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): December 7, 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 December 7, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") will present a poster entitled *"The AtEase Study: A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL in the Treatment of Military-Related PTSD"* (the "Poster"), at the 55th Annual Meeting of the American College of Neuropsychopharmacology being held in Hollywood, Florida. The Poster will be presented by Dr. Gregory Sullivan, M.D., Chief Medical Officer of the Company. This Poster replaces the prior version of a poster that the Company filed on a Form 8-K on December 2, 2016.

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.

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: A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL in the Treatment of Military-Related PTSD* Poster*

* 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: December 7, 2016

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

The AtEase Study:

A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL* in the Treatment of Military-Related PTSD

Gregory Sullivan[1], Judy Gendreau[1], R Michael Gendreau[2], Amy Schaberg[3], Bruce Daugherty[1], Heather Jividen[1], Ashild Peters[1], Perry Peters[1], Frank Weathers[4], Seth Lederman[1]

[1]Tonix Pharmaceuticals Inc, [2]Gendreau Consulting, [3]Schaberg Consulting, [4]Auburn University/National Center for PTSD

*TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

INTRODUCTION

- Posttraumatic stress disorder (PTSD) is a seriously impairing psychiatric condition that is widely prevalent in United States military personnel
- There is an urgent unmet need for pharmacotherapies for this population
- TNX-102 SL is a low dose sublingual formulation of cyclobenzaprine (CBP), a tricyclic molecule with high affinity and functional antagonism for 5-HT_{2A}, α_1-adrenergic, and histamine-H_1 receptors, all with roles in sleep regulation
  - Targets sleep disturbance and hyperarousal, core PTSD symptoms
  - Hypothesized to play a critical role in PTSD global recovery by allowing sleep-dependent memory processing (e.g. extinction consolidation)
- TNX-102 SL differs from orally administered CBP; it was designed to enhance sublingual transmucosal absorption at bedtime, resulting in peak CBP plasma levels during sleep hours and reduced daytime exposure
  - Avoids first-pass hepatic metabolism, reducing formation of long-lived active metabolite, norcyclobenzaprine
- The "AtEase Study" was our first evaluation of the efficacy and safety of TNX-102 SL in military-related PTSD including combat-only PTSD

METHODS

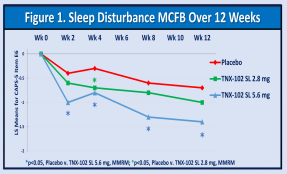
- Multicenter, 12-week, double-blind placebo-controlled Phase 2 study
- Inclusions: both sexes; ages 18-65; PTSD DSM-5 Criterion A trauma(s) during military service since 9/11/2001; current PTSD by Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) and Baseline total CAPS-5 score ≥ 29; free of antidepressants ≥ 2 months; free of or washed off of other psychotropics; not participating in trauma-focused psychotherapy
- Exclusions: serious suicide risk; substance use disorders within 6 months; lifetime bipolar, psychotic, obsessive-compulsive, or antisocial personality disorders
- Randomized in 2:1:2 ratio to TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg, Placebo at 24 U.S. sites; dynamic randomization (site, sex, current MDD)
- Primary efficacy analysis: comparison of mean change from baseline (MCFB) at Week 12 in CAPS-5 score between TNX-102 SL 2.8 mg and Placebo, mixed model repeated measures analysis (MMRM)
- Key 2◦ endpoints: Clinical Global Impression–Improvement (CGI-I), Sheehan Disability Scale (SDS), PROMIS Sleep Disturbance (SD). Also: CAPS-5 clusters, Patient Global Impression of Change (PGIC)
- CAPS-5 raters ≥ Master's degree-level in mental health; rigorously trained/certified; and reliability monitoring over course of study

RESULTS

Of 245 patients randomized, 231 were included in the modified intent-to-treat (mITT) efficacy population (14 randomized patients failed to return for post-baseline efficacy assessment). The mITT comprised 90 on TNX-102 SL 2.8 mg, 49 on TNX-102 SL 5.6 mg, and 92 on Placebo; completion rates of 79%, 84%, and 73%, respectively. **Table 1** shows demographic and clinical characteristics.

