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 7, 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 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 7, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that it entered into an agreement with Massachusetts General Hospital, a teaching hospital of Harvard Medical School, to evaluate the Company's TNX-1900 product candidate in an investigator initiated Phase 2 clinical trial as a potential treatment for patients with binge eating disorder. 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 7, 2022, the Company issued a press release announcing that it entered into an agreement with Massachusetts General Hospital to evaluate TNX-1900, a proprietary potentiated formulation of oxytocin, in an investigator initiated Phase 2 clinical trial as a potential treatment for patients with binge eating disorder. The Phase 2 trial, a randomized, double-blind, placebo-controlled study of 60 patients with binge eating disorder and obesity, is expected to start in the second half of 2022 and to provide data to evaluate the potential clinical benefit of TNX-1900 on binge eating disorder. The 8-week study will evaluate the efficacy and safety of TNX-1900 as a treatment for binge eating disorder and determine whether TNX-1900 reduces bingeing frequency and body weight in adults with binge eating disorder and obesity, and underlying mechanisms. Elizabeth A. Lawson, M.D., M.M.Sc., Director, Interdisciplinary Oxytocin Research Program, Neuroendocrine Unit, Massachusetts General Hospital and Associate Professor of Medicine at Harvard Medical School, is principal investigator of the trial.

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-1900, 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 7, 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 7, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Collaboration with Massachusetts General Hospital to Evaluate TNX-1900 (Intranasal Potentiated Oxytocin) for Treating Binge Eating Disorder

An Investigator Initiated Phase 2 Clinical Trial of TNX-1900 In Patients with Binge Eating Disorder Planned for Second Half 2022

Binge Eating Disorder is Estimated to Affect 2.8 Million American Adults[1-3]

Expands Uses of Tonix's Proprietary Potentiated Oxytocin for Intranasal Administration to a Potential New Indication

CHATHAM, N.J., March 7, 2022 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement with Massachusetts General Hospital, a teaching hospital of Harvard Medical School, to evaluate TNX-1900* in an investigator initiated Phase 2 clinical trial as a potential treatment for patients with binge eating disorder. The Phase 2 clinical trial is expected to start in the second half of 2022.

"Binge eating disorder is a serious mental health condition associated with behavioral and metabolic morbidity for which there are few treatment options," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Oxytocin is a well-known natural hormone that is used therapeutically in certain other indications including as an *i.v.* medication for the induction of labor in pregnancy with a medical indication. We are hopeful that our proprietary intranasal dosage form will enhance its properties for use in the underserved population of patients suffering from binge eating disorder."

TNX-1900* is also in development for the treatment of chronic migraine and is expected to enter a multi-site Phase 2 potential pivotal clinical trial for the prevention of migraine headache in chronic migraineurs in the second half of 2022.

"The binge eating disorder trial is expected to provide a rich source of data to evaluate the potential clinical benefit of TNX-1900 on binge eating disorder, which is often seen in association with other behavioral conditions such as depression, substance abuse and posttraumatic stress disorder, and is often under-diagnosed and under-treated," said Elizabeth A. Lawson, M.D., M.M.Sc., Director, Interdisciplinary Oxytocin Research Program, Neuroendocrine Unit, Massachusetts General Hospital and Associate Professor of Medicine at Harvard Medical School and principal investigator of the trial. "While available psychological and pharmacological treatments produce remission from binge eating in some cases, up to 50% of patients continue to binge, and weight loss in those with obesity is difficult to achieve and sustain. There is accumulating evidence that oxytocin may reduce food intake by acting on neural pathways involved in reward and impulse control, which have been implicated in binge eating disorder. We are excited to investigate TNX-1900 as a potential novel therapy to reduce binge eating and excess body weight in individuals with binge eating disorder."

Dr. Lawson previously led a program of research suggesting intranasal oxytocin reduces food intake, modulates the neural circuitry driving eating behavior, and enhances impulse control in men with overweight and obesity.[4-7]

The planned investigator initiated Phase 2 clinical trial will be a randomized, double-blind, placebo-controlled study of 60 patients with binge eating disorder and obesity. The 8-week study will evaluate the efficacy and safety of TNX-1900 as a treatment for binge eating disorder and determine whether TNX-1900 reduces bingeing frequency and body weight in adults with binge eating disorder and obesity, and underlying mechanisms.

