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): June 11, 2020

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 June 11, 2020, 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 Trigemina, Inc. ("Trigemina") and certain shareholders named therein (the "Executive Shareholders") pursuant to which Tonix acquired Trigemina assets related to migraine and pain treatment technologies (the "Assets"). In connection with the acquisition of the Assets, Tonix assumed Trigemina's rights and obligations under that certain Amended and Restated Exclusive License Agreement, dated November 30, 2007, as amended, by and between Trigemina and The Board of Trustees of the Leland Stanford Junior University ("Stanford") (the "License "Agreement") pursuant to an Assignment and Assumption Agreement with Stanford ("Assignment and Assumption Agreement"), dated June 11, 2020. As consideration for entering into the Asset Purchase Agreement, Tonix has agreed to pay $774,759 to Trigemina and issued to Trigemina 2,000,000 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), and has agreed to pay to Stanford $250,241 pursuant to the terms of the Assignment and Assumption Agreement. The Common Stock is unregistered and subject to a 12 month lock-up and a Shareholder Voting Agreement, dated June 11, 2020 (the "Voting Agreement"), pursuant to which Trigemina and the Executive Shareholders have agreed to vote the Common Stock on any matter put to a vote of the shareholders of the Company in accordance with management's recommendations. Pursuant to the terms of the Asset Purchase Agreement, Trigemina and the Executive Shareholders are prohibited from engaging, for a period of three years, in the development or commercialization of any therapeutic containing oxytocin, noiciceptin or any derivatives thereof.

Pursuant to the terms of the Assignment and Assumption Agreement, Stanford has granted to Tonix an exclusive license, with the right to sublicense, certain patents related to the Assets. Stanford has reserved for itself the right to practice under the patents for academic research and educational purposes. Tonix is obligated to use commercially reasonable efforts to diligently develop, manufacture, and sell products claimed or covered by the patent and will use commercially reasonable efforts to diligently develop markets for such products 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 Stanford.

The foregoing descriptions of the Asset Purchase Agreement, License Agreement, Assignment and Assumption Agreement and Voting 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 June 30, 2020. 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 3.02 Unregistered Sales of Equity Securities

The information contained above in Item 1.01 is hereby incorporated by reference into this Item 3.02.

Item 8.01 Other Events

On June 11, 2020, the Company issued a press release in connection with the Asset Purchase 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	Press Release dated June 11, 2020, 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: June 11, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Acquisition of Non-Addictive Migraine and Pain Treatment Programs from Trigemina and Assumption of License

TNX-1900 Intranasal Oxytocin has the Potential to Treat Migraine and Craniofacial Pain

NEW YORK, June 11, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby Tonix will acquire the migraine and pain treatment technologies of Trigemina, Inc., and will assume the license for some of the technologies from Stanford University. The lead asset, TNX-1900 (formerly TI-001, oxytocin solution for intranasal delivery), is a proprietary, patented enhanced formulation of nasal oxytocin, with demonstrated activity in several non-clinical studies in pain including migraine prophylaxis and neuropsychiatric models and with safety data from non-U.S studies.

“Tonix is excited to develop intranasal oxytocin as a non-addictive treatment for migraine and craniofacial pain,” said Seth Lederman, M.D., President and Chief Executive Officer. “The preclinical data that we have seen to date are promising and show that oxytocin, a natural hormone, is capable of blocking the release of the neurotransmitter calcitonin gene-related peptide (CGRP) in the brain coverings and trigeminal ganglia, thus potentially preventing a key step in the causation of migraine. It has been shown that intra-nasally delivered oxytocin selectively reaches the trigeminal ganglia with low systemic absorption. Overall, we believe that TNX-1900 has the potential to be a safe, natural, non-addicting, non-constipating and easy to administer alternative to opioids to treat migraine and craniofacial pain.”

“We are excited that Tonix will continue to advance the progress Trigemina has made with these assets and look forward to potentially facilitating their development,” said Shashidar H. Kori, M.D., Chief Medical Officer, Trigemina Inc. “This agreement further validates our previous development work and its continued potential.”

About TNX-1900

TNX-1900, Tonix’s patented intranasal oxytocin formula, is currently being studied as a candidate for prophylaxis of chronic migraine. TNX-1900 is in the pre-Investigational New Drug (IND) stage and has not been approved for any indication. TNX-1900 is based on a proprietary formulation of oxytocin and is being developed first for the treatment of migraine. Oxytocin is a naturally occurring human hormone that acts as a neurotransmitter in the brain. Oxytocin is approved by the U.S. Food and Drug Administration (FDA) as Pitocin®, an intravenous infusion or intramuscular injection drug, for use in pregnant women to induce labor. An intranasal form of oxytocin was marketed by Novartis to assist in nursing as Syntocinon®, but the product was withdrawn and the New Drug Application (NDA) has been discontinued. In clinical and preliminary research, it has been observed that low oxytocin levels in the body can lead to increase in headache frequency, and that increased oxytocin levels can relieve headaches. Certain other chronic pain conditions are also associated with decreased oxytocin levels. Oxytocin when delivered via the nasal route, results in enhanced binding of oxytocin to receptors on neurons in the trigeminal system, inhibiting transmission of pain signals. Intranasal oxytocin has been well tolerated in several clinical trials and established in adults and children. Intranasal oxytocin has been shown in animals that it can also block CGRP release, a pathway known to be critical to the pathogenesis of migraine attacks. In preclinical research, nasally applied TNX-1900 selectively inhibits the activity of trigeminal pain-sensing nerve cells and blocks the release of CGRP. TNX-1900 is believed to interrupt pain signals at the trigeminal ganglia by suppressing electrical impulses, a potentially different activity than drugs that just block CGRP. Migraine attacks are caused, in part, by the release of CGRP from pain-sensing nerve cells that are part of the trigeminal system. The CGRP binds to receptors on other nerve cells and starts a cascade of events that eventually results in a severe headache. This, in turn, reduces various kinds of trigeminal nerve associated pain and prevents CGRP from acting at receptors in the central nervous system that are involved in migraine. Targeted delivery results in low systemic exposure and lower risk of non-nervous system, off-target effects which could potentially occur with systemic CGRP antagonists. For example, CGRP has roles in dilating blood vessels in response to ischemia, including in the heart. We believe targeted delivery of oxytocin could translate into selective blockade of CGRP release in the trigeminal ganglion and not throughout the body, which could be a potential safety advantage over systemic CGRP inhibition. In addition, daily dosing is more quickly reversible, in contrast to monthly or quarterly dosing, giving physicians and their patients greater control.

*Pitocin® is a trademark of Par Pharmaceutical, Inc.

**Syntocinon® is a trademark of BGP Products Operations GmbH

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. In 2020, Tonix announced a program to develop a potential vaccine, TNX-1800* (live modified horsepox virus vaccine for percutaneous administration) to protect against the novel coronavirus disease emerging in 2019, or COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform and is molecularly designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. TNX-801* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL**, is in Phase 3 development as a bedtime treatment for FM and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in FM and expects results from an unblinded interim analysis in September of 2020 and topline data in the first quarter of 2021. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya***) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, *i.v.* solution), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. TNX-1200* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

**TNX-1800, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.*

***TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

****Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.*

This press release and further information about Tonix can be found atwww.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 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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