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 31, 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 May 31, 2016, Tonix Pharmaceuticals Holding Corp. (the "Company") will present data from its Phase 2 dose-finding clinical study (the "AtEase Study") of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related post-traumatic stress disorder in an oral scientific presentation entitled "*A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD*" (the "Presentation"), at the American Society of Clinical Psychopharmacology 2016 Annual Meeting in Scottsdale, Arizona (the "ASCP Annual Meeting").

The Company intends to place the Presentation on its website, which may contain non-public information. A copy of the Presentation is filed as Exhibit 99.01. The foregoing description of the Presentation is qualified in its entirety by reference to the Presentation, a copy of which is filed as Exhibit 99.01 to, and is incorporated by reference in, this report.

On June 1, 2016, the Company will present data from the AtEase Study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related post-traumatic stress disorder in a poster entitled "*A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD*" (the "Poster"), at the ASCP Annual Meeting.

The Company intends to place the Poster on its website, which may contain non-public information. A copy of the Poster is filed as Exhibit 99.02. The foregoing description of the Poster is qualified in its entirety by reference to the Poster, a copy of which is filed as Exhibit 99.02 to, and is incorporated by reference in, this report.

On May 31, 2016, the Company issued a press release announcing the Presentation and the Poster. A copy of the press release that discusses these matters is filed as Exhibit 99.03 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	Presentation by the Company at the ASCP Annual Meeting*
99.02	*A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD* Poster*
99.03	Press Release, dated May 31, 2016, 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 31, 2016

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

Exhibit 99.01

TONIX PHARMACEUTICALS

A Randomized Placebo-Controlled Multicenter Trial of a Low-Dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD

Results from the "AtEase" Study

Presented by
Gregory Sullivan MD
at
American Society of Clinical Psychopharmacology
Annual Meeting, Scottsdale AZ May 31, 2016

The AtEase Study
Why We Studied Military PTSD

- **Characteristics of military-related PTSD population**
  - Combat traumas but could include non-combat traumas during service (e.g. sexual assault)
  - Male-predominant (85:15) vs. civilian female-predominant (67:33)[1]
  - More commonly repeated traumas during deployments vs. discrete traumas
  - Both military and civilian PTSD diagnosed using DSM-5/CAPS-5[2]
- **Unmet need treating military-related PTSD**
  - No treatment response observed in US military population with the two FDA-approved therapies for PTSD
    - Sertraline – negative large multicenter trial in US military veterans[3]
      - Placebo numerically superior on CAPS-2
    - Paroxetine – not studied in military population
  - Inconsistent treatment response observed in males
    - Sertraline – FDA-conducted post-hoc analysis concluded no effect for male civilian subgroup[4]
    - Paroxetine – no sex-related difference in treatment outcomes in civilian population[5]
  - Important tolerability issues with SSRIs in this population
    - Sexual dysfunction
    - Insomnia

[1] Tolin & Foa. Psychol Bull 2006;132:959-92. [2] Weathers FW et al. The Clinician-Administered PTSD Scale for DSM-5 (CAP-5), National Center for PTSD at ptsd.va.gov. [3] Friedman MJ et al. J Clin Psychiatry 2007;68:711-20.
[4] Zoloft® Package Insert, Pfizer, NY, NY; August 2014. [5] Paxil® Package Insert, Glaxo, June 2014

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The AtEase Study
Rational for TNX-102 SL for PTSD

- **TNX-102 SL is a sublingual formulation of cyclobenzaprine (CBP)**
  - Transmucosal absorption
  - Tricyclic molecule – not antidepressant
  - Targets receptors believed to play key roles in sleep physiology
    - functional studies show antagonism at each of[1]
      - 5-HT_{2A}
      - α_1-adrenergic
      - Histamine-H_1
- **TNX-102 SL is designed for bedtime administration and nighttime pharmacokinetic and pharmacodynamics effects**
  - Rapid sublingual transmucosal absorption (reduced lag-time)
  - Avoidance of first-pass metabolism
    - reduces exposure to active metabolite, norcyclobenzaprine (nCBP)
      - Long-lived active metabolite ($t_{1/2}$~72 hours)
      - Distinct receptor binding profile less selective for target receptors
      - Potentially undesirable off-target functional activities
      - Exposure (AUC_{0-48}) for CBP/nCBP of 1.9 for TNX-102 SL vs. 1.2 for oral IR form[2]

[1] Daugherty et al. Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015 Toronto, Ontario, Canada.
[2] Lederman et al. European Congress of Rheumatology, Rome, June 2015
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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The AtEase Study
Rational for Targeting of Sleep for Treatment of PTSD

- **Previous work of TNX-102 SL in a bedtime, nightly regimen improved fibromyalgia symptoms and supported a mechanism in which TNX-102 SL improved sleep quality**
  - PTSD has clinical overlap with fibromyalgia
  - PTSD has comorbidity with fibromyalgia

- **PTSD patients complain of sleep disturbance as a core symptom**
  - Distressing dreams (nightmares) are part of "re-experiencing"
  - Sleep disturbance is part of the hyperarousal cluster of PTSD diagnostic criteria
    - Altered autonomic and neurohormonal balance
    - May interfere with processing of emotionally charged memories[2]
      - i.e. attenuated extinction consolidation

- **Sleep disturbance also correlates with depression, substance abuse and suicidal behaviors in PTSD[3]**

[1] Moldofsky et al, J Rheumatol 2011, 38:2653-63; Lederman et al. European Congress of Rheumatology, Rome, June 2015.
[2] Pace-Schott et al. Biology of Mood & Anxiety Disorders 2015;5(3):1-19.
[3] Germain, Am J Psychiary 2013;170:372-382; McHugh et al, J Traumatic Stress 2014:27:82-89; Betts et al, Journal of Anxiety Disorders 2013;27:735-41.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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The AtEase Study
Phase 2 Trial of TNX-102 SL in PTSD

