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 15, 2016

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

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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))

Item 8.01 Other Events.

On August 16, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") will present a poster entitled "*The AtEase Study: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD*" (the "Poster"), at the 2016 Military Health System Research Symposium, to be hosted by the United States Department of Defense, in Kissimmee, Florida (the "MHSRS Meeting"). The Poster will be presented by Dr. Gregory M. Sullivan, M.D., the Company's chief medical officer.

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 15, 2016, the Company issued a press release announcing the Poster presentation at the MHSRS Meeting. A copy of the press release that discusses this matter 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: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD* Poster*
99.02	Press Release, dated August 15, 2016, issued by Tonix Pharmaceuticals Holding Corp.*

* Furnished herewith.

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 15, 2016

By: */s/ BRADLEY SAENGER*
Bradley Saenger
Chief Financial Officer

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

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

[1]Tonix Pharmaceuticals, Inc., New York, NY 10022; [2]Gendreau Consulting, Poway, CA 92064; [3]Schaberg Consulting, Cary, NC 27513

INTRODUCTION

Posttraumatic stress disorder (PTSD) is among the most prevalent and disabling psychiatric conditions of Warfighters deployed to OEF/OIF/OND combat theaters. Only two pharmacotherapies, both selective serotonin reuptake inhibitors (SSRIs), are FDA-approved for PTSD. One failed to show efficacy in Veterans and males with PTSD, and the other was never studied in a predominantly military-related PTSD population. The serotonin-norepinephrine reuptake inhibitor (SNRI), venlafaxine ER, also had no effect on PTSD or disability in the combat subsample (N=77) of a pooled analysis. These findings highlight the urgent unmet need for a pharmacotherapy with a distinct mechanism of action for military-related PTSD.

TNX-102 SL[a] is a proprietary formulation of cyclobenzaprine, unique among tricyclics for potent binding and antagonist activity at 5-HT_{2A}, α_2-adrenergic, and H_1-histaminergic receptors, presumed to result in improvement in sleep architecture and sympatholytic effects. TNX-102 SL was designed for bedtime sublingual administration and rapid transmucosal absorption, detectable in plasma in minutes. This bypasses first-pass hepatic metabolism, resulting in lower exposure to a long-lived active metabolite, norcyclobenzaprine, compared to the orally ingested products. This Phase 2 study was a double-blind, placebo-controlled randomized trial to assess the safety and efficacy of TNX-102 SL in military-related PTSD, with the hypothesis that symptoms of PTSD could be improved via TNX-102 SL effects on sleep and hyperarousal.

METHODS

The 'AtEase Study' was a Phase 2 multicenter, 12-week, double-blind placebo-controlled, randomized trial in adults meeting a DSM-5 diagnosis of PTSD, assessed by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). Patients were randomized to TNX-102 SL 2.8 mg, 5.6 mg (2 x 2.8 mg tablets), or placebo in a 2:1:2 ratio at 24 US sites (double dummy design). Eligible participants must have experienced PTSD Criterion A-qualifying trauma(s) during military service since 2001. Inclusion criteria: CAPS-5 score at baseline ≥ 29; no antidepressant treatment within 2 months; off other psychotropics. Exclusions: severe suicide risk; unstable medical conditions; substance use disorders in prior 6 months; lifetime bipolar 1 or 2, psychotic disorders, obsessive compulsive disorder, or antisocial personality disorder. The primary efficacy endpoint was mean change from baseline (MCFB) in CAPS-5 severity score between TNX-102 SL 2.8 mg and placebo. Secondary endpoints included: CAPS-5 symptom cluster scores; Clinical Global Impression – Improvement scale (CGI-I); Sheehan Disability Scale (SDS); Montgomery-Asberg Depression Rating Scale (MADRS). CAPS-5 raters were Masters-level or above mental health clinicians who underwent a rigorous rater training and certification program. A Safety Planning Intervention was employed for C-SSRS suicidal ideation > Type 1 during participation.

RESULTS

- 245 patients were randomized; 237 of those made up the safety population; 231 made up the modified intent-to-treat (mITT) population
- Completers: Placebo 73%; TNX-102 SL 2.8 mg 79%; TNX-102 SL 5.6 mg 84%

[a]TNX-102 SL is an Investigational New Drug and has not been approved for any indication

