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): May 20, 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))

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 May 20, 2019, Tonix Pharmaceuticals Holding Corp. (the "Company") 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, for itself and on behalf of the University of Kentucky and the University of Michigan (collectively, the "Institutions") granted to the Company an exclusive license, with the right to sublicense, certain patents, technical information and material (collectively, the "Technology") related to a double-mutant cocaine esterase, and to develop and commercialize products thereunder (each, a "Product"). Pursuant to the terms of the License Agreement, Columbia has reserved for itself and the Institutions the right to practice the Technology for academic research and educational purposes.

As consideration for entering into the License Agreement, the Company has agreed to pay a six-digit license fee to Columbia. The Company 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.

The Company has agreed to pay Columbia single-digit royalties on net sales of (i) Products sold by the Company or a sublicensee and (ii) any other products that involve material or technical information related to the Product and transferred to the Company pursuant to the License Agreement ("Other Products") sold by the Company 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, (ii) a specified period of time after the first commercial sale of a Product in the country in question, or (iii) expiration of any market exclusivity period granted by a regulatory agency. Royalties on each particular Other Product are payable on a country-by-country and product-by-product basis until the later of (i) a specified period of time after the first commercial sale of such particular Other Product in such country or (ii) expiration of any market exclusivity period granted by a regulatory agency. Royalties payable on net sales of the Product and Other Products may be reduced by 50% of the royalties payable by the Company to any third party for intellectual property rights which are necessary for the practice of the rights licensed to the Company under the License Agreement, provided that the royalty payable on a Product or Other Product may not be reduced by more than 50%.

The Company is also obligated to make contingent milestone payments to Columbia totaling $3 million on a Product-by-Product basis upon the achievement of certain development, approval and sales milestones related to a Product. In addition, the Company shall pay Columbia 5% of consideration, other than royalty payments and certain other categories of consideration, payable to the Company by a sublicensee.

Dr. Donald Landry, a member of the faculty of Columbia and an inventor on key patents and patent applications being licensed pursuant to the License Agreement, resigned from the Board of Directors of the Company (the "Board") on May 16, 2019. Under applicable Columbia policies, Dr. Landry has a pecuniary interest in certain proceeds that Columbia receives under the License Agreement. Pursuant to the requirements of the Nevada Revised Statutes, the disinterested members of the Board approved the License Agreement with Columbia.

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 Quarterly Report on Form 10-Q for the period ending June 30, 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-Q.

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 May 23, 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: May 23, 2019

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

Exhibit 99.01

Tonix Pharmaceuticals Expands Pipeline with Mid-stage Biologic Candidate TNX-1300 for Cocaine Intoxication

Phase 2 Program Granted Breakthrough Therapy Designation by FDA

Emergency Room Visits for Cocaine Abuse Total More than 500,000 Annually in U.S.

NEW YORK, May 23, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company focused on developing small molecules and biologics to treat psychiatric, pain and addiction conditions as well as to improve biodefense, announced today that it has in-licensed a Phase 2 asset, TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution)* for the treatment of cocaine intoxication. TNX-1300 is designated as a breakthrough therapy by the U.S. Food and Drug Administration (FDA).

TNX-1300, formerly RBP-8000, is a recombinant enzyme that efficiently degrades and metabolizes cocaine in cocaine abusers, as demonstrated in a Phase 2 randomized, double-blind, placebo-controlled clinical study, providing support of the use of TNX-1300 as a treatment for cocaine intoxication.[1]

Currently there is no specific pharmacotherapy indicated for cocaine intoxication, a state characterized by acute agitation, hyperthermia, tachycardia, arrhythmias, and hypertension, with the potential life-threatening sequalae of myocardial infarction, cerebrovascular accident, rhabdomyolysis, respiratory failure, and seizures. Patients are currently managed only by supportive care for the adverse effects of cocaine overdose on the cardiovascular and central nervous systems. By targeting the cause of cocaine intoxication, rather than the symptoms like other medicines in emergency usage, we believe TNX-1300 may offer significant advantages to the current standard of care for cocaine overdose. TNX-1300 was developed by Columbia University, University of Kentucky and University of Michigan, and in-licensed by Tonix from Columbia University. Financial terms were not disclosed.

“TNX-1300 is an excellent strategic fit within our focus on breakthrough psychiatry and non-opiate centrally-acting analgesic treatments and expands our pipeline into addiction treatment with a disruptive therapeutic technology in mid-stage clinical development,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “TNX-1300 also represents our first in-licensed product, as we have historically developed products and technologies internally through our own discovery and R&D efforts. This transformative product meets our standards for innovation, value and impact.”

Dr. Lederman continued, “There are approximately 505,000 emergency room visits annually due to cocaine abuse, with approximately 61,000 of the visits involving detox services to treat cocaine overdose. In 2017, about 13,900 deaths occurred in the U.S. due to cocaine overdose.[2] We believe that TNX-1300 has the potential to be a new treatment option for the substantial morbidity and mortality caused by cocaine intoxication.”

As a biologic and new molecular entity, TNX-1300 is eligible for 12 years of U.S. market exclusivity upon approval by the FDA, in addition to expected patent protection through 2029. The in-licensing transaction also includes an inventory of investigational drug product, which will be requalified for Good Manufacturing Practice (GMP) purposes.

