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 11, 2021

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.)**

28 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.

Tonix Pharmaceuticals Holding Corp (the "Company") issued a press release announcing that it licensed technology for treating Prader-Willi syndrome from the French National Institute of Health and Medical Research ("Inserm"). A copy of the press release is furnished as Exhibit 99.01 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 February 11, 2021, the Company announced that it licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from Inserm (the French National Institute of Health and Medical Research), Aix-Marseille Université and Centre Hospitalier Universitaire of Toulouse. The licensing agreement has been negotiated and signed by Inserm Transfert, the private subsidiary of Inserm, on behalf of Inserm.

The co-exclusive license allows Tonix to expand its intranasal potentiated oxytocin development program to a new indication. The new program at Tonix has the designation TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. 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.

Since Prader-Willis Syndrome is an orphan disease that occurs in approximately one in 15,000 births, the Company plans, at the appropriate time, to submit an application to the U.S. Food and Drug Administration for Orphan Drug and Fast Track designations for TNX-2900.

The Company'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.

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 licensing and 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 statements 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 11, 2021

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 11, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Licenses Technology for Treating Prader-Willi Syndrome, a Rare Genetic Eating Disorder, from the French National Institute of Health and Medical Research (Inserm)

Expands Proprietary Uses of Tonix's Potentiated Oxytocin for Intranasal Administration

Disorder Stunts Growth of Newborns and, Paradoxically, Can Cause Excessive Hunger During Childhood and Beyond

CHATHAM, N.J., February 11, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby Tonix has licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome and non-organic failure to thrive disease from Inserm. The licensing agreement has been negotiated and signed by 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.

The co-exclusive license allows Tonix to expand its intranasal potentiated oxytocin development program to a new indication. The new program at Tonix has the designation TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. 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.

"Prader-Willi syndrome is a rare genetic disorder of failure to thrive in infancy and uncontrolled appetite and obesity in childhood and adulthood with no approved treatments available," said Tonix's President and Chief Executive Officer, Seth Lederman, M.D. "With the license from Inserm Transfert , we have the opportunity to expand our ongoing efforts with intranasal potentiated oxytocin to this new indication. Since Prader-Willi syndrome is an orphan disease that occurs in approximately one in 15,000 births, we plan at the appropriate time to submit an application to the U.S. Food and Drug Administration for Orphan Drug and Fast Track designations for TNX-2900."

Prader-Willi syndrome results in physical, mental and behavioral problems. A key feature of Prader-Willi syndrome in infants is a lack of suckling and poor muscle strength which leads to malnutrition and failure to thrive. However, paradoxically in children and adults, the key feature of Prader-Willi syndrome is a constant sense of hunger (hyperphagia), which leads to severe obesity. Intranasal oxytocin improves suckling in newborn animals but also suppresses feeding behaviors in adult animal models. 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.

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. 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 (FDA) 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 (NDA) has been discontinued. TNX-2900 and TNX-1900 are in the pre-Investigational New Drug (IND) stage and have not been approved for any indication.

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

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

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

About TNX-1900* (Intranasal Potentiated Oxytocin)

TNX-1900 is based on a proprietary potentiated formulation of oxytocin and is currently being developed as a candidate for prophylaxis of chronic migraine and for the treatment of insulin resistance and related conditions.

TNX-1900 for Migraine: In clinical and preliminary research, it has been observed that low oxytocin levels in the body can lead to increase in headache frequency, and that increased oxytocin levels can relieve headaches. Oxytocin, when delivered via the nasal route, results in enhanced binding of oxytocin to receptors on neurons in the trigeminal system, inhibiting transmission of pain signals. Intranasal oxytocin has been well tolerated in several clinical trials in adults and children. Intranasal oxytocin has been shown to block calcitonin gene-related peptide (CGRP) release in animals, a pathway known to be critical to the pathogenesis of migraine attacks. TNX-1900 is believed to interrupt pain signals at the trigeminal ganglia by suppressing electrical impulses, a potentially different activity than drugs that just block CGRP. Migraine attacks are caused, in part, by the release of CGRP from pain-sensing nerve cells that are part of the trigeminal system. Targeted delivery results in low systemic exposure and lower risk of non-nervous system, off-target effects which could potentially occur with systemic CGRP antagonists. For example, CGRP has roles in dilating blood vessels in response to ischemia, including in the heart. Tonix believes targeted delivery of oxytocin could translate into selective blockade of CGRP release in the trigeminal ganglion and not throughout the body, which could be a potential safety advantage over systemic CGRP inhibition. TNX-1900 is also believed to provide augmented analgesia in the treatment of pain, relative to oxytocin.

TNX-1900 for Insulin Resistance: Tonix recently acquired the exclusive license to develop TNX-1900 for the treatment of insulin resistance and related conditions from the University of Geneva. The license allows Tonix to expand its intranasal potentiated oxytocin development program into cardiometabolic syndromes, which include insulin resistance, impaired glucose tolerance, obesity, diabetes management and related metabolic complications. The patents covering the technology are expected to provide Tonix market exclusivity 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., independently of other Tonix-held patents covering the formulation and potentiation technologies related to TNX-1900. The University

of Geneva technology is based on the discovery that oxytocin administration in an animal model of obesity improved lipid metabolism by increasing lipolysis and fatty acid-β-oxidation in adipose tissue accompanied by improvements in glucose intolerance and insulin resistance, independent of food intake[1]. A number of studies have shown that intranasal oxytocin has effects on insulin resistance and weight[2-4],". Intranasal oxytocin has been reported toimprove glucose homeostasis, improve pancreatic β-cell responsivity, decrease energy-induced and reward-induced eating, and support cognitive control of food choices.[2-9]

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

[1]Deblon N, et al. (2011) *PLoS ONE* 6(9): e25565. doi:10.1371/journal.pone.0025565
[2]Lawson EA. (2017) *Nat Rev Endocrinol.* 13(12):700-709. doi: 10.1038/nrendo.2017.115. PMID: 28960210
[3]Olszewski PK, et al. (2017) *Curr Opin Endocrinol Diabetes Obes.* 24(5):320-325. doi: 10.1097/MED.0000000000000351. PMID: 28590323.
[4]Ding C, et al. (2019) *Obes Rev*. 2019 Jan;20(1):22-40. doi: 10.1111/obr.12757. PMID: 30253045.
[5]Lawson EA, et al. (2015) *Obesity*. 23:950–956. DOI: 10.1002/oby.21069 PMID: 25865294
[6]Klement, J et al. (2017) Diabetes 66(2) 264-271; DOI: 10.2337/db16-0569
[7]Ott V, et al. (2013) *Diabetes*. 62:3418–3425. DOI: 10.2337/db13-0663 PMID: 23835346
[8]Thienel M, et al. (2016) *Int J Obes*. 40(11):1707-1714. DOI: 10.1038/ijo.2016.149 PMID: 27553712
[9]Striepens N, et al. (2016) *Human Brain Mapp.* 37(12):4276–4285. DOI: 10.1002/hbm.23308 PMID: 27381253

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 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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Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL[1], is in mid-Phase 3 development for the management of fibromyalgia, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY, in the second quarter of 2021[2] and topline data in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800 [3], is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801[3], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.
[2]Pending submission and agreement from FDA on statistical analysis plan.
[3]TNX-1800 and TNX-801 are investigational new biologics and have 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 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, and periodic reports filed with the SEC on or after the date thereof. All 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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