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 21, 2019

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.)**

509 Madison Avenue, Suite 1608, New York, New York 10022
(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 8.01 Other Events.

On August 21, 2019, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the signing of a research collaboration agreement with Massachusetts General Hospital to develop a humanized monoclonal antibody for the prevention and treatment of organ transplant rejection. A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

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 Securities and Exchange Commission. 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 dated August 21, 2019, issued by the Company

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 21, 2019

By: /s/ Seth Lederman
Seth Lederman
Chief Executive Officer

Exhibit 99.1

Tonix Pharmaceuticals and Massachusetts General Hospital Enter into Research Collaboration to Develop Tonix's Third Generation Anti-CD154 Monoclonal Antibody, TNX-1500, for the Treatment and Prevention of Organ Transplant Rejection

NEW YORK, August 21, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the signing of a research collaboration agreement with Massachusetts General Hospital (MGH), a teaching hospital of Harvard Medical School, to develop TNX-1500, a humanized monoclonal antibody (mAb) that targets CD154 for the prevention and treatment of organ transplant rejection. TNX-1500 is another step in the strategic broadening of Tonix's portfolio of high-value programs, whose risk is mitigated by previous clinical data and extensive preclinical science. Although transplantation is the first targeted indication for TNX-1500, it is also a potential treatment for autoimmune conditions including systemic lupus erythematosus, rheumatoid arthritis and multiple sclerosis.

Tonix and MGH have agreed to work jointly under a research agreement which will bring together Tonix's internally developed, proprietary anti-CD154 mAb, TNX-1500, with transplantation experts from MGH, led by 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 Harvard Medical School (HMS). The goal of the collaboration is to advance TNX-1500 as a potential first-in-class therapeutic for organ transplant rejection. Transplant organ rejection occurs when the immune system of the organ recipient attacks the new organ as if it was an infection or tumor.

Tonix's President and Chief Executive Officer, Seth Lederman, M.D. said, "A substantial body of evidence in humans and animals indicates that mAbs targeting CD154 have the potential to be an important therapeutic option for preventing or treating transplant organ rejection and as a treatment for autoimmune disorders. Despite the recognized promise of anti-CD154 therapy, first generation anti-CD154 mAbs were limited because their constant fragment (Fc) domain interacted with a receptor called FcγRII, which raised concerns over an increased risk of thrombosis. Second generation anti-CD154 mAbs had dramatically reduced binding to FcγRII, but had other issues, including decreased efficacy.[1-3] TNX-1500 is a third generation anti-CD154 mAb that has been designed by protein engineering to target CD154 therapeutically, while decreasing FcγRII binding and the potential for thrombosis."

Dr. Pierson of MGH and HMS said, "Anti-CD154 therapy has a unique activity in controlling the immune response to organ transplants.[4,5] There remains a significant need for new treatments with improved activity and tolerability to prevent or treat organ transplant rejection. Anti-CD154 has shown great promise to facilitate 'transplant tolerance' in multiple preclinical transplant models. A safe, effective anti-CD154 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.'" [6,7]

Dr. Lederman added, "Nearly 30 years ago, the laboratory that I directed as an Assistant Professor at Columbia University, discovered and characterized CD154, generated the first anti-CD154 monoclonal antibody, 5c8, and elucidated the molecular basis of T cell helper function.[8] It is exciting to return to the anti-CD154 field and to bring forth a third generation anti-CD154 mAb potential biologic therapeutic for treating and preventing organ transplant rejection that stands on the shoulders of previous work. We believe that TNX-1500 has the potential to maintain therapeutic activity of first generation anti-CD154 mAbs, but with reduced risk of thrombosis. We believe that the combined expertise of Tonix and MGH will be strongly synergistic. Preventing and treating organ rejection remains the greatest obstacles to long term survival in transplantation."

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

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

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

[4] O'Neill NA, et al. *Transplantation.* 101(9): 2038 (2017)

[5] Zhang T, et al. *Immunotherapy.* 7(8):899 (2015)

[6] Längin M, et al. *Nature.* 564(7736):430 (2018)

[7] Pierson RN 3rd. *J Thorac Cardiovasc Surg.* Jun 13. pii: S0022-5223(19)31024-4. doi: 10.1016/j.jtcvs.2019.04.087. (2019)

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

About CD154

CD154 is a protein expressed on the surface of activated T lymphocytes that mediates T cell helper function. CD154 is also known as the CD40-ligand (CD40-L), the T cell-B cell activating molecule (T-BAM), TRAP or gp39. CD154 is a member of the Tumor Necrosis Factor (TNF) Super Family. No mAb against CD154 has been licensed anywhere in the world. Other TNF Super Family members have proven to be targets for antagonist mAbs. Licensed 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. A licensed 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 and developing small molecules and biologics to treat psychiatric, pain and addiction conditions, to improve biodefense through potential medical counter-measures and to prevent and treat organ transplant rejection. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder, to be developed under separate Investigational New Drug applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development, the agitation in Alzheimer's program is Phase 2 ready and the alcohol use disorder program is in the pre-IND application stage. TNX-1300** (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. Tonix has two other programs in the pre-IND application stage of development for PTSD, but with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate) and TNX-1600***, a triple reuptake inhibitor. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted outside of the U.S. TNX-801 (live virus vaccine for percutaneous (scarification) administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. Finally, TNX-1500 is being developed to prevent and treat organ transplant rejection, as well as to treat autoimmune conditions, and is in the pre-IND application stage.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL for the treatment of PTSD. TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

****TNX-1600* ((2*S*,4*R*,5*R*)-5-(((2-aminobenzo[*d*]thiazol-6-yl)methyl)amino)-2-(bis(4-fluorophenyl)methyl)tetrahydro-2*H*-pyran-4-ol) is an inhibitor of reuptake of three monoamine neurotransmitters (serotonin, norepinephrine and dopamine), or a "triple reuptake" inhibitor.

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; 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Scott Stachowiak (media)
Russo Partners
scott.stachowiak@russopartnersllc.com
(646) 942-5630

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