- Primary analysis: The primary analysis of 2.8 mg TNX-102 SL did not separate from Placebo at Week 12 (p=0.259, NS), however, the 5.6 mg arm showed a strong trend for improvement versus Placebo in MCFB in CAPS-5 (p=0.053, NS), with an effect size of 0.36 (Cohen's *d*); and sensitivity analyses of the 5.6 mg dose v. Placebo on CAPS-5 MCFB were statistically significant (see **Table 2**)
- The CAPS-5 Arousal & Reactivity cluster was significantly more improved for the 2.8 mg arm than Placebo at Weeks 2, 4 and 8 (p<0.05); the 5.6 mg arm was significantly more improved at Weeks 2, 8, and 12 (p<0.05)
- The sleep disturbance item (E6) of CAPS-5 was significantly more improved in the 5.6 mg arm over Placebo early by Week 2 and maintained at all other assessments (Weeks 4, 8, and 12); the 2.8 mg arm was significantly more improved at Week 4 only (See **Figure 1**)
- The exaggerated startle item (E4) of CAPS-5 was significantly more improved for the 5.6 mg arm over Placebo at Week 12
- The systemic adverse events reported were consistent with those reported with CBP; tongue numbness was common, generally transient, and never rated as severe; with overall good tolerability (see **Table 5**)

Figure 1. Sleep Disturbance MCFB Over 12 Weeks



*p<0.05, Placebo v. TNX-102 SL 5.6 mg, MMRM; †p<0.05, Placebo v. TNX-102 SL 2.8 mg, MMRM

Table 1. Patient Demographics and Characteristics

Variable	TNX-102 SL 2.8 mg N=90	TNX-102 SL 5.6 mg N=49	Placebo N=92
Females, no. (%)	6 (6.7%)	4 (8.2%)	6 (6.5%)
Mean age, yrs (SD)	34.5 (8.3)	34.8 (9.0)	32.0 (6.5)
Weight, kg (SD)	90.9 (18.2)	90.8 (17.4)	91.6 (16.9)
BMI, kg/m^2 (SD)	29.0 (5.2)	29.0 (4.7)	28.9 (4.4)
Education, some college or beyond	80 (88.9%)	41 (83.7%)	72 (78.2%)
% currently employed	56 (62.2%)	33 (67.3%)	54 (58.7%)
% in military service at index trauma	85 (94.4%)	49 (100%)	91 (98.9%)
Active Duty/Reservists/Veterans	9/5/71	5/7/37	8/4/79
Law Enforcement Officers	5	0	1
Ave time since trauma, yrs (SD)	7.3 (3.3)	6.2 (3.3)	7.1 (3.6)
Ave deployments, military (SD)	2.3 (2.15)	2.6 (2.16)	2.2 (1.84)
Baseline CAPS-5 Scores (SD)	39.5 (8.0)	39.3 (8.1)	39.5 (7.7)
Baseline MADRS Scores (SD)	17.6 (5.18)	16.1 (5.54)	17.3 (6.53)

Table 2. Results of Primary and Sensitivity Analyses

Assessment	Domain	Analysis	p-Values	
			2.8 mg	5.6 mg
CAPS-5	Total	MMRM (Primary Analysis)	0.259^	0.053
	Total	MMRM with Multiple Imputation	0.211	0.031*
	Total	MMRM w/ Hybrid LOCF/BOCF	0.172	0.037*
	Total	ANCOVA	0.090	0.038*

*p<0.05; ^Primary analysis not significant; BOCF, baseline observation carried forward; LOCF, last observation carried forward; MMRM, mixed model repeated measures

