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 29, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On August 29, 2017, Tonix Pharmaceuticals Holding Corp. (the "**Company**") presented two posters entitled "*Phase 2 Trial of a Low Dose, Bedtime, Proprietary, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL*) for the Treatment of Military-Related PTSD: Mediators and Moderators of Treatment Response"* (the "**First Poster**") and *"Efficacy and Safety of a Low Dose, Bedtime, Proprietary, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL*) for the Treatment of Military-Related PTSD: Study Protocol of a Phase 3 Randomized Placebo-Controlled Trial (P301)"* (the "**Second Poster**" and with the First Poster, the "**Posters**"), at the 2017 Military Health System Research Symposium in Kissimmee, Florida (the "**MHSRS**").

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

The foregoing description of the Posters is qualified in its entirety by reference to each of the Posters, a copy of each of which is filed as Exhibit 99.1 and Exhibit 99.2, respectively, to, and each is incorporated by reference in, this Current Report.

On August 29, 2017, the Company issued a press release announcing the Poster presentation at the MHSRS. A copy of the press release that discusses this matter is filed as Exhibit 99.3 to, and incorporated by reference in, this Current 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.

99.1	*Phase 2 Trial of a Low Dose, Bedtime, Proprietary, Sublingual Formulation of Cyclobenzaprine (TNX-102SL *) for the Treatment of Military-Related PTSD: Mediators and Moderators of Treatment Response Poster***
99.2	*Efficacy and Safety of a Low Dose, Bedtime, Proprietary, Sublingual Formulation of Cyclobenzaprine (TNX-102SL *) for the Treatment of Military-Related PTSD: Study Protocol of a Phase 3 Randomized Placebo-Controlled Trial (P301)"***
99.3	Press Release, dated August 29, 2017, 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 29, 2017

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

Exhibit 99.1

Phase 2 Trial of a Low Dose, Bedtime, Proprietary Sublingual Formulation of Cyclobenzaprine (TNX-102 SL*) for the Treatment of Military-Related PTSD: Mediators and Moderators of Treatment Response

#521

Gregory M. Sullivan[1], Helen Stillwell[1], Florence Porterfield[1], Judy Gendreau[1], R. Michael Gendreau[2], Ashild Peters[1], Perry Peters[1], Seth Lederman[1]

[1]Tonix Pharmaceuticals, Inc., New York, NY 10022; [2]Gendreau Consulting, Poway, CA 92064

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

INTRODUCTION

Posttraumatic stress disorder (PTSD) is one of the most prevalent and disabling psychiatric conditions in United States (US) warfighters. The "AtEase Study" was a Phase 2 efficacy and safety trial of Tonmya*[1] or TNX-102 SL (cyclobenzaprine HCl sublingual tablets)) in participants who experienced index traumas during military service ("military-related PTSD") during 2001 or later.

TNX-102 SL is a patented sublingual tablet formulation designed for bedtime administration and rapid transmucosal absorption, which bypasses first-pass metabolism and has desirable parent and major metabolite pharmacokinetic profiles. The active ingredient, cyclobenzaprine HCl, has potent 5-HT_{2A}, α_1-adrenergic, and H_1-histaminergic receptor antagonism and is hypothesized to improve global symptoms of PTSD through therapeutic effects on sleep disturbance and hyperarousal. The US Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for TNX-102 SL for the treatment of PTSD. The retrospective analyses herein examine treatment response and remission to TNX-102 SL in military-related PTSD.

*Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD

METHODS

The "AtEase Study" was a multicenter, double-blind, placebo-controlled, 12-week Phase 2 study conducted at 24 US sites. Participants meeting the diagnosis of PTSD, assessed by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), were randomized in a 2:2:1 ratio to Placebo, TNX-102 SL 2.8 mg, or TNX-102 SL 5.6 mg. Eligible participants had to meet the following criteria:

Inclusions: males and females; ages 18-65; PTSD DSM-5 Criterion A trauma(s) incurred during military service since 9/11/2001; baseline total CAPS-5 score ≥ 29; free of antidepressants ≥ 2 months; free of or washed off of other psychotropics; not participating in a trauma-focused psychotherapy during study or within one month prior.

