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): July 27, 2018

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 306, 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. ☐

Item 8.01 Other Events.

On July 27, 2018, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release (the "Press Release") announcing the outcome of the interim analysis for the Company's Phase 3 HONOR Study for its lead product candidate in military-related posttraumatic stress disorder. A copy of the Press Release is filed as Exhibit 99.01 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release dated July 27, 2018, issued by Tonix Pharmaceuticals Holding Corp.

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: July 27, 2018

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Outcome of Interim Analysis for Phase 3 HONOR Study of Tonmya® in Military-Related PTSD

HONOR Study will Stop due to Inadequate Separation from Placebo at Week-12

Results at Week-4 Demonstrated Meaningful Clinical Improvement

Company Plans to Meet with FDA to Discuss Next Steps for this Breakthrough Therapy

NEW YORK, July 27, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix), today announced that it will stop the Phase 3 HONOR study of Tonmya*(cyclobenzaprine HCl sublingual tablets) in military-related posttraumatic stress disorder (PTSD) due to inadequate separation from placebo on the primary endpoint at week 12.

The primary analysis was the change from baseline in the severity of PTSD symptoms as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with Tonmya and those receiving placebo, after 12 weeks of treatment. The Independent Data Monitoring Committee (IDMC) reviewed the results of the first 50 percent of participants (n=274) randomized in the HONOR study and recommended stopping the trial based on a pre-specified study continuation threshold at week 12. However, meaningful improvement in overall PTSD symptoms was observed at week 4. At week 4, the Tonmya treated group separated from placebo in CAPS-5 ($p = 0.019$) and in the Clinical Global Impression – Improvement (CGI-I) scale ($p = 0.015$), a key secondary endpoint. Also, at week 4, sleep quality improved as measured by both the PROMIS sleep disturbance scale and the CAPS-5 sleep disturbance item, supporting the proposed mechanism of action of Tonmya.

Preliminary safety data from these participants did not reveal any serious and/or unexpected adverse events and the decision to discontinue the study is not related to safety.

“We are encouraged by the meaningful clinical improvement at week 4, which replicates findings in the previously-reported Phase 2 AtEase Study. We believe the results from the HONOR study will help to design the next pivotal study. We plan to meet with the FDA as soon as possible to discuss the HONOR results and our proposal to conduct the primary analysis at the week-4 time point in the next pivotal study,” commented Seth Lederman, M.D., President and Chief Executive Officer. “These results underscore the challenges in designing and conducting well-controlled clinical studies in PTSD, especially military-related PTSD. We thank the participants, their families and friends, and the investigators who participated in the HONOR study. We are committed to seeking potential treatments for PTSD including advancing TNX-601 (tianeptine oxalate) for daytime treatment of PTSD.”

The Phase 3 HONOR Study

The HONOR study was a randomized, placebo-controlled study of up to 550 participants with PTSD at 40 U.S. clinical sites. A formal unblinded interim analysis was completed when approximately 50 percent (n=274) of participants were randomized and completed the 12-week course of treatment with bedtime sublingual Tonmya 5.6 mg (2 x 2.8 mg tablets) or placebo sublingual tablets. The primary efficacy endpoint was the 12-week 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. Earlier versions of the CAPS were used to support the approval of the two currently marketed PTSD treatments.

About Tonmya and PTSD

Tonmya or TNX-102 SL is a sublingual transmucosal tablet formulation of cyclobenzaprine. PTSD is a serious condition that affects approximately 11 million U.S. adults, and is characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. In addition to Tonmya, Tonix is developing TNX-102 SL, which has been granted Fast Track designation by the FDA, as a bedtime treatment for agitation in Alzheimer's disease under an IND to support a Phase 2, potential pivotal, efficacy study. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a unique mechanism and designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

This press release and further information about Tonix can be found at www.tonixpharma.com.

**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.*

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; 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, 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.

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 Partners
peter.vozzo@westwicke.com
(443) 213-0505