Retrospective Analysis Using CAPS-5 ≥ 33 as Threshold for Study Entry

For inclusion, prior registration studies of approved PTSD pharmacotherapies required a baseline severity score of ≥50 on previous versions of CAPS. Those versions scored PTSD severity based on 17 items using DSM-III-R or DSM-IV criteria, each item rated on 0-4 for intensity & 0-4 for frequency (maximum possible score = 136). The AtEase protocol required CAPS-5 severity of ≥29 for enrollment. To compare the AtEase population with prior studies, we retrospectively imputed a CAPS-IV (iCAPS-IV) for DSM-IV in AtEase using the 17 common items and multiplying by 2. Using the iCAPS-IV, 10 subjects with iCAPS-IV ≤50 (range 44-50) were found. A retrospective analysis of the AtEase patients with CAPS-5 ≥33 at entry, excluded those 10 patients and 20% of the AtEase population. Analysis of efficacy in the population with baseline CAPS-5 ≥33 is shown in **Figure 2**. The CAPS-5 assessments MCFB are significant for TNX-102 SL 5.6 mg at all assessments at Weeks 2, 4, 8 and 12. Week 12 comparison of TNX-102 SL 5.6 mg with Placebo showed an effect size of 0.53 (see **Table 3**).

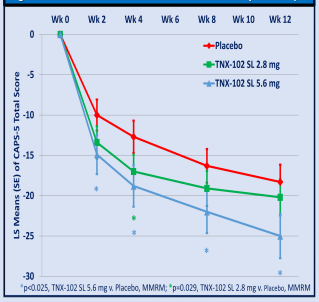
Table 3 shows p-values and effect sizes of CAPS-5 total and cluster scores, CAPS-5 items E6 & E2, CGI-I responders, and SDS total and item scores comparing TNX-102 SL 5.6 mg v. Placebo at Week 12 using the per protocol threshold of ≥29 and, separately, the subsample with CAPS-5 baseline score of ≥33. Effect sizes are substantial for CAP-5 total score and clusters B, D & E for the ≥33 subsample.

Table 3. Week 12 Outcome Measures for TNX-102 SL 5.6 mg v. Placebo in Military-Related PTSD for Both Entry Thresholds

	PBO N=92, 5.6mg N=49; CAPS-5 ≥ 29		PBO N=77, 5.6mg N=38; CAPS-5 ≥ 33	
Outcome Measure	ES[1]	p-value[2]	ES[1]	p-value[2]
CAPS-5				
Total score	0.36	0.053	0.53	*0.013
Cluster B (intrusion)	0.26	0.161	0.46	*0.026
Cluster C (avoidance)	0.04	0.963	0.12	0.522
Cluster D (mood/cognition)	0.35	0.062	0.39	0.065
Cluster E (arousal and reactivity)	0.35	*0.048	0.52	*0.012
E6 (Sleep item)	0.51	*0.010	0.51	*0.013
E2 (Reckless/Self Destruct)	0.15	0.140	0.30	*0.012
CGI–I (responders)	2.11	*0.041	2.29	*0.042
SDS				
Total Score	0.33	0.079	0.35	0.093
Work/School item	0.34	0.050	0.41	*0.040
Social/Leisure item	0.38	*0.031	0.35	0.116
Family Life/Home Responsibilities item	0.12	0.524	0.15	0.455

[1]Cohen's *d* for CAPS-5 and SDS outcome measures; odds ratio for CGI-I.
[2]CAPS-5 and SDS outcome: p-values from MMRM comparing TNX-102 SL 5.6 mg and placebo; CGI-I: p-values from a repeated measure logistic regression (Responder: "1" very much improved, or "2" much improved at week 12)
*p<0.05, not adjusted; Abbreviations: 5.6 mg=TNX-102 SL 5.6 mg; ES=Effect Size; N=number of patients; PBO=Placebo

Figure 2. CAPS-5 MCFB Over 12 Weeks in ≥33 Entry Subsample



*p<0.025, TNX-102 SL 5.6 mg v. Placebo, MMRM; †p<0.029, TNX-102 SL 2.8 mg v. Placebo, MMRM

Sub-Group Analysis of Combat PTSD

We defined military-related PTSD as resulting from any DSM-5 Criterion A-qualifying trauma that occurred during military service. Yet, the majority of index traumas (85.0%) in our AtEase study were directly related to combat and would be considered combat PTSD as strictly defined. A sub-group analysis of patients whose index traumas were combat-related (N=197) was performed; significantly greater improvement in the CAPS-5 total, CAPS-5 clusters (intrusion, mood and hyperarousal), certain items (e.g., sleep quality), and the global measures, and work and social function items on the SDS was observed in the 5.6 mg group (**Table 4**). Moreover, the subset of combat-trauma patients with CAPS-5 ≥33 had statistically significant improvement over placebo in both hyperarousal (cluster E) and intrusion (cluster B) as well as certain key items (e.g., sleep, reckless and self-destructive behavior) with the most substantial effect sizes observed with TNX-102 SL 5.6 mg (**Table 4**).