Exclusions: severe suicide risk; substance use disorders within 6 months; lifetime bipolar 1 or 2, psychotic, obsessive-compulsive, or antisocial personality disorders.

The primary efficacy endpoint was mean change from baseline (MCFB) in CAPS-5 score between TNX-102 SL and Placebo at Week 12 using mixed model repeated measures (MMRM) analysis. Key secondary endpoints included Clinical Global Impression–Improvement (CGI-I), Sheehan Disability Scale (SDS), PROMIS Sleep Disturbance (SD).

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=69
Females, no. (%)	6 (6.5%)	6 (6.7%)	4 (8.2%)
Avg age, yrs. (SD)	32.0 (6.5)	34.5 (8.3)	34.8 (9.0)
Active Duty/Reservists/Veterans	8/4/79	9/5/71	5/7/37
Avg time since trauma, yrs. (SD)	7.1 (3.6)	7.3 (3.3)	6.2 (3.3)
Combat index trauma, no. (%)	74 (80.4%)	77 (85.6%)	46 (93.8%)
Avg deployments (SD)	2.2 (1.84)	2.3 (2.15)	2.6 (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)

RESULTS

Of 245 participants randomized, 231 were included in the modified intent-to-treat (mITT) efficacy population. Trial completion rates for mITT were: 73% for Placebo; 79% for TNX-102 SL 2.8 mg; 84% for TNX-102 SL 5.6 mg. Demographic and clinical characteristics were similar between groups (**Table 1**).

Primary analysis: TNX-102 SL 2.8 mg did not separate from Placebo at Week 12 (p=0.258; NS). The TNX-102 SL 5.6 mg showed a strong trend for difference from Placebo in MCFB in CAPS-5 (p=0.053 NS; effect size=0.36). Sensitivity analyses that correct for missing data were significant for the comparison of TNX-102 SL 5.6 mg and Placebo: MMRM with Multiple Imputation, p=0.031; MMRM with Hybrid Last/Baseline Observation Carried Forward, p=0.037.

- The CAPS-5 Arousal & Reactivity cluster was significantly improved for the 5.6 mg dose, as were global measures, and work and social domains on the SDS.
- The CAPS-5 sleep disturbance item (E6) was significantly more improved in the TNX-102 SL 5.6 mg arm over Placebo early by Week 2, and maintained at 4, 8 & 12 Weeks. The 2.8 mg arm was significantly more improved at Week 4 .
- The CAPS-5 exaggerated startle item (E4) was significantly more improved for the 5.6 mg arm over Placebo at Week 12 but not for the 2.8 mg arm.
- The most commonly reported adverse event was the administration site reaction of oral hypoaesthesia (tongue numbness), which was never rated as severe. Systemic adverse events that were higher than Placebo, consistent with marketed cyclobenzaprine orally ingested products, included somnolence, dry mouth, headache, and sedation (**Table 2**). Despite marginally increased rates of these systemic AEs in the TNX-102 SL 5.6 mg arm, 84% were completers, and none discontinued due to AE

Table 2. 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 oris#	2.1%	38.7%	36.0%
Paraesthesia	3.2%	16.1%	4.0%
Glossodynia	1.1%	3.2%	6.0%

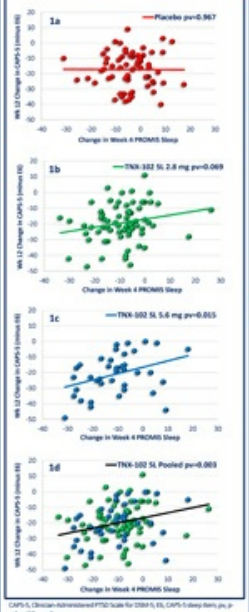
*One hypoaesthesia (tongue numbness) was most common AE, generally transient (<30 minutes), and rated mild in 89% and moderate in 11% on TNX-102 SL. #Safety Population (N=237)

Improvement in Sleep Quality as Potential Mediator of Treatment Response:

Recovery in PTSD involves new learning processes, e.g. extinction learning. Consolidation of extinction, in which short term memory of extinction learning is consolidated into long term memory, occurs during sleep, with roles for both slow wave and rapid eye movement sleep in the process. Thus restoration of the quality of critical sleep stages with TNX-102 SL may be permissive to consolidation of extinction memory, allowing normal recovery from the effects of traumatic stressors over several weeks. In AtEase, the PROMIS Sleep Disturbance (SD) scale (version 8a) was administered on Weeks 4, 8 and 12. To better understand the relationship between early treatment response in sleep and improvement in overall PTSD symptoms at Week 12, a linear regression analysis examined the relationship between change in PROMIS SD T-scores at Week 4 and change in PTSD severity by Week 12 in completers in the three treatment groups. To avoid co-linearity effects between the two variables, Week 12 CAPS-5 total change from baseline without the sleep item (E6) was used. The regression model included treatment, sleep, and treatment by sleep interaction.

As seen in **Figures 1a-d**, Week 4 sleep improvement and Week 12 treatment response were not related among Placebo participants (**Figure 1a**); whereas, for TNX-102 SL 2.8 mg there was a trend for a positive relationship (**Figure 1b**). Consistent with the hypothesis that the PTSD response from TNX-102 SL is mediated by its direct effects on sleep quality, the strongest evidence of correlation for the two variables was seen in the TNX-102 SL 5.6 mg group (**Figure 1c**). Combining the two TNX-102 SL groups provided the most statistical power, showing the highest statistical significance (**Figure 1d**). Thus, early sleep response at Week 4 can reasonably be used to predict Week 12 improvement in PTSD severity in TNX-102 SL 5.6 mg-treated participants, but not in Placebo.

Figures 1a-d: Sleep Mediation of PTSD Treatment Response – Week 4 Sleep Change v. Week 12 CAPS-5 Response



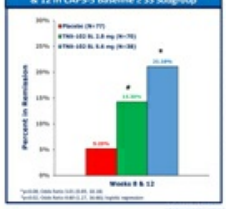
CAPS-5, Clinician-Administered PTSD Scale for DSM-5; E6, CAPS-5 sleep item; p=, p-value; Wk, week

Assessment of CAPS-5 Entry Threshold: To compare the AtEase population with prior studies, we retrospectively imputed a CAPS for DSM-IV (CAPS-IV) for each participant's baseline using the 17 common items and multiplying by 2. The means (SD) of the iCAPS-IV for Placebo, TNX-102 SL 2.8 mg, and TNX-102 SL 5.6 mg were 69.4 (13.7), 70.1 (13.5), and 69.9 (15.2), respectively. And the primary analysis performed on the entire sample using calculated iCAPS-IV MCFB scores was significant for the TNX-102 SL 5.6 mg group v. Placebo at Week 12 (p=0.045, MMRM).

It was found that 4.3% of the sample had an iCAPS-IV at baseline of ≤50 (range 44-50). Selecting a threshold of CAPS-5 ≥33 (instead of the per protocol CAPS-5 ≥29) at entry resulted in exclusion of all of these participants, and a total exclusion of about 20% of the AtEase population. The primary analysis was therefore performed on the CAPS-5 ≥33 entry subgroup, finding MCFB in CAPS-5 for TNX-102 SL 5.6 mg was significantly greater than Placebo at all timepoints (Weeks 2, 4, 8 and 12; **Figures 2**), and the effect size (ES) at Week 12 was 0.53 (p=0.13, MMRM). For the PTSD cluster subscores, Week 12 comparison of TNX-102 SL 5.6 mg and Placebo also showed moderate effect sizes for CAPS-5 hyperarousal (ES=0.52, p=0.012) and intrusion clusters (ES=0.46, p=0.026).