About TNX-1300

TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution) is being developed under an Investigational New Drug application (IND) for the treatment of cocaine intoxication. TNX-1300 (formerly known as RBP-8000) is a recombinant protein enzyme produced through rDNA technology in a non-disease-producing strain of *E. coli* bacteria. Cocaine Esterase (CocE) was identified in bacteria (*Rhodococcus*) that use cocaine as its sole source of carbon and nitrogen and that grow in soil surrounding coca plants.[3] The gene encoding CocE was identified and the protein was extensively characterized.[3-6] CoCE catalyzes the breakdown of cocaine into metabolite ecgonine methyl ester and benzoic acid. Wild-type CocE is unstable at body temperature, so targeted mutations were introduced in the CocE gene and resulted in the T172R/G173Q Double-Mutant CocE, which is active for approximately 6 hours at body temperature[7]. In a Phase 2 study, TNX-1300 at 100 mg or 200 mg *i.v.* doses was well tolerated and interrupted cocaine effects after cocaine 50 mg *i.v.* challenge.[1]

About Cocaine Intoxication and Overdose

Cocaine is an illegal recreational drug which is taken for its pleasurable effects and associated euphoria. Pharmacologically, cocaine blocks the reuptake of the neurotransmitter dopamine from central nervous system synapses, resulting in the accumulation of dopamine within the synapse and an amplification of dopamine signaling and its role in creating positive feeling. With the continued use of cocaine, however, intense cocaine cravings occur resulting in a high potential for abuse and addiction (dependence), as well as the risk of cocaine intoxication. Cocaine intoxication refers to the deleterious effects on other parts of the body, especially those involving the cardiovascular system. Common symptoms of cocaine intoxication include tachyarrhythmias and elevated blood pressure, either of which can be life-threatening. As a result, individuals with known or suspected cocaine intoxication are sent immediately to the emergency department, preferably by ambulance in case cardiac arrest occurs during transit. There are approximately 505,000 emergency room visits for cocaine abuse each year in the U.S., of which 61,000 require detoxification services. According to the National Institute on Drug Abuse, over 13,900 individuals died of cocaine overdose in 2017.[7] According to a recent report by the U.S. Centers for Disease Control and Prevention[8], and covered by news reports[9,10], among all 2017 U.S. drug overdose deaths, approximately 20% involved cocaine. Overdose deaths nvolving cocaine increased 34 percent from 2016 to 2017.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on developing small molecules and biologics to treat psychiatric, pain and addiction conditions as well as to improve biodefense, through potential medical counter-measures. 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. Tonmya for PTSD has been designated a Breakthrough Therapy by the FDA. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate INDs to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development and the agitation in Alzheimer's program is Phase 2 ready. In fibromyalgia, TNX-102 SL acts as a non-opioid, centrally-acting analgesic that would provide a new therapeutic option for fibromyalgia patients. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. 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. A Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 will be conducted outside of the U.S. in 2019. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

**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.*

***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.*

References

[1] Nasser AF, Fudala PJ, Zheng B, Liu Y, Heidbreder C. A randomized, double-blind, placebo-controlled trial of RBP-8000 in cocaine abusers: pharmacokinetic profile of rbp-8000 and cocaine and effects of RBP-8000 on cocaine-induced physiological effects. J Addict Dis. 2014;33(4):289-302.

[2] National Institute on Drug Abuse (NIDA) - https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates; accessed May 11, 2019

[3] Bresler MM, Rosser SJ, Basran A, Bruce NC. Gene cloning and nucleotide sequencing and properties of a cocaine esterase from Rhodococcus sp. strain MB1.Appl Environ Microbiol. 2000. 66(3):904-8.

[4] Larsen NA, Turner JM, Stevens J, Rosser SJ, Basran A, Lerner RA, Bruce NC, Wilson IA. Crystal structure of a bacterial cocaine esterase. Nat Struct Biol. 2002. 9(1):17-21.

[5] Turner JM, Larsen NA, Basran A, Barbas CF 3rd, Bruce NC, Wilson IA, Lerner RA. Biochemical characterization and structural analysis of a highly proficient cocaine esterase. Biochemistry. 2002. 41(41):12297-307.

[6] Gao D, Narasimhan DL, Macdonald J, Brim R, Ko MC, Landry DW, Woods JH, Sunahara RK, Zhan CG. Thermostable variants of cocaine esterase for long-time protection against cocaine toxicity. Mol Pharmacol. 2009. 75(2):318-23.

[7] Overdose Death Rates - National Institute on Drug Abuse - https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates; accessed May 11, 2019

[8] Kariisa, M, Scholl, L, Wilson, N, Seth, P, Hoots, B.Drug Overdose Deaths Involving Cocaine and Psychostimulants with Abuse Potential — United States, 2003–2017. MMWR Weekly / May 3, 2019 / 68(17);388–395 - https://www.cdc.gov/mmwr/volumes/68/wr/mm6817a3.htm?s_cid=mm6817a3_w; accessed May 11, 2019

[9] Fottrell, Q. MarketWatch, Fatal drug overdoses involving cocaine and other stimulants have surged by over 52%[8], May 3, 2019 - https://www.marketwatch.com/story/fatal-drug-overdoses-involving-cocaine-and-other-stimulants-have-surged-by-over-52-2019-05-03; accessed May 11, 2019

[10] Cocaine deaths up in U.S. and opioids are a big part of it. Associated Press.https://www.msn.com/en-us/news/us/cocaine-deaths-up-in-us-and-opioids-are-a-big-part-of-it/ar-AAAOxs8?ocid=se; accessed May 11, 2019

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 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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