Table 4. Week 12 Outcome Measures for TNX-102 SL 5.6 mg v. Placebo in Combat-Only PTSD for Both Entry Thresholds

	PBO N=74, 5.6mg N=46; CAPS-5 ≥ 29		PBO N= 64, 5.6mg N=35; CAPS-5 ≥ 33	
Outcome Measure	ES[1]	p-value[2]	ES[1]	p-value[2]
CAPS-5				
Total score	0.42	*0.037	0.57	*0.013
Cluster B (intrusion)	0.26	0.183	0.50	*0.031
Cluster C (avoidance)	0.04	0.824	0.11	0.570
Cluster D (mood/cognition)	0.41	*0.035	0.42	0.061
Cluster E (arousal and reactivity)	0.40	*0.036	0.57	*0.012
E6 (Sleep item)	0.58	*0.003	0.58	*0.010
E2 (Reckless/Self Destruct)	0.15	0.178	0.30	*0.019
CGI–I (responders)	2.15	*0.049	2.12	0.082
SDS				
Total Score	0.41	*0.039	0.47	*0.032
Work/School item	0.40	*0.026	0.40	*0.015
Social/Leisure item	0.50	*0.013	0.51	*0.028
Family Life/Home Responsibilities item	0.19	0.328	0.22	0.274

[1]Cohen's *d* for CAPS-5 and SDS outcome measures; odds ratio for CGI-I.
[2]CAPS-5 and SDS outcome: p-values from MMRM comparing TNX-102 SL 5.6 mg and placebo; CGI-I: p-values from a repeated measure logistic regression (Responder: "1" very much improved, or "2" much improved at week 12)
*p<0.05, not adjusted; Abbreviations: 5.6 mg=TNX-102 SL 5.6 mg; ES=Effect Size; N=number of patients; PBO=Placebo

Table 5 shows adverse events (AEs) for TNX-102 SL in PTSD. Despite marginally increased rates of a few systemic AEs in the 5.6 mg arm, 84% completed the study, and no one in the TNX-102 SL 5.6 mg arm discontinued due to AE. Tongue numbness was never rated as severe.

Table 5: Adverse Events (at rate of ≥5% in either drug-treated group)

	Placebo (N=94)*	TNX-102 SL 2.8 mg (N=93)*	TNX-102 SL 5.6 mg (N=50)*
Systemic Adverse Events			
Somnolence	6.4%	11.8%	16.0%
Dry Mouth	10.6%	4.3%	16.0%
Headache	4.3%	5.4%	12.0%
Insomnia	8.5%	7.5%	6.0%
Sedation	1.1%	2.2%	12.0%
Administration Site Reactions			
Hypoaesthesia oral[a]	2.1%	38.7%	36.0%
Paraesthesia	3.2%	16.1%	4.0%
Glossodynia	1.1%	3.2%	6.0%

[a]Oral hypoaesthesia (tongue numbness) was most common AE, generally transient (<60 minutes), and rated mild in 89% and moderate in 11% on TNX-102 SL; *Safety Population (N=237)

CONCLUSIONS

- TNX-102 SL 5.6 mg reduced total CAPS-5 severity and provided global improvement, including on work & social function in military-related PTSD
- A retrospective analysis indicated a study entry CAPS-5 severity score of ≥33 is more aligned with previous PTSD pharmacotherapy registration trials that used prior CAPS versions, and TNX-102 SL 5.6 mg has substantial effect sizes on total and cluster scores on this subsample
- The subgroup of AtEase with combat PTSD had the most robust effects of TNX-102 SL 5.6 mg on CAPS-5 severity and cluster scores, and on overall functional improvement by SDS total score, work and social items
- The TNX-102 SL 5.6 mg group had a high completion rate and no AE discontinuations; tongue numbness was common, generally transient, and never rated as severe; with overall good tolerability