**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 3, 2022**

# 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 Jersey07928
**(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 Global 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 3, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") granted orphan drug designation for its TNX-2900 (intranasal potentiated oxytocin) product candidate for the treatment of Prader-Willi in adolescents and adults with hyperphagia. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, 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 3, 2022, the Company issued a press release announcing that the FDA granted orphan drug designation for TNX-2900 for the treatment of Prader-Willi in adolescents and adults with hyperphagia.

*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 development of TNX-2900, 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 March 3, 2022 |
| 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 3, 2022

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

**Exhibit 99.01**

# Tonix Pharmaceuticals Announces FDA Orphan-Drug Designation for TNX-2900 for the Treatment of Prader-Willi Syndrome

CHATHAM, N.J., March 3, 2022 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan-Drug Designation for TNX-2900* (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome.

"Orphan-Drug Designation by the FDA is an important milestone and further validates our efforts to investigate the utility of TNX-2900 for Prader-Willi syndrome," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "It underscores the urgent, unmet medical need for patients diagnosed with this disease, and will benefit us as we continue to advance our program."

As recently announced, Tonix entered into a sponsored research agreement with Inserm Transfert, the private subsidiary of Inserm, on behalf of Inserm (the French National Institute of Health and Medical Research) and Aix-Marseille Université to study oxytocin in the genetically engineered mouse model of Prader-Willi syndrome, a rare genetic disorder that causes distinct, but related pathological eating disorders in adults and newborns. In adults, Prader-Willi causes hyperphagia, or pathological over-eating, which leads to obesity and other complications associated with significant mortality. In newborns, Prader-Willi causes a deficiency in suckling, which has been shown to be normalized by oxytocin treatment.

The FDA's Office of Orphan Drug Products grants orphan status to the active moiety of drugs and biologics that demonstrate promise for the treatment of diseases or conditions affecting fewer than 200,000 people in the United States. Orphan drug designation provides Tonix Pharmaceuticals with certain development incentives, including tax credits for qualified clinical testing, exemptions from certain FDA application fees, and potential market exclusivity for seven years, if approved.

**TNX-2900 is an investigational new drug and has not been approved for any indication.*

**About Prader-Willi Syndrome**

Prader-Willi syndrome is recognized as the most common genetic cause of life-threatening childhood obesity[1] and affects males and females with equal frequency and all races and ethnicities. The hallmarks of Prader-Willi syndrome are lack of suckling in infants and, in children and adults, severe hyperphagia, an overriding physiological drive to eat, leading to severe obesity and other complications associated with significant mortality. There is currently no approved treatment for either the suckling deficit in babies or the obesity and hyperphagia in older children associated with Prader-Willi syndrome.

[1] *Foundation for Prader-Willi Research (fpwr.org).*

**About TNX-2900 and Tonix's Potentiated Oxytocin Platform**

TNX-2900 is based on 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. Tonix is also developing a different intranasal formulation and device, designated TNX-1900, for prophylaxis of chronic migraine and for the treatment of insulin resistance and related conditions. Oxytocin is a naturally occurring human hormone that acts as a neurotransmitter in the brain. 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 form of oxytocin was marketed in the U.S. by Novartis to assist in the production of breast milk as Syntocinon®** (oxytocin nasal 40 units/ml), but the product was discontinued, and the New Drug Application was withdrawn.

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

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

---

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of immunology, infectious disease, and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500[1] which is a humanized monoclonal antibody targeting CD40 ligand being developed for the prevention of allograft rejection treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second half of 2022. Tonix's infectious disease pipeline includes next-generation vaccines to prevent COVID-19, an antiviral to treat COVID-19, and a potential treatment for Long COVID. The pipeline also includes a vaccine in development to prevent smallpox. Tonix's lead vaccine candidate for COVID-19, TNX-1800[2], is a live virus vaccine based on Tonix's recombinant pox vaccine (RPV) platform. TNX-3500[3] (sangivamycin, *i.v.* solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. TNX-102 SL[4] , (cyclobenzaprine HCl sublingual tablets), is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition. Tonix expects to initiate a Phase 2 study in Long COVID in the first half of 2022. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL, is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study expected to start in the first half of 2022. Finally, TNX-1300[5] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the first quarter of 2022.

[1] *TNX-1500 is an investigational new biologic and has not been approved for any indication.*

[2] *TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.*

[3] *TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.*

[4] *TNX-102 SL is an investigational new drug and has not been approved for any indication.*

[5] *TNX-1300 is an investigational new biologic and has 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 the development of TNX-2900, the 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, 2020, as filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2021, 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.

**Contacts**

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Olipriya Das, Ph.D. (media)
Russo Partners
olipriya.das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)
ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505