

**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 18, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(IRS Employer
Identification No.)

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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 Capital 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 September 18, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced data relevant to the proposed mechanism of the Company's TNX-1900 (intranasal potentiated oxytocin) product candidate in treating chronic migraine in a poster and an oral presentation at the 2023 International Headache Congress ("IHC"), held September 14, 2023 to September 17, 2023, entitled *Human trigeminal ganglia possess oxytocin receptors on CGRP positive neurons: expression increased by inflammation* (the "Presentation"). A copy of the press release that discusses this matter is filed as [Exhibit 99.01](#) hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including [Exhibit 99.01](#) attached hereto, 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 September 18, 2023, the Company announced the Presentation at the IHC conference by David C. Yeomans, Ph.D. Data from the Presentation shows that oxytocin receptors are co-expressed with calcitonin gene-related peptide ("CGRP") on isolated human trigeminal ganglia neurons, similar to previous findings in animal trigeminal ganglia. The inflammatory cytokine IL-6 upregulated expression of oxytocin receptors on human trigeminal neurons, consistent with the previously observed impact of inflammation on the potency of oxytocin. In animals, oxytocin has been shown to functionally inhibit the excitability of trigeminal neurons, which is consistent with oxytocin inhibiting the release of CGRP at trigeminal nerve terminals, which the Company believes relates to its mechanism in preventing migraines. The data also demonstrates that oxytocin receptors are present on human trigeminal ganglia neurons, and that these same neurons express CGRP, a key peptide in the pathogenesis of migraine. These data support the proposed mechanism of TNX-1900, which the Company believes inhibits the release of CGRP from trigeminal neurons that otherwise would trigger a cascade leading to migraine. In addition, the inflammatory mediator IL-6 induces robust upregulation of oxytocin receptors on human trigeminal ganglia neurons. In the presence of inflammation, which is persistently present in chronic migraine, there is a robust increase in the expression of both oxytocin receptors and CGRP in human trigeminal neurons.

Forward-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 SEC. 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 September 18, 2023
	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: September 18, 2023

By: /s/ Bradley Saenger

Bradley Saenger

Chief Financial Officer

Tonix Pharmaceuticals Announces Presentation of Non-Clinical Studies Supporting the Mechanism of TNX-1900 (Intranasal Potentiated Oxytocin) at the 2023 International Headache Congress

Oxytocin receptors and CGRP are co-expressed on human trigeminal ganglia neurons and their expression is increased in inflammation

Human tissue data support the proposed mechanism of action of TNX-1900 in treating headache: oxytocin treatment blocks the release of CGRP

CHATHAM, N.J., September 18, 2023 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that David C. Yeomans, Ph.D. presented data relevant to the proposed mechanism of TNX-1900 (intranasal potentiated oxytocin) in treating chronic migraine in a poster and an oral presentation at the 2023 International Headache Congress (IHC), being held September 14-17, 2023, in Seoul, South Korea. The poster and oral presentation titled, “*Human trigeminal ganglia possess oxytocin receptors on CGRP positive neurons: expression increased by inflammation*,” include research sponsored by and licensed to Tonix Pharmaceuticals. Professor Yeomans was a founder of Trigemina, which Tonix acquired, and he remains a consultant to Tonix. A copy of the poster is available under the [Scientific Presentations](#) tab of the Tonix Pharmaceuticals corporate website at www.tonixpharma.com.

The presentations show that oxytocin receptors are co-expressed with calcitonin gene-related peptide (CGRP) on human trigeminal ganglia neurons, which is similar to Professor Yeomans’ previous findings in animal trigeminal ganglia. The inflammatory cytokine IL-6 upregulated expression of oxytocin receptors on human trigeminal neurons, consistent with the previously observed impact of inflammation on the potency of oxytocin. In animals, oxytocin has been shown to functionally inhibit the excitability of trigeminal neurons, which is consistent with oxytocin inhibiting the release of CGRP at trigeminal nerve terminals.¹

“In animal studies, oxytocin has been shown to inhibit trigeminal neurons which we believe relates to its mechanism in preventing migraines,”¹ said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “The data presented at 2023 IHC by Professor Yeomans shows that oxytocin receptors are present on human trigeminal ganglia neurons, and that these same neurons express CGRP, a key peptide in the pathogenesis of migraine. These data support the proposed mechanism of TNX-1900, which we believe inhibits the release of CGRP from trigeminal neurons that otherwise would trigger a cascade leading to migraine.”

“Similar to animals, human trigeminal ganglia neurons express oxytocin receptors and also co-express CGRP,” said Professor Yeomans. “In addition, the inflammatory mediator IL-6 induces robust upregulation of oxytocin receptors on human trigeminal ganglia neurons. In the presence of inflammation, which is persistently present in chronic migraine, there is a robust increase in the expression of both oxytocin receptors and CGRP in human trigeminal neurons.”

In February 2023, Tonix initiated enrollment in the Phase 2 ‘PREVENTION’ study of TNX-1900 for the prevention of migraine headache in chronic migraineurs. Topline results from the study are expected in the fourth quarter of 2023. In addition, TNX-1900 is also being evaluated in investigator-initiated Phase 2 trials in adolescent obesity (initiated July 2023), binge eating disorder and social anxiety disorder.

1. Tzabazis A, et al. *Cephalalgia*. 2016. 36(10):943-50.

Tonix Pharmaceuticals Holding Corp. *

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix’s development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’s CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, having completed enrollment of a potentially confirmatory Phase 3 study in the third quarter of 2023, with topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition. Topline results from a proof-of-concept Phase 2 study were reported in the third quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily oral formulation being developed as a treatment for major depressive disorder (MDD), that completed enrollment in a Phase 2 proof-of-concept study in the third quarter of 2023, with topline results expected in the fourth quarter of 2023. TNX-4300 (estianeptine) is a single isomer version of TNX-601, a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer’s disease and Parkinson’s disease. Relative to tianeptine, estianeptine lacks activity on the μ -opioid receptor while maintaining activity in the rat Novel Object Recognition test *in vivo* and the ability to activate PPAR- β/δ and neuroplasticity in tissue culture. TNX-1900 (intranasal potentiated oxytocin), is in development for preventing headaches in chronic migraine, and has completed enrollment in a Phase 2 proof-of-concept study with topline data expected in the fourth quarter of 2023. TNX-1900 is also being studied in binge eating disorder, pediatric obesity and social anxiety disorder by academic collaborators under investigator-initiated INDs. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the fourth quarter of 2023. Tonix’s rare disease development portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix’s immunology development portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 was initiated in the third quarter of

2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

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

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc. All other marks are property of their respective owners.

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 the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; 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, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, 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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