- **Table 1** shows selected demographics and **Table 2** lists index traumas

Table 1. Patient Demographics and Characteristics

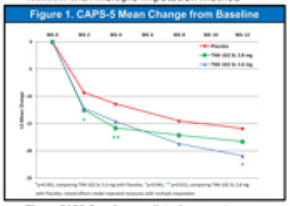
Variable	Placebo N=92	TNX-102 SL 2.8 mg N=90	TNX-102 SL 5.6 mg N=49
Females, no. (%)	6 (6.5%)	6 (6.7%)	4 (8.2%)
Mean age, yrs (SD)	32.0 (6.5)	34.5 (8.3)	34.8 (9.0)
Weight, kg (SD)	91.6 (16.9)	90.9 (18.2)	90.8 (17.4)
Body Mass Index (BMI), kg/m2 (SD)	28.9 (4.4)	29.0 (5.2)	29.0 (4.7)
Education, some college or beyond	72 (78.2%)	80 (88.9%)	41 (83.7%)
% currently employed	54 (58.7%)	56 (62.2%)	33 (67.3%)
% in military service at index trauma	91 (98.9%)	85 (94.4%)	49 (100%)
Active Duty/Reservists/Veterans	8/4/79	9/5/71	5/7/37
Law Enforcement Officers	1	1	0
Ave time since index trauma, yrs (SD)	7.1 (3.6)	7.3 (3.3)	6.2 (3.3)
Ave deployments, military/veterans (SD)	2.2 (1.84)	2.3 (2.15)	2.4 (2.1)
Baseline CAPS-5 Scores (SD)	39.5 (7.7)	39.5 (8.0)	39.3 (8.1)
Baseline MADRS Scores (SD)	17.3 (6.53)	17.6 (5.18)	16.1 (5.54)

Table 2. Index Trauma Categories

Index Traumas During Military Service Related to PTSD Dx	Patient Count
Being involved in an IED explosion or suicide bombing	35
Being attacked or ambushed	33
Witnessing death or injury of fellow soldiers	30
Witnessing IED explosion	29
Receiving incoming artillery, rocket, or mortar fire	10
Being wounded or injured	9
Being responsible for the death of a noncombatant	9
Witness suicide-related deaths or injury	9
Seeing ill or injured women or children you were unable to help	8
Witnessing death or injury of civilians	7
Handling or uncovering human remains	6
Sexual assault	6
Involved in serious vehicular accident (Humvee, helicopter, plane)	6
Shooting or directing fire at the enemy	5
All other categories	23

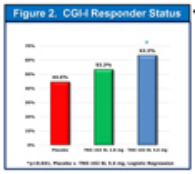
- **Figure 1** shows the visit by visit mean change from Baseline in total CAPS-5 score utilizing the MMRM with multiple imputation method

Figure 1. CAPS-5 Mean Change from Baseline



- The CAPS-5 sleep disturbance item was significantly improved at all assessments for the TNX-102 SL 5.6 mg group and Week 4 for 2.8 mg.
- **Figure 2** On a global scale, the CGI-I, 63.3% of TNX-102 SL 5.6 mg group responded at Week 12

Figure 2. CGI-I Responder Status

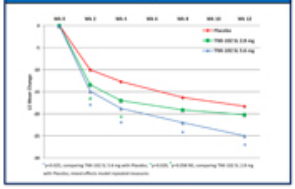


- From a functional perspective, the TNX-102 SL 5.6 mg group showed significant improvement over placebo in the work/school and the social/leisure domains of the Sheehan Disability Scale (**Figure 3A&B**)

Figure 3. Sheehan Disability Scale Domain Scores

- CAPS-5 has not previously been employed in a pharmacotherapy trial; entry severity threshold not clear - ≥ 29 used in AtEase
- Imputing CAPS for DSM-IV (iCAPS-IV), by using 17 common items and multiplying by 2, showed 4 subjects with iCAPS-IV < 50 (range 44-48)
- Using entry criterion of CAPS-5 ≥ 33, 20% of sample excluded but all iCAPS-IVs are > 50
- Analysis of patients with CAPS-5 ≥ 33 showed an effect size of 0.53 on mean change from baseline at Week 12 in TNX-102 SL 5.6 mg group **(Figure 4)**

Figure 4. CAPS-5 Mean Change from Baseline for CAPS ≥ 33



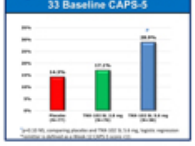
- **Table 3** shows the significance levels and effect sizes of the CAPS-5 cluster scores (MMRM analyses) using a CAPS-5 baseline entry criterion of ≥ 33 and the per protocol threshold of ≥ 29

Table 3. CAPS-5 Cluster Scores

CAPS-5 Cluster	Entry criteria of CAPS-5 ≥ 33 5.6 mg vs Placebo Effect Size	Entry criteria of CAPS-5 ≥ 33 5.6 mg vs Placebo P-value*	Entry criteria of CAPS-5 ≥ 29 5.6 mg vs Placebo Effect Size	Entry criteria of CAPS-5 ≥ 29 5.6 mg vs Placebo P-value*
Cluster B (Intrusion)	0.46	**0.026**	0.26	0.161
Cluster C (Avoidance)	0.12	0.522	0.04	0.963
Cluster D (Mood)/Cognitions)	0.39	0.063	0.35	0.062
Cluster E (Arousal & Reactivity)	0.53	**0.012**	0.35	**0.048**

