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): September 6, 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 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") intends to utilize an updated investor presentation to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain non-public information. A copy of the presentation is filed as Exhibit 99.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01, is furnished pursuant to, and shall not be deemed to be "filed" for the purposes of, Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in Item 7.01 of this Current Report shall not be incorporated by reference into any registration statement or any other document filed pursuant to the Securities Act of 1933, as amended, except as otherwise expressly stated in such filing. By filing this Current Report on Form 8-K and furnishing the information contained in this Item 7.01, including Exhibit 99.01, the Company makes no admission as to the materiality of any such information that it is furnishing.

Item 8.01 Other Events.

On September 6, 2016, the Company issued a press release announcing preliminary topline results from its Phase 3 clinical study, AFFIRM, designed to evaluate the safety and efficacy of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, in patients with fibromyalgia.

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	Corporate Presentation by the Company for September 2016*
99.02	Press release, dated September 6, 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: September 6, 2016

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

Exhibit 99.01

NASDAQ: TNXP

Investor Presentation

September 2016

Version: P0028 09-06-2016

Cautionary note on forward-looking statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by 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," 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 U.S Food and Drug Administration clearances or approvals and noncompliance with its regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by the Company on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. 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 the Company's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

TONIX PHARMACEUTICALS

Developing innovative medicines for large and growing markets

- **Targeting common central nervous system disorders**
  - One clinical-stage proprietary candidate targeting posttraumatic stress disorder (PTSD)
  - Differentiated product with potential for sustainable competitive advantages
- **PTSD – Phase 2 trial reported May 2016**
  - TNX-102 SL[1] 5.6 mg was active in treating military-related PTSD
  - Serious mental health problem[2]
  - Planning Phase 3 program in military-related PTSD
  - Planning Phase 3 program in civilian PTSD
- **All intellectual property owned by Tonix**

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

[2]*Schnurr, PP et al., Contemporary Clinical Trials 2015;41:75.*

TONIX PHARMACEUTICALS

Overview: PTSD program

- **Results from multi-center, double-blind, randomized, placebo-controlled Phase 2 trial in military-related PTSD reported May 2016**
  - TNX-102 SL 5.6 mg was active in treating military-related PTSD
    - Reduction in symptoms and disease severity [(Clinician-Administered PTSD Scale) CAPS-5]
    - Improvement in clinical global impression (CGI-I)
    - Improvement in function (Sheehan Disability Scale domains for work/school and social/leisure)
  - Systemic side effects include somnolence, dry mouth, headache and sedation
  - Administrative site reactions were common (transient tongue numbness)
  - Completion rate for TNX-102 SL 5.6 mg was 84% and for placebo was 73%

- **Phase 3 program planned**
  - U.S. Food and Drug Administration (FDA) acceptance of proposed Phase 3 program at August 2016 EOP2/Pre-Phase 3 meeting
  - TNX-102 SL 5.6 mg is the appropriate dose for confirmatory study
  - Confirmatory study design similar to Phase 2 AtEase study, except CAPS-5 enrollment threshold will be changed from ≥ 29 to ≥ 33
  - Potential for Breakthrough Designation
  - Two confirmatory trials being planned
    - Q1 2017: military-related PTSD
    - Q2 2017: predominantly civilian PTSD

TONIX PHARMACEUTICALS

Tonix is developing TNX-102 SL for PTSD

- **Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP)**
  - Designed for daily bedtime administration with no titration
  - Efficient transmucosal absorption
  - Avoidance of first-pass metabolism reduces formation of long-lived metabolite
- **TNX-102 SL's pharmacologic action is believed to improve sleep quality**
  - Disturbed sleep is a common clinical feature of PTSD
  - TNX-102 SL targets receptors believed to play key roles in sleep physiology
- **Phase 2 "AtEase" study was successfully completed in May 2016**

TONIX PHARMACEUTICALS

PTSD is a chronic stress disorder triggered by a traumatic event

- **PTSD is characterized by:**
  - Re-experiencing the triggering event
  - Negative alterations in mood/cognition
  - Situation/stimulus avoidance
  - Hyperarousal (anxiety, agitation & sleep disturbance)
- **Considered a stress response, but prolonged and does not resolve with time**
  - 20% of women and 8% of men in the U.S. who experience significant trauma develop PTSD[1]
- **Associated with significant life disruption**
  - Social isolation, inability to maintain employment, loss of independent living
  - Unpredictable acts of violence, suicidal thoughts

