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 3, 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))

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, par value $0.001 per share	TNXP	The NASDAQ Global Market

Item 8.01. Other Events.

On August 4, 2020, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that on August 3, 2020, the Company received a letter from The NASDAQ Stock Market LLC ("NASDAQ") stating that because the Company's shares had a closing bid price at or above $1.00 per share for a minimum of ten consecutive business days, the Company's stock had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Global Market, as set forth in NASDAQ Listing Rule 5450(a)(1), and that the matter is now closed. A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Also on August 4, 2020, the Company posted a presentation which was presented at the American Academy of Neurology's Sports Concussion Conference held July 31, 2020 and August 1, 2020 (the "Presentation"). Copies of the Presentation and the press release which discusses this matter are filed as Exhibits 99.02 and 99.03, respectively, and are incorporated by reference in, this report.

F*orward- 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 of the Company, dated August 4, 2020
99.02	Poster Presentation
99.03	Press Release of the Company, dated August 4, 2020

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 4, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals Regains Compliance with NASDAQ Minimum Bid Price Requirement

NEW YORK, August 4, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company) a clinical-stage biopharmaceutical company, announced that it has regained compliance with the minimum bid price requirement for continued listing on the NASDAQ Global Market. The Company received a letter from The NASDAQ Stock Market LLC on August 3, 2020 stating that because its shares had a closing bid price at or above $1.00 per share for a minimum of ten (10) consecutive business days, the Company's stock had regained compliance with the minimum bid price requirement of $1.00 per share for continued listing on the NASDAQ Global Market, as set forth in NASDAQ Listing Rule 5450(a)(1), and the matter is now closed.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix is also developing TNX-2300*, a second live replicating vaccine candidate for the prevention of COVID-19, but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth 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 life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor) , a new molecular entity being developed as a treatment for PTSD; 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-1800, TNX-801, TNX-2300, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have not been approved for any indication.

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; 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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Exhibit 99.02

Intranasal (IN) Oxytocin Relieves Pain and Depressive Behavior in a Rodent Model of Mild Traumatic Brain Injury (TBI)

TONIX PHARMACEUTICALS

July 2020

Shashidhar H Kori, MD, FAHS, David Yeomans, PhD, Michael Klukinov, PhD

Version P0238 7-29-20 (Doc 0676)

DISCLOSURES

SHASHIDHAR H KORI:
Full-time employee, Chief Medical Officer, Trigemina Inc. Consultant: Tonix Pharma, Exalys, Satsuma, NewBio

DAVID YEOMANS:
Full-time employee, Stanford University. Consultant: Trigemina Inc, Tonix, Exalys, NewBio, SiteOne, CereVu

Michael Klukinov: Full-time employee, Stanford University. Consultant: Trigemina, Inc.

Consequences of TBI

- Post traumatic headaches (PTH)
- Cognitive deficits in memory, attention, and concentration
- Somatic complaints of fatigue, disordered sleep, dizziness
- Affective complaints of irritability, anxiety, and depression
- Post Traumatic Stress Disorder (PTSD)

Hoffman et al 2020

Post Traumatic Headache (PTH) is a Disabling Symptom of TBI

- TBI is the most common brain disorder, the incidence of which exceeds that of dementia, epilepsy and stroke
- 1.7 million TBIs are sustained each year in the United States, most of which are of mild initial severity
- 5.3 million Americans live with TBI-related disability
- PTH is one of the most prevalent TBI sequelae (up to 89% of patients suffer from it), is one of the longest lasting post-concussion symptoms, causes significant morbidity, and might be associated with slower neurocognitive recovery

Finkel et al 2012

CGRP and PACAP are Believed to Play a Critical Role in Post-traumatic Headache (PTH)

- Most PTH are migraine like in character (Finkel 2012)
- Some PTH have autonomic features (Finkel 2012)
- CGRP (Friburg 1994) and PACAP (Amin 2014) are elevated in jugular blood during migraine attack
- CGRP injection causes migraine headache in 63% of migraineurs
- PACAP-38 injection induces migraine headache in 73% of migraineurs
- CGRP antibodies are highly effective in approx. 50% of chronic migraine pts
- PACAP has been implicated in 15-40% of chronic migraineurs (Vollesen 2017)
- CGRP has been implicated in animal models of PTH (Navratilova et al., 2019)
- In an open label study, a CGRP antibody was found effective in PTH (Ashina et al, 2020)

