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): **March 26, 2026**

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.

200 Connell Drive, Berkeley Heights, New Jersey, 07922
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(862) 799-8599**

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 Select 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 7.01 Regulation FD Disclosure.

On March 26, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the first participant was dosed in a Phase 1 investigator-initiated study to evaluate the effect of its TNX-1900 (intranasal potentiated oxytocin) product candidate on trigeminal nerve-mediated vasodilation of the forehead using capsaicin and electrical stimulation.

The information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On March 26, 2026, the Company announced that the first participant was dosed in a Phase 1 investigator-initiated study to evaluate the effect of TNX-1900 on trigeminal nerve-mediated vasodilation of the forehead using capsaicin and electrical stimulation, a model for trigeminal neurovascular reactivity, in healthy female human volunteers. Dr. Antoinette Maassen van den Brink, Professor of Neurovascular Pharmacology, Erasmus University Medical Center, is the principal investigator for the study pursuant to a collaborative research agreement with the Company.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release of the Company, March 26, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 26, 2026

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

Exhibit 99.01

Tonix Pharmaceuticals Announces First Participant Dosed in Phase 1 Investigator-Initiated Pharmacodynamic Study of TNX-1900 (Intranasal Potentiated Oxytocin) to Assess Potential for Treating Migraine and Craniofacial Pain

Intranasal oxytocin blocks the release of calcitonin gene-related peptide (CGRP) in animal models and is the core technology of TNX-1900 for craniofacial pain conditions, including migraine and trigeminal neuralgia

TNX-1900 will be studied in the trigeminal neurovascular reactivity model, by measuring the forehead skin blood flow response to capsaicin and electrical stimulation by Laser Speckle Contrast Imaging (LSCI)

Oxytocin treatment affects a pathway distinct from the recently available CGRP migraine treatment drug class

BERKELEY HEIGHTS, N.J., March 26, 2026 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a fully integrated, commercial biotechnology company, today announced that the first participant has been dosed in a Phase 1 investigator-initiated study to evaluate the effect of TNX-1900 (intranasal potentiated oxytocin) on trigeminal nerve-mediated vasodilation of the forehead using capsaicin as well as electrical stimulation, a model for trigeminal neurovascular reactivity, in healthy female human volunteers. Dr. Antoinette Maassen van den Brink, Professor of Neurovascular Pharmacology, Erasmus University Medical Center, is serving as principal investigator and sponsor for the study in a collaborative research agreement with Tonix.

In animal studies, intranasal oxytocin has been shown to bind to oxytocin receptors in the trigeminal ganglion, blocking the release of calcitonin gene-related peptide (CGRP), a potent vasodilator critically involved in the pathogenesis of migraine.1 Dr. Maassen van den Brink has previously found a CGRP inhibitor and a triptan to inhibit the forehead dermal blood flow response to capsaicin in migraineurs and healthy volunteers, respectively.[2,3]

“We are excited to collaborate with Professor Maassen van den Brink on this proof-of-concept study investigating the potential for TNX-1900 for treating migraine, craniofacial pain, and other related conditions,” said Seth Lederman, MD, Chief Executive Officer of Tonix Pharmaceuticals. “While there are several CGRP inhibitors approved for the treatment of migraine, TNX-1900’s oxytocin treatment affects a distinct pathway that could address unmet needs. The results of the new study will guide future development of this potential non-opioid treatment for migraine and other craniofacial pain conditions.”

As part of the preliminary work in support of this study, Dr. Maassen van den Brink’s team recently validated a newer detection method for dermal blood flow known as Laser Speckle Contrast Imaging (LSCI) in the trigeminal neurovascular reactivity model.[4]

“We are excited to be using LSCI in this study of TNX-1900, which adds to our established model by providing real-time and higher resolution dermal blood flow measurements, compared to Laser Doppler Perfusion Imaging used in earlier studies,” said Dr. Maassen van den Brink. “Oxytocin represents a potential new therapeutic option, targeting a pathway in migraine and craniofacial pain that is distinct from both the triptan and CGRP inhibitor migraine treatment drug classes.”

About Migraine

Migraine is a neurovascular condition that typically manifests in a throbbing moderate to severe headache which lasts at least four hours, often on one side of the head and aggravated by routine physical activity. It can also be accompanied by nausea, vomiting, visual disturbances, and sensitivity to bright light and loud noises.[5] Epidemiological studies indicate that globally, approximately 1.2 billion individuals suffer from migraines annually.[6] In the U.S., approximately 39 million Americans suffer from migraines, and among these individuals, approximately four million experience chronic migraines (15 or more headache days per month, at least eight of which are migraines).[6]