[1] *Kessler et al, Arch Gen Psychiatry 1995;52:1048.*

TONIX PHARMACEUTICALS

PTSD is a prevalent problem for both civilians and the military

- **~70% are considered to have moderate to severe symptoms**
- **Of those diagnosed, ~50% utilize professional healthcare (psychotherapy/pharmacotherapy)[2]**

- **Higher prevalence in military population**
  - 20% of veterans from recent conflicts will have potential/provisional PTSD[3]
  - ~638,000 veterans with PTSD in the Veterans Affairs (VA) health system (2012)[4]
  - Majority are male
  - Alcohol and substance abuse are common

[1]Kessler RC at al, Arch Gen Psychiatry 2005;62:617; U.S. Census Bureau, 2013 Projection.
[2]Wang et al, Arch Gen Psychiatry 2005;62:629.
[3]Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD.
[4]Bowe et al, J Dual Diagnosis 2015;11:22.

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Limitations of current FDA-approved pharmacotherapies for military-related PTSD

- **No treatment response observed in U.S. military population**
  - Sertraline: negative large multi-center trial in U.S. military veterans[1]
    - 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[2]
  - Paroxetine: no gender-related difference in treatment outcome[3]
- **Important tolerability considerations with SSRIs in this population**
  - Sexual dysfunction
  - Insomnia

SSRI: Selective Serotonin Reuptake Inhibitor.
[1]Friedman MJ et al. J Clin Psychiatry 2007;68:711-20.
[2]Zoloft® Package Insert, Pfizer, August 2014.
[3] Paxil® Package Insert, Glaxo, June 2014.

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Phase 2 AtEase study of TNX-102 SL in PTSD

AtEase Study

- Randomized, double-blind, placebo-controlled trial
- DSM-5 diagnostic criteria for PTSD
- 231* participants studied 2:1:2 at 24 U.S. sites
  - 1 x TNX-102 SL 2.8 mg tablet: 2 x TNX-102 SL 2.8 mg tablets: placebo
- Evaluated the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) as primary endpoint
  - Pre-specified primary analysis was 2.8 mg dose

*Modified intent-to-treat (mITT) population

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Phase 2 AtEase trial of TNX-102 SL in PTSD

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

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

Placebo at bedtime once-daily
N= 92

- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- Analysis from 231 patients; 24 U.S. clinical sites
- **Primary efficacy endpoint:**
  - Difference in CAPS score between TNX-102 SL 2.8 mg and placebo at week 12

TNX-102 SL was active at 5.6 mg dose

Enrolled patients with baseline CAPS-5 ≥ 29

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AtEase study of TNX-102 SL in PTSD

Key Demographics / Characteristics of AtEase

- 93% of the patients were male
- 98% had trauma during military service and were deployed on average 2.3 times
- Mean time since index trauma was 7 years
- Race and ethnicity generally consistent with U.S. military distribution
- Similar baseline CAPS-5 scores and MADRS[1] scores across treatment arms
  - Average CAPS-5 scores were greater than 39 for all groups ('severe' PTSD[2])

[1]*Montgomery–Åsberg Depression Rating Scale*
[2]*personal communication – Frank Weathers PhD, National Center for PTSD*

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AtEase results on key clinical endpoints

TNX-102 SL 5.6 mg compared to placebo

Category	Endpoint – week 12[1]	*p* value
PTSD Symptoms	CAPS-5 (MMRM with MI)	**0.031**
Global improvement	CGI-I (Logistic Regression)	0.041
Arousal and reactivity	CAPS-5 cluster (MMRM)	0.048
Sleep Quality	CAPS-5 sleep (MMRM)	0.010

$p < 0.05$ → statistically significant

AtEase pre-specified primary analysis: change from baseline at week 12 mean CAPS-5 score on 2.8 mg (p=0.259, MMRM)

- MMRM with MI: Mixed-effect Model Repeated Measures with Multiple Imputation
- CAPS-5: Clinician Administered PTSD Scale-5
- CGI-I: Clinical Global Impression- Improvement

[1]Modified Intent-to-treat analysis, N=231 (TNX-102 SL 2.8 mg N=90, TNX-102 SL 5.6 mg N= 49, placebo N=92).

