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 1, 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 1.02 Termination of a Material Definitive Agreement.
Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On December 1, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") elected to eliminate the position of Chief Scientific Officer. In connection with the elimination of such position, the employment agreement entered into by and between the Company and Dr. Bruce Daugherty, Ph.D. is being terminated, effective as of December 31, 2016. Effective as of the date of such termination, Dr. Daugherty will resign from his positions as the Company's Chief Scientific Officer, Controller and Secretary and all positions of the Company's subsidiaries.

Pursuant to Dr. Daugherty's Employment Agreement with the Company, dated March 14, 2014, and previously filed with the Securities and Exchange Commission as Exhibit 10.01 to the Company's Current Report on Form 8-K filed on March 19, 2014, Dr. Daugherty will receive (i) a severance payment equal to his current annual base salary, (ii) payment of the full cost of health benefits coverage for Dr. Daugherty and his eligible dependents for one year and (iii) the automatic acceleration of the vesting and exercisability of outstanding unvested stock awards as to the number of stock awards that would have vested over the 12-month period following the effective date of Dr. Daugherty's termination. Pursuant to his employment agreement, all payments and benefits to Dr. Daugherty thereunder are subject to his compliance with the confidentiality and non-competition provisions thereof and his execution of a general release of claims against the Company.

Item 8.01 Other Events.

On December 7, 2016, the Company will present a poster entitled *"The AtEase Study: A 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.

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

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* 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 2, 2016

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

The AtEase Study:
A 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, safety, and tolerability of TNX-102 SL in military-related PTSD

METHODS

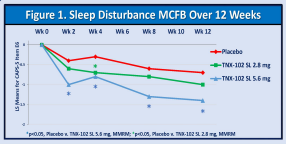
- Multicenter, 12-week, double-blind placebo-controlled Phase 2 study conducted at 24 US sites
- Inclusions: both sexes; ages 18-65; PTSD DSM-5 Criterion A trauma(s) during military service since 9/11/2001; current PTSD by Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) and Baseline total CAPS-5 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 1 or 2, 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; dynamic randomization (stratification for site, sex, current MDD status)
- Primary efficacy analysis: comparison of mean change from baseline (MCFB) at Week 12 in CAPS-5 score between TNX-102 SL and Placebo, mixed model repeated measures analysis (MMRM) without imputation
- 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). Primary analysis of TNX-102 SL 5.6 mg 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 TNX-102 SL 5.6 mg dose v. placebo on CAPS-5 MCFB were significant (See **Table 2**)
- The CAPS-5 Arousal & Reactivity cluster, sleep and startle items were significantly improved for the 5.6 mg dose, as were global measures, and work and social domains on the SDS (See **Table 2**)
- The sleep disturbance item (E6) of CAPS-5 was significantly more improved in the TNX-102 SL 5.6 mg arm over placebo early by Week 2 and maintained at all other assessments (Weeks 4, 8, and 12) (See **Figure 1**)
- 12-weeks of sublingual bedtime dosing of TNX-102 SL was well tolerated and the most frequently reported adverse events were related to local administration reactions (**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 Secondary Analyses

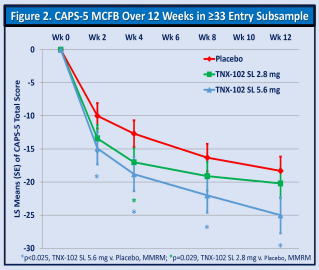
Assessment	Domain	Analysis	p-Values 2.8 mg	p-Values 5.6 mg
CAPS-5	Total	MMRM (Primary Analysis)	0.259^	0.053
	Total	MMRM with Multiple Imputation	0.211	0.031*
	Total	MMRM w/ Hybrid LOCF/BOCF	0.172	0.037*
	Total	ANCOVA	0.090	0.038*
Clusters/items	Arousal & Reactivity	MMRM	0.141	0.048*
	Sleep item	MMRM	0.185	0.010*
	Exaggerated Startle	MMRM	0.336	0.015*
CGI-I	Responders	Logistic Regression	0.240	0.041*
PGIC	Mean score	MMRM	0.075	0.035*
SDS	Work/school item	MMRM	0.123	0.050*
	Social/leisure item	MMRM	0.198	0.031*

*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 weeks 2, 4, 8 and 12. Week 12 showed an effect size of 0.53.

