

**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): August 18, 2015

**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

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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))
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**Item 8.01 Other Events.**

On August 18, 2015, Tonix Pharmaceuticals Holding Corp. (the "Company") will present an overview of its development of TNX-102 SL for post-traumatic stress disorder with a poster entitled "*The AtEase Study: An Evaluation of the Efficacy of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL tablet) for the Treatment of Military-Related PTSD*" (the "Poster"), at the 2015 Military Health System Research Symposium in Fort Lauderdale, Florida.

The foregoing description of the Poster is qualified in its entirety by reference to the Poster, a copy of which is filed as Exhibit 99.01 to, and is incorporated by reference in, this report.

On August 18, 2015, the Company issued a press release announcing the presentation of the Poster, which also provided an update that the Company has achieved 50% of its target enrollment in the AtEase trial. A copy of the press release that discusses these matters is filed as Exhibit 99.02 to, and incorporated by reference in, this report.

The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

- 99.01 The AtEase Study: An Evaluation of the Efficacy of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL tablet) for the Treatment of Military-Related PTSD Poster
- 99.02 Press Release, dated August 18, 2015, 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: August 18, 2015

By: /s/ LELAND GERSHELL

Leland Gershell  
Chief Financial Officer

## The AtEase Study: An Evaluation of the Efficacy of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD

Gregory M. Sullivan<sup>1</sup>, Judy F. Gendreau<sup>1</sup>, R. Michael Gendreau<sup>2</sup>, Amy Schaberg<sup>3</sup>, Bruce L. Daugherty<sup>1</sup>, Heather Jividen<sup>1</sup>, Ashild Peters<sup>1</sup>, Perry Peters<sup>1</sup>, Seth Lederman<sup>1</sup>

<sup>1</sup>Tonix Pharmaceuticals, Inc., New York, NY 10022; <sup>2</sup>Gendreau Consulting, Poway, CA 92064; <sup>3</sup>Schaberg Consulting, Cary, NC 27513

### INTRODUCTION

- There is an urgent unmet need for efficacious pharmacotherapy interventions for military-related posttraumatic stress disorder (PTSD)
- TNX-102 SL<sup>®</sup> is a proprietary formulation of low dose cyclobenzaprine (CBP) HCl, a tricyclic molecule, administered by sublingual (SL) route nightly at bedtime
- Efficacy of tricyclic class in PTSD is supported by clinical data<sup>1</sup>
- In a Phase 2b trial in fibromyalgia, TNX-102 SL demonstrated significant improvement on sleep disturbance ( $p=.005$ ), and anxiety ( $p=.015$ ) and sensory sensitivity ( $p=.017$ ) item scores, relevant to PTSD; while being well tolerated over 12 weeks of treatment<sup>2\*</sup>
- TNX-102 SL is intended to target sleep disturbance and hyperarousal in order to improve global symptoms of PTSD
- The 'AtEase Study' (TNX-CY-P201) is evaluating the potential clinical benefit of TNX-102 SL in the treatment of military-related PTSD

### INVESTIGATIONAL PRODUCT

- TNX-102 SL: a proprietary formulation of low dose cyclobenzaprine 2.8 mg tablets for sublingual administration
  - more rapid absorption into the circulation (Fig 1)
  - Bypasses "first pass" metabolism to norcyclobenzaprine (nCBP), a long half-life (72 hr) active metabolite, by liver (Fig 2); AUC<sub>0-48</sub> for CBP/nCBP of 1.9 vs. 1.2 for oral IR form<sup>2</sup>
  - CBP is a multifunctional agent with potent 5-HT<sub>2A</sub>,  $\alpha_1$ -adrenergic, and H<sub>1</sub>-receptor blocking properties (Fig 3 & 4)

### METHODS

- Randomized, double blind, placebo-controlled 12-week trial testing 3 groups in 2:2:1 ratio:
  - (1) placebo, (2) TNX-102 SL 2.8 mg, and (3) TNX-102 SL 5.6 mg
- Total N=220
- 25 private trial clinics within the continental United States (US)
- Male and female US military personnel and veterans age 18-65 with PTSD DSM-5 Criterion A trauma(s) that occurred during military service in last 14 years

<sup>1</sup>TNX-102 SL is an Investigational New Drug and has not been approved for any indication

\*Most common adverse event: oral hypoesthesia, 42% in TNX-102 SL vs. 1% in placebo

Figure 1 – Plasma concentration vs. time for TNX-102 SL & CBP IR

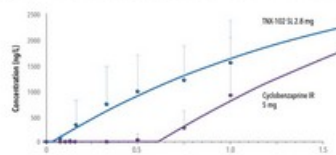


Figure 2 – Hepatic metabolism of CBP to active metabolite



Figure 3 – Schematic of inhibitory activities of CBP & nCBP

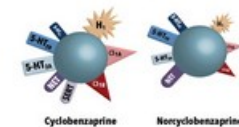
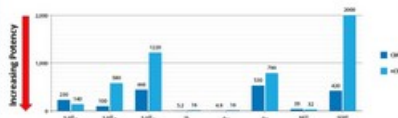


