNX-1500 (Fc-modified humanized anti-CD40L mAb) in Healthy Volunteers

Single Ascending Dose Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of TNX-1500

Study Designed to Support Planned Phase 2 Trial in Prevention of Kidney Transplant Rejection

Multiple Possible Indications, Including Bone Marrow Transplantation and Autoimmune Diseases: Potential Pipeline in a Product

TNX-1500 is the First of Tonix's Internally-Developed Biologic Candidates to Reach the Clinic

CHATHAM, N.J., August 16, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the initiation of a Phase 1 single ascending dose escalation study of TNX-1500 (Fc-modified humanized anti-CD40L monoclonal antibody or mAb) in healthy volunteers. The primary objectives of the study are to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous (IV) TNX-1500.

TNX-1500 is in development for the prevention of kidney transplant rejection and other potential transplant and autoimmune disorder indications. Recent animal studies indicate that TNX-1500 prevents organ rejection and preserves graft function either as a single agent or in combination with other drugs.[1,2] Eligible participants enrolled in the Phase 1 study will be evaluated regularly over a 120-day period after dosing. Target enrollment is 36 participants. Initiation of this first-in-human study is intended to support dosing in a planned Phase 2 trial in kidney transplant recipients.

"Despite advancements in the field of solid organ transplantation, there remains a significant need for new treatments with improved activity and tolerability," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-1500 has demonstrated single agent activity for long-term organ acceptance and induction of tolerance in animals.[1,2] Potentially related to its activity, in preclinical studies, TNX-1500 preserves T regulatory cells, or Tregs, which are key to maintaining tolerance to grafts as well as to self-antigens. We believe TNX-1500 has the potential to prevent organ transplant rejection and improve long-term graft survival with reduced long-term toxicity burden compared to current immunosuppressive regimens. In addition, TNX-1500 has the potential to address multiple indications, including a number of autoimmune diseases. The range of potential indications suggests 'pipeline in a product' potential."

"We are excited to advance TNX-1500 into the clinic by initiating this Phase 1 trial," said Dr. Greg Sullivan, Chief Medical Officer of Tonix. "TNX-1500 is a third generation anti-CD40L mAb that has been designed by protein engineering to decrease FcγRIIA binding. Preclinical studies in non-human primates demonstrated that TNX-1500 is active in preventing allograft organ rejection and is well tolerated. Specifically, thrombotic complications associated with first generation anti-CD40L mAbs, were not observed, suggesting that the protein engineering underlying TNX-1500 has achieved its design goals."

Dr. Lederman continued, "Recently, positive clinical data with other CD40L blockers have been reported by Sanofi, with its Fc-modified humanized anti-CD40L mAb frexalimab in treating relapsing multiple sclerosis,[3] and from Horizon Therapeutics plc with its tn03 fusion protein dazodalibep in treating Sjögren's syndrome.[4,5] UCB is in Phase 3 development with its anti-CD40L pegylated Fab, dapirolizumab pegol, for the treatment of systemic lupus erythematosus.[6] Based on results from animals, we consider Fc-modified humanized TNX-1500 to be a potential best-in-class therapeutic in the CD40L blocker space."

CD40L is a member of the TNF-α superfamily, which includes TNF-α and RANKL. TNF-α is the target for several established drugs, including Humira® (adalimumab), Remicade® (infliximab), Enbrel® (etanercept), and Cimzia® (certolizumab). RANKL is targeted by Prolia® and Xgeva® (denosumab). Emerging TNF-α superfamily targets for therapeutics include TL1A, CD30L, Ox40L, and 41BBL. Merck acquired Prometheus Biosciences for its anti-TL1A and anti-CD30L programs.

Dr. Lederman concluded, "TNX-1500 is the first of Tonix's internally-developed biologic candidates to reach the clinic. Tonix owns worldwide rights to TNX-1500, which are unencumbered by royalties. Our ability to develop and advance protein therapeutics is facilitated by our Research and Development Center (RDC) in Frederick, Md. and our Advanced Development Center (ADC) in Dartmouth, Mass."

About TNX-1500

TNX-1500 (Fc-modified humanized 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 was 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
3. Sanofi press release May 31, 2023 "Press Release: Positive Phase 2 data of novel investigational anti-CD40L antibody frexalimab show significantly reduced disease activity in relapsing multiple sclerosis": https://www.sanofi.com/en/media-room/press-releases/2023/2023-05-31-05-00-00-2678991 (accessed August 11 2023)
4. Horizon press release September 12, 2022 "Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint" https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating (accessed August 11 2023)

5. Horizon Press Release January 18, 2023 “Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren’s Syndrome Meets Primary Endpoint in the Second Study Population; Only Phase 2 Trial to Meet Primary Endpoint in Both Patient Populations ”https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-0 (accessed August 11 2023)
6. https://www.ucb.com/our-science/pipeline (accessed August 11 2023)

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 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 the fourth quarter of 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 are expected 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 proof-of-concept study in the third quarter of 2023, with topline results expected in the fourth quarter of 2023. TNX-4300 (estianeptine) is a single isomer version of TNX-601, 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 μ-opioid receptor while maintaining activity in the rat Novel Object Recognition test *in vivo* and the ability to activate PPAR-β/δ and neuroplasticity in tissue culture. TNX-1900 (intranasal potentiated oxytocin), is in development for preventing headaches in chronic migraine, and has completed enrollment in a Phase 2 proof-of-concept study with topline data expected in the fourth quarter of 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 third 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.

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

Tonix Medicines has contracted to acquire the Zembrace SymTouch and Tosymra registered trademarks. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc.

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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