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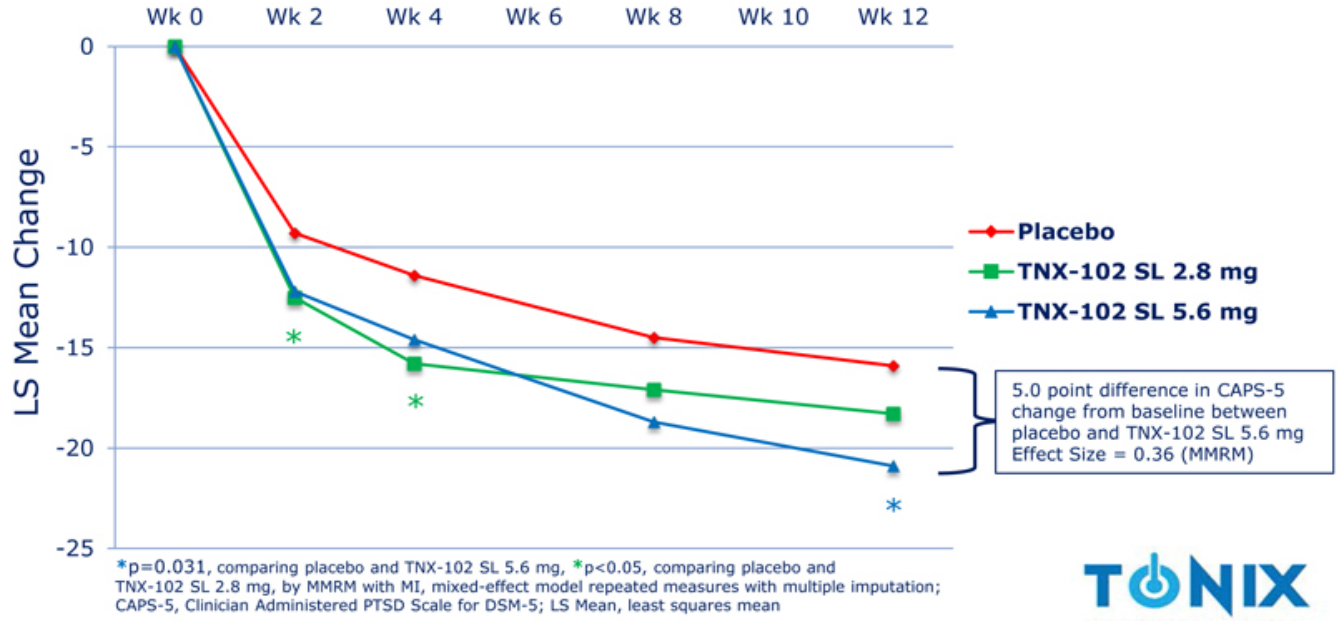
AtEase study results:
CAPS-5 total score mean change from baseline