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

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

Table 3. Week 12 CAPS-5 Total Score & Cluster Score Comparisons for TNX-102 SL 5.6 mg v. Placebo

Outcome Measure	CAPS-5 ≥ 33[a] ES[c]	CAPS-5 ≥ 33[a] p-value	CAPS-5 ≥ 29[b] ES[c]	CAPS-5 ≥ 29[b] p-value
CAPS-5 Total Score	0.53	*0.013	0.36	0.053
CAPS-5 Cluster B (Intrusion)	0.46	*0.026	0.26	0.161
CAPS-5 Cluster C (Avoidance)	0.12	0.522	0.04	0.963
CAPS-5 Cluster D (Mood/Cognition)	0.39	0.065	0.35	0.062
CAPS-5 Cluster E (Arousal/Reactivity)	0.52	*0.012	0.35	*0.048

*p<0.05, statistically significant; [c]ES = effect size; [a]Placebo n = 77, TNX-102 SL 5.6 mg n = 38; [b]Placebo n = 92, TNX-102 SL 5.6 mg n = 49;

Table 4 shows mean differences from placebo as well as the p-values and effect sizes for each of the 20 CAPS-5 item scores comparing TNX-102 SL 5.6 mg v. Placebo at Week 12 in the subsample with CAPS-5 baseline entry criterion of ≥33. Ordered by largest to smallest effect size, it may be seen that the largest effect of TNX-102 SL is on the sleep disturbance of PTSD, item E6; this effect emerged early in treatment, by the Week 2 assessment (p=0.002), and continued throughout the 12 weeks. The second largest effect was on triggered physical anxiety responses, item B5; but here TNX-102 SL did not significantly separate from placebo until Week 8 (p=0.003). Similarly, for exaggerated startle, item E4, separation from placebo only occurred late, by Week 12.

Table 4. Week 12 CAPS-5 Item Comparisons of MCFB Between TNX-102 SL 5.6 mg and Placebo in ≥33 Entry Subsample

			LS Mean Diff (SE)	P-Value	Effect Size
20	E6	Problems falling asleep or staying asleep	-0.7 (0.29)	0.013*	0.51
5	B5	Physical reactions when something reminded you of [EVENT]	-0.6 (0.27)	0.025*	0.46
18	E4	Strong startle reactions	-0.6 (0.25)	0.016*	0.43
13	D6	Felt distant or cut off from other people	-0.6 (0.30)	0.045*	0.43
19	E5	Problems with concentration	-0.5 (0.27)	0.071	0.38
12	D5	Less interest in activities that you used to enjoy	-0.5 (0.28)	0.083	0.37
3	B3	Suddenly acted or felt as if [EVENT] happening again (flashback)	-0.4 (0.20)	0.050*	0.30
16	E2	Taking more risks or doing things that might have caused you harm[a]	-0.4 (0.15)	0.012*	0.30
4	B4	Emotional upset when something reminded you of [EVENT]	-0.4 (0.27)	0.191	0.28
2	B2	Unpleasant dreams about [EVENT]	-0.4 (0.28)	0.192	0.24
9	D2	Strong negative beliefs about yourself, other people, or the world[b]	-0.3 (0.30)	0.284	0.22
1	B1	Unwanted memories of [EVENT]	-0.3 (0.28)	0.233	0.22
17	E3	Especially alert or watchful, even when no specific threat or danger	-0.2 (0.27)	0.500	0.20
14	D7	Difficulty experiencing positive feelings like love or happiness[a]	-0.3 (0.28)	0.342	0.20
11	D4	Strong negative feelings such as fear, horror, anger, guilt, or shame[b]	-0.2 (0.27)	0.380	0.14
10	D3	Blamed yourself for [EVENT] or what happened as a result of it[b]	-0.2 (0.24)	0.339	0.13
7	C2	Tried to avoid activities, places, or people that reminded of [EVENT]	-0.2 (0.29)	0.596	0.13
6	C1	Tried to avoid thoughts or feelings about [EVENT]	-0.2 (0.30)	0.521	0.11
8	D1	Difficulty remembering some important parts of [EVENT]	-0.1 (0.19)	0.623	0.09
15	E1	Felt especially irritable or angry & showed it in your behavior	0.0 (0.27)	0.892	0.00

[a]Different from CAPS-IV: "Felt there is no need to plan for the future, that somehow your future will be cut short?"
[b]Different from CAPS-IV: "Felt emotionally numb or had trouble experiencing feelings like love or happiness?"
[c]One of the three new items in CAPS-5; *significant at p<0.05; MCFB, mean change from baseline

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 on 5.6 mg discontinued due to AE.

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 symptoms and provided global improvement, including greater work and social function
- A retrospective analysis of patients with entry CAPS-5 ≥33 is more aligned with previous PTSD pharmacotherapy registration trials using prior CAPS versions, and TNX-102 SL 5.6 mg has substantial effect sizes on total and cluster scores on this subsample
- Impairment in fear extinction memory is posited to be centrally involved in PTSD pathophysiology, with adequate sleep quality essential for emotional memory consolidation. Early and robust improvement in sleep with TNX-102 SL is followed (by several weeks) by improvement in symptoms presumed to require sufficient extinction learning for amelioration. This approach of targeting sleep quality appears to provide broad improvement across several items of the Intrusion and Arousal & Reactivity symptom clusters (**Table 4**).
- 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