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 25, 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 25, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the U.S. Food and Drug Administration ("FDA") granted Rare Pediatric Disease Designation to its TNX-2900 (intranasal potentiated oxytocin) product candidate to treat Prader-Willi syndrome ("PWS") in children and adolescents. A copy of the press release that discusses this matter is filed as Exhibit 99.01 and 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 March 25, 2024, the Company announced that the FDA granted Rare Pediatric Disease Designation to TNX-2900 to treat PWS in children and adolescents.

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, dated March 25, 2024
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 25, 2024

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

EXHIBIT 99.01

Tonix Pharmaceuticals Receives Rare Pediatric Disease Designation from the FDA for TNX-2900 for the Treatment of Prader-Willi Syndrome

TNX-2900 is a proprietary magnesium-potentiated formulation of intranasal oxytocin, a naturally occurring hormone that reduces appetite and eating

Prader Willi syndrome is the most common genetic cause of life-threatening childhood obesity

CHATHAM, N.J., March 25, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation to TNX-2900* (intranasal potentiated oxytocin), a proprietary magnesium ($Mg2^{+}$)-potentiated formulation of intranasal oxytocin, to treat Prader-Willi syndrome (PWS) in children and adolescents. TNX-2900 was previously granted Orphan Drug designation by the FDA in 2022 for the treatment of PWS and the investigational new drug (IND) application was cleared by the FDA in 2023. The Company may be eligible to receive a transferable Priority Review Voucher if TNX-2900 for PWS is approved for marketing. Recently, vouchers have sold for approximately $100 million.

“The Rare Pediatric Disease Designation is an important regulatory milestone in the development of TNX-2900. With PWS being the most common genetic cause of life-threatening childhood obesity, we are excited that the FDA has recognized this significant unmet need in children and adolescents, particularly for PWS hyperphagia, which currently has no approved treatments[1,2],” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “As PWS is a genetic disorder associated with abnormalities of the oxytocin system, Tonix believes TNX-2900’s unique formulation has the potential to improve intranasal oxytocin’s therapeutic action by addressing limitations in efficacy observed at high-dose intranasal oxytocin that is not $Mg2^{+}$-potentiated[3,4].”

The FDA defines a rare pediatric disease as a serious or life-threating disease that primarily affects individuals aged from birth to 18 years and affects under 200,000 people in the United States.

About FDA’s Rare Pediatric Disease Priority Voucher Program

The FDA’s Rare Pediatric Disease Priority Voucher Program is intended to encourage the development of new drugs to treat certain rare pediatric diseases. Under the FDA’s Rare Pediatric Disease Designation and Voucher Program, if TNX-2900 is approved for marketing, Tonix may qualify for a priority review voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product. Priority review vouchers may also be sold or transferred to another sponsor. The new sponsor can redeem the voucher to receive priority review for a different product, which reduces the review time of NDAs from 10 months to six months. There is no limit on the number of times a priority review voucher can be transferred. A 2020 U.S. Government Accounting Office analysis [5] of the voucher program found that in the ten years since launch of the program in 2009, the price of buying priority review vouchers ranged from $67 million to $350 million. More recently, priority review vouchers were acquired by Novo Nordisk for $110 million in June of 2022, and by Novartis for $100 million from Marinus in July of 2022.[6] Bluebird Bio sold vouchers for $102 million, $95 million and $103 million in November 2022, January 2023, and October 2023, respectively.[7-9] In June of 2023, Novartis bought a priority review voucher from Pharming for $21 million, a price that had been negotiated as part of a purchase agreement when Pharming acquired the asset from Novartis.[5]

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.[10] There is no approved medication to treat poor feeding in newborns or hyperphagia in children and adolescents with PWS. Given the 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 correcting behavioral characteristics of the *Magel2* knock-out mouse model for PWS and autism.[11-13] Six clinical trials have investigated intranasal oxytocin as a treatment in pediatric patients with PWS. Four studies showed evidence for improvement in PWS-related behaviors/symptoms[14-17]; three clinical studies reported evidence for improvement in hyperphagia[14,15,17]; and one clinical study showed an improvement in sucking in infants[16].

About TNX-2900 and Tonix’s Potentiated Oxytocin Platform

TNX-2900 is based on Tonix’s patented intranasal Mg^{2+}-potentiated oxytocin formulation intended for use by children and adolescents. This formulation is believed to enhance the potency of oxytocin as well as increase specificity for oxytocin receptors relative to vasopressin receptors, potentially reducing unwanted side effects from activating vasopressin receptors. Tonix is also developing a different intranasal formulation, designated TNX-1900 for adolescent obesity, binge eating disorder, bone health in autism, and social anxiety disorder. 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.[18] It was initially 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 and control postpartum bleeding or hemorrhage. An intranasal formulation of oxytocin is marketed in some European countries to assist in breast milk production as Syntocinon®*** (oxytocin nasal 40 units/ml).

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.

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*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.

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

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

Citations

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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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