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 16, 2019

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.)**

509 Madison Avenue, Suite 1608, New York, New York 10022
(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 8.01. Other Events.

On December 16, 2019, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its plans to develop TNX-601 CR for the treatment of major depressive disorder, in addition to posttraumatic stress disorder. A copy of the press release discussing this matter is filed as Exhibit 99.01, and incorporated by reference in, this report.

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 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 Securities and Exchange Commission. 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 Tonix Pharmaceuticals Holding Corp., dated December 16, 2019

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 16, 2019

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Plan to Develop TNX-601 CR Tablets for Once-Daily Treatment of Major Depressive Disorder, in Addition to PTSD, After Successful Completion of Phase 1 Pharmacokinetic Study

TNX-601 CR Active Ingredient, Tianeptine, is Approved and Marketed as an Immediate Release Three-Times-a-Day Antidepressant in Europe, Asia, Russia and Latin America

First Efficacy Trial Planned ex-U.S. in 2020

NEW YORK, December 16, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has developed a controlled release formulation of tianeptine oxalate, TNX-601 CR (tianeptine oxalate controlled release) tablets, designed for once-daily dosing, after completion of a Phase 1 study evaluating the pharmacokinetics (PK) of different prototypes. Tonix plans to develop TNX-601 CR for major depressive disorder (depression) in addition to posttraumatic stress disorder (PTSD). Tonix plans to start the first efficacy trial ex-U.S. in 2020 and request a pre-IND meeting with Food and Drug Administration (FDA) in the first half of 2020. Currently there is no tianeptine-containing product approved in the U.S. and no controlled release (CR) tianeptine product approved in any jurisdiction.

The completed open-label Phase 1 PK and formulation selection study compared the bioavailability and safety of TNX-601, immediate release (IR) and different CR prototype tablets, with the reference product, Stablon®[1] (tianeptine sodium) IR tablets, in 12 healthy male and female volunteers over six different dosing periods. The study evaluated the PK profile of tianeptine and its active metabolite, MC5. The study was conducted outside of the U.S. The Company believes that the Phase 1 study demonstrated that TNX-601 CR was well tolerated and the side effects were consistent with the known safety profile of tianeptine sodium.

Tianeptine sodium IR three times a day (*t.i.d.*), was first marketed for depression in France in 1989, and is approved as an antidepressant in Europe, Russia, Asia and Latin America with significant post-marketing experience. Tianeptine is an indirect modulator of the glutamatergic system that reverses adverse neuroplastic changes that are observed during periods of stress and elevated corticosteroid exposure. Tonix is pursuing an indication for once-daily TNX-601 CR in the treatment of depression, in addition to PTSD, leveraging the established efficacy and safety profile of tianeptine sodium IR tablets from decades of use as a *t.i.d.* dosed antidepressant.

“We are pleased to have the results of this Phase 1 study which enabled us to select a formulation for continued development of TNX-601 CR as a once-daily medicine. We believe the six periods of single-dose testing in each of the 12 volunteers confirmed the favorable safety profile of the proprietary oxalate salt of tianeptine,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “We are also excited to announce the pursuit of the depression indication with TNX-601 CR as we believe this development path can leverage the established efficacy and safety of the tianeptine sodium IR tablets as a treatment for depression outside of the U.S. Depression is a well-established commercial market and despite multiple approved products in the U.S., there remains significant interest in new treatments, particularly for medicines that modulate the glutamatergic system. The tianeptine IR product marketed ex-U.S. is reported to have substantial anti-anxiety effects in depression, and low incidence of sexual side effects. Once-daily dosing is believed to be an advantage over three times a day dosing for adherence.”

[1] Stablon is a registered trademark of Les Laboratoires SERVIER (France).

About Major Depressive Disorder

According to the National Institute of Mental Health, depression affects approximately 16 million adults in the U.S.[1], with approximately 2.5 million adults treated with adjunctive therapy.[2,3] Depression is a condition characterized by symptoms such as a depressed mood or loss of interest or pleasure in daily activities most of the time for two weeks or more, accompanied by appetite changes, sleep disturbances, motor restlessness or retardation, loss of energy, feelings of worthlessness or excessive guilt, poor concentration, and suicidal thoughts and behaviors. These symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. The majority of people who suffer from depression do not respond adequately to initial antidepressant therapy.[4]

About TNX-601 CR

TNX-601 CR is a novel oral formulation of tianeptine oxalate designed for once-daily daytime dosing that is in the pre-IND (Investigational New Drug) stage of development. Tianeptine sodium (amorphous) immediate release was first marketed for depression in France in 1989 and has been available for decades in Europe, Russia, Asia, and Latin America for the treatment of depression. Tianeptine sodium has an established safety profile from decades of use in these jurisdictions. Currently there is no tianeptine-containing product approved in the U.S. and no controlled release tianeptine product approved in any jurisdiction. Tonix discovered a novel oxalate salt of tianeptine that may provide improved stability, consistency, and manufacturability compared to known forms of tianeptine. Tianeptine is believed to work in depression as a modulator of the glutamatergic system. Tianeptine modulates the glutamatergic system indirectly since it does not interact with NMDA, AMPA or kainate receptors. In animals, tianeptine has been shown to reverse the adverse neuroplastic changes that are observed during periods of stress and elevated corticosteroid exposure. Tianeptine and its MC5 metabolite are weak mu-opioid receptor (MOR) agonists. Neither tianeptine nor MC5 have been shown to bind other neurotransmitter receptors. Tianeptine's reported pro-cognitive and anxiolytic effects as well as its ability to attenuate the neuropathological effects of excessive stress responses suggest that it may be used to treat PTSD by a different mechanism of action than TNX-102 SL.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Tonix's lead product candidate, TNX-102 SL*, is in development for posttraumatic stress disorder (PTSD), fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder (AUD). TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD (trade name Tonmya**) and fibromyalgia. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling and results from an interim analysis are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. The Company has started enrollment in the Phase 3 RELIEF trial in fibromyalgia. The agitation in Alzheimer's disease program is Phase 2 ready and the development for AUD is in the pre-Investigational New Drug (IND) application stage. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for PTSD, as well as for depression. The first efficacy study will be performed outside the U.S. and it is expected to be IND-ready in 2020. TNX-1600 (a triple reuptake inhibitor) is a third product candidate being developed for PTSD, as a daytime treatment. Tonix's programs for treating addiction conditions also include TNX-1300*** (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. Finally, TNX-801 (live virus vaccine for percutaneous [scarification] administration) to potentially prevent smallpox and TNX-701 (undisclosed small molecule) to prevent radiation effects are being advanced as medical countermeasures to improve biodefense.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL for the treatment of PTSD.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) 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.

References

[1]National Institute of Mental Health. (2017). Major Depression. Retrieved from http://www.nimh.nih.gov/health/statistics/major-depression.shtml

[2]IMS NSP, NPA, NDTI MAT-24 month data through Aug 2017.

[3]PLOS One, Characterization of Treatment Resistant Depression Episodes in a Cohort of Patients from a US Commercial Claims Database, Oct 2013, Vol 8, Issue 10.

[4]Rush AJ, et al. (2007) Am J. Psychiatry 163:11, pp. 1905-1917 (STAR*D Study).

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; 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Scott Stachowiak (media)
Russo Partners
scott.stachowiak@russopartnersllc.com
(646) 942-5630

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