Figure 2. CAPS-5 MCFB Over 12 Weeks (≥ 33 CAPS-5 entry subgroup)

Figure 3. Sustained Remission at Both Weeks 8 & 12 in CAPS-5 Baseline ≥ 33 Subgroup



Sustained Remission from PTSD:

The optimal outcome of treatment is achievement of remission, a virtually asymptomatic state. The definition of remission used in AtEase was "Loss of Diagnosis and Endpoint CAPS-5 Score <11". Remission is more clinically meaningful if it is sustained. In order to look at sustained remission in AtEase, the rates of participants who met remission status at both Week 8 and Week 12 were determined in the CAPS-5 ≥33 entry subgroup.

As seen in **Figure 3**, 21% of the TNX-102 SL 5.6 mg participants met criteria for sustained remission v. 5% of Placebo (p=0.02).

CONCLUSIONS

- Phase 2 clinical investigation established that TNX-102 SL 5.6 mg is the potentially efficacious and relatively safe dose to treat PTSD in a military-related PTSD population (TNX-102 SL 5.6 mg, N=49 v. Placebo, N=92)
- Relationship between early sleep improvement and Week 12 PTSD recovery supports the mechanistic hypothesis that improved sleep quality is a mediator of TNX-102 SL treatment response
- CAPS-5 ≥33 was determined as the appropriate entry threshold for Phase 3 studies to confirm AtEase findings in a larger military-related PTSD population
- TNX-102 SL 5.6 mg treatment resulted in sustained remission between Weeks 8 and 12 in 21% of participants that was statistically significant relative to Placebo and approximately 4 times the rate of Placebo in the CAPS-5 ≥33 entry subgroup (TNX-102 SL 5.6 mg, N=38 v. Placebo, N=77)
- The TNX-102 SL 5.6 mg was well-tolerated with a high completion rate and no AE-related discontinuations; non-dose-related tongue numbness was common, generally transient, and never rated as severe
- Phase 3 clinical investigation of TNX-102 SL 5.6 mg in military-related PTSD is ongoing in the HONOR Study (see Poster #519)

ClinicalTrials.gov identifier: NCT02277704

Efficacy and Safety of a Low Dose, Bedtime, Proprietary, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL#) for the Treatment of Military-Related PTSD: Study Protocol of a Phase 3 Randomized Placebo-Controlled Trial (P301)

#519

Gregory M. Sullivan[1], Helen Stillwell[1], Florence Porterfield[1], Judy Gendreau[1], R. Michael Gendreau[2], Ashild Peters[1], Perry Peters[1], Seth Lederman[1]

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

INTRODUCTION

Posttraumatic stress disorder (PTSD) is one of the most prevalent and disabling psychiatric conditions afflicting US Warfighters and is associated with symptom clusters of hyperarousal, re-experiencing (intrusion) phenomena, blunted mood and negative cognitions, and behavioral avoidance. Only two medications, both selective serotonin reuptake inhibitor (SSRI) antidepressants, have received Food and Drug Administration (FDA) approval for treatment of PTSD, in 1999 and 2001, respectively. A crisis has been declared by experts in the field in the development of evidence-based pharmacotherapy treatments for PTSD,[1] because since 2001 there has been no new pharmacological treatment approved by the FDA for PTSD. In the same period between 2001 and present, over 2.7 million military personnel served tours of duty in Iraq and Afghanistan.

In recent years, Tonix Pharmaceuticals has made substantial progress towards developing TNX-102 SL or Tonmya#, a proprietary sublingual formulation of the tricyclic molecule cyclobenzaprine or TNX-102, as a bedtime medicine for the treatment of PTSD. TNX-102 potently binds to and antagonizes 5-HT$_{2A}$, α_1-adrenergic, and histamine-1 (H$_1$) receptors, each of which play roles in sleep regulation and nocturnal memory processing. The sublingual route results in rapid transmucosal absorption to blood and avoids first pass hepatic metabolism, reducing exposure to its active long-lived major metabolite, norcyclobenzaprine.

PTSD has come to be understood as a "disorder of recovery" in which new learning is impeded due to insufficient sleep-dependent memory processing, e.g. consolidation of extinction memory.[2] Vulnerability to memory intrusions and trauma-associated triggers continues if new extinction memory consolidation does not occur in sleep. Via sleep-period blockade of 5-HT$_{2A}$, α_1-adrenergic, and H$_1$ receptors, TNX-102 is hypothesized to enhance the sleep quality necessary for sleep-dependent recovery processes to occur (**Figure 1**).

