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 21, 2024

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.)**

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 March 21, 2024, the Company announced the presentation of a poster at the American Chemistry Society ("ACS") Spring 2024 Meeting, held March 17, 2024 to March 21, 2024. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference. A copy of the poster is furnished hereto as Exhibit 99.02, and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01 and 99.02 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 March 21, 2024, the Company announced the presentation of a poster at the ACS Spring 2024 Meeting. The poster presentation, entitled,*Oxytocin Analogs with Enhanced Craniofacial Antinociceptive Effects in Low Magnesium Formulations,* describes the discovery and characterization of novel oxytocin analogues that are candidate treatments for craniofacial pain, excessive eating (including Prader Willi Syndrome), and endocrinological conditions, including bone health in autism and insulin resistance. The Company believes that the oxytocin analogues described in the poster have enhanced binding to Mg^{++}, and consequently their activity does not require Mg^{++} augmentation, which preclinical evidence demonstrates is required for the activity of intranasal oxytocin.

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, March 21, 2024
99.02	Oxytocin Analogs with Enhanced Craniofacial Antinociceptive Effects in Low Magnesium Formulations
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 21, 2024

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

EXHIBIT 99.01

Tonix Pharmaceuticals Announces Poster Presentation Describing Discovery of Novel Next-Generation Oxytocin Analogues at the American Chemistry Society (ACS) Spring 2024 Meeting

Four Phase 2 investigator-initiated studies of TNX-1900 (intranasal potentiated oxytocin) are ongoing for pediatric obesity, binge eating disorder, bone health in autism and social anxiety disorder

TNX-2900 (intranasal potentiated oxytocin) is being developed under an IND as a treatment for Prader-Willi Syndrome, an Orphan Disease characterized by excessive eating

TNX-1900 and TNX-2900 may serve as novel neuroendocrine treatments for certain pain, eating and endocrine disorders

CHATHAM, N.J., March 21, 2024 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announces a poster presentation at the American Chemistry Society (ACS) Spring 2024 Meeting, held March 17-21, 2024, in New Orleans, Louisiana. A copy of the poster is available under the scientific presentations page of the Tonix website at www.tonixpharma.com.

The poster presentation titled, *Oxytocin Analogs with Enhanced Craniofacial Antinociceptive Effects in Low Magnesium Formulations,* describes the discovery and characterization of novel oxytocin analogues that are candidate treatments for craniofacial pain, excessive eating (including Prader Willi Syndrome), and endocrinological conditions including bone health in autism and insulin resistance.

“Intranasal oxytocin has several potential therapeutic applications,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Preclinical studies have shown that oxytocin, a hypothalamic peptide hormone, simultaneously reduces food intake and increases energy expenditure, leading to weight loss.[1-3] Intranasal oxytocin is well-tolerated and in published studies of adults, results in reduced caloric intake, increased fat burning and improved insulin sensitivity.”[1-3]

Dr. Lederman continued, “There is preclinical evidence that the activity of intranasal oxytocin is dependent on magnesium (Mg^{++}) concentration.[4-6] Our current intranasal oxytocin formulations of TNX-1900 and TNX-2900 contain Mg^{++} to augment the activity. We believe the new oxytocin analogues described in the poster have enhanced binding to Mg^{++} and consequently their activity does not require Mg^{++} augmentation.”

Four Phase 2 investigator-initiated studies of TNX-1900 are currently ongoing; three at the Massachusetts General Hospital (MGH) and one at the University of Washington. The Phase 2 ‘POWER’ study at MGH is investigating the efficacy and safety of TNX-1900 as a novel therapeutic agent to induce weight loss and improve indicators of cardiometabolic risk in adolescent patients with obesity. The Phase 2 ‘STROBE’ study at MGH is investigating the efficacy and safety of TNX-1900 as a novel therapeutic agent to reduce binge eating frequency in adults with binge-eating disorder. The Department of Defense (DoD)-funded Phase 2 ‘BOX’ study at MGH is investigating the efficacy and safety of TNX-1900 as a novel therapeutic agent to improve bone health in children with autism spectrum disorder. In addition, a Phase 2 study at the University of Washington is investigating the potential role of TNX-1900 in enhancing vicarious extinction learning in social anxiety disorder, compared to healthy controls.