TNX-CY-P201 Began Enrolling in 1Q 2015; Finished Enrolling in Q4 of 2015

TNX-102 SL at bedtime once-daily
5.6 mg — *N = 49**

TNX-102 SL at bedtime once-daily
2.8 mg — *N = 90**

Placebo at bedtime once-daily
0 mg — *N = 92**

Randomized, double-blind, placebo-controlled trial in **military-related PTSD**

N=231*; 24 U.S. clinical sites (2 VA; 2 University; 20 private)

Primary efficacy endpoint:
Difference in Clinician-Administered PTSD Scale for DSM-5 (**CAPS-5**) score between TNX-102 SL 2.8 mg and placebo at 12 weeks

12 weeks → ***12 week open-label extension***

* modified Intent-to-Treat (mITT) population

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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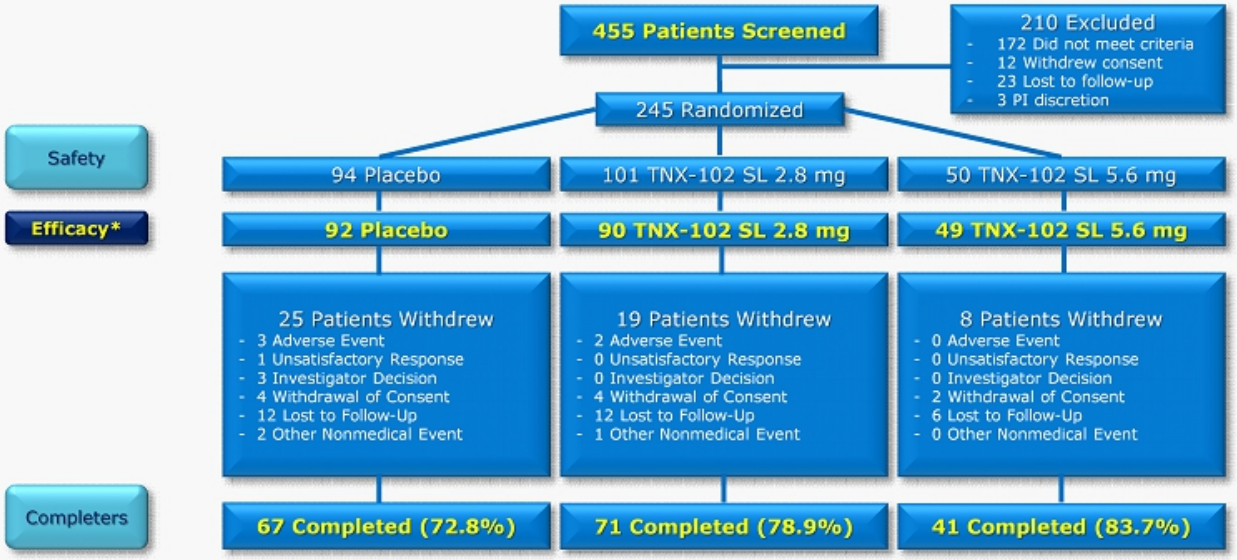
The AtEase Study
Consort Diagram of TNX-CY-P201



* at least one post-baseline assessment in modified Intent-to-Treat population (mITT)

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AtEase Study
Selected Demographics and Characteristics

- **93% of the sample was male**
- **98% had trauma during military service**
  - Deployed an average of 2.3 times
- **Mean time since index trauma was 7 years**
- **Race and ethnicity generally consistent with US military distribution**
- **Fibromyalgia 7% by ACR 2010 criteria**
- **Current Major Depression Disorder 14% by MINI 7.0**
- **Similar baseline CAPS-5 scores and MADRS scores across treatment arms**
  - Entry criteria included a CAPS-5 score ≥ 29

Variable	Placebo N=92	TNX-102 SL 2.8 mg N=90	TNX-102 SL 5.6 mg N=49	Overall N=231
Baseline CAPS-5 Scores (SD)	39.5 (7.7)	39.5 (8.0)	39.3 (8.1)	39.5 (7.85)
Baseline MADRS Scores (SD)	17.3 (6.5)	17.6 (5.2)	16.1 (5.5)	17.1 (5.83)

CAPS-5, Clinician Administered PTSD Scale for DSM-5
MADRS, Montgomery-Åsberg Depression Rating Scale
MINI, Mini-International Neuropsychiatric Interview

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AtEase Study
Severity of Baseline CAPS-5 Scores

CAPS-5 PTSD Severity*	Score
Asymptomatic/few symptoms	0 – 10
Mild PTSD/subthreshold	11 - 22
Moderate PTSD/threshold	23 - 34
Severe PTSD symptomatology	35 - 46
Extreme PTSD symptomatology	≥ 47

Mean CAPS-5 Score at Baseline (SD)

39.5 (7.85)

CAPS-5: 20 severity items
0-4 rating for *combined* intensity and frequency
maximum score = 80

*personal communication – Frank Weathers PhD, National Center for PTSD

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AtEase Study
Index Traumas During Military Service

Index Traumas During Military Service Related to Dx of PTSD (Categories with >5 Patients)	Patient Count
Being involved in an IED explosion or suicide bombing	35
Being attacked or ambushed	33
Witnessing death or injury of fellow soldiers	30
Witnessing IED explosion	29
Receiving incoming artillery, rocket, or mortar fire	10
Being wounded or injured	9
Being responsible for the death of a noncombatant	9
Witness suicide-related deaths or injury	9
Seeing ill or injured women or children you were unable to help	8
Witnessing death or injury of civilians	7
Handling or uncovering human remains	6
Sexual assault	6
Involved in serious vehicular accident (Humvee, helicopter, plane)	6