Figure 1: Mechanistic Hypothesis for TNX-102 Action in PTSD

Proof of concept for TNX-102 SL in the treatment of PTSD was supported by results of a multicenter Phase 2 trial in military PTSD, P201/the "AtEase" Study, the results of which were announced in 2016 (**See Figure 2**: Highlights of the AtEase Study). Based on the Phase 2 results, TNX-102 SL was granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. The Phase 3 study (P301/the "HONOR" Study), which is of similar design to AtEase, initiated enrollment in March 2017 to confirm the efficacy and safety of TNX-102 SL 5.6 mg in participants with military-related PTSD (**See Figure 3**).

Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD

METHODS

- HONOR is a 12-week, multicenter, randomized, double-blind, placebo-controlled trial, investigating a fixed-dose of TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) taken at bedtime for the treatment of military-related PTSD at 35 U.S. sites.
- Eligible participants (males/females) ages 18-75 years, experienced DSM-5 PTSD Criterion A-qualifying trauma(s) during military service since 2001; meet PTSD criteria as diagnosed by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5); have an entry CAPS-5 severity score ≥ 33, not on antidepressants, and free or washed off other psychotropic medications.

Figure 2: Highlights of Phase 2 AtEase Results Supporting the Phase 3 HONOR Study

- **TNX-102 SL 5.6 mg significantly reduced CAPS-5 score greater than placebo over 12-weeks by mixed-effects models repeated measures analysis (MMRM) with multiple imputation (p=0.031)**
- **Effect of TNX-102 SL 5.6 mg was preserved in the 85% of the sample with PTSD due to combat traumas (p=0.037, MMRM)**
- **CAPS-5 entry threshold of ≥33, rather than ≥29, was more similar to the entry threshold used in prior registration studies for PTSD using earlier versions of CAPS**
  - **Entry CAPS-5 ≥33 subsample in AtEase had effect size 0.53 supporting entry CAPS-5 ≥33 for the Phase 3 HONOR Study**
- **Correlation between improvement in sleep by week 4 of trial with week 12 improvement in PTSD by CAPS-5 supported hypothesis that treatment effects of TNX-102 SL in PTSD are medicated by changes in sleep**
- **TNX-102 SL 5.6 mg was well-tolerated with a high completion rate and no AE-related discontinuations; non-dose-related tongue numbness was common, generally transient, and never rated as severe. Systemic adverse events profile is consistent with marketed cyclobenzaprine orally-ingested products.**

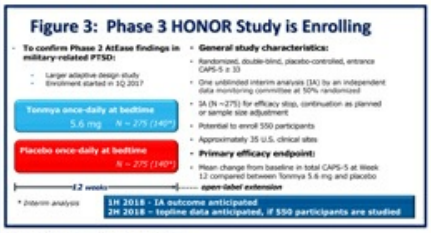
- Approximately 550 participants will be randomized in a 1:1 ratio to placebo or TNX-102 SL 5.6 mg.
- The primary efficacy endpoint is mean change from baseline (MCFB) in CAPS-5 score at Week 12. Secondary endpoints include CGI-I score, the Sheehan Disability Scale (SDS), and PROMIS Sleep Disturbance scale.
- Safety monitoring includes following adverse events, changes from baseline in clinical labs, vital signs, and weight, changes on the Beck Depression Inventory-II and Columbia Suicide Severity Rating Scale, as well as monitoring patient-rated morning sedation and changes in sexual function.
- Participants' identities are protected under a Certificate of Confidentiality (CoC) provided by the FDA under the authority of Health and Human Services (HHS) for research conducted as part of IND 115936 by Tonix Pharmaceuticals and its contractors.

