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): November 10, 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 November 10, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") will present a poster entitled "*Low-Dose Sublingual Cyclobenzaprine (TNX-102 SL) in Military-Related PTSD: Results of a 12-Week Randomized, Double-Blind, Placebo-Controlled Multicenter Phase 2 Trial*" (the "Poster"), at the International Society for Traumatic Stress Studies 32nd Annual Meeting, in Dallas, Texas (the "ISTSS Annual Meeting").. The Poster will be presented by Dr. Gregory 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 November 10, 2016, the Company issued a press release announcing the Poster presentation at the ISTSS Annual 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	*Low-Dose Sublingual Cyclobenzaprine (TNX-102 SL) in Military-Related PTSD: Results of a 12-Week Randomized, Double-Blind, Placebo-Controlled Multicenter Phase 2 Trial Poster**
99.02	Press Release, dated November 10, 2016, issued by Tonix Pharmaceuticals Holding Corp.*

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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: November 10, 2016

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

Low-Dose Sublingual Cyclobenzaprine (TNX-102 SL*) in Military-Related PTSD: Results of a Phase 2 Randomized, Placebo-Controlled Multicenter Trial

Gregory M. Sullivan[1], Judith 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

Continuing Medical Education Commercial Disclosure

I, Gregory M. Sullivan, have the following commercial relationship to disclose:
Tonix Pharmaceuticals, Inc., Employee (Chief Medical Officer), Stockholder

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

INTRODUCTION

Evidence-based pharmacotherapies for military-related posttraumatic stress disorder (PTSD) are lacking. TNX-102 SL is a low-dose sublingual (SL) formulation of cyclobenzaprine (CBP), a tricyclic molecule previously FDA-approved for short-term use in muscle spasm at higher total daily oral doses (15-30 mg/day). Intended for bedtime administration, TNX-102 SL is rapidly absorbed via SL mucosa, resulting in peak CBP plasma levels ~4 hours into the sleep period and falling sharply thereafter. Because the SL route bypasses first-pass hepatic metabolism, there is reduced formation of a long-lived active metabolite, norcyclobenzaprine, with off-target functional activities. CBP is unique among tricyclics for high affinity and functional antagonism for 5-HT_{2A}, α_1-adrenergic, and histamine-H_1 receptors, all with roles in sleep regulation. TNX-102 SL is hypothesized to target sleep disturbance and nocturnal hyperarousal, potentially providing global benefit in PTSD by allowing sleep-dependent emotional memory (e.g. extinction) consolidation necessary for recovery. The "AtEase Study" was conducted to assess the efficacy, safety and tolerability of TNX-102 SL in the treatment of military-related PTSD.

METHODS

- Multicenter, 12-week, double-blind placebo-controlled (DB-PC) Phase 2 study.
- Eligible participants were: male or female, ages 18-65; incurred PTSD DSM-5 Criterion A trauma(s) during military service and since 9/11/2001; met current PTSD by Clinician-Administered PTSD Scale for DSM-5 (CAPS-5); had a total CAPS-5 severity score ≥ 29 at Screening and Baseline; were free of antidepressants ≥ 2 months and free of or washed off other psychotropics; and were not participating in a trauma-focused psychotherapy (TFP) during the study. Prior TFP had to have concluded >1 month before Screening.
- Exclusions: serious suicide risk; unstable medical illness; substance use disorders within 6 months; lifetime bipolar 1 or 2, psychotic, obsessive-compulsive, or antisocial personality disorders.
- Conducted at 24 US sites; patients randomized in a 2:1:2 ratio to TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg, or Placebo; dynamic randomization minimized imbalances by site, sex, and current major depression.
- Primary efficacy analysis: comparison of mean change from baseline (MCFB) at Week 12 in CAPS-5 severity score between TNX-102 SL 2.8 mg and Placebo, via mixed-effects model repeated measures (MMRM).
- Key secondary endpoints were: Clinical Global Impression – Improvement (CGI-I) scale, Sheehan Disability Scale (SDS) and PROMIS Sleep Disturbance. Others secondaries: CAPS-5 cluster scores and remission rates
- CAPS-5 raters were ≥ Master's degree-level in mental health fields; underwent rigorous training and certification process; and there was CAPS-5 reliability monitoring throughout trial.
- For CAPS-5, maximum possible score is 80; and PTSD severity is as follows: 0-10 is asymptomatic/remission, 11-22 is mild, 23-34 is moderate, 35-46 is severe, and 47+ is extreme PTSD.