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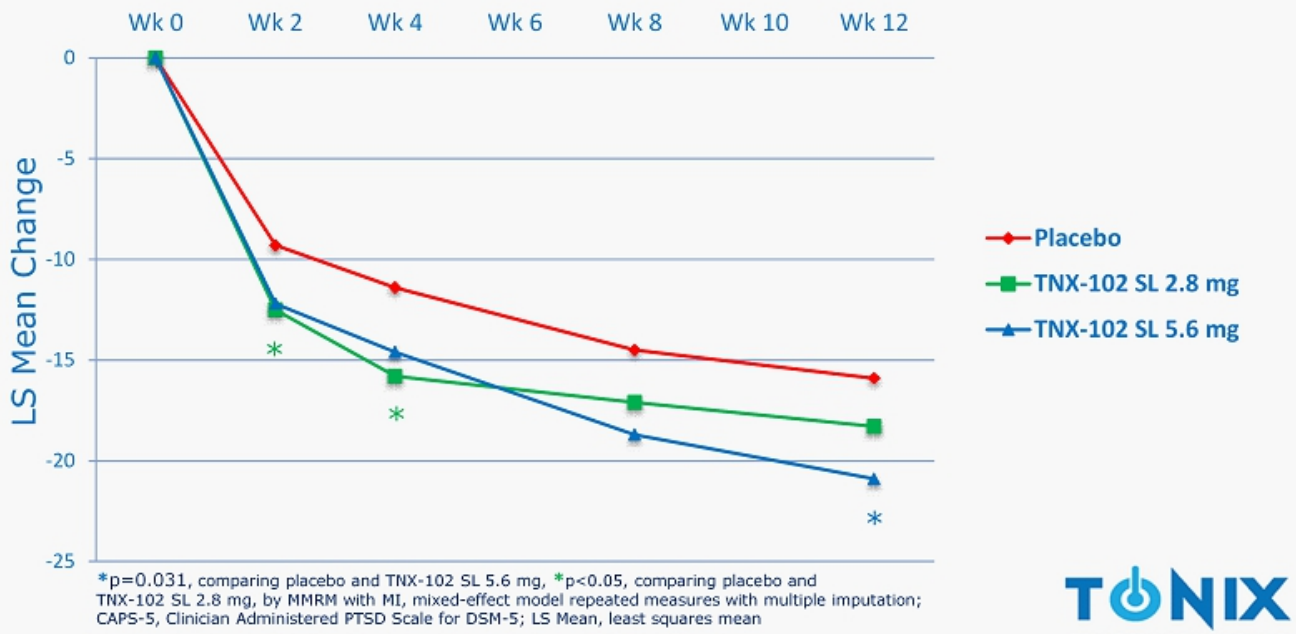
AtEase Study Results
CAPS-5 Total Score Mean Change from Baseline



*p=0.031, comparing placebo and TNX-102 SL 5.6 mg, *p<0.05, comparing placebo and TNX-102 SL 2.8 mg, by MMRM with MI, mixed-effect model repeated measures with multiple imputation; CAPS-5, Clinician Administered PTSD Scale for DSM-5; LS Mean, least squares mean

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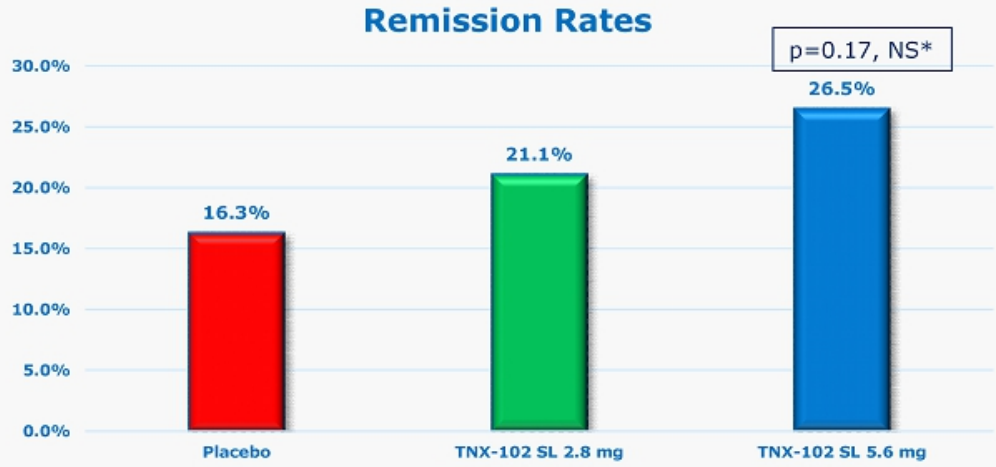
AtEase Study Results
Remission Rates (CAPS-5 Score <11)



*NS, Not significant, Logistic Regression, comparing Placebo and TNX-102 SL 5.6 mg

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AtEase Study Results
CAPS-5 Arousal and Reactivity Cluster Score Mean Change

*p<0.05, comparing TNX-102 SL 5.6 mg to placebo, mixed-effect model repeated measures
*p<0.05, comparing TNX-102 SL 2.8 mg to placebo, mixed-effect model repeated measures