*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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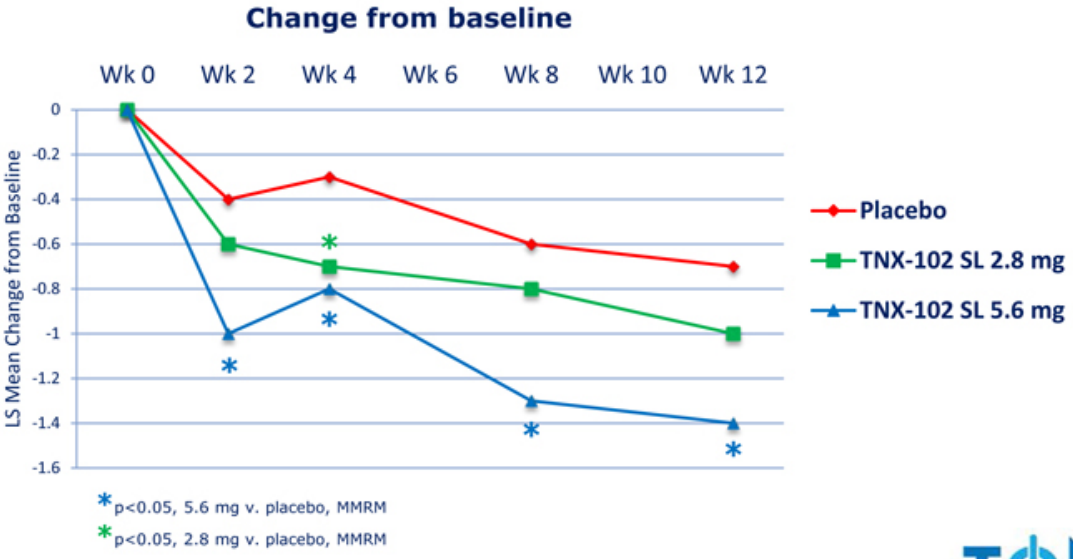
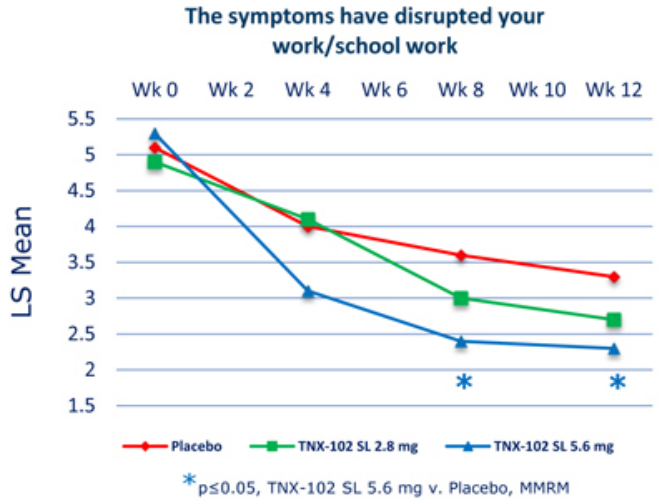
AtEase study results: CAPS-5 sleep disturbance

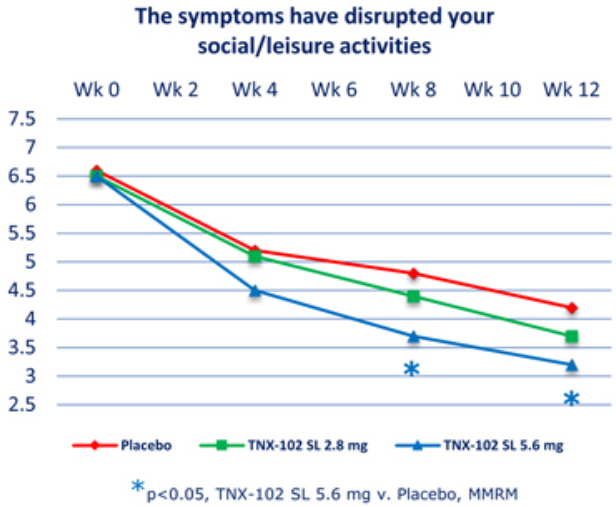


AtEase study results: Sheehan Disability Scale

Sheehan Disability Scale – Work/School & Social Leisure Domains



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



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

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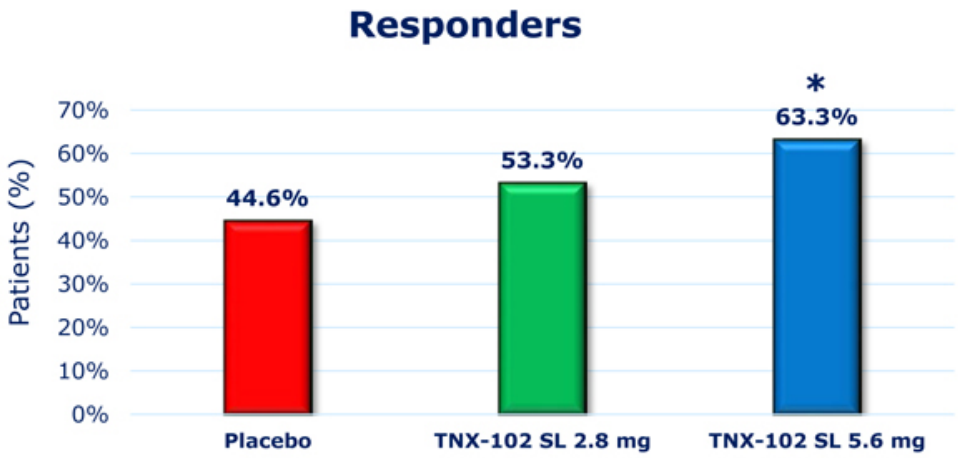
AtEase study results: Clinical Global Impression

