

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 19, 2019

TONIX PHARMACEUTICALS HOLDING CORP.  
(Exact name of registrant as specified in its charter)

Nevada  
(State or Other Jurisdiction  
of Incorporation)

001-36019  
(Commission  
File Number)

26-1434750  
(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))

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.

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

**Item 1.01 Entry into Material Definitive Agreement**

On August 19, 2019, Tonix Pharmaceuticals, Inc. (“Tonix”), a wholly-owned subsidiary of Tonix Pharmaceuticals Holding Corp. (the “Company”), entered into an asset purchase agreement (the “Asset Purchase Agreement”) with TRImaran Pharma, Inc. (“TRImaran”) and the selling shareholders named therein (the “Selling Shareholders”) pursuant to which Tonix acquired TRImaran’s assets related to certain pyran-based compounds (the “Assets”). In connection with the acquisition of the Assets, Tonix entered into a First Amended and Restated Exclusive License Agreement (the License “Agreement”) with Wayne State University (“WSU”) on August 19, 2019. As consideration for entering into the Asset Purchase Agreement, Tonix has agreed to pay \$100,000 to TRImaran and has assumed certain liabilities of TRImaran totaling \$68,500. Upon the achievement of specified development, regulatory and sales milestones, Tonix also agreed to pay TRImaran and the Selling Shareholders, in restricted stock or cash, at Tonix’s option, a total of approximately \$3.4 million. Pursuant to the terms of the Asset Purchase Agreement, TRImaran and the Selling Shareholders are prohibited from disclosing confidential information related to the Assets and are restricted from engaging, for a period of three years, in the development or commercialization of any therapeutic containing any pyran-based drug compound for the treatment of post-traumatic stress disorder, attention deficit hyperactivity disorder or major depressive disorder. Also for a period of three years, if TRImaran or any Seller Shareholder engage in the research or development of any potential therapeutic compound for the treatment of any central nervous system disorder, TRImaran or such Seller Shareholder is obliged to provide notice and opportunity to Tonix to make an offer to acquire or license rights with respect to such product candidate.

Pursuant to the terms of the License Agreement, WSU has granted to Tonix an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the “Technology”) related to the Assets. WSU has reserved for itself the right to practice the Technology for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to obtain regulatory approval for one or more products utilizing the Technology (“Products”) and to use commercially reasonable marketing efforts throughout the term of the License Agreement. The License Agreement specifies developmental milestones and the period of time during which such milestones must be completed, and provides for an annual maintenance fee payable to WSU. Tonix is obligated to substantially manufacture Products in the United States if Products will be sold in the United States.

Pursuant to the License Agreement, Tonix has agreed to pay \$75,000 to WSU as reimbursement of certain patent expenses, and, upon the achievement of specified development, regulatory and sales milestones, the Company also agreed to pay WSU, milestone payments totaling approximately \$3.4 million. Tonix has also agreed to pay WSU single-digit royalties on net sales of Products sold by Tonix or a sublicensee on a tiered basis based on net sales, and additional sublicense fees on certain consideration received from sublicensees. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the date of expiration of the last valid claim in the last to expire of the issued patents covered by the License Agreement. Royalties payable on net sales of Products may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the License Agreement, provided that the royalty payable on a Product may not be reduced by more than 50%. Each party also has the right to terminate the agreement for customary reasons such as material breach and bankruptcy. The License Agreement contains provisions relating to termination, indemnification, confidentiality and other customary matters for an agreement of this kind.

The foregoing descriptions of the Asset Purchase Agreement and License Agreement do not purport to be complete and are qualified in their entirety by reference to the complete text of the agreements, which will be filed as exhibits to the Company’s Quarterly Report on Form 10-Q for the period ending September 30, 2019. Certain terms of the Asset Purchase Agreement and License Agreement have been omitted from this Form 8-K and will be omitted from the versions to be filed as exhibits to the Form 10-Q.

**Item 8.01 Events**

On August 20, 2019, the Company issued a press release in connection with the License Agreement. A copy of the press release is included as Exhibit 99.1 hereto.

**Item 9.01 Financial Statements and Exhibits**

(d)	Exhibit No.	Description.
	99.01	<a href="#">Press Release dated August 20, 2019, issued by the Company</a>

**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 20, 2019

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

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**Tonix Pharmaceuticals Expands Preclinical Pipeline with Triple Reuptake Inhibitor, TNX-1600, for the Treatment of PTSD**

NEW YORK, August 20, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today an exclusive agreement to in-license a triple reuptake inhibitor (TRI), TNX-1600 (formerly D-578), to treat posttraumatic stress disorder (PTSD) and potentially other central nervous system (CNS) disorders. The compound was developed and pharmacologically characterized by Alope Dutta, Ph.D., professor of Pharmaceutical Sciences at Wayne State University, with funding from a National Institutes of Health grant (grant number MH084888), and the patents covering the compounds were licensed to TRImaran Pharma, Inc. (TRImaran). The transaction announced today is a license agreement with Wayne State and an asset acquisition with TRImaran.