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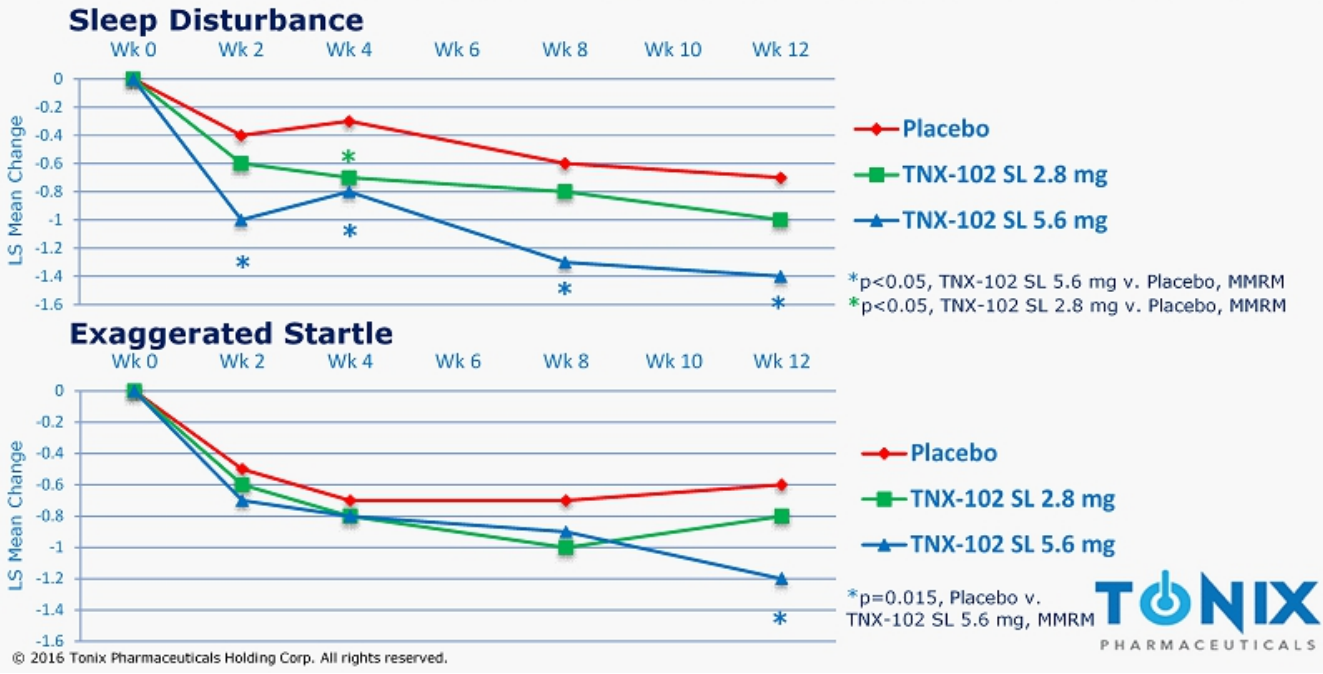
AtEase Study Results
CAPS-5: Sleep Disturbance and Exaggerated Startle Items



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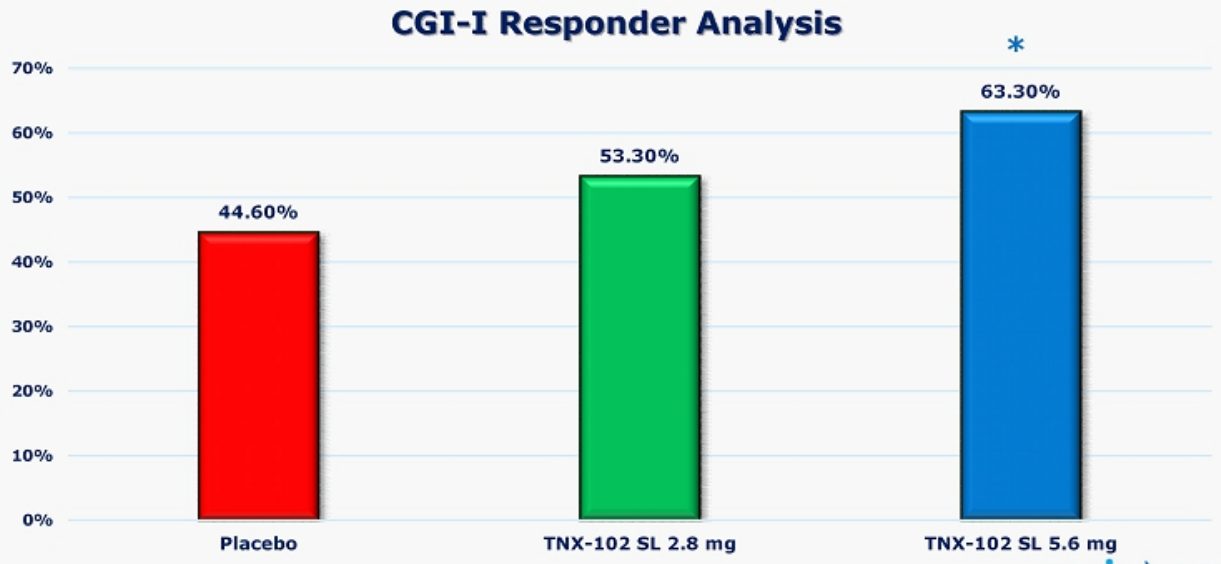
AtEase Study Results
Clinician Global Impression – Improvement Scale Responders



*p=0.041, Logistic regression comparing placebo and TNX-102 SL 5.6 mg
Responders are those rated as "much improved" or "very much improved"

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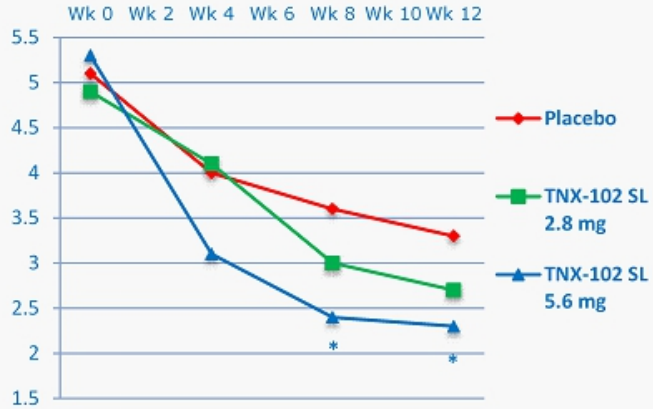
AtEase Study Results