About TNX-1900 and TNX-2900

TNX-1900 and TNX-2900 (intranasal potentiated oxytocin) are proprietary formulations of oxytocin. TNX-1900 is in Phase 2 development under investigator-initiated INDs as a candidate for adolescent obesity, binge eating disorder, bone health in autism and social anxiety disorder. TNX-1900 is also planned for development in treating insulin resistance. TNX-2900 is in development as a treatment for Prader Willi Syndrome. TNX-2900 has received orphan drug designation from the U.S. Food and Drug Administration (FDA) and its IND has been cleared. In 2020, TNX-1900 was acquired from Trigemina, Inc. who had licensed the technology underlying the composition and method from Stanford University. TNX-1900 is a drug-device combination product, based on an intranasal actuator device that delivers oxytocin into the nasal cavity. Tonix’s patented intranasal potentiated oxytocin formulation intended for use by adults and adolescents. Tonix’s patented potentiated oxytocin formulation is believed to increase specificity for oxytocin receptors relative to vasopressin receptors as well as to enhance the potency of oxytocin. Oxytocin is a naturally occurring human hormone that acts as a neurotransmitter in the brain. Oxytocin is believed to be more than 600 million years old and is present in vertebrates including mammals, birds, reptiles, amphibians and fish.[7] It was originally approved by the U.S. Food and Drug Administration as Pitocin®*, an intravenous infusion or intramuscular injection drug, for use in pregnant women to induce labor. An intranasal formulation of oxytocin is marketed in some European countries to assist in the production of breast milk as Syntocinon®** (oxytocin nasal 40 units/ml). Oxytocin has no recognized addiction potential. Oxytocin, when delivered via the nasal route, concentrates in the trigeminal system[1] resulting in binding of oxytocin to receptors on neurons in the trigeminal system. With TNX-1900 and TNX-2900, the addition of magnesium to the oxytocin formulation enhances oxytocin receptor binding[8] as well as its inhibitory effects 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. Tonix also has a license with the University of Geneva to use TNX-1900 for the treatment of insulin resistance and related conditions.

About Prader-Willi Syndrome (PWS)

PWS is recognized as the most common genetic cause of life-threatening childhood obesity and affects males and females with equal frequency and all races and ethnicities. PWS results from the absence of expression of a group of genes on the paternally acquired chromosome 15. The hallmarks of PWS are lack of suckling in newborns and, in children and adolescents, severe hyperphagia, an overriding physiological drive to eat, leading to severe obesity and other complications associated with significant mortality. A systematic review of the morbidity and mortality as a consequence of hyperphagia in PWS found that the average age of death in PWS was 22.1 years.[11] There is no approved medication to treat poor feeding in newborns or hyperphagia in children and adolescents with PWS. Given these serious or life-threatening manifestations of these conditions, there is a critical need for effective treatments to decrease morbidity and mortality, improve quality of life, and increase life expectancy in people with PWS. Oxytocin has potent effects in adult mice correcting behavioral characteristics of the *Magel2* knock-out mouse model for PWS and autism.[1,2] In addition, oxytocin has potent effects in correcting behavioral characteristics of the neonatal *Magel2* knock-out mouse model for PWS and autism[1,3] and intriguing effects in a clinical trial of neonates with PWS.[14]

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

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

References

[1]Lawson EA, et al. *J Neuroendocrinol* 2020;32(4):e12805. doi: 10.1111/jne.12805.
[2]Niu J, et al. *Front Neurosci* 2021;15:743546. doi: 10.3389/fnins.2021.743546.
[3]Maejima Y, et al. *Neuroendocrinology* 2018;107(1):91-104.
[4]Yeomans DC, et al. *Transl Psychiatry*. 2021. 11(1):388.
[5]Tzabazis A, et al. *Cephalalgia*. 2016. 36(10):943-50.
[6]Meyerowitz JG, et al. *Nat Struct Mol Biol*. 2022. 29(3):274-281.
[7]Gruber CW. *Exp Physiol*. 2014. 99(1):55-61. doi: 10.1113/expphysiol.2013.072561.
[8]Antoni FA and Chadio SE. *Biochem J*. 1989. 257(2):611-4.
[9]Cai Q, et al., *Psychiatry Clin Neurosci*. 2018. 72(3):140-151.
[10]Yeomans, DC et al. 2017. US patent US2017368095
[11]Bellis SA, et al. *Eur J Med Genet*. 2022. 65(1):104379.
[12]Meziane H, et al. *Biol Psychiatry*. 2015. 78(2):85-94.
[13]Bertoni A, et al. *Mol Psychiatry*. 2021. 26(12):7582-7595.
[14]Tauber M, et al. *Pediatrics*. 2017. 139(2):e20162976.

Tonix Pharmaceuticals Holding Corp.[*]

Tonix is a biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for Tonmya, a product candidate for which two positive Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction as well as fibromyalgia-type Long COVID. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase) a biologic designed to treat cocaine intoxication with Breakthrough Therapy designation. Tonix's immunology development portfolio consists of 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. Tonix also has product candidates in development in the areas of rare disease and infectious disease. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication. Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration as the tradename for TNX-102 SL for the management of fibromyalgia.