RESULTS

Of 245 patients randomized, 231 were included in the modified intent-to-treat (mITT) efficacy population (14 of the 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, with completion rates of 79%, 84%, and 73%, respectively. Demographic and clinical characteristics were similar across the three groups (**Table 1**).

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	Overall N=231
Females, no. (%)	6 (6.7%)	4 (8.2%)	6 (6.5%)	16 (6.9%)
Mean age, yrs (SD)	34.5 (8.3)	34.8 (9.0)	32.0 (6.5)	33.6 (7.8)
Weight, kg (SD)	90.9 (18.2)	90.8 (17.4)	91.6 (16.9)	91.1 (17.5)
BMI, kg/m2 (SD)	29.0 (5.2)	29.0 (4.7)	28.9 (4.4)	28.9 (4.8)
Education, some college or beyond	80 (88.9%)	41 (83.7%)	72 (78.2%)	193 (83.6%)
% currently employed	56 (62.2%)	33 (67.3%)	54 (58.7%)	143 (61.9%)
% in military service at time of index trauma	85 (94.4%)	49 (100%)	91 (98.9%)	225 (97.4%)
Number of: Active Duty/Reservists/Veterans	9/5/71	5/7/37	8/4/79	22/16/187
Number of: Law Enforcement Officers	5	0	1	6
Ave time since index trauma, yrs (SD)	7.3 (3.3)	6.2 (3.3)	7.1 (3.6)	7.0 (3.4)
Ave deployments, military/veterans (SD)	2.3 (2.15)	2.6 (2.1)	2.2 (1.84)	2.3 (2.00)
Baseline CAPS-5 Scores (SD)	39.5 (8.0)	39.3 (8.1)	39.5 (7.7)	39.5 (7.85)

- Primary analysis: The primary analysis did not demonstrate that TNX-102 SL 2.8 mg was different from Placebo at Week 12 (p=0.259, NS). Yet TNX-102 SL 5.6 mg showed a strong trend for difference from placebo in MCFB in CAPS-5 (p=0.053), with an effect size of 0.36 (Cohen's *d*); and several 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 clinician- and patient-rated global measures, and work and social domains on the SDS.

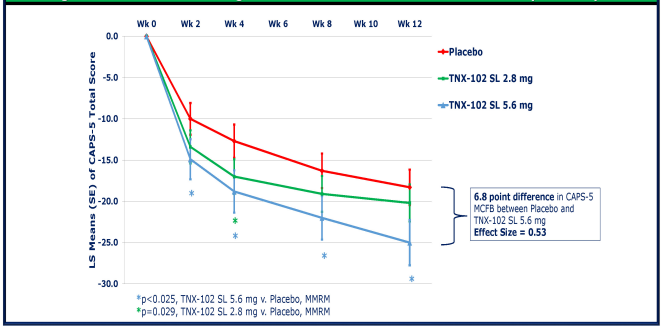
Table 2. Results of Primary and Secondary Analyses

Assessment	Domain	Analysis	p-Values	
			2.8 mg (N=90)	5.6 mg (N=49)
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*
CAPS-5 clusters/items	Arousal & Reactivity cluster (E)	MMRM	0.141	0.048*
	Sleep item (E6)	MMRM	0.185	0.010*
	Exaggerated Startle item (E4)	MMRM	0.336	0.015*
CGI-I	Responders	Logistic Regression	0.240	0.041*
PGIC	Mean score	MMRM	0.075	0.035*
Sheehan Disability Scale	Work/school item	MMRM	0.123	0.050*
	Social/leisure item	MMRM	0.198	0.031*

*p<0.05; ^Primary analysis p-value not significant comparing TNX-102 SL 2.8 mg v. placebo; BOCF, baseline observation carried forward; CGI-I, Clinical Global Impression - Improvement scale; LOCF, last observation carried forward; MMRM, mixed model repeated measures; PGIC, Patient Global Impression of Change