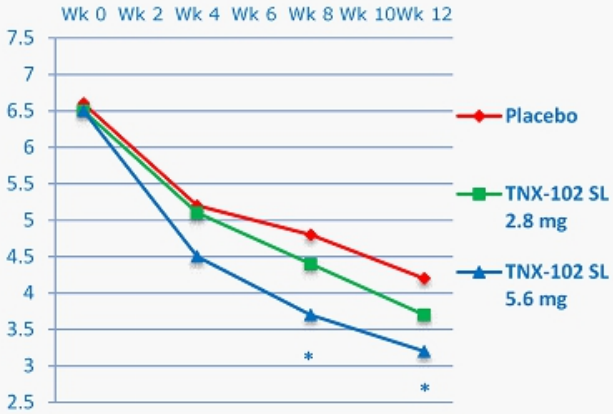
Sheehan Disability Scale – Work/School & Social/Leisure Domains

The symptoms have disrupted your work/school work



*p≤0.05, TNX-102 SL 5.6 mg v. Placebo, MMRM, MMRM, mixed-effects model repeated measure

The symptoms have disrupted your social/leisure activities



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

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AtEase Study Results
Adverse Events (≥5% rate in any group)

Preferred Term	Placebo N=94*	TNX-102 SL 2.8 mg N=93*	TNX-102 SL 5.6 mg N=50*	Overall N=237*
Local Administration Site Conditions				
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)	54 (37.8%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)	17 (11.9%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)	6 (4.2%)
Systemic Adverse Events				
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)	19 (13.3%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)	12 (8.4%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)	11 (7.7%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)	10 (7.0%)
Sedation	1 (1.1%)	2 (2.2%)	6 (12.0%)	8 (5.6%)
Upper respiratory tract infection	5 (5.3%)	3 (3.2%)	2 (4.0%)	5 (3.5%)
Abnormal dreams	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)
Weight increased	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)

* safety population

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The AtEase Study
Results Summary

- **Recruited a population with severe military-related PTSD, almost exclusively combat traumas incurred during OIF/OEF/OND deployments:**
  - Predominantly male

- **TNX-102 SL at 5.6 mg daily at bedtime for 12 weeks:**
  - Reduced severity of PTSD (CAPS-5, p=0.031, Effect Size=0.39)
  - Reduced key symptoms (hyperarousal, insomnia, startle)
  - Improved global symptoms (CGI-I) and function (SDS work/school and social/leisure)
  - Tolerability evidenced by retention rate (84%) and low systemic side effects with only one discontinuation for AE (increased nightmares)

- **TNX-102 SL at 2.8 mg daily at bedtime for 12 weeks:**
  - Reduced PTSD symptoms (CAPS-5) at weeks 2 and 4
  - Reduced hyperarousal at weeks 2, 4 and 8
  - Non-significant intermediate effects at week 12 on PTSD symptoms, global and functional improvement (CAPS-5 total, sleep and startle items, CGI-I, SDS)

OIF/OEF/OND, Operation Iraqi Freedom/Operation Enduring Freedom/Operation New Dawn
CGI-I, Clinician Global Impression – Improvement scale; CAPS-5, Clinician Administered PTSD Scale for DSM-5;
SDS, Sheehan Disability Scale

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AtEase Study
Conclusions: TNX-102 SL in Military-Related PTSD

- **This is the first multicenter randomized clinical trial of any medication that has demonstrated efficacy in a population with military-related PTSD**
  - Male predominant (93%)
  - Low incidence of comorbid fibromyalgia (7%)
  - Low incidence of current major depression (14%)
- **Early effects on sleep and hyperarousal are consistent with the mechanistic hypothesis that TNX-102 SL's primary actions on sleep architecture and autonomic balance underlie the observed PTSD treatment effect**
  - Late effect of TNX-102 SL 5.6 mg on exaggerated startle consistent with longer time of recovery of sleep-related memory processing (consolidation)
- **Next steps**
  - Phase 3 trial in military-related PTSD
  - Phase 3 trial in civilian PTSD

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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AtEase Study
Acknowledgements

- **We wish to thank the military personnel, veterans, and law enforcement officers for their participation in AtEase**

- **Tonix personnel responsible for AtEase include:**
  - Seth Lederman, Judy Gendreau, Heather Jividen, Bruce Daugherty, Ashild Peters, Perry Peters, Ron Notvest, Gregory Sullivan

- **And key consultants to Tonix for AtEase include:**
  - Michael Gendreau, Amy Schaberg, Pauliana Hall
  - Frank Weathers (Dept. National Center for PTSD) and Jonathan Davidson (Emeritus Professor, Duke University)

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AtEase Study
Acknowledgements

Principal Investigator	Institution
Arnold, Lesley	UNIVERSITY OF CINCINNATI COLLEGE OF MEDICINE
Bari, Mohammed	SYNERGY CLINICAL RESEARCH
Brenner, Ronald	NEUROBEHAVIORAL RESEARCH, INC.
Chueh, Daniel	NRC RESEARCH INSTITUTE
Croft, Harry	CLINICAL TRIALS OF TEXAS
Duffy, Walter	PREMIER PSYCHIATRIC RESEARCH INSTITUTE, INC.
Goenjian, Armen	CNS, INC.
Kelley, Lee Ann	NOESIS PHARMA
Kunovac, Jelena	ALTEA RESEARCH INSTITUTE
Lohr, Jim	VA, San Diego
Khan, Arifulla	NORTHWEST CLINICAL RESEARCH CENTER
McNamara, Nora	UNIVERSITY HOSPITALS CASE MEDICAL CENTER
Molpus, Robert	CLINICAL NEUROSCIENCE SOLUTIONS, INC.
Munir, Mohammad	NOVEX CLINICAL RESEARC
Ng, Bernardo	SUN VALLEY RESEARCH CENTER
Pilkinton, Patricia	TUSCALOOSA VA MEDICAL CENTER
Riesenberg, Robert	ALTLANTA CENTER FOR MEDICAL RESEARCH (ACMR)
Ross, Jeff	GREAT LAKES CLINICAL TRIALS
Sarkis, Elias	SARKIS CLINICAL TRIALS
Sedillo, Andrew	MCB CLINICAL RESEARCH CENTERS
Soefje, Sherry	EXCELL RESEARCH, INC.
Sunder, Rajagopal	CITRIALS
Thurman, Louise	IPS RESEARCH COMPANY
White, Kimberly	COMPASS RESEARCH NORTH, LLC

We would also like to gratefully acknowledge the contributions of our trial sites' principal investigators and staff

TONIX PHARMACEUTICALS

A Randomized Placebo-Controlled Multicenter Trial of a Low-Dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL*) for the Treatment of Military-Related PTSD

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

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Funded by Tonix Pharmaceuticals, Inc.

