

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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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): October 31, 2018

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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 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.

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**Item 8.01 Other Events.**

On October 31, 2018, Tonix Pharmaceuticals Holding Corp. issued a press release (the “Press Release”) announcing a new Phase 3 trial for its lead product candidate in posttraumatic stress disorder. A copy of the Press Release is filed as Exhibit 99.01, and incorporated by reference in, this report.

**Item 9.01 Financial Statements and Exhibits.**

(d) **Exhibit**

<b>No.</b>	<b>Description.</b>
<u>99.01</u>	<u><a href="#">Press Release dated October 31, 2018, issued by the Company</a></u>

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**Tonix Pharmaceuticals Announces Innovative Design in Next Phase 3 Study of Tonmya<sup>®</sup> for PTSD, Following FDA Meeting**

*New Phase 3 Trial of Tonmya<sup>®</sup> for the treatment of PTSD to Commence First Quarter 2019*

*Primary Endpoint of New Study will be Week 4 Change from Baseline in CAPS-5*

NEW YORK, October 31, 2018 (GLOBE NEWSWIRE) — Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), today announced that it plans to start a new Phase 3 trial of Tonmya<sup>®</sup>\* for the treatment of posttraumatic stress disorder (PTSD) in the first quarter of 2019, based on guidance from its recent Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA).

Tonix submitted interim analysis results from the original Phase 3 HONOR study of Tonmya in military-related PTSD to support a new Phase 3 study design discussion with the FDA. The Company plans to incorporate several new design features into the new Phase 3 study, including restricting enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening. Retrospective analysis of the Phase 3 HONOR study revealed a treatment effect in this subgroup over the 12-week study. Another new feature of the planned Phase 3 study is the inclusion of study participants who have experienced civilian traumas, in addition to inclusion of those with military-related traumas. Two previous studies by the Company restricted enrollment to participants who experienced traumas during military service since 2001. 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), is the same as that used in the Phase 3 HONOR study and the Phase 2 AtEase study, but the CAPS-5 primary endpoint will be assessed at Week 4 instead of at Week 12. The Week 4 assessment of CAPS-5 in the Phase 3 HONOR study showed clinically meaningful improvement at this timepoint in the entire modified Intent-to-Treat sample (difference from placebo of -3.6 CAPS-5 points,  $p = 0.019$ ).

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, “Results from our Phase 3 HONOR study strengthened the design of the new Phase 3 study, which has been accepted by the FDA as a potential pivotal efficacy study to support NDA approval. We believe the innovative design features of this new Phase 3 study will expedite the development of Tonmya for PTSD.”

The new Phase 3 trial will be a double-blind, randomized, placebo-controlled study of Tonmya 5.6 mg over 12 weeks of treatment for civilian and military-related PTSD. The primary efficacy endpoint will be the Week 4 mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with Tonmya and those receiving placebo. A key secondary endpoint will be the Week 12 mean change from baseline in CAPS-5. 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.

*\*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.*

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### **About the Phase 3 HONOR Study**

The HONOR study was a double-blind, 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 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 HONOR study was stopped at the interim analysis when the primary endpoint did not cross a predefined study continuation threshold; however, a clinically meaningful improvement in CAPS-5 was observed at Week 4 (p = 0.019)

### **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. Tonix is developing Tonmya, which has been granted Breakthrough Therapy designation, as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under a separate IND to support a Phase 2, potential pivotal, efficacy study and has been granted Fast Track designation by the FDA for this indication. TNX-601 (tianepetine 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](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; 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.

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## **Contacts**

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