Clinical Global Impression – Improvement Scale



*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"

TNX-102 SL safety and tolerability profile in the AtEase study

No serious adverse events reported with TNX-102 SL deemed related to treatment 17

Systemic Adverse Events*	Placebo (N=94)	TNX-102 SL 2.8 mg (N=93)	TNX-102 SL 5.6 mg (N=50)	Total TNX-102 SL (N=143)
Somnolence	6.4%	11.8%	16.0%	13.3%
Dry Mouth	10.6%	4.3%	16.0%	8.4%
Headache	4.3%	5.4%	12.0%	7.7%
Insomnia	8.5%	7.5%	6.0%	7.0%
Sedation	1.1%	2.2%	12.0%	5.6%
Administration Site Reactions*				
Hypoaesthesia oral	2.1%	38.7%	36.0%	37.8%
Paraesthesia	3.2%	16.1%	4.0%	11.9%
Glossodynia	1.1%	3.2%	6.0%	4.2%

Trial completion rates: 73% placebo; 79% TNX-102 SL 2.8 mg; 84% TNX-102 SL 5.6 mg

*at rates of >5% in either drug-treated arm, Safety population N=237

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Determining CAPS-5 severity criteria for entry in phase 3 trials

- **CAPS-5 has not been employed previously in a pharmacotherapy trial; entry severity threshold not clear; ≥ 29 used in the Phase 2 AtEase study**
- **Prior pharmacotherapy trials in PTSD using earlier versions of CAPS with different scoring range have most frequently used a score of ≥ 50 for entry (similar to CAPS-5 ≥ 33[1])**
- **Analysis of patients with CAPS-5 ≥ 33 showed an effect size of 0.53 on mean change from baseline at Week 12 in TNX-102 SL 5.6 mg group (see figure on next slide)**

[1]*Sullivan, Gregory, et al. "The AtEase Study: Efficacy and Safety of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL) for the Treatment of Military-Related PTSD." Poster session presented at: Military Health System Research Symposium (MHSRS) 2016 Annual Meeting; 2016 Aug 15-18; Kissimmee, FL. URL: http://bit.ly/2bFo4mx*

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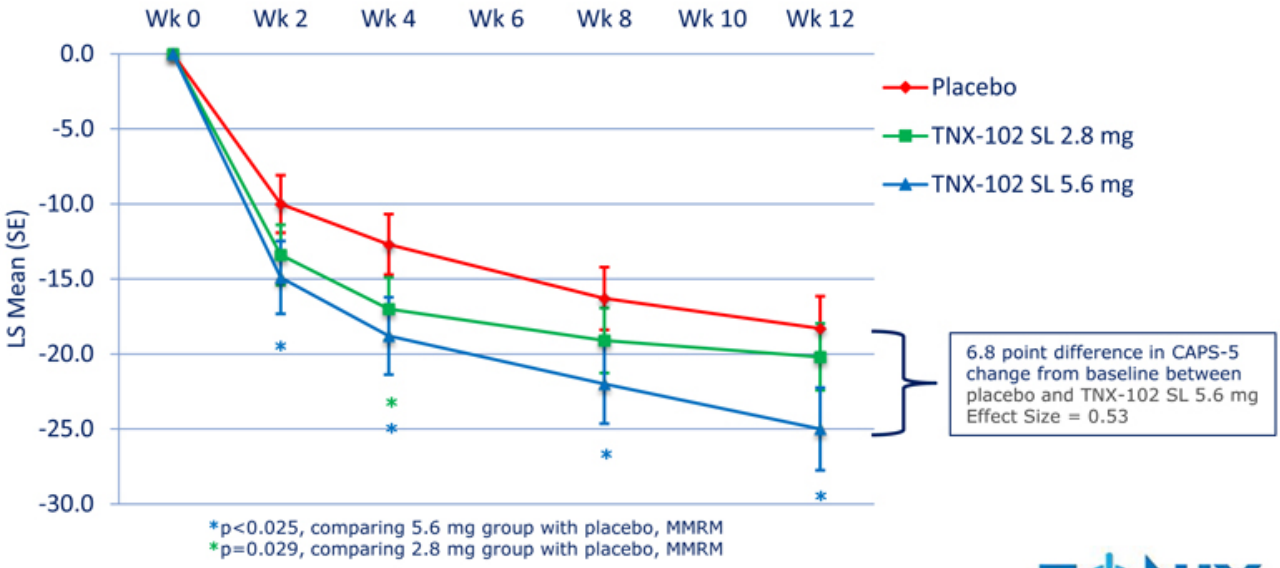
CAPS-5 mean change from baseline for entry CAPS ≥ 33

