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): May 20, 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 May 20, 2017, Tonix Pharmaceuticals Holding Corp. (the "Company") presented a poster entitled "*Phase 2 Multisite Double-Blind Placebo-Controlled Trial of TNX-102 SL in Military-Related Posttraumatic Stress Disorder: Mediators and Moderators of Treatment Response*" (the "Poster"), at the 72nd Annual Scientific Convention of the Society of Biological Psychiatry, in San Diego, California (the "SOBP Meeting").

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 May 22, 2017, the Company issued a press release announcing the Poster presentation at the SOBP 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	*Phase 2 Multisite Double-Blind Placebo-Controlled Trial of TNX-102 SL in Military-Related Posttraumatic Stress Disorder: Mediators and Moderators of Treatment Response* Poster*
99.02	Press Release, dated May 22, 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: May 22, 2017

By: */s/ SETH LEDERMAN*
Seth Lederman
Chief Executive Officer

Phase 2 Multisite Double-Blind Placebo-Controlled Trial of TNX-102 SL* in Military-Related Posttraumatic Stress Disorder (PTSD): Mediators and Moderators of Treatment Response

Gregory Sullivan[1], Judy Gendreau[1], R Michael Gendreau[2], Jean Engels[3], Perry Peters[1], Ashild Peters[1], Seth Lederman[1]

[1]Tonix Pharmaceuticals Inc, [2]Gendreau Consulting, [3]Engels Consulting

*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 with particularly high prevalence in United States (US) military personnel deployed to zones of conflict
- There is an urgent need for evidence-based pharmacotherapies for military-related PTSD
- TNX-102 SL is a patented low dose sublingual formulation of cyclobenzaprine (CBP), a tricyclic molecule with high affinity & functional antagonism for 5-HT$_{2A}$, α_1-adrenergic, and histamine-H$_1$ receptors, all involved in sleep regulation
  - Targets sleep disturbance & hyperarousal, core PTSD symptoms
  - Potentially plays a critical role in overall recovery from PTSD by allowing sleep-dependent memory processing (e.g. extinction consolidation)
- TNX-102 SL differs from orally ingested CBP; the sublingual tablet was designed to enable transmucosal absorption at bedtime, resulting in peak CBP plasma levels during sleep hours and reduced daytime exposure
  - Produces circadian pattern of rapid rise and fall of plasma CBP during normal sleep phase
  - Avoids first-pass hepatic metabolism, substantially reducing formation and plasma levels of long-lived undesirable active metabolite, norcyclobenzaprine
- The "AtEase Study" was our first clinical study demonstrating the therapeutic benefits of TNX-102 SL in military-related PTSD.
- Based on the results of the AtEase study, the FDA has designated TNX-102 SL for PTSD a Breakthrough Therapy.

METHODS

- Phase 2 multicenter, 12-week, double-blind placebo-controlled study conducted at 24 trial sites in the US
- Inclusions: men and women; ages 18-65; PTSD DSM-5 Criterion A trauma(s) incurred during military service since 9/11/2001; current PTSD by Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) and Baseline CAPS-5 score ≥29; free of antidepressants ≥2 months from baseline; free of or washed off of other psychotropics; not participating in trauma-focused psychotherapy ≥1 month from baseline
- Exclusions: serious suicide risk; substance/alcohol use disorders within 6 months; lifetime bipolar I or II, psychotic, obsessive-compulsive, or antisocial personality disorders.
- Randomized in 2:2:1 ratio to Placebo, TNX-102 SL 2.8 mg, TNX-102 SL 5.6 mg; 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 (MMRM) analysis without imputation
- Key secondary endpoints: Clinical Global Impression–Improvement (CGI-I) scale, Sheehan Disability Scale (SDS), PROMIS Sleep Disturbance instrument. Also: CAPS-5 clusters, Patient Global Impression of Change (PGIC), Montgomery-Åsberg Depression Rating Scale (MADRS)
- CAPS-5 raters with ≥ Master's degree-level in mental health; rigorously trained/certified; reliability monitoring over study

