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): February 28, 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 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 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 February 28, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that it 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), Aix-Marseille Université and Centre Hospitalier Universitaire of Toulouse ("Inserm") to study oxytocin in the genetically engineered mouse model of Prader-Willi syndrome. 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 February 28, 2022, the Company issued a press release announcing that that it entered into a research agreement with Inserm to study oxytocin in the genetically engineered mouse model of Prader-Willi syndrome. The proposed research, directed by Professor Françoise Muscatelli at the Institut de Neurobiologie de la Méditerranée (INMED-Inserm UMR1249/Aix-Marseille Université), will involve *in vitro* and *in vivo* studies designed to characterize the mechanism by which oxytocin normalizes the suckling and maturation of feeding behavior during infancy in mice that have been genetically modified to recapitulate part of the genetic alterations underlying Prader-Willi in humans. The results of this work are expected to increase the understanding of the mechanism by which oxytocin regulates feeding behavior in a mouse model of Prader-Willi. The Company has submitted an application to the U.S. Food and Drug Administration for orphan drug designation for its TNX-2900 (intranasal potentiated oxytocin) product candidate 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 intellectual property rights and protections related to TNX-1700, 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 February 28, 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: February 28, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Research Agreement with the French National Institute of Health and Medical Research (Inserm) to Study the Mechanism of Oxytocin-Mediated Improvement of Eating Behaviors in Prader-Willi Mice

Tonix is Developing TNX-2900 (Intranasal Potentiated Oxytocin) for the Treatment of Prader-Willi in Adolescents and Adults with Hyperphagia or Excessive Eating

Planned Studies in Prader-Willi Mice Will Focus on Oxytocin-Mediated Normalization of Suckling in Newborns

CHATHAM, N.J., February 28, 2022 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has 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.

“Tonix is excited to enter into this new research collaboration, which we hope will expand our understanding of oxytocin’s potential to treat Prader-Willi syndrome,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Currently, there is no approved treatment for Prader-Willi syndrome. With this new research collaboration, our goal is to learn how oxytocin-based pharmacological treatment improves and normalizes feeding behavior in infancy.”

Tonix is developing TNX-2900* (intranasal potentiated oxytocin) for the treatment of Prader-Willi Syndrome in adults and adolescents. A related intranasal potentiated oxytocin product candidate, TNX-1900*, is under development for the treatment of chronic migraine and is expected to enter a Phase 2 clinical trial for the prevention of migraine headache in chronic migraineurs in the second half of 2022.

The proposed research, directed by Professor Françoise Muscatelli at the Institut de Neurobiologie de la Méditerranée (INMED-Inserm UMR1249/Aix-Marseille Université), will involve *in vitro* and *in vivo* studies designed to characterize the mechanism by which oxytocin normalizes the suckling and maturation of feeding behavior during infancy in mice that have been genetically modified to recapitulate part of the genetic alterations underlying Prader-Willi in humans. The results of this work are expected to increase the understanding of the mechanism by which oxytocin regulates feeding behavior in a mouse model of Prader-Willi.

In 2021, Tonix licensed technology for treating Prader-Willi syndrome from Inserm, Aix Marseille Université and Centre Hospitalier Universitaire of Toulouse. The patents covering the technology are expected to provide market exclusivity for the co-licensees in the U.S. and Europe through 2031, which exclusivity could be extended after marketing authorization by a Supplemental Protection Certificate in Europe or a Patent Term Extension in the U.S., independent of other Tonix-held patents covering the formulation and oxytocin potentiation technologies for intranasal administration. Additionally, Tonix has submitted an application to the FDA for orphan drug designation.

**TNX-2900 and TNX-1900 are investigational new drugs and have 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 Inserm Transfert

Inserm Transfert, the private subsidiary of the French National Institute of the Health and Medical Research (Inserm), is responsible for value creation of Inserm and its academic partners’ innovations in human health and promotes long-term technology transfers in line with international best practices. Inserm Transfert SA was founded in 2000, and manages, under a Public Service Management Contract (Délégation de Service Public), the entire promotion and transfer of knowledge emerging from the Inserm research laboratories to the industrial world, from invention disclosure to industrial partnerships and startups incorporation. Inserm Transfert also offers services relating to setting up and managing national, European and international projects, as well as supporting the technology transfer of clinical research and health data/databases. In 2009, Inserm Transfert and Inserm established an investment fund to finance proofs of concept. In 2005, Inserm Transfert Initiative, a dedicated seed money fund for life sciences, was created. Since 2017 a pathway for pre-entrepreneurship supports researchers/inventors that aspire to become involved in entrepreneurship. www.inserm-transfert.com

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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 infectious disease, central nervous system (CNS) and immunology product candidates. Tonix's infectious disease portfolio of product candidates includes next-generation vaccines to prevent COVID-19, an antiviral to treat COVID-19, and a potential treatment for Long COVID. The portfolio also includes a vaccine in development to prevent smallpox. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. The immunology portfolio includes biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate for COVID-19, TNX-1800[1], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. TNX-3500[2] (sangivamycin, i.v. solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL[3] (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. 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. TNX-1300[4] 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-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.*

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

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

[4] *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 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 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.

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