Retrospective Analysis Using CAPS-5 ≥ 33 as Threshold for Study Entry: For inclusion, previous registration studies of approved PTSD pharmacotherapies required a severity score of ≥50 at baseline on prior versions of CAPS. Those versions scored severity based on 17 items using DSM-III-R or DSM-IV criteria, each item rated on 0-4 for intensity and 0-4 for frequency (maximum possible score = 136). The protocol for AtEase included CAPS-5 severity of ≥29. Yet, retrospectively imputing a CAPS for DSM-IV (iCAPS-IV) in AtEase using the 17 common items and multiplying by 2, 10 subjects with iCAPS-IV ≤50 (range 44-50) were found. If instead an entry criterion of CAPS-5 ≥ 33 is used for AtEase patients, 20% of sample was excluded but all iCAPS-IVs are >50. A post-hoc analysis of efficacy was therefore conducted using baseline CAPS-5 ≥33. As seen in **Figure 4**, all assessment points are significant for TNX-102 SL 5.6 mg; Week 12 MCFB showed an effect size of 0.53.

Figure 1. CAPS-5 Mean Change From Baseline 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: Week 12 CAPS-5 Total Score and Cluster Score Comparisons for TNX-102 SL 5.6 mg v. Placebo

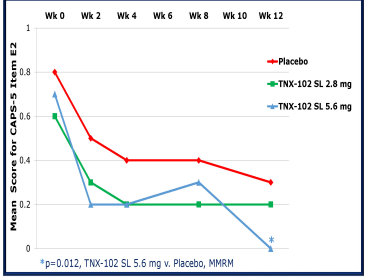
Outcome Measure	CAPS-5 ≥ 33[a]		CAPS-5 ≥ 29[b]	
	ES[c]	p-value	ES[c]	p-value
CAPS-5 Total Score	0.53	*0.013	0.36	0.053
CAPS-5 Cluster B (Intrusion)	0.46	*0.026	0.26	0.161
CAPS-5 Cluster C (Avoidance)	0.12	0.522	0.04	0.963
CAPS-5 Cluster D (Mood/Cognition)	0.39	0.065	0.35	0.062
CAPS-5 Cluster E (Arousal/Reactivity)	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 3 shows significance levels 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 entry criterion of ≥33 and, separately, the per protocol threshold of ≥29. Effect sizes are substantial for CAP-5 total score and Clusters B, D and E for the ≥33 subsample.

Effects of TNX-102 SL 5.6 mg on Reckless or Self-Destructive Behavior Item: New to the hyperarousal cluster in DSM-5 is an item for "***reckless or self-destructive behavior***," which can include dangerous driving, high-risk thrill-seeking, excessive alcohol or drug use, injurious behaviors to self or others, or suicidal behaviors. In the AtEase subsample (CAPS-5 ≥33 at entry), the effects of TNX-102 SL on this item are shown in **figure 2**. By Week 12, TNX-102 SL 5.6 mg significantly reduced this item (p=0.012) to a mean of zero. At baseline, mean item scores on this item for the three groups ranged from 0.6-0.8, seemingly low in severity. But only a small proportion of patients in each group scored >0 on this item at Baseline. The means (SD) at Baseline of only patients scoring >0 on this item are: Placebo (N=25 of 77) 2.5 (0.65); TNX-102 SL 2.8 mg (N=15 of 70) 2.7 (0.72); and TNX-102 SL 5.6 mg (N=9 of 38) 2.8 (0.67). By Week 12, these were reduced by: Placebo (N=19) -1.8 (1.34); TNX-102 SL 2.8 mg (N=11) -2.0 (1.18); and TNX-102 SL 5.6 mg (N=8) -2.9 (0.64).

