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): **September 16, 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 1.01 Entry into Material Definitive Agreement

On September 16, 2019, Tonix Pharmaceuticals, Inc. (a wholly owned subsidiary of Tonix Pharmaceuticals Holding Corp. (the "Company")) ("Tonix") and The Trustees of Columbia University in the City of New York ("Columbia") entered into an exclusive License Agreement (the "License Agreement") pursuant to which Columbia granted to Tonix an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the "Technology") related to a recombinant Trefoil Family Factor 2 (TFF2), and to develop and commercialize products thereunder (each, a "Product"). Pursuant to the terms of the License Agreement, Columbia has reserved for itself the right to practice the Technology for academic research and educational purposes.

As consideration for entering into the License Agreement, Tonix has agreed to pay a five-digit license fee to Columbia. Tonix is obligated to use Commercially Reasonable Efforts, as defined in the License Agreement, to develop and commercialize the Product, and to achieve specified developmental milestones.

Tonix has agreed to pay Columbia single-digit royalties on net sales of (i) Products sold by Tonix or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to Tonix pursuant to the License Agreement ("Other Products") sold by Tonix or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the License Agreement, and (ii) a specified period of time after the first commercial sale of a Product in the country in question. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until a specified period of time after the first commercial sale of such particular Other Product in such country. Royalties payable on net sales of the Product and Other 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 or Other Product may not be reduced by more than 50%.

Tonix is also obligated to make contingent milestone payments to Columbia totaling $3.1 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a Product. In addition, Tonix shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to Tonix by a sublicensee.

The License Agreement may be terminated by either party for cause and contains customary indemnification provisions.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the year ending December 31, 2019. Certain terms of the License Agreement have been omitted from this Form 8-K and will be omitted from the version to be filed as an exhibit to the Form 10-K.

A press release issued by the Company in connection with the License Agreement is included as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release dated September 16, 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: September 16, 2019

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Licensing Agreement with Columbia University for the Development of Recombinant Trefoil Family Factor 2 (rTFF2), or TNX-1700, for the Treatment of Gastric and Pancreatic Cancers

First-in-Class Biologic for the Treatment of Gastric and Pancreatic Cancers

NEW YORK, September 16, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has obtained an exclusive license from Columbia University for the development of TNX-1700 (rTFF2) for the treatment of gastric and pancreatic cancers. TNX-1700 is a biologic currently in preclinical development. The licensed assets were developed, in part, by Dr. Timothy C. Wang, Chief, Division of Digestive and Liver Diseases, and Director of the Gastrointestinal and Pancreas Cancer Program and Tumor Biology and Microenvironment (TBM) program in the Herbert Irving Cancer Center at Columbia University.

Tonix's President and Chief Executive Officer, Seth Lederman, M.D. said, "Tonix is excited to have in-licensed this technology to bring into development. Dr. Wang is an expert in the molecular mechanisms of carcinogenesis and for many years has studied the carcinogenic role of inflammation in modulating stem cell functions. These studies have led to fundamental insights on the role of TFF2 at regulating this process and potentially using rTFF2 to make cancer cells susceptible to checkpoint inhibitors."

Dr. Wang added, "Our research has demonstrated that knockout of the TFF2 gene leads to faster tumor growth, while overexpression of TFF2 markedly suppressed tumor growth by curtailing the proliferation and expansion of myeloid progenitors that would otherwise give rise to myeloid-derived suppressor cells. We believe that the novel mechanism that allows activation of CD8+ T cells, by limiting myeloid cells, may have implications for both cancer prevention and cancer treatment. Furthermore, our modified version of human TFF2 appears to show greater stability and efficacy than native TFF2."

About Trefoil Factor 2 (TFF2)

TFF2 is a small secreted protein, encoded by the TFF2 gene in humans, that is expressed in gastrointestinal mucosa where it functions to protect and repair mucosa. TFF2 is also expressed at low levels in splenic immune cells and is now appreciated to have intravascular roles in spleen and in the tumor microenvironment. In gastric cancer, TFF2 is epigenetically silenced, and TFF2 is suggested to be protective against cancer development through several mechanisms.

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 life-threatening 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.

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