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): December 22, 2020

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: (212) 980-9155

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 the Company acquired an exclusive license to the University of Geneva's technology for oxytocin-based treatments for treating insulin resistance, diabetes and obesity, expanding proprietary uses for TNX-1900. 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 December 22, 2020, the Company announced that it acquired an exclusive license to the University of Geneva's technology for using oxytocin to treat insulin resistance and related syndromes, including obesity, from privately held Katana Pharmaceuticals, Inc. The license allows the Company to expand its intranasal potentiated oxytocin development program, TNX-1900, into cardiometabolic syndromes, which include insulin resistance, impaired glucose tolerance, and obesity. The patents covering the technology are expected to provide Tonix with freedom to operate in these indications as well as market exclusivity in the U.S. and Europe through 2031, upon its approval, 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.

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 results of the Phase 3 RELIEF study, 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 December 22, 2020

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: December 22, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals Acquires Exclusive License to University of Geneva Technology for Oxytocin-Based Treatments for Treating Insulin Resistance, Diabetes and Obesity, Expanding Proprietary Uses for TNX-1900 (Intranasal Potentiated Oxytocin)

University of Geneva Technology Covers Broad Applications for Cardiometabolic Syndromes

CHATHAM, N.J., December 22, 2020 - Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby Tonix has acquired the exclusive license to the University of Geneva's technology for using oxytocin to treat insulin resistance and related syndromes, including obesity, from privately held Katana Pharmaceuticals, Inc. This license allows Tonix to expand its intranasal potentiated oxytocin development program, TNX-1900, into cardiometabolic syndromes, which include insulin resistance, impaired glucose tolerance, and obesity. The patents covering the technology are expected to provide Tonix with freedom to operate in these indications as well as market exclusivity in the U.S. and Europe through 2031, upon its approval, 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].

"The important new technology from University of Geneva will allow Tonix to develop intranasal oxytocin on a broader platform to treat both central nervous system (CNS) and cardiometabolic conditions. We believe that TNX-1900 has the potential to be a safe, natural, non-addictive, and easy to administer treatment alternative for a number of CNS disease states. Our lead indication for TNX-1900 is for the treatment of migraine," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals.

"Subsequent to the University of Geneva inventions, a number of studies have shown that intranasal oxytocin has effects on insulin resistance and weight[2-4]," continued Dr. Lederman. "Intranasal oxytocin has been reported to improve glucose homeostasis, improve pancreatic β-cell responsivity, decrease energy-induced and reward-induced eating, and support cognitive control of food choices.[2-9] The effects of intranasal oxytocin on improving peripheral insulin sensitivity, pancreatic function and lipid metabolism encourage us to develop TNX-1900 as a potential therapeutic in obesity, insulin resistance, diabetes management and related metabolic complications."

In June 2020, Tonix acquired its potentiated oxytocin technology and development program from Trigemina, Inc., and assumed licenses for certain related technologies from Stanford University. TNX-1900 has demonstrated activity in several non-clinical studies in CNS disease models. In addition, prior to the acquisition from Trigemina, TNX-1900 was studied in the U.S. under a physician-requested Investigational New Drug Application.

[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 TNX-1900 (Intranasal Potentiated Oxytocin)*

TNX-1900, Tonix's proprietary intranasal oxytocin is currently being studied as a candidate for prophylaxis of chronic migraine. TNX-1900 is in the pre-Investigational New Drug (IND) stage and has not been approved for any indication. It is based on a proprietary formulation of oxytocin and is being developed first for the treatment of migraine. Oxytocin is a naturally-occurring human hormone that acts as a neurotransmitter in the brain. It is 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. 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 in the pre-IND phase 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 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**, is in mid-Phase 3 development for the management of fibromyalgia since positive data on the RELIEF Phase 3 trial were recently reported. The Company expects topline data for a 2nd Phase 3 study, RALLY, 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***, 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*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

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

***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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