Figure 2: CAPS-5 Reckless or Self-Destructive Behavior (Item E2) in ≥33 Entry Subsample



*p=0.012, TNX-102 SL 5.6 mg v. Placebo, MMRM

Safety: Overall TNX-102 SL was well tolerated. Adverse events occurring at > 5% rate in either TNX-102 SL group are summarized below in **Table 3.**

Table 3: Adverse Events*

Systemic Adverse Events	Placebo (N=94)	TNX-102 SL 2.8 mg (N=93)	TNX-102 SL 5.6 mg (N=50)
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[#]	2.1%	38.7%	36.0%
Paraesthesia	3.2%	16.1%	4.0%
Glossodynia	1.1%	3.2%	6.0%

[#]Oral hypoaesthesia (tongue numbness) was the most common AE, was generally transient (<60 minutes), and rated as mild in 89% and moderate in 11% on TNX-102 SL;
*Adverse events at a rate of >5% in either TNX-102 SL treated group in the safety population (N=237)

CONCLUSIONS

- The AtEase study identified 5.6 mg as an effective dose for TNX-102 SL as a potential treatment for military-related PTSD, with an effect size of 0.36.
- Retrospective analysis of the AtEase sample using an entry severity threshold of ≥33, more comparable to prior registration studies, indicates substantially larger effect sizes for TNX-102 SL 5.6 mg compared with per protocol of ≥29 on total CAPS-5 (0.53 v. 0.36) and the Arousal & Reactivity (0.52 v. 0.35), Intrusion (0.46 v. 0.26), and Mood/Cognitions (0.39 v. 0.35) clusters.
- TNX-102 SL 5.6 mg in the ≥33 subsample significantly reduced reckless or self-destructive behaviors, potentially fulfilling a critical need in the military and veteran populations with PTSD who have elevated rates of suicidal behaviors, and vehicular and other accidents resulting from high risk behaviors
- The CAPS-5 severity score of ≥33 was determined to be appropriate for inclusion in planned Phase 3 clinical investigation of TNX-102 SL 5.6 mg in PTSD.
- TNX-102 SL was well tolerated. Oral hypoaesthesia was most common, generally transient, and never rated as severe.

Exhibit 99.02

Tonix Pharmaceuticals to Present New Clinical Results from Retrospective Analysis of Phase 2 AtEase Study in Military-Related PTSD

New Results to be Presented in Poster Session at International Society for Traumatic Stress Studies 32nd Annual Meeting

NEW YORK, Nov. 10, 2016 – Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for posttraumatic stress disorder (PTSD), will announce new results today from a retrospective analysis of the data from the AtEase study, a 12-week, randomized, double-blind, placebo-controlled Phase 2 clinical study evaluating TNX-102 SL*, 5.6 mg, in military-related PTSD.

The retrospective analysis focused on patients whose total CAPS-5 entry score was greater than or equal to 33. The analysis revealed that at the 5.6 mg dose, TNX-102 SL had a significant improvement (p=0.012) in reckless or self-destructive behavior, which can include dangerous driving, high-risk thrill-seeking, excessive alcohol or drug use, injurious behaviors to self or others, or suicidal behaviors.

Gregory Sullivan, M.D., chief medical officer of Tonix, will present these findings at the International Society for Traumatic Stress Studies 32nd Annual Meeting today, November 10, 2016, in Dallas, Texas in a poster session. The poster showcasing this new data can be found on Tonix's website on the Scientific Presentations page.

Dr. Sullivan commented, "Not only did the retrospective analysis support the viability of TNX-102 SL, 5.6 mg, as a potential treatment for military-related PTSD, it also demonstrated that Tonix's lead compound could potentially fulfill a critical need in the military and veteran populations with PTSD who have elevated rates of suicidal behaviors, as well as vehicular and other accidents resulting from high-risk behaviors." Dr. Sullivan continued, "The most common side effect in AtEase was transient tongue numbness at the site of administration in about 38% of those on TNX-102 SL. Systemic side effects that were elevated over those seen with placebo were somnolence, headache, and sedation at rates of 12-16% in the TNX-102 SL, 5.6 mg, group."

Seth Lederman, M.D., president and chief executive officer of Tonix, added, "These findings further validate our focus on PTSD and our commitment to the patients who await a new therapeutic option. The anticipated commencement of the Phase 3 HONOR study in the first quarter of 2017 provides an opportunity for patients with military-related PTSD to take part in a milestone study."

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an Investigational New Drug and has not been approved for any indication.*

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, with its lead program focusing on posttraumatic stress disorder. This disorder is a serious condition 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 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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