Figure 4 – Functional antagonism (IC<sub>50</sub>) of CBP and nCBP



ClinicalTrials.gov Identifier: NCT02277704

- Primary Outcome Measure: The Clinician Administered PTSD Scale for DSM-5 (CAPS-5), which is a standardized structured clinical interview that is the gold standard in research for measuring PTSD symptom severity

### Inclusion criteria include:

- PTSD diagnosed by CAPS-5; severity  $\geq 29$
- No antidepressant treatment within 2 months
- Willing and able to discontinue medications including opioids,  $\alpha$ -adrenergic agents, mood stabilizers, antipsychotics, stimulants, benzodiazepines, non-benzodiazepine hypnotics for period of the study
- No trauma-focused psychotherapy during study

### Exclusion criteria include:

- Greatly increased suicidal risk (based on C-SSRS & MINI 7.0 criteria, and/or history of attempt within prior 12 months)
- Moderate or severe traumatic brain injury (TBI)
- Severe depression based on MADRS score of  $\geq 30$
- Unstable medical conditions; BMI > 40
- Lifetime diagnosis bipolar disorder, psychotic disorder, OCD, or antisocial personality disorder by MINI 7.0
- Alcohol or substance use disorder in remission <6 months
- Efficacy Assessments
  - Primary outcome: change in PTSD severity on the CAPS-5
  - Secondary efficacy assessments include PTSD Checklist-5 (PCL-5), CGI-I, PGIC, PROMIS Sleep Disturbance, Pain Questionnaire, Sheehan Disability Scale (SDS)

### CURRENT STUDY STATUS

- Currently enrolling; over 50% enrolled to date
- Recruitment information found at [AtEaseStudy.com](http://AtEaseStudy.com)

### CONCLUSIONS

- Prior clinical studies of TNX-102 SL in fibromyalgia suggest evidence of broad activity relevant to PTSD treatment in concert with good systemic tolerability
- The AtEase Study, a registration quality clinical trial of TNX-102 SL for the treatment of military-related PTSD, is currently enrolling across the US

<sup>1</sup>Davidson J. J. Psychopharm 29(3):264-9, 2015; <sup>2</sup>Lederman et al., European Congress of Rheumatology, Rome, June 2015

**Tonix Pharmaceuticals Presents on the Development of TNX-102 SL for Post-Traumatic Stress Disorder (PTSD) at the 2015 Military Health System Research Symposium**

*TNX-102 SL is currently being evaluated in patients with military-related PTSD*

New York, NY – August 18, 2015 – [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ: TNXP) (“Tonix”) today presented an overview of its development of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD, including a review of the design of the AtEase Clinical Study, at the [2015 Military Health System Research Symposium](#) held in Fort Lauderdale, Florida.

Gregory M. Sullivan, M.D., Tonix’s Chief Medical Officer, presented a poster entitled, “*The AtEase Study: An Evaluation of the Efficacy of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL tablet) for the Treatment of Military-Related PTSD*” (Abstract ID: MHSRS-15-0900; Poster ID: 1220).

“PTSD is a serious chronic illness, and many of those with military-related PTSD do not respond to existing treatments. There is an urgent unmet medical need for this patient population,” said Seth Lederman, M.D., chairman and CEO of Tonix. “Recruitment into AtEase recently reached 50% of its target enrollment goal of 220 patients, and we expect to report top line data in the first half of 2016.”

**About the AtEase Clinical Study**

The [AtEase Clinical Study](#) is a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of TNX-102 SL for the treatment of patients with military-related PTSD. The trial is expected to enroll approximately 220 participants who will receive study medication daily at bedtime for twelve weeks. The primary efficacy endpoint will evaluate the performance of TNX-102 SL 2.8 mg on the total Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) score. Tonix expects to report top-line results in the first half of 2016. To learn more, please visit [www.ateasestudy.com](http://www.ateasestudy.com).

**About TNX-102 SL**

[TNX-102 SL](#) efficiently delivers a low dose of cyclobenzaprine to the bloodstream via sublingual (under the tongue) absorption, and is designed for chronic use at bedtime to improve sleep quality. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is intended to provide broad-spectrum symptom improvement in PTSD by targeting sleep and the stress response.

**About Post-Traumatic Stress Disorder**

PTSD afflicts approximately 8.5 million Americans each year, and its prevalence rate in the military population is higher than that among civilians. Both of the drugs approved by the U.S. Food and Drug Administration (FDA) for PTSD lack reliable evidence of efficacy in combat-related trauma and carry suicidality warnings.

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## **About Tonix Pharmaceuticals Holding Corp.**

Tonix is dedicated to the invention and development of novel pharmaceutical products for medical conditions that it believes have broad societal impact, that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's Tonmya™ is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

*TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved for any indications.*

## **Safe Harbor / 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" 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, substantial competition; our possible 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2014 and Quarterly Report on Form 10-Q for the period ended June 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and August 7, 2015, respectively, and future periodic reports filed with the SEC on or after the date hereof. 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 hereof.*

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