Intranasal Oxytocin (IN OT) as a Treatment for PTH

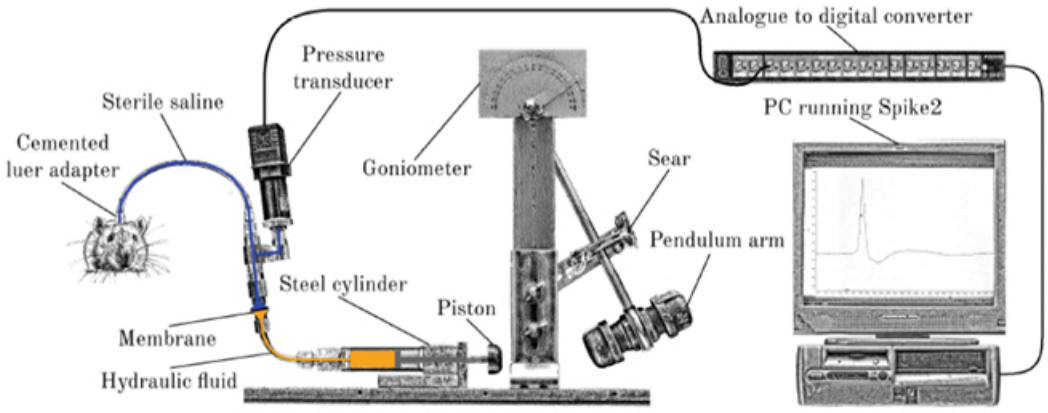
- Natural hormone, deficiency of which is believed to lower pain threshold
- Intranasal oxytocin is taken up by trigeminal (TG) system and believed to act in TG
- Has multiple mechanism of action, suppresses trigeminal nociceptive transmission, blocks CGRP and PACAP
- Has little systemic effect, and hence does not appear to block CGRP or PACAP elsewhere in the body
- Believed to have anti-dependence effect and has been used in treating PTH patients with medication overuse headache (MOH)
- Believed to have anti-anxiety effects, a common co-morbidity in TBI patients
- Extensive history of use and tolerability: clinically use for more than 60 years
- No recognized addictive potential, and no tachyphylaxis has been described

Efficacy of IN OT Has Been Demonstrated in Other Headache Models

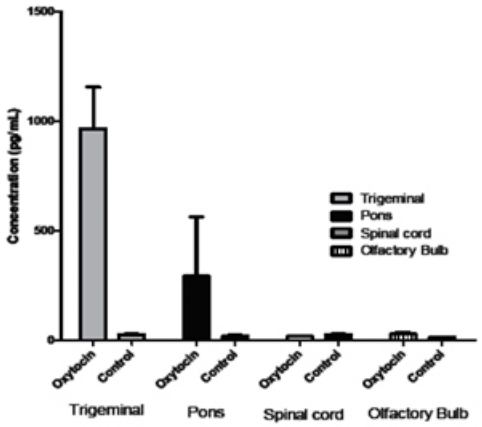
- Synergistic action between oxytocin and Mg demonstrated
- Naso-cerebral pathway proved by radiolabeling studies
- Decreased action potentials in TG cells demonstrated by elegant electrophysiological studies
- Blockage of CGRP and PACAP release by oxytocin demonstrated*
- Pain relief in TG system by intranasal oxytocin, but not IV oxytocin, demonstrated in animal models of TMJ inflammation and trigeminal neuropathy
- Oxytocin receptors demonstrated in SPG, a key parasympathetic contributor to cranial pain persistence

*Yeomans et al 2017

Efficacy of nasal OT was tested in a rat model of mild-moderate traumatic brain injury (TBI)

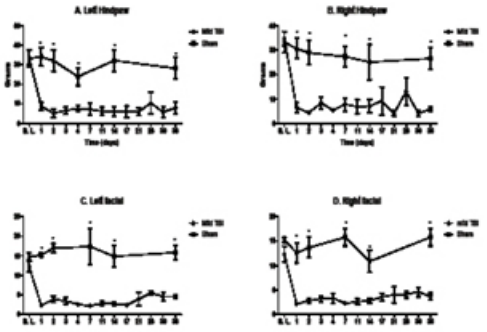


Elevated levels of OT in trigeminal ganglia and pons after nasal application of OT vs vehicle control

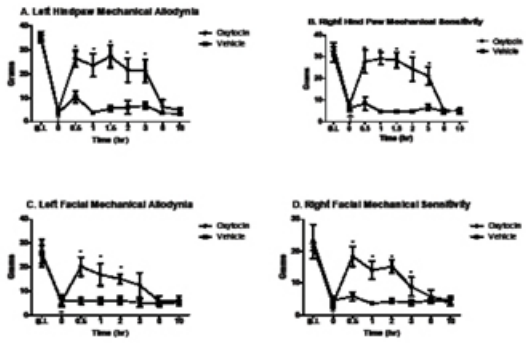


Nasal OT effects on post-TBI pain

Mechanical sensitivity (von Frey) after mild TBI or sham surgery

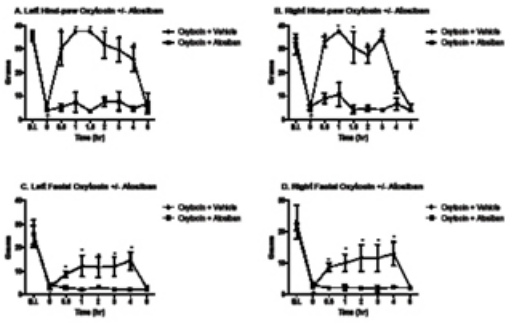


The effect of nasal oxytocin on allodynia after mild TBI.