* MMRM, mixed-effects model repeated measures

Figure 5. CAPS-5 Remitters* in ≥ 33 Baseline CAPS-5



- **Figure 5** shows the rate of remission from PTSD in each arm in the ≥ 33 sample, with a trend for a greater rate in the TNX-102 SL 5.6 mg group compared with Placebo
- **Table 4** shows administration site and systemic AEs. The TNX-102 SL 5.6 mg group had minimally higher systemic AE rates for somnolence, dry mouth, headache, and sedation, yet there were no discontinuations in the group due to AE, suggesting they were tolerable

Table 4. Adverse Events*

Preferred Term	Placebo N=94	TNX-102 SL 2.8 mg N=93	TNX-102 SL 5.6 mg N=50
Local Administration Site Reactions			
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)
Systemic Adverse Events			
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)
Sedation	1 (1.1%)	2 (2.2%)	4 (12.0%)

*Adverse events listed only for those occurring at >5% in either TNX-102 SL treatment arm in the safety population

CONCLUSIONS

The AtEase Study demonstrated that TNX-102 SL 5.6 mg is effective for the treatment of military-related PTSD. Evidence of efficacy on sleep and hyperarousal symptoms were consistent with the hypothesized mechanism of action of TNX-102 SL in PTSD. High completer rate and no discontinuations due to AE in 5.6 mg group suggested good tolerability. Threshold for trial entry of CAPS-5 ≥ 33 is appropriate for Phase 3.

ClinicalTrials.gov Identifier: NCT02277704

Exhibit 99.02

Tonix Pharmaceuticals Presents Poster on the Development of TNX-102 SL for Post-Traumatic Stress Disorder (PTSD) at the 2016 Military Health System Research Symposium

NEW YORK, Aug. 15, 2016 – Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced today that it will present efficacy and safety results of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), for the treatment of military-related PTSD, in a poster at the 2016 Military Health System Research Symposium being held August 15-18, 2016 in Kissimmee, FL.

Gregory M. Sullivan, M.D., chief medical officer of Tonix, will present the poster, titled, " *The AtEase Study: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD*" (Abstract ID: MHSRS-16-0816; Poster No.: 1133).

Event: 2016 Military Health System Research Symposium
Title: The AtEase Study: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD
Date: Tuesday, August 16, 2016
Time: 1:00 PM - 3:30 PM (Eastern Time)

Seth Lederman, M.D., president and chief executive officer of Tonix, said, "We are committed to developing TNX-102 SL for PTSD, a serious chronic illness, and are encouraged by the positive results from our Phase 2 AtEase study, as we plan for the next phase of development."

Pending the final meeting minutes from an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), a Phase 3 study of TNX-102 SL, 5.6 mg, in military-related PTSD is expected to be initiated in the first quarter of 2017. This trial will have a similar design to the Phase 2 AtEase study and is expected to enroll approximately 500 patients across approximately 35 clinical sites in the U.S.

TNX-102 SL is an investigational new drug and has not been approved for any indication.

About the AtEase Clinical Study

In the first quarter of 2015, Tonix initiated the AtEase study, a Phase 2 randomized, double-blind, placebo-controlled, 12-week study of TNX-102 SL, in military-related PTSD. Patients were randomized in a 2:1:2 ratio to TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg (2 x 2.8 mg), or placebo sublingual tablets, administered at bedtime daily for 12 weeks. AtEase was conducted at 24 U.S. centers with 231 patients in the modified intent-to-treat population. The primary efficacy endpoint of the study was the 12-week mean 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 TNX-102 SL and those receiving placebo. In May 2016, Tonix announced positive topline results from the Phase 2 AtEase study, which identified 5.6 mg as the effective and well-tolerated dose for further Phase 3 studies. The 2.8 mg dose showed a positive trend but was not statistically significant. There were no drug-related serious adverse events. The most commonly reported adverse events were oral hypoaesthesia, somnolence, and dry mouth. AtEase was the first large, multicenter, adequate and well-controlled clinical trial of a pharmaceutical product that showed promising results with an investigational new drug product to treat military-related PTSD.

About TNX-102 SL

TNX-102 SL is designed to deliver cyclobenzaprine to the bloodstream rapidly via sublingual (under the tongue) absorption and to bypass first-pass hepatic metabolism. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is under clinical development for the treatment of fibromyalgia and PTSD and is intended to provide broad spectrum improvement by targeting sleep quality and the stress response. Tonix is developing TNX-102 SL, 2.8 mg, for daily bedtime administration for the treatment of fibromyalgia and TNX-102 SL, 5.6 mg, for daily bedtime administration for the treatment of PTSD. The FDA has provisionally accepted the trademark Tonmya® for TNX-102 SL for the treatment of fibromyalgia.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at 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, 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, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, 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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