About TNX-1900

TNX-1900 (intranasal potentiated oxytocin) is a proprietary formulation of oxytocin in development as a candidate for the treatment of migraine and craniofacial pain. TNX-1900 is a drug-device combination product, based on an intranasal actuator device that delivers oxytocin into the nasal cavity. Oxytocin is a naturally occurring human peptide hormone that also acts as a neurotransmitter in the brain. Oxytocin has no recognized addiction potential. Oxytocin when delivered via the nasal route, concentrates in the trigeminal system[7] resulting in binding of oxytocin to receptors on neurons in the trigeminal system, inhibiting the release of CGRP and transmission of pain signals returning from the site of CGRP release.[1] Blocking CGRP release is a distinct mechanism compared with CGRP receptor antagonist and anti-CGRP antibody drugs, which block the binding of CGRP to its receptor, or bind to the peptide CGRP. The addition of magnesium to the oxytocin formulation in TNX-1900 enhances oxytocin receptor binding[8] as well as having an inhibitory effect on trigeminal neurons and resultant craniofacial analgesic effects, as demonstrated in animal models.[9] Intranasal oxytocin has been shown to be well tolerated in several clinical trials in both adults and children.[10] Targeted nasal delivery results in low systemic exposure and lower risk of non-nervous system, off-target effects, which could potentially occur with systemic CGRP receptor antagonists and anti-CGRP (receptor) antibodies.[11] For example, CGRP has roles in dilating blood vessels in response to ischemia, including in the heart. The Company believes nasally targeted delivery of oxytocin could translate into selective blockade of CGRP release from neurons in the trigeminal ganglion and not throughout the body, which could be a potential safety advantage over systemic CGRP inhibition. This mechanism is being investigated in a Phase 1 study to evaluate the effect of TNX-1900 on trigeminal nerve-mediated vasodilation of the forehead model for craniofacial pain. In addition, daily dosing is more rapidly reversible, in contrast to monthly or quarterly dosing, as is the case with anti-CGRP antibodies, giving physicians and their patients greater control. In addition to craniofacial pain conditions, TNX-1900 is being developed for treatment of binge eating disorder, adolescent obesity, bone health in pediatric autism and arginine-vasopressin deficiency. Tonix also has a license with the University of Geneva to use TNX-1900 for the treatment of insulin resistance and related conditions.

Citations

[1]Tzabazis A, et al. Oxytocin receptor: Expression in the trigeminal nociceptive system and potential role in the treatment of headache disorders. *Cephalalgia*. 2016. 36(10):943-50.

[2]de Vries Lentsch S, et al. CGRP-mediated trigeminovascular reactivity in migraine patients treated with erenumab. *J Neurol Neurosurg Psychiatry*. 2022 Aug;93(8):911-912.

[3]Ibrahimi K, et al. A human trigeminovascular biomarker for antimigraine drugs: A randomized double-blind, placebo-controlled, crossover trial with sumatriptan. *Cephalalgia*. 2017 Jan;37(1):94-98.

[4]van Lohuizen et al. 2025. Trigeminovascular activity using a forehead dermal blood flow model: preliminary results of a validation study. *J Headache and Pain* 26 (Suppl 2): 138.

[5]The International Classification of Headache Disorders, 3rd Edition. *Cephalalgia*. 2018. 38(1):1-211.

[6]Burch et al. Migraine: Epidemiology, Burden, and Comorbidity. *Neurol Clin* 37 (2019):631–649.

[7]Yeomans DC, et al. Nasal oxytocin for the treatment of psychiatric disorders and pain: achieving meaningful brain concentrations. *Transl Psychiatry*. 2021. 11(1):388.

[8]Antoni FA and Chadio SE. Essential role of magnesium in oxytocin-receptor affinity and ligand specificity. *Biochem J.* 1989. 257(2):611-4.

[9]Cai Q, et al. Systematic review and meta-analysis of reported adverse events of long-term intranasal oxytocin treatment for autism spectrum disorder. *Psychiatry Clin Neurosci*. 2018. 72(3):140-151.

[10]Yeomans, DC et al. 2017. US patent US2017368095.

[11]MaassenVanDenBrink A, et al. Wiping out CGRP: potential cardiovascular risks. *Trends Pharmacol Sci*. 2016. 37(9):779-788.

Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully-integrated, commercial-stage biotechnology company focused on central nervous system (CNS) and immunology treatments in areas of high unmet medical need. TONMYA® (cyclobenzaprine HCl sublingual tablets 2.8 mg), is the first new treatment for fibromyalgia in adults in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace® Symtouch® (sumatriptan injection 3 mg) and Tosymra® (sumatriptan nasal spray 10 mg). Tonix is investigating TONMYA® in Phase 2 clinical trials to evaluate its potential in major depressive disorder and acute stress disorder/acute stress reaction. In addition, the Company's CNS portfolio includes TNX-2900 (intranasal oxytocin), which is Phase 2 ready for the treatment of Prader-Willi syndrome, a rare disease. Tonix is also advancing a pipeline of immunology programs, including long-acting human monoclonal antibody TNX-4800 for Lyme disease prophylaxis, and TNX-1500, a third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. To learn more, visit www.tonixpharma.com and follow the Company on LinkedIn and X.

*Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statements that are predictive in nature. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. 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 the failure to successfully launch and commercialize TONMYA and any of our approved products; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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 Company's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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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