RESULTS

- Of 245 participants randomized, 231 were included in the modified intent-to-treat (mITT) efficacy population (**Figure 4**)
- The mITT comprised 92 participants on Placebo, 90 on TNX-102 SL 2.8 mg, and 49 on TNX-102 SL 5.6 mg (**Figure 4**)
- The completion rates for the mITT were 73% for Placebo, 79% for TNX-102 SL 2.8 mg, and 84% for TNX-102 SL 5.6 mg (**Figure 4**)
- **Table 1** shows demographic and clinical characteristics
- The TNX-102 SL 2.8 mg treatment group's change from baseline in CAPS-5 total score was not significantly different from Placebo at Week 12 (p=0.259, not significant)
- The TNX-102 SL 5.6 mg group showed a strong trend for improvement versus Placebo in MCFB in CAPS-5 (p=0.053), with a Cohen's d effect size of 0.36
- Sensitivity analyses that correct for missing data were statistically significant for the comparison of TNX-102 SL 5.6 mg dose and Placebo on CAPS-5 MCFB, as was ANCOVA (**Table 2**)
- The CAPS-5 Arousal & Reactivity cluster (E) was significantly more improved for the 2.8 mg group than Placebo at Weeks 2, 4 and 8, and the 5.6 mg arm at Weeks 2, 8, and 12 (**Figure 1**)
- The sleep disturbance item (E6) of CAPS-5 improved early in treatment for the 5.6 mg group, significantly more improved than Placebo by Week 2 and all other assessments; sleep in 2.8 mg group was significantly more improved at Week 4 (**Figure 2**)
- The exaggerated startle item (E4) of CAPS-5 was significantly more improved for the 5.6 mg arm over Placebo at Week 12
- CGI-I responder analysis showed a significantly greater response rate in the 5.6 mg group over Placebo at Week 12 (**Table 3**)
- The 5.6 mg arm showed trend for greater reduction in SDS total score and work/school disability domain, and significantly greater improvement in social life domain (**Table 3**) at Week 12
- Subgroup analysis of combat-only type traumas (N=197) showed significant effects of TNX-102 SL 5.6 on CAPS-5 total severity, clusters B and E, and functional improvement by SDS (**Table 4**)
- Reported systemic adverse events (AE) were consistent with those reported with orally ingested CBP-containing products; AE of tongue numbness, related to the oral site of administration, was most common in TNX-102 SL groups, generally transient, and never rated as severe; overall good tolerability with high completion rate (84%) and no withdrawals due to AE in 5.6 mg group (**Table 6**)

Table 1. Participant Demographics and Clinical Characteristics

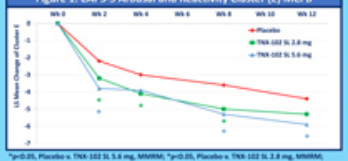
Variable	Placebo N=92	TNX-102 SL 2.8 mg N=90	TNX-102 SL 5.6 mg N=49
Females, no. (%)	6 (6.5%)	6 (6.7%)	4 (8.2%)
Age, yrs (SD)	32.0 (6.5)	34.5 (8.3)	34.8 (9.0)
Weight, kg (SD)	91.6 (16.9)	90.9 (18.2)	90.8 (17.4)
BMI, kg/m^2 (SD)	28.9 (4.4)	29.0 (5.2)	29.0 (4.7)
Education, some college or more	72 (78.2%)	80 (88.9%)	41 (83.7%)
Currently employed, no. (%)	54 (58.7%)	56 (62.2%)	33 (67.3%)
In military at trauma, no. (%)	91 (98.9%)	85 (94.4%)	49 (100%)
Active Duty/Reservists/Veterans	8/4/79	9/5/71	5/7/37
Law Enforcement Officers	1	5	0
Time since trauma, yrs (SD)	7.1 (3.6)	7.3 (3.3)	6.2 (3.3)
Deployments, military (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)

