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): January 13, 2021

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: (212) 980-9155

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 Global 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.

Tonix Pharmaceuticals Holding Corp (the "Company") issued a press release announcing the publication of a patent application for TNX-1500 (monoclonal antibody aAnti-CD40-ligand) in development for the prevention and treatment of organ transplant rejection and treating autoimmune conditions. A copy of the press release is furnished as Exhibit 99.01 hereto 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 January 13, 2021, the Company closed its previously announced registered direct offering (the "Offering") of an aggregate of 50,000,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), at a price of $0.80 per share, for gross proceeds of $40,000,000, before deducting placement agent fees and other offering expenses.

On January 13, 2021, the Company issued a press release announcing the closing of the Offering. A copy of the press release is attached hereto as Exhibit 99.02 and is incorporated herein by reference.

On January 14, 2021, the Company announced the publication of a patent application for TNX-1500 in development for the preventing and treatment of organ transplant rejection and treating autoimmune conditions. The World Intellectual Property Organization published a patent application filed under the Patent Cooperation Treaty covering TNX-1500, a humanized monoclonal antibody (mAb) directed against CD40-ligand, which is also known as CD154, T-BAM, 5c8 antigen, TRAP and gp39. The patent application is titled "Anti-CD154 Antibodies and Uses Thereof" and published under International Publication No. WO 2021/001458 A1. If claims are granted, a patent issuing from a national stage of this application could potentially provide U.S. patent coverage for the TNX-1500 composition of matter through 2040 excluding possible patent term extensions or patent term adjustments. The Company is developing the manufacturing processes for TNX-1500 and expects Good Manufacturing Practice (GMP) TNX-1500 to be available in the third quarter of 2021.

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 consummation of the Offering, the Company's intellectual property and patent applications, 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 January 14, 2021
	99.02	Press release of the Company, dated January 13, 2021

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: January 14, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Publication of Patent Application for TNX-1500 (Monoclonal Antibody Anti-CD40-Ligand) in Development for Preventing and Treating Organ Transplant Rejection and Treating Autoimmune Conditions

GMP Production of TNX-1500 is Expected to be Available in the Third Quarter of 2021

CHATHAM, N.J., January 14, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the World Intellectual Property Organization has published a patent application filed under the Patent Cooperation Treaty covering TNX-1500, a humanized monoclonal antibody (mAb) directed against CD40-ligand, which is also known as CD154, T-BAM, 5c8 antigen, TRAP and gp39. The patent application is titled "Anti-CD154 Antibodies and Uses Thereof" and published under International Publication No. WO 2021/001458 A1. If claims are granted, a patent issuing from a national stage of this application could potentially provide U.S. patent coverage for the TNX-1500 composition of matter through 2040 excluding possible patent term extensions or patent term adjustments.

Tonix's President and Chief Executive Officer, Seth Lederman, M.D. said, "Nearly 30 years ago my laboratory at Columbia University generated the first anti-CD40-ligand mAb (5c8), discovered and characterized human CD40-ligand and elucidated the molecular basis of T cell helper function[1]. Collaborating with a team at Biogen Inc., we determined the crystal structure of CD40-ligand[2], developed a humanized version of our antibody (hu5c8, ruplizumab, or Antova®) and tested it in human trials for preventing organ transplant rejection and autoimmunity. Our studies and those of others generated a substantial body of evidence in humans and animals that indicates anti-CD40-ligand mAbs have the potential to be an important therapeutic option for preventing or treating transplant organ rejection and for treating autoimmune disorders."

Dr. Lederman continued, "Despite the recognized promise of anti-CD40-ligand mAb therapy, first generation anti-CD40-ligand mAbs were limited because their crystallizable fragment (Fc) domain interacted with a cell surface receptor called FcγRII, which resulted in an increased risk of thrombosis. Second generation anti-CD40-ligand mAbs had dramatically reduced binding to FcγRII, but had other issues, including decreased efficacy[3-5]. TNX-1500 is a third generation anti-CD40-ligand mAb that has been designed by protein engineering to decrease FcγRII binding and the potential for thrombosis, while retaining efficacy. We believe TNX-1500 has the potential for treating and preventing organ transplant rejection and treating autoimmunity."

TNX-1500 incorporates the antigen binding fragment (Fab) region of hu5c8, which has been extensively characterized including at the atomic level in complex with CD40-ligand[6]. The newly published patent application includes claims related to proprietary anti-human CD40-ligand mAbs that were engineered to have modified effector function, including TNX-1500, which have reduced potential for Fc binding to FcγRII. The patent application also claims uses of TNX-1500 for preventing and treating conditions, such as organ transplant rejection and autoimmune disorders.