Sample Size and Interim Analysis: Sample size was determined using P201/"AtEase" efficacy data assuming an ~25% dropout rate. Using a two-sided test with an alpha of 0.05, a sample size of 275 per group provides a power of ~90% if the true effect size is 0.32. Yet, the effect size in AtEase for the subsample with entry CAPS ≥ 33 was 0.53, and this is the severity threshold for entry being used in the HONOR Study. If the true effect size is 0.53, again with a dropout rate of ~25%, a sample size of 105 per group provides a power of ~90%. Therefore an adaptive design was chosen for HONOR in which an interim analysis to reassess sample size and for stopping early for success will be performed 12 weeks after 50% of the subjects have been randomized. An independent unblinded analysis group will perform this analysis, and an independent data monitoring committee will make a recommendation based on the unblinded interim analysis results.

CAPS-5 Rater Training, Certification, Inter-Rater Reliability: For training and certification, the following is completed under supervision of Frank Weathers PhD (CAPS-5 author and expert):
Attend Didactic Talks: potential raters attend didactic sessions, provided at the IM, along with small group breakout training using CAPS-5 interview role playing with scripted patient symptoms.
Calibration Training: potential raters complete online calibration exercises that involve achieving a passing rating of a CAPS-5 interview. (Passing requires <6 1-pt difference and no > 1-pt differences from expert. Up to three calibration attempts on different interviews are allowed to pass.
Mock Interview: potential raters administer the CAPS-5 on a mock PTSD patient (scripted symptoms), complete the scoring procedures, and submit audio file/score sheet for expert review. By successfully completing all tasks, rater receives CAPS-5 rater certification from Dr. Weathers.
Inter-Rater Reliability (IRR): ≥10% of all CAPS-5 audiotaped interviews are sampled for IRR throughout study.

Trial Information: https://theHONORstudy.com/

Figure 3: Phase 3 HONOR Study is Enrolling



MEDIATING RECRUITMENT CHALLENGES

Overcoming concerns about confidentiality: The CoC provides significant protection, but it is important to disseminate this information to prospective participants early in recruitment process, at prescreening.
Conveying the "mission" of this research: The military population is unique in the high level of altruism common to most, genuinely choosing to enroll in research for the purpose of helping determine if a drug may be efficacious and safe for the future treatment of PTSD in their military "brothers and sisters" and Country. Understanding this mission tends to be motivating and is conducive to *accurate reporting* of symptoms and change, as this offers the best chance to learn if a drug in a double-blind study is effective.
Providing access to the experimental treatment for all: The HONOR Study is followed by a 12-week open-label extension trial of TNX-102 SL 5.6 mg (P303). Prospective double-blind study participants almost invariably want to know how the experimental treatment may or may not work for them. Awareness there is 100% chance of receiving TNX-102 SL after completing 12 weeks of double-blind treatment (50% chance of getting TNX-102 SL) is encouraging for taking on the mission.
Adapting to the demographics of a military/Veteran population: The AtEase Study provided important demographics specific to this population. For example, 84% had some college or beyond, with many in school during the study; and 62% were employed, making daytime site visits difficult for many. This taught the importance for sites to provide flexible visit hours, offering evenings and/or weekend visits when needed. Minimizing visits, assessment time, and burden was also a priority in the design of HONOR.
Respecting the sensitivity of traumatic memories and the difficulties in being forthcoming: Participating in CAPS-5 interviews can be painful, is potentially destabilizing, and recalling traumas and associated morbidity is often among what is most ardently avoided in PTSD. Providing privacy, uninterrupted attention, and respect for the great efforts being made by participants during the CAPS-5 interviews was identified as essential for establishing a collaborative relationship and likely a significant factor in retention.
Appreciating the major differences in military culture: At a minimum, site staff need to be aware of the marked difference in military culture, and, for those without military experience or significant military cultural competence training, that most assumptions are likely to be incorrect and potentially alienating. Emphasis on these differences and how to avoid pitfalls in interactions with military/Veterans is provided to sites at the IM, with encouragement for training (suggested: www.deploymentpsych.org/military-culture).