* *TNX-1900 is an investigational new drug and has not been approved for any indication.*

[1] *https://www.bingeeatingdisorder.com/hcp/patient-demographics (accessed Feb 23, 2022)*

[2] *Hudson JI, et al. (2007) [Published correction appears in Biol Psychiatry. 2012;72(2):164.] Biol Psychiatry. 61(3):348-358.doi: 10.1016/j.biopsych.2006.03.040.*

[3] *Howden LM and Meyer JA. (2011) Age and sex composition: 2010. US Census Bureau*

[4] *Lawson EA et al. (2015) Oxytocin reduces caloric intake in men. Obesity 23(5):950-6. doi: 10.1002/oby.21069.*

[5] *Plessow F. et al. (2018) Effects of intranasal oxytocin on the blood oxygenation level-dependent signal in food motivation and cognitive control pathways in overweight and obese men. Neuropsychopharmacology 43(3):638-645. doi: 10.1038/npp.2017.226.*

[6] *Kerem L et al. (2020) Oxytocin reduces the functional connectivity between brain regions involved in eating behavior in men with overweight and obesity. In J Obes 44(5):980-989. doi: 10.1038/s41366-019-0489-7.*

[7] *Plessow F et al. (2021) Oxytocin administration increases proactive control in men with overweight or obesity: A randomized, double blind, placebo-controlled crossover study. Obesity 29(1):56-61. doi: 10.1002/oby.23010.*

About Binge Eating Disorder

Binge-eating disorder is a psychiatric illness characterized by frequent episodes of uncontrollable consumption of large amounts of food. It is the most common eating disorder and often leads to obesity-associated complications and later psychopathology[1]. Binge eating disorder is characterized by increased homeostatic appetite and sensitivity to reward (including food reward), which may lead to initiation of binge episodes, and a reduced ability to control behavioral impulses and formed habits, creating an imbalance in the sensitive interplay between these bottom-up and top-down processes governing the adaptive regulation of food intake and energy balance[2-5].

[1] *Field AE et al.(2012) Prospective association of common eating disorders and adverse outcomes. Pediatrics, 130: e289–95. doi: 10.1542/peds.2011-3663.*

[2] *Dawe S. & Loxton NJ, (2004) The role of impulsivity in the development of substance use and eating disorders Neurosci Biobehav Rev. 28(3):343-51doi: 10.1016/j.neubiorev.2004.03.007.*

[3] *Giel KE et al. (2017) Food-Related Impulsivity in Obesity and Binge Eating Disorder-A Systematic Update of the Evidence. Nutrients 9(11):1170 doi: 10.3390/nu9111170.*

[4] *Hernandez D et al. (2019) Meal-Related Acyl and Des-Acyl Ghrelin and Other Appetite-Related Hormones in People with Obesity and Binge Eating. Obesity 27(4):629-635. doi: 10.1002/oby.22431.*

[5] *Schag K et al. (2013) Food-related impulsivity in obesity and binge eating disorder--a systematic review. Obes Rev. 14(6):477-95. doi: 10.1111/obr.12017.*

About TNX-1900 and Tonix's Potentiated Oxytocin Platform

TNX-1900 is based on a proprietary potentiated formulation of oxytocin and is currently being developed as a candidate for prophylaxis of chronic migraine, the treatment of insulin resistance[1] and related conditions.TNX-1900 is based on Tonix's patented intranasal potentiated oxytocin formulation. Tonix is also developing a different intranasal formulation, designated TNX-2900, for the treatment of Prader-Willi syndrome. 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 withdrawn, and the New Drug Application has been discontinued. TNX-1900 and TNX-2900 are in the pre-Investigational New Drug stage and have not been approved for any indication.

[1]Deblon N, et al. (2011) PLoS ONE 6(9): e25565. doi:10.1371/journal.pone.0025565
**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 at the pre-IND stage of development and has not been approved for any indication.

[2]TNX-1800 is an investigational new biologic at the pre-IND stage of development 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-1900; 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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