Table 2. Results of Primary and Sensitivity Analyses

	CAPS-5 LS MCFB at Week 12			CAPS-5 LS Mean Difference from PBO		p-Values	
	PBO	TNX-102 SL 2.8 mg	TNX-102 SL 5.6 mg	TNX-102 SL 2.8 mg	TNX-102 SL 5.6 mg	TNX-102 SL 2.8 mg	TNX-102 SL 5.6 mg
MMRM (Primary Analysis)	-17.0	-19.2	-21.5	-2.2	-4.5	0.259*	0.053
MMRM with MI	-15.9	-18.3	-20.9	-2.4	-5.0	0.211	0.031*
MMRM w/Hybrid LOCF/BOCF	-13.8	-16.4	-18.6	-2.6	-4.9	0.172	0.037*
ANCOVA	-16.2	-19.7	-21.3	-3.5	-5.1	0.090	0.038*

*p<0.05. *Primary analysis not significant; ANCOVA, analysis of covariance; BOCF, baseline observation carried forward; LOCF, last observation carried forward; LS, least squares; MCFB, mean change for baseline; MI, multiple imputation; MMRM, mixed model repeated measures; PBO, placebo

Figure 1. CAPS-5 Arousal and Reactivity Cluster (E) MCFB



*p<0.05, Placebo v. TNX-102 SL 5.6 mg, MMRM; †p<0.05, Placebo v. TNX-102 SL 2.8 mg, MMRM; MCFB, mean change from baseline; MMRM, mixed models repeated measure

Figure 2. CAPS-5 Sleep Disturbance Item (E6) MCFB

*p<0.05, Placebo v. TNX-102 SL 5.6 mg, MMRM; †p<0.05, Placebo v. TNX-102 SL 2.8 mg, MMRM; MCFB, mean change from baseline; MMRM, mixed models repeated measure

Moderators of Treatment Response: Greater Baseline Severity [as Threshold for Entry] & Combat PTSD

Using Baseline CAPS-5 ≥ 33 as Threshold for Study Entry

A retrospective analysis of baseline severity was conducted to assess the relationship between CAPS-5 baseline score and final outcome. The original CAPS-5 entry criterion of ≥29 was based on picking an entry criterion similar to previous registration studies of approved PTSD pharmacotherapies that required a baseline severity score of ≥50 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 & 0-4 for frequency (maximum possible score = 136). To compare the AtEase population with prior studies, we imputed a CAPS-IV (CAPS-IV) for DSM-IV in AtEase using the 17 common items and multiplying by 2. Using this imputed score, 10 participants with iCAPS-IV ≤50 (range 44-50) were identified. A retrospective analysis of the AtEase participants choosing a CAPS-5 score of ≥33 at entry excluded all 10 of those participants and, overall, 20% of the AtEase mITT population. Treatment efficacy in AtEase subsample with baseline CAPS-5 ≥33 is shown in **Figure 3**. CAPS-5 MCFB differences are significantly greater for TNX-102 SL 5.6 mg than Placebo at all visits; Week 12 comparison of TNX-102 SL 5.6mg with Placebo showed an effect size of 0.53 (**Table 3**).

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

Outcome Measures	PBO N=92, 5.6 mg N=49; CAPS-5 ≥ 29		PBO N=77, 5.6 mg N=38; CAPS-5 ≥ 33	
	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/Neg Cog)	0.35	0.062	0.39	0.065
Cluster E (Arousal & React)	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				
CGI-I (Responders)	2.11[3]	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 Resp	0.12	0.524	0.15	0.455

[1]Cohen's d for CAPS-5 and SDS outcome measures; [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; [3]odds ratio for CGI-I. Abbreviations: 5.6 mg= TNX-102 SL 5.6 mg; ES= Effect Size; N= number of patients; PBO= Placebo

Sub-Group Analysis of Combat PTSD

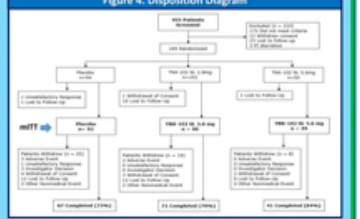
We defined military-related PTSD as resulting from any DSM-5 Criterion A-qualifying trauma that occurred during military service. Yet, the majority of index traumas (85.0%) in our AtEase study were directly related to combat activities and would be considered combat PTSD as strictly defined. A sub-group 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 relative to placebo (**Table 4**). Moreover, the subset of combat-trauma participants with CAPS-5 ≥33 treated with TNX-102 SL 5.6 mg 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) (**Table 4**). In addition, the subset of combat-trauma participants with CAPS-5 ≥33 treated with TNX-102 SL 5.6 mg had statistically significant improvement over Placebo in the total Sheehan Disability Scale.