CONCLUSIONS

- The 'HONOR' study is an ongoing, FDA-registration quality, randomized placebo-controlled Phase 3 trial to confirm the efficacy and safety of TNX-102 SL 5.6 mg taken daily at bedtime as a potential pharmacotherapy for the treatment of PTSD.
- In addition to centralized rater training to ensure proper administration of CAPS-5 interview, ensuring confidentiality, understanding the barriers to seeking treatment and unique demographics, and appreciating the differences in military from civilian culture are essential features for recruiting and retaining a population with military-related PTSD.
- Results of the interim analysis are expected in the first half of 2018, and results from complete enrollment, if necessary, are expected in the second half of 2018.

CITATIONS

[1] Krystal JH, et al. *Biol Psychiatry*. 2017 Mar 14. [Epub ahead of print]; [2] Pace-Schott, et al. Biology of Mood & Anxiety Disorders. 2015;5:3.

ClinicalTrials.gov Identifier: NCT03062540

Exhibit 99.3

Tonix Pharmaceuticals Presented Additional Phase 2 Clinical Results in Military-Related PTSD and Design of Ongoing Phase 3 Trial at the 2017 Military Health System Research Symposium

Phase 2 Study of U.S. FDA-Designated Breakthrough Therapy Tonmya® (Cyclobenzaprine HCI Sublingual Tablets) in PTSD Indicates Early Sleep Quality Improvements Correlate with Later Response to Treatment

Phase 3 HONOR Study Designed to Confirm Phase 2 Results and Address Needs and Culture of Population with PTSD from Trauma During Military Service

NEW YORK, August 29, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company in Phase 3 development of Tonmya*, or TNX-102 SL, a U.S. Food and Drug Administration (FDA)-designated Breakthrough Therapy for the treatment of posttraumatic stress disorder (PTSD), and in various development stages for other innovative pharmaceutical and biological products to address public health challenges, today presented additional analyses of the Phase 2 AtEase study of Tonmya for PTSD as well as the design features of the ongoing Phase 3 HONOR study of Tonmya for military-related PTSD.

Retrospective analysis of the AtEase study demonstrated a link between improvements in sleep quality at Week 4 and symptom improvement at Week 12 as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5), supporting the mechanistic hypothesis that sublingual cyclobenzaprine acts by improving sleep quality and improving sleep-dependent memory processing to produce the therapeutic effect observed in the Phase 2 study.

The Phase 3 HONOR study is designed to confirm the Phase 2 results. The execution of the Phase 3 HONOR study addresses the needs of study participants by appreciating the military and veteran culture and respecting the sensitivity of traumatic memories for participants suffering from PTSD. To assist in enrollment and retention, all participants who complete the 12-week double-blind phase of HONOR will be eligible to continue to a 12-week open-label extension study, in which they will all receive the study drug Tonmya.

“Leveraging our expertise in PTSD research and development, Tonix continues to lead in the development of pharmacotherapies for military-related PTSD as we explore approaches that could lead to new treatment paradigms,” commented Seth Lederman, M.D., president and chief executive officer of Tonix. “The link between improvement in sleep quality and subsequent improvement in PTSD observed in the AtEase Phase 2 trial supports the mechanistic hypothesis that Tonmya improves sleep-dependent memory processing. In addition, the execution of the Phase 3 trial builds on our experiences from Phase 2 to obtain high quality data, and efficiently enroll and retain participants suffering from military-related PTSD.”

The results were presented today in two poster presentations at the 2017 Military Health System Research Symposium in Kissimmee, Florida. The presentations can be found on the Scientific Presentations page of the Tonix website.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

About Tonmya and the Phase 3 HONOR Study

Tonmya is a patented sublingual transmucosal formulation of cyclobenzaprine that is in Phase 3 development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets), was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the United States, the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants across approximately 35 clinical sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that a single-study new drug application (NDA) approval could be possible if the topline data from the HONOR study are statistically very persuasive and an additional abuse assessment study is not required for the NDA filing. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540. The U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon FDA approval of the NDA, with U.S. market exclusivity until 2034.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges. In addition to Tonmya for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage, designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, to be developed as a potential smallpox-preventing vaccine.

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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017,
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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