Background

Posttraumatic stress disorder (PTSD) is a chronic debilitating disorder impacting individuals, their families and society. Of the two FDA-approved drugs for its treatment, one failed to show a benefit in male-predominant military-related PTSD in a large multicenter study, while the other was not tested. Trials have also been inconsistent in civilian males, with one of the two drugs shown to be ineffective. Both have tolerability issues relevant when treating male-predominant military-related PTSD, such as sexual dysfunction and insomnia. Tonix seeks to develop a treatment alternative with a mechanism of action distinct from the current approved therapies, recognizing the potentially critical role of improving sleep in providing global benefit in PTSD. TNX-102 SL, a low dose sublingual formulation of cyclobenzaprine (CBP), was developed to take advantage of CBP's high affinity and functional antagonism for 5-HT_{2A}, α_1-adrenergic, and histamine H_1 receptors, potentially offering therapeutic effects for sleep disturbance and hyperarousal, core symptoms of PTSD. TNX-102 SL differs from orally administered CBP in that it has been designed to enhance sublingual transmucosal absorption at bedtime, resulting in peak CBP plasma levels during sleep hours and avoidance of first-pass metabolism, reducing formation of a long-lived active metabolite with potentially undesirable off-target functional activities. Study TNX-CY-P201 (the AtEase Study) was conducted in order to assess the efficacy, safety, and tolerability of TNX-102 SL in the treatment of military-related PTSD.

Methods

In this multicenter, 12-week, double-blind placebo-controlled (DB-PC) study, adults meeting a DSM-5 diagnosis of PTSD as assessed by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) were randomized to TNX-102 SL 2.8 mg, 5.6 mg, or Placebo in a 2:1:2 ratio at 24 sites (2 VA, 2 academic, 20 private) in the US. Eligible male and female participants were 18-65 years of age, had experienced DSM-5 Criterion A-qualifying trauma(s) during military service since 2001, had at least moderate PTSD severity as indicated by a CAPS-5 score ≥ 29, and were free of antidepressants for ≥ 2 months and free of or washed off other psychotropics. (Note: military contractors, Homeland Security, and law enforcement were also includable.) Exclusions included serious suicide risk, unstable medical illness, substance use disorders within 6 months, and lifetime bipolar 1 or 2, psychotic disorders, obsessive compulsive disorder, or antisocial personality disorder.

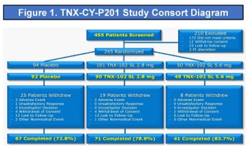
The primary efficacy analysis was the comparison of mean change from baseline in the CAPS-5 severity score between the TNX-102 SL 2.8 mg and Placebo groups analyzed via mixed-effects model repeated measures (MMRM); the TNX-102 SL 5.6 mg group was also compared with Placebo on CAPS-5 change. Key secondary endpoints were the Clinical Global Impression – Improvement (CGI-I) scale, the Sheehan Disability Scale (SDS), and the PROMIS Sleep Disturbance. Other secondary measures included CAPS-5 Cluster scores and Montgomery-Asberg Depression Rating Scale. A dynamic randomization procedure minimized trial-wide imbalances between treatment arms by site, sex, and presence (yes/no) of current major depressive disorder. CAPS-5 raters were MA-level or above in mental health fields who underwent a rigorous training and certification process, and reliability monitoring throughout the trial. For CAPS-5, maximum possible score is 80; and PTSD severity is as follows: 0-10 is asymptomatic, 11-22 is mild, 23-34 is moderate, 35-46 is severe, and 47+ is extreme.[1]

Results

- 245 patients were randomized; 237 of those randomized made up the safety population; and 231 were included in the modified intent-to-treat (mITT) population (14 did not return for any post-baseline efficacy assessment); **Figure 1** shows the study consort diagram displaying total screens, randomizations, reasons for discontinuation and completers.

[1]Personal communication, Frank Weathers PhD, National Center for PTSD

Figure 1. TNX-CY-P201 Study Consort Diagram



- Of interest, **83.7%** of patients in the TNX-102 SL 5.6 mg completed the study, compared to **72.8%** in the placebo group.
- As seen in **Table 1**, demographic and clinical characteristics were similar across the three groups. Overall, **97.4%** of the sample had military-related PTSD. Mean CAPS-5 scores for all groups were in the severe range at baseline.
- **Table 2** displays the index traumas for the study patients and confirms an overall high rate of combat-related traumas in the sample.

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

Table 2. Index Trauma Categories

Index Traumas During Military Service Related to Dx of PTSD	Patient Count
Being involved in an IED explosion or suicide bombing	35
Being attacked or ambushed	33
Witnessing death or injury of fellow soldiers	30
Witnessing IED explosion	29
Receiving incoming artillery, rocket, or mortar fire	10
Being wounded or injured	9
Being responsible for the death of a noncombatant	9
Witness suicide-related deaths or injury	9
Seeing ill or injured women or children you were unable to help	8
Witnessing death or injury of civilians	7
Handling or uncovering human remains	6
Sexual assault	6
Involved in serious vehicular accident (Humvee, helicopter, plane)	6
Shooting or directing fire at the enemy	5
Knowing someone seriously injured or killed	4
Being responsible for the death of an enemy combatant	4
Seeing dead bodies or human remains	4
Trauma during training – live fire, grenades, gas exposure	3
Being shot at or receiving small-arms fire	3
Had a close call, was shot or hit, but protective gear saved you	2
Physical assault	1
Seeing dead or seriously injured Americans	1
Engaging in hand-to-hand combat	1

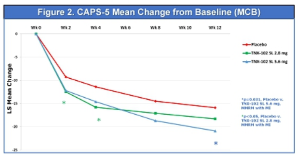
- As noted, the total CAPS-5 score was the primary efficacy variable for the study and the data was analyzed using several analytic and imputation methods for missing data.
- The primary analysis used the Mixed-effects Model Repeated Measures (MMRM) without imputation, and the TNX-102 SL 2.8 mg group was not significantly different from Placebo at Week 12 (p=0.259, NS).
- Although not powered to demonstrate significance in this study, the 5.6 mg group was significant using several analyses and imputation methods (**Table 3**). **Effect size** (Cohen's *d*) for MMRM with LOCF/BOCF was calculated to be **0.39**.