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

Outcome Measures	PBO N=74, 5.6 mg N=46; CAPS-5 ≥ 29		PBO N=64, 5.6 mg N=35; CAPS-5 ≥ 33	
	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/Neg Cog)	0.41	0.035*	0.42	0.061
Cluster E (Arousal & React)	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				
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 Resp	0.19	0.328	0.22	0.274

[1]Cohen's d for CAPS-5 and SDS outcome measures, [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; [3]odds ratio for CGI-I. Abbreviations: 5.6 mg= TNX-102 SL 5.6 mg; ES= Effect Size; N= number of patients; PBO= Placebo

Figure 4. Disposition Diagram



Safety and Tolerability

TNX-102 SL up to 5.6 mg (2 x 2.8 mg tablets) was well-tolerated as evidenced by the high (84%) completion rate (**Figure 4**) and no AE-related discontinuations in the 5.6 mg group. No clinically significant changes in heart rate, systolic and diastolic blood pressure, or body weight were observed in participants treated with TNX-102 SL for the 12 weeks of study among completers of the safety population (**Table 5**).

Table 6 shows adverse events (AEs) for TNX-102 SL in the AtEase study. Despite marginally increased rates of a few systemic AEs in the TNX-102 SL 5.6 mg group (somnolence, headache, sedation) compared to Placebo, no participant dropped out due to AE. The most common AE, tongue numbness, a non-dose related local administration site reaction, occurred at similar rate in the two TNX-102 SL groups (39% & 36%).

Few AEs were related to sexual dysfunction in the study. In Placebo, one (1.1%) participant reported decreased libido and one (1.1%) reported erectile dysfunction. In TNX-102 SL groups, one (1.1%) 2.8 mg participant reported decreased libido, one (2.0%) 5.6 mg participant reported increased libido and one (2%) 5.6 mg participant reported disturbance in sexual arousal.

Table 5. Changes in Heart Rate, Blood Pressure, and Body Weight Over 12 Weeks of Study by Treatment Group

Measure	Placebo (N=67)*	TNX-102 SL 2.8 mg (N=75)*	TNX-102 SL 5.6 mg (N=41)*
ΔHR (bpm)	+1.0 (11.30)	+2.8 (11.09)	+1.4 (12.03)
ΔSBP (mmHg)	-0.1 (10.17)	-0.5 (10.59)	-4.4 (11.23)
ΔDBP (mmHg)	-1.4 (7.33)	+1.1 (9.05)	-1.5 (7.37)
ΔWeight (kg)	+0.08 (3.01)	+0.09 (3.22)	+0.64 (2.48)

bpm, beats-per-minute; DBP, diastolic blood pressure; HR, heart rate; kg, kilogram; mmHg, millimeters of mercury; SBP, systolic blood pressure; *Completers of the safety population

Table 6: Adverse Events (at rate of ≥5% in either drug-treated group)

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%
Local 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 most common AE, generally transient (<60 minutes), non-dose related 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 overall improvement and reduction in disability 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 the effect sizes (ES) of TNX-102 SL 5.6 mg are substantial (ES=0.5) on total and cluster B and E scores in this subsample
- The subgroup of AtEase participants with PTSD from combat-type traumas had beneficial effects of TNX-102 SL 5.6 on CAPS-5 total severity (ES=0.6) and clusters B (ES=0.5) and E (ES=0.6), and on overall functional improvement by SDS total score, work and social items
- 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. No clinically significant changes in weight or vital signs over the 12 weeks of study were observed.
- Sexual dysfunction is a common complaint in treatments with selective serotonin reuptake inhibitor and serotonin-norepinephrine reuptake inhibitor classes. Low rates of reported sexual dysfunction AEs with TNX-102 SL, similar in rates to Placebo, may potentially be an advantage for TNX-102 SL as a treatment for PTSD.