Dr. Lederman added, "We believe the development risk of TNX-1500 is mitigated by previous clinical data and extensive preclinical science with ruplizumab. We are developing the manufacturing processes for TNX-1500 and expect Good Manufacturing Practice (GMP) TNX-1500 to be available in the third quarter of 2021. There remains a significant need for new treatments with improved activity and tolerability to prevent or treat organ transplant rejection and to treat autoimmune conditions, including systemic lupus erythematosus, rheumatoid arthritis and multiple sclerosis."

[1] Lederman, S. et al. *J. Exp. Med.* 175:1091-1101 (1992)

[2] Karpusas, M et al., *Structure* 3:1031-1039 (1995)

[3] Waters J, *Biocentury*; October 26, (2018)

[4] NCT02273960; *ClinicalTrials.gov*; "Study to Evaluate Safety and Efficacy in Adult Subjects With ITP (ITP)"; results posted April 1, 2019, updated July 29, 2019 and accessed Jan 11, 2021

[5] Ferrant JL et al., *International Immunol.* (11):1583 (2004)

[6] Karpusas M, *et al. Structure.* 9(4):321-9. (2001)

About CD40-Ligand

CD40-ligand is a protein expressed on the surface of activated T lymphocytes that mediates T cell helper function. CD40-ligand is also known as CD154, the T cell-B cell activating molecule (T-BAM), TRAP and gp39. CD154 is a member of the Tumor Necrosis Factor (TNF) Super Family. No mAb against CD154 has been approved for commercial use anywhere in the world. Other TNF Super Family members have been successfully targeted by antagonist mAbs. Approved mAbs against TNFα include: infliximab (Remicade®), adalimumab (Humira®), certolizumab pegol (Cimzia®), and golimumab (Simponi®) for the treatment of certain autoimmune conditions. Also, etanercept (Enbrel®) is a TNFα antagonist receptor fusion protein. An approved mAb against RANKL (CD254) is denosumab (Prolia® or Xgeva®) for the treatment of osteoporosis, treatment-induced bone loss, metastases to bone, and giant cell tumor of bone.

Remicade® and Simponi® are trademarks of Janssen; Humira® is a trademark of AbbVie Inc.; Cimzia® is a trademark of UCB S. A.; Enbrel®, Prolia® and Xgeva® are trademarks of Amgen Inc.

Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL*, is in mid-Phase 3 development for the management of fibromyalgia, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data for the Phase 3 RALLY study in the second quarter of 2021** and topline data in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800***, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801***, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

*TNX-102 SL is an investigational new drug and has not been approved for any indication.
** Pending submission and agreement from FDA on statistical analysis plan.

***TNX-1800 and TNX-801 are investigational new biologics and have not been approved for any indication.

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 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, 2019, as filed with the Securities and Exchange Commission (the “SEC”) on March 24, 2020, and periodic reports filed with the SEC on or after the date thereof. All 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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Exhibit 99.02

TONIX PHARMACEUTICALS HOLDINGS CORP. CLOSES $40M COMMON STOCK OFFERING PRICED AT-THE-MARKET UNDER NASDAQ RULES

CHATHAM, NJ, January 13, 2021 – TONIX PHARMACEUTICALS HOLDINGS CORP. (NASDAQ: TNXP) ("Tonix" or the "Company"), a clinical-stage biopharmaceutical company, today announced the closing of its previously announced registered direct offering, priced at-the-market, with gross proceeds of $40.0 million before deducting fees and other estimated offering expenses. The Company sold 50,000,000 shares of common stock at $0.80 per share.

A.G.P./Alliance Global Partners acted as sole placement agent for the offering.

This offering was made pursuant to effective shelf registration statements on Form S-3 (File No. 333-224586 and 333-237610) previously filed and declared effective by the U.S. Securities and Exchange Commission (the "SEC"). This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction. A final prospectus relating to the offering was filed with the SEC on January 12, 2021 and is available on the SEC's website located at http://www.sec.gov. Copies of the prospectus supplement, together with the accompanying prospectuses, can be obtained at the SEC's website at www.sec.gov or from A.G.P./Alliance Global Partners, 590 Madison Avenue, 28th Floor, New York, New York 10022 or by email at prospectus@allianceg.com.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL*, is in mid-Phase 3 development for the management of fibromyalgia since positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data for the Phase 3 RALLY study in the second quarter of 2021** and topline data in the Phase 3 RALLY study in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800***, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801***, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.
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** Pending submission and agreement from the U.S. Food and Drug Administration (FDA) on the statistical analysis plan.

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