Table 3. CAPS-5 Primary Endpoint Results

Analysis Method	CAPS-5 LS Mean Changes from Baseline at Week 12			CAPS-5 LS Mean Difference from PBO		p-values	
		TNX-102 SL		TNX-102 SL		TNX-102 SL	
	PBO	2.8 mg	5.6 mg	2.8 mg	5.6 mg	2.8 mg	5.6 mg
MMRM w/ multiple imputation	-15.9	-18.3	-20.9	-2.4	-5.0	0.211	*0.031
MMRM w/ LOCF/BOCF	-14.8	-17.4	-20.2	-2.6	-5.4	0.158	*0.016
ANCOVA analysis	-18.0	-20.6	-22.6	-3.5	-5.1	0.090	*0.038

- **Figure 2** represents the visit by visit mean change from Baseline in total CAPS-5 score utilizing the MMRM with multiple imputation method.

Figure 2. CAPS-5 Mean Change from Baseline (MCB)



- **Figure 3** demonstrates the advantage of TNX-102 SL 5.6 mg over Placebo for Arousal and Reactivity, the CAPS-5 cluster that is a manifestation of the autonomic imbalance central to PTSD pathophysiology; **Figure 4** demonstrates treatment effects on the specific CAPS-5 items Sleep Disturbance and Startle
- From a functional perspective, the TNX-102 SL 5.6 mg group showed statistically significant improvement over Placebo in the work/school category and the social/leisure domains of the Sheehan Disability Scale (**Figure 5**).

Figure 3. CAPS-5 Arousal and Reactivity Cluster MCB

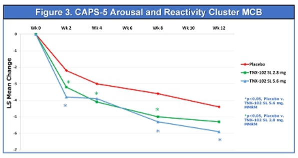
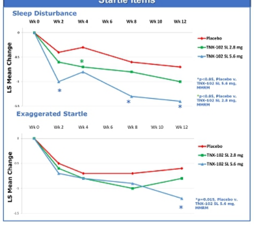


Figure 4. CAPS-5 Sleep Disturbance and Exaggerated Startle Items



- On a global clinical scale, 63.3% of TNX-102 SL 5.6 mg group responded at Week 12 (defined as a score of 1 or 2) on the CGI-I scale. This was statistically significant compared to Placebo (**Figure 6**).

Figure 5. Sheehan Disability Scale Work/School and Social/Leisure Domain Scores

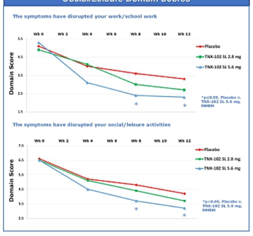


Table 4 shows administration site and systemic AEs. The TNX-102 SL 5.6 mg group had minimally higher systemic AE rates for somnolence, dry mouth, headache, and sedation, yet there were no discontinuations in the group due to AE suggesting they were tolerable.

Figure 6. CGI-I Responder Status

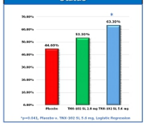


Table 4. Adverse Events (≥ 5% rate in any group)

Preferred Term	Placebo N=94	TNX-102 SL 2.8 mg N=93	TNX-102 SL 5.6 mg N=50	Overall N=237
Local Administration Site Reactions				
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)	54 (37.8%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)	17 (11.9%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)	6 (4.2%)
Systemic Adverse Events				
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)	19 (13.3%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)	12 (8.4%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)	11 (7.7%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)	10 (7.0%)
Sedation	1 (1.1%)	2 (2.2%)	6 (12.0%)	8 (5.6%)
Upper respiratory tract infection	5 (5.3%)	3 (3.2%)	2 (4.0%)	5 (3.5%)
Abnormal dreams	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)
Weight increased	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)

Conclusions

- First large, multi-center, randomized DB-PC trial demonstrating significant treatment effect in military-related PTSD
- AtEase enrolled a mostly male population with severe PTSD resulting almost exclusively from combat traumas during OIF/OEF/OND
- TNX-102 SL at 5.6 mg daily at bedtime for 12 weeks:
  - Reduced severity of PTSD (CAPS-5, p=0.031, Effect Size=0.39)
  - Reduced key symptoms (hyperarousal, insomnia, startle)
  - Improved global symptoms (CGI-I) and function (SDS work/school and social/leisure)
  - Tolerability evidenced by retention rate (84%) and low systemic side effects with no AE discontinuations
- TNX-102 SL at 2.8 mg daily at bedtime for 12 weeks:
  - Reduced PTSD symptoms (CAPS-5) at weeks 2 and 4
  - Reduced hyperarousal, similar to the 5.6 mg group, at weeks 2, 4 and 8
  - Non-significant intermediate effects at week 12 on PTSD symptoms, global and functional improvement (CAPS-5 total, sleep and startle items, CGI-I, SDS)

Discussion

- Early effects on sleep and hyperarousal are consistent with the mechanistic hypothesis that TNX-102 SL's primary actions on sleep architecture and autonomic balance underlie the observed PTSD treatment effect
- Results support advancing TNX-102 SL 5.6 mg for the treatment of PTSD to Phase 3