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 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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EXHIBIT 99.02

Oxytocin Analogs with Enhanced Craniofacial Antinociceptive Effects in Low Magnesium Formulations

Darryl Rideout, Ph.D.[1*], Bruce Daugherty, Ph.D.[1], David T. Hsu, Ph.D.[1], Xinmin Simon Xie, M.D., Ph.D.[2], David Yeomans, Ph.D.[3], Brent Stranix, Ph.D.[4], Daniel St-Cyr, Ph.D.[4], Jan-Felix Scholtes, Ph.D.[4], Cristobal Alhambra, Ph.D.[4], Luciana Leo, Ph.D.[5], Sam R.J Hoare, Ph.D[5]., Seth Lederman, M.D.[1], Gregory M. Sullivan, M.D.[1]

[1]Tonix Pharmaceuticals Inc., 26 Main St, Suite 101 Chatham NJ 07928 [2]AfaSci Research Laboratories, 522 Second Avenue, Redwood City, CA 94063 [3]Stanford University Dept. of Anesthesiology, Perioperative and Pain Medicine 300 Pasteur Drive, Room H3580 MC 5640 Stanford, CA 94305 [4]X-Chem, Inc. 4800 Rue Levy-Suite 200, Montreal, QC, Canada H4S 1Z9 [5]Montana Molecular, 366 Gallatin Park Dr., Bozeman, MT 59715

* Presenter

INTRODUCTION

EXPERIMENTAL METHODS-CHEMICAL SYNTHESIS

Chemical Design and Synthesis

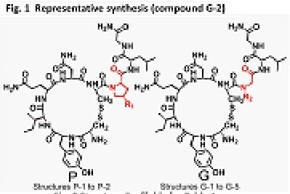
Biological assays.

Antinociception in Rats with craniofacial pain

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
oxytocin (OT)	P-1	-H	--	6.5	13.5	9.0	100	100	0
--	P-2	-OH	--	8.5	12.0	3.6	96	92	-4
--	G-1	--	[illegible]	5	6	1.0	73	89	16
R721	G-2	--	[illegible]	9.5	8.5	-1.0	36	65	29
--	G-3	--	[illegible]	7.5	13.5	6.0	---	---	---
--	G-4	--	[illegible]	8.5	7.7	7.2	92	94	2
--	G-5	--	[illegible]	9	5.8	2.8	---	---	---

Table 1

Fig. 1 Representative synthesis (compound G-2)



Structures P-1 to P-2 Structures G-1 to G-5

Fig. 2 Structure Scaffolds for Table 1

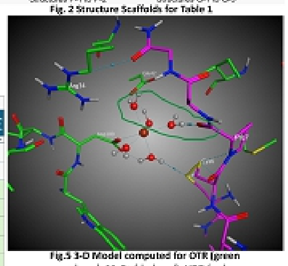


Fig.5 3-D Model computed for OTR (green carbons), Mg2+ (dark red), H2O (red, white) and OT (magenta carbons)

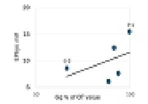


Fig. 3 Ephys vs. Gq at high Mg2+

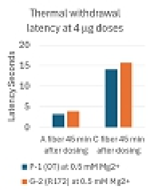


Fig. 4 P-1 and G-2 antinociception at 4 µg in male rats

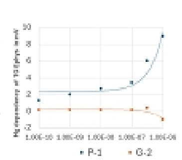


Fig. 6 Ephys Mg2+ Dependence for P-1 and G-2 (1.75 mM vs 0.5 mM)

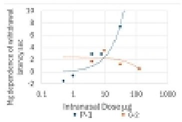


Fig. 7 C-fiber Antinociceptive Mg2+ Dependence for P-1 (300 mM vs 0 mM, Bharadwaj) and G-2 (1.75 mM vs 0.5 mM)

Concentration of G-2 (R721)	Withdrawal Latency (s) 0.5 mM $MgCl_2$	Withdrawal Latency (s) 1.75 mM $MgCl_2$
4 µg	1.725	1.175
10 µg	1.55	1.325
32 µg	2.6	2.275
128 µg	2.3125	2.6875

Table 2 Comparison of A-fiber antinociceptive effect in low and high Mg2+ concentrations

RESULTS

In vitro Gq assays.

EPhys.

Craniofacial Antinociception.

DISCUSSION AND CONCLUSIONS

Discussion

Conclusion

References

www.tonixpharma.com Presented at the American Chemical Society Spring 2024 Meeting March 20, 2024