

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): November 4, 2019

TONIX PHARMACEUTICALS HOLDING CORP.  
(Exact name of registrant as specified in its charter)

Nevada  
(State or Other Jurisdiction  
of Incorporation)

001-36019  
(Commission  
File Number)

26-1434750  
(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))

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.

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

**Item 8.01 Other Event.**

Tonix Pharmaceuticals Holding Corp. (the “Company”) announced that the timing of the primary endpoint analysis for its lead product candidate has been modified based on guidance from the U. S. Food and Drug Administration. 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)	<b>Exhibit No.</b>	<b>Description.</b>
	<u>99.01</u>	Press release of Tonix Pharmaceuticals Holding Corp., dated November 4, 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: November 4, 2019

By: /s/ Bradley Saenger

Bradley Saenger

Chief Financial Officer

---

**Tonix Pharmaceuticals Announces 12-Week Primary Endpoint and Addition of Adaptive Design Features in the Currently-Enrolling Phase 3 RECOVERY Study of Tonmya® for PTSD, Following FDA Meeting**

*Primary Endpoint Will be Mean Change from Baseline in CAPS-5 at Week 12, Instead of Week 4*

*Results from Added Interim Analysis Expected in First Quarter 2020*

*Topline Data Expected in Second Quarter 2020 Based on Currently Planned Sample Size*

NEW YORK, November 4, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNPX) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that in the currently-enrolling Phase 3 study of Tonmya®\* (or TNX-102 SL, cyclobenzaprine sublingual tablets, 5.6 mg) for the treatment of posttraumatic stress disorder (PTSD), the timing of the primary endpoint analysis has been changed from Week 4 to Week 12 and the Company plans to add an interim analysis that allows for a potential sample size adjustment, based on guidance from its recent Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA).

The Phase 3 study design changes are being implemented after the FDA indicated the importance of showing persistence of treatment effect at Week 12 in a pivotal study. In the revised protocol, the primary endpoint, mean change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), will be assessed at Week 12 instead of Week 4. Week 12 measurement of CAPS-5 was the same timepoint measurement used for the primary endpoint in the previous Phase 3 HONOR (P301) and the Phase 2 AtEase (P201) studies of Tonmya for PTSD.

In addition, the RECOVERY study will include an unblinded interim analysis that allows for a potential sample size re-estimation. It will be conducted when 50 percent (n=125) of the current target number of participants (n=250) are randomized and have either completed or discontinued the 12-week course of treatment with bedtime Tonmya or placebo sublingual tablets. The introduction of the potential sample size re-estimation was added to address the potential impact of more drop-outs between Week 4 and Week 12, since the study was originally powered for a Week 4 endpoint. The data will be reviewed by an Independent Data Monitoring Committee (IDMC) which will make a non-binding recommendation to the Company based on the unblinded interim analysis.

Pending final approval by FDA, the planned interim analysis will have three possible recommendations: 1) keep the current sample size and continue as planned; 2) provide the opportunity to increase the sample size to include up to a maximum of 120 additional participants, based on certain criteria; and 3) stop the study early for futility. The proposed design will not include an option to stop for positive efficacy at the interim analysis. The proposed sample size re-estimation methodology maintains the statistical hurdle of  $p < 0.05$ . If the current sample size is kept at 250 participants at the interim analysis, there will be no statistical penalty on average compared to the current design. With an increase in sample size, the results from the cohorts before and after the interim analysis will be averaged with equal weight and  $p < 0.05$  will still be required for success. This methodology has been successfully utilized in other pivotal studies and was a component of the Phase 3 HONOR study's interim analysis that was agreed to by the FDA.

Since more than 125 participants have already been enrolled, the Company expects to report the results of the interim analysis and the recommendation of the IDMC in the first quarter of 2020. If the current projected population of 250 study participants remains unchanged, the Company expects to report topline data in the second quarter of 2020.

*\*Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

#### **About the Phase 3 RECOVERY Study**

The RECOVERY Phase 3 study is a double-blind, randomized, placebo-controlled study of Tonmya 5.6 mg (2 x 2.8 mg sublingual tablets) over 12 weeks of treatment for civilian and military-related PTSD. The RECOVERY Phase 3 study restricts enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening. Two previous PTSD studies of Tonmya by the Company (P201 and P301) restricted enrollment to participants who experienced traumas during military service since 2001. The primary efficacy endpoint is the Week 12 mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with Tonmya and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. A formal unblinded interim analysis will be completed when 50 percent (n=125) of participants have been randomized and have completed or discontinued the 12-week course of treatment with bedtime Tonmya 5.6 mg or placebo sublingual tablets. The Company expects to report the results of the interim analysis and the recommendation of the IDMC in the first quarter of 2020. If the current projected population of 250 study participants remains unchanged, the Company expects to report topline data in the second quarter of 2020.

#### **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, with topline data in PTSD expected in the second quarter of 2020 if the sample size remains n=250 participants. 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. Tonix is advancing two other PTSD therapeutic programs in the pre-IND stage, with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate controlled release CR tablets) and TNX-1600 (a triple reuptake inhibitor). TNX-601 is in clinical formulation testing outside of the U.S and is expected to be IND-ready in 2020. Tonix has two programs for treating addiction conditions: TNX-1300\*\* (double-mutant cocaine esterase) is in Phase 2 development for the treatment of cocaine intoxication and TNX-102 SL is in pre-IND development for AUD. 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-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](http://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; 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](mailto:investor_relations@tonixpharma.com)  
(212) 980-9159

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

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

---