Exhibit 99.02

Tonix Pharmaceuticals Presented Analyses of Potential Moderators of Treatment Response to U.S. FDA-Designated Breakthrough Therapy for PTSD, TNX-102 SL, in Phase 2 AtEase Study in Military-Related PTSD

Additional Important Findings Presented in Poster Session at the 72nd Annual Scientific Convention of the Society of Biological Psychiatry

NEW YORK, May 22, 2017 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, presented a poster on May 20, 2017, entitled "Phase 2 Multisite Double-Blind Placebo-Controlled Trial of TNX-102 SL in Military-Related Posttraumatic Stress Disorder: Mediators and Moderators of Treatment Response" (Poster No. 3001130) at the 72nd Annual Scientific Convention of the Society of Biological Psychiatry in San Diego. The poster can be found on the Scientific Presentations page on Tonix's website. A moderator is a characteristic of study participants that is associated with a treatment response.

Baseline posttraumatic stress disorder (PTSD) severity threshold and combat trauma-related PTSD were two potential moderators of treatment response that were further examined. A retrospective analysis of the Phase 2 AtEase* data indicated a study entry Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) severity score of ≥33 is more aligned with the entry criteria of previous PTSD pharmacotherapy registration trials using prior CAPS versions. In the AtEase CAPS-5 ≥33 subset, the effect size of TNX-102 SL** 5.6 mg is approximately 0.5 on total CAPS-5 and also approximately 0.5 on cluster B (intrusion) and cluster E (arousal and reactivity) scores. Another potential moderator of treatment response was combat trauma, and the subgroup of AtEase with PTSD from combat-type traumas had statistically significant effects of TNX-102 SL 5.6 on CAPS-5 total severity and cluster B and cluster E, and on overall functional improvement by Sheehan Disability Scale total score, work and social items. TNX-102 SL was well-tolerated with a high completion rate in AtEase. There were no adverse event-related discontinuations; non-dose related tongue numbness was common, generally transient, and never rated as severe. No clinically significant changes in weight or vital signs over the 12 weeks of study were observed.

Seth Lederman, M.D., president and chief executive officer of Tonix, commented, "We continue to work with the U.S. Food and Drug Administration (FDA) to accelerate the development and registration of TNX-102 SL for PTSD. Our Phase 3 HONOR study is currently enrolling participants with military-related PTSD. A planned unblinded interim analysis on approximately 50% of the randomized participants (N=275) is on track for the first half of 2018."

** AtEase is a Phase 2 multicenter, 12-week, double-blind placebo-controlled study conducted at 24 U.S. sites in men and women ages 18-65 years. Inclusions: PTSD DSM-5 Criterion A trauma(s) incurred during military service since 2001; screening and baseline CAPS-5 score ≥29; free of antidepressants ≥2 months from baseline; free of or washed off from other psychotropics; not participating in trauma-focused psychotherapy within a month from baseline. Exclusions: serious suicide risk; substance/alcohol use disorders within 6 months; lifetime bipolar I or II, psychotic, obsessive-compulsive, or antisocial personality disorders. Participants were randomized in 2:2:1 ratio to placebo, TNX-102 SL 2.8 mg or TNX-102 SL 5.6 mg. Primary analysis: comparison of mean change from baseline at Week 12 in CAPS-5 score between TNX-102 SL 2.8 mg and placebo.*

***TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

About TNX-102 SL and the Phase 3 HONOR Study

TNX-102 SL 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, TNX-102 SL 5.6 mg 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 TNX-102 SL 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 TNX-102 SL 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 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. 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 TNX-102 SL formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary TNX-102 SL composition. This patent is expected to provide TNX-102 SL with U.S. market exclusivity until 2034 upon NDA approval.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address major public health challenges. In addition to TNX-102 SL 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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