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

Exhibit 99.03

Tonix Pharmaceuticals Presents Positive Results from Phase 2 AtEase Study of TNX-102 SL in Post-Traumatic Stress Disorder (PTSD) at the American Society of Clinical Psychopharmacology (ASCP) 2016 Annual Meeting

- *Study Successfully Identified Effective and Well-tolerated Dose for Registration Studies*
- *Phase 3 Clinical Program Planned*

New York, NY – May 31, 2016 – Tonix Pharmaceuticals Holding Corp. (NASDAQ: TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and PTSD, today announced the presentation of positive results from its Phase 2 dose-finding clinical study (AtEase Study) of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of military-related PTSD. Data are featured in oral and poster presentations on May 31 and June 1 at the American Society of Clinical Psychopharmacology Annual Meeting (ASCP, formerly NCDEU) in Scottsdale, Arizona. Tonix's abstract, titled, " *A Randomized Placebo-controlled Multicenter Trial of a Low-dose Bedtime Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD,"* is being presented by Gregory Sullivan, M.D., Tonix's chief medical officer. The abstract and presentation materials are available on Tonix's website at www.tonixpharma.com.

"The data being presented by Dr. Sullivan confirm that the study was a success and that a 5.6 mg dose of TNX-102 SL was efficacious and well-tolerated in the treatment of military-related PTSD," commented Seth Lederman, M.D., president and chief executive officer of Tonix. "We are pleased to have successfully identified the 5.6 mg dose for our upcoming Phase 3 program for the treatment of PTSD."

The goal of the multicenter, 12-week, double-blind study was to evaluate the potential clinical benefit of TNX-102 SL in treating military-related PTSD at a dose of 2.8 mg or 5.6 mg in a randomized, placebo-controlled study of 231 patients with PTSD at 24 U.S. clinical sites. Patients were provided with a bedtime sublingual dose of 2.8 mg TNX-102 SL (n=90) or 5.6 mg TNX-102 SL (n=49), and were compared to placebo (n=92).

Adults meeting a DSM-5 diagnosis of PTSD as assessed by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) were recruited and randomized to TNX-102 SL 2.8 mg, 5.6 mg or placebo in a 2:1:2 ratio. Eligible participants were between 18 and 65 years old, had experienced DSM-5 PTSD Criterion A-qualifying trauma(s) during military service since 2001, had at least a moderate level of PTSD severity as indicated by a CAPS-5 score $\geq$ 29, and were free of antidepressants for at least two months and free of or washed off other psychotropic medications. Exclusion criteria for the study included serious suicide risk, unstable medical illness, substance use disorders within the prior six months, and lifetime history of bipolar 1 or 2, psychotic disorders, obsessive compulsive disorder, or antisocial personality disorder. A dynamic randomization procedure was used to minimize trial-wide imbalances among the three treatment arms by site, sex and presence of current major depressive disorder. CAPS-5 raters were certified MA-level or above in mental health fields who underwent a rigorous training and certification process.

The primary efficacy analysis was the 12-week mean change from baseline in the CAPS-5 severity score between the TNX-102 SL 2.8 mg and placebo groups, and the TNX-102 SL 5.6 mg group also was compared with placebo. Key secondary endpoints were the Clinical Global Impression–Improvement (CGI-I) scale, and the Sheehan Disability Scale (SDS). Other secondary measures included the CAPS-5 Cluster scores and Montgomery-Asberg Depression Rating Scale.

Tonix's AtEase study successfully identified a dose-response relationship on multiple efficacy and safety measurements. On the Arousal and Reactivity CAPS-5 cluster, both dosage groups had a significantly greater mean change from baseline at several time points: at weeks 2, 8 and 12 for the TNX-102 SL 5.6 mg group, and at weeks 2, 4, and 8 for the TNX-102 SL 2.8 mg group. At week 12, the TNX-102 SL 5.6 mg group had significantly more responders (much improved or very much improved) on the CGI-I. TNX-102 SL 2.8 mg and 5.6 mg were well tolerated as evidenced by the high overall completion rate in the active treatment groups, which exceeded the completion rate in the placebo group.

There were four distinct serious adverse events (SAEs); three were in the placebo group, and one (proctitis/peri-rectal abscess), in the TNX-102 SL group, was reported to be unrelated to TNX-102 SL. The most common systemic adverse reactions included: (i) for the TNX-102 SL 5.6 mg group, somnolence (16%), dry mouth (16%), headache (12%), insomnia (6%) and sedation (12%); and (ii) for the 2.8 mg group, somnolence (12%), dry mouth (4%), headache (5%), insomnia (8%) and sedation (2%).

Dr. Lederman concluded, "We are grateful to the participants in the AtEase study and to their families. This is an important step in developing a promising treatment for those who suffer from PTSD. We are now making plans to meet with the Food and Drug Administration to discuss a registration program for PTSD, with an interest in conducting trials in military-related and civilian PTSD."

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

About Post-Traumatic Stress Disorder

PTSD can develop from witnessing or experiencing a traumatic event or ordeal in which there was the severe threat or actual occurrence of grave physical harm. PTSD affects approximately 8.4 million Americans in any year and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of intrusive memories, flashbacks, and nightmares. PTSD is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and is sometimes associated with clinical depression, substance use disorders, and unpredictable violent or suicidal behaviors. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. It is estimated that 20 percent of the over 2.5 million US military personnel returning from tours of duty in the recent conflicts in Iraq and Afghanistan suffer from PTSD.

About TNX-102 SL

TNX-102 SL is designed to deliver cyclobenzaprine to the bloodstream rapidly via sublingual (under the tongue) absorption and to bypass first-pass hepatic metabolism. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is under clinical development for the treatment of PTSD and is intended to provide broad spectrum improvement by targeting sleep and hyperarousal. Tonix is developing TNX-102 SL 2.8 mg for daily bedtime administration for the treatment of fibromyalgia and TNX-102 SL 5.6 mg for daily bedtime administration for the treatment of PTSD.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. These disorders are 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.

Safe Harbor / 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 possible 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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