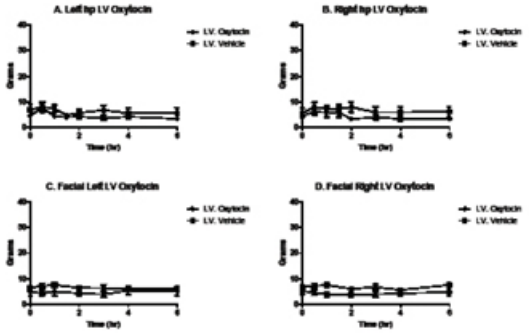


Nasal OT effects on post-TBI pain

Anti-allodynic effect of nasal OT is blocked by the OT antagonist Atosiban



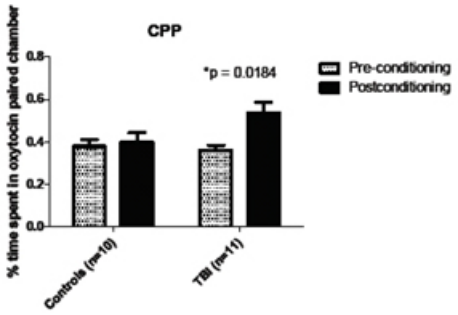
IV OT is ineffective in preventing post-TBI allodynia

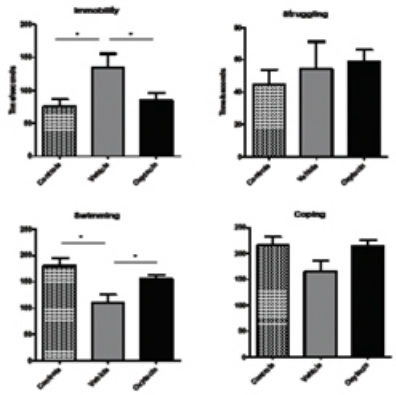


Nasal OT effects on post-TBI pain

Nasal OT has no effect on Conditioned Place Preference in control animals: analgesia without addictive potential

Nasal OT is effective in some aspects of post-TBI Depression in the forced swim test

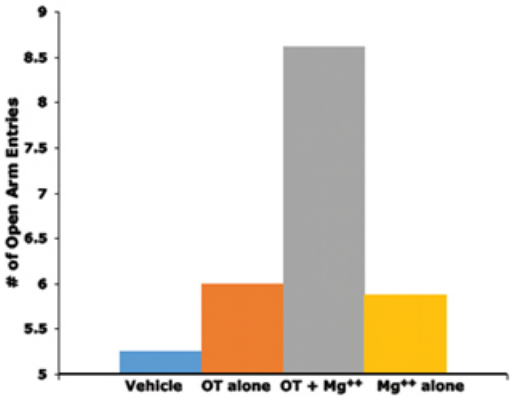




IN OT for Core PTSD Symptom of Anxiety

- Proprietary Formulation of Nasal Oxytocin Plus Mg++ Provides Synergistic Improvement in Elevated Plus Maze test of Anxiety

Elevated Plus Maze Test of Anxiety



Conclusions: IN Oxytocin in Post-traumatic Headache (PTH)

- After intranasal application, oxytocin concentrates in the trigeminal system
- Intranasal, but not IV Oxytocin attenuates pain responses in a rat model of traumatic brain injury without addictive potential
- These analgesic effects can be blocked by an oxytocin antagonist showing receptor specificity
- Intranasal oxytocin also attenuates post-TBI depressive and anxiety behaviors
- Addition of magnesium enhances the effects of intranasal oxytocin

Exhibit 99.03

Tonix Pharmaceuticals Announces that Results from a Preclinical Study of TNX-1900 are Posted at the AAN Sports Concussion Virtual Conference

NEW YORK, August 4, 2020 - Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that preclinical results of TNX-1900 (oxytocin solution for intranasal delivery) are posted at the American Academy of Neurology's first-ever Sports Concussion Conference. The research was sponsored by Trigemina, Inc. In June 2020 Tonix acquired the assets of Trigemina, including certain rights to the data described in the presentation. The virtual meeting was held July 31, 2020 and August 1, 2020. The presentation can be found on the Scientific Presentations page of Tonix's website.

The presentation, titled "*Intranasal (IN) Oxytocin Relieves Pain and Depressive Behavior in a Rodent Model of Mild Traumatic Brain Injury (TBI),*" includes data from a preclinical study which investigated the efficacy of intranasal oxytocin in relieving pain and associated depressive behavior following traumatic brain injury. The data show that intranasal oxytocin, but not intravenous oxytocin or vehicle, attenuated both reactive and spontaneous pain following mild traumatic brain injury in an animal model. Intranasal oxytocin was also shown to attenuate post-traumatic brain injury depressive and anxiety behaviors in the same animal model. These effects were blocked by the oxytocin receptor antagonist, Atosiban, indicating the effects of intranasal oxytocin were mediated by oxytocin receptors. Intranasal oxytocin was shown to result in high concentrations of oxytocin primarily in the trigeminal ganglia.

"The preclinical data that we have seen to date show that intranasal oxytocin has the potential to be a treatment for pain and depressive behavior associated with traumatic brain injury headaches and post-concussion syndrome," said Seth Lederman, M.D., Chief Executive Officer of Tonix.

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This press release and further information about Tonix can be found at www.tonixpharma.com.

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