“We are excited to expand our pipeline and are looking forward to developing TNX-1600 as a potential treatment for PTSD,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “We plan to utilize our clinical experience in PTSD to evaluate the therapeutic benefit of TNX-1600. PTSD is a heterogeneous condition, so we believe different PTSD patients may respond to different medicines. In some cases, more than one drug will be required for effective treatment. TNX-1600 is our third drug candidate in development for PTSD. Our most advanced candidate is TNX-102 SL, which is in Phase 3 development. We are also developing TNX-601 which is entering a Phase 1 trial imminently. TNX-1600 is in the pre-IND phase of development with encouraging data from animal models of PTSD.”

Frank Bymaster, Chief Scientific Officer and co-founder of TRImaran Pharma Inc. said, “TNX-1600 is a novel TRI that inhibits simultaneously the reuptake of three key neurotransmitters: serotonin, norepinephrine and dopamine. Each of these three neurotransmitters plays a key modulatory role in many CNS processes. Inhibiting reuptake of all three may provide an effective treatment for PTSD.”

According to Dr. Alope Dutta, “We have developed an innovative triple reuptake inhibitor, D-578, based on a unique pyran molecular scaffold to address the current therapeutic needs for PTSD and other neurological disorders. Based on our preliminary data, we expect a pharmacological synergy from their potent modulatory effect on the level of monoamine neurotransmitters in the brain which should facilitate effective treatment of these disorders.”

Under the terms of the agreement, Tonix has been granted an exclusive license from Wayne State University for technology and patents related to TNX-1600 and other pyran-based compounds. Another member of the class, D-473, has also shown effects in a rodent model of depression<sup>2,3</sup>.

<sup>1</sup>Bymaster, FP, Lisieski M, Harutyunyan, A, Das, D, Liberzon, I, Hsu, T, Reith, MEA, Perrine, SA, Dutta, AK. A Novel Orally Active Triple Reuptake Inhibitor for the Treatment of Post-traumatic Stress Disorder (PTSD): D-578 Attenuates Abnormal Fear Behavior in a Rodent Model of Traumatic Stress.

<sup>2</sup>Soumava Santra, S, Gogoi, S, Gopishetty, B, Antonio, T, Zhen, J, Reith, MEA and Dutta, AK. Structural Exploration of (3S,6S)-6-Benzhydryl-N- benzyltetrahydro-2H-pyran-3-amine Analogues: Identification of Potent Triple Monoamine Reuptake Inhibitors as Potential Antidepressants. ChemMedChem, 2012

<sup>3</sup>Dutta, AK, Santra, S, Sharma, H, Voshavar, C Xu, L, Mabrouk, O, Antonio, T and Reith, MEA. Pharmacological and behavioral characterization of an orally active triple reuptake inhibitor D-473: Effects of drug on extracellular levels of dopamine, serotonin and norepinephrine. Plos One, 2014, 9, e11342 0.

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### **About TRImaran**

TRImaran Pharma, Inc. was co-founded by Frank Bymaster (CSO), Dr. Timothy Hsu (CMO) and Walter Piskorski (CEO), along with Alope Dutta, Ph.D. (inventor/scientific advisor), to apply their psychiatric drug development expertise, particularly for TRIs. TRImaran originally in-licensed the exclusive rights to these compounds from Wayne State University and, as part of this transaction, transferred those rights to Tonix.

### **About Wayne State University**

Wayne State University is one of the nation's pre-eminent public research universities in an urban setting. Through its multidisciplinary approach to research and education, and its ongoing collaboration with government, industry and other institutions, the university seeks to enhance economic growth and improve the quality of life in the city of Detroit, state of Michigan and throughout the world. For more information about research at Wayne State University, visit <http://www.research.wayne.edu>.

### **About Triple Reuptake Inhibitors (TRIs)**

TRIs inhibit simultaneously the reuptake of three key neurotransmitters: serotonin, norepinephrine and dopamine. Single selective serotonin reuptake inhibitors are known as SSRIs and have been successful in a number of psychiatric conditions and include the drugs Prozac® (fluoxetine), Paxil® (paroxetine), Zoloft® (sertraline), and Celexa® (escitalopram). Double serotonin and norepinephrine inhibitors are known as SNRIs and include successful drugs like Effexor® (venlafaxine) and Cymbalta® (duloxetine). A number of TRIs are in development, but none have been approved by the FDA for marketing.

### **About 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. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a different mechanism from TNX-102 SL and designed for daytime dosing. 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.*

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

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## **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 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.

## **Contacts**

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