Retrospective subset analysis of patients with entry CAPS-5 ≥ 33



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CAPS-5 cluster scores

Comparing CAPS-5 Severity Entry Criteria ≥ 33 and ≥ 29

- Table shows the significance levels and effect sizes of the CAPS-5 cluster scores, comparing TNX-102 SL 5.6 mg and placebo, using a CAPS-5 baseline entry criterion of ≥ 33 and the per protocol threshold of ≥ 29

	Entry criteria of CAPS-5 ≥ 33		Entry criteria of CAPS-5 ≥ 29	
	5.6 mg (N=38) vs Placebo (N=77)		5.6 mg (N=49) vs Placebo (N=92)	
CAPS-5 Cluster	**Effect Size**	**P-value***	**Effect Size**	**P-value***
Cluster B (Intrusion)	0.46	**0.026**	0.26	0.161
Cluster C (Avoidance)	0.12	0.522	0.04	0.963
Cluster D (Mood/Cognitions)	0.39	*0.065*	0.35	*0.062*
Cluster E (Arousal & Reactivity)	0.52	**0.012**	0.35	**0.048**

* MMRM, mixed-effects model repeated measures

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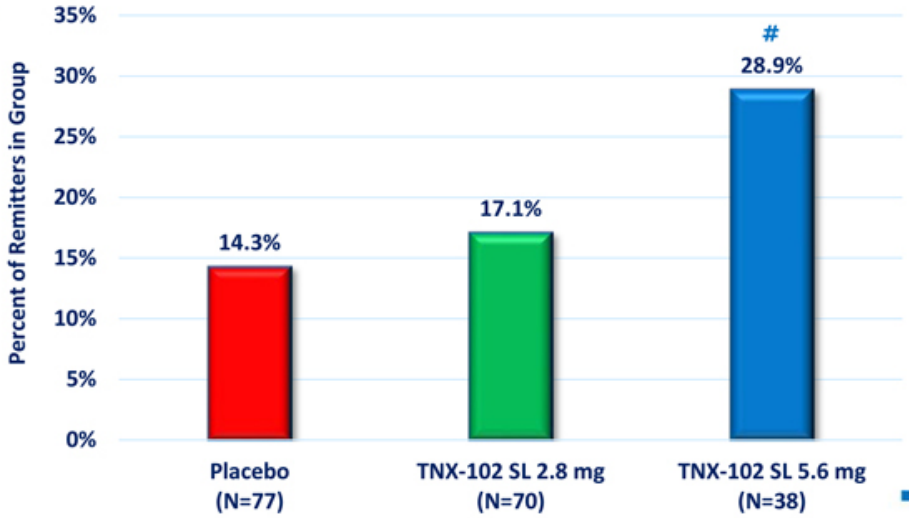
Rate of remission from PTSD in each treatment arm

Retrospective subset analysis of patients with entry CAPS-5 ≥ 33

- Remission is defined as CAPS-5 score <11 at week 12
- Trend for greater rate in TNX-102 SL 5.6 mg versus placebo in entry CAPS-5 ≥ 33 sample



#p=0.10 NS, comparing placebo and TNX-102 SL 5.6 mg, logistic regression

TONIX PHARMACEUTICALS

AtEase study conclusions

- **This Phase 2 trial is the first large multi-center trial of an investigational new drug product that demonstrated efficacy in a population with military-related PTSD**
  - Symptom reduction (CAPS-5)
  - Functional improvement (Sheehan Disability Scale domains)
  - Global improvement (CGI-I)
- **Early effects on sleep and hyperarousal are consistent with the mechanistic hypothesis of TNX-102 SL primary actions on sleep disturbance and autonomic balance**
- **Systemic side effects included include somnolence, dry mouth, headache and sedation; local reactions to sublingual TNX-102 SL administration were common (transient tongue numbness)**
- **A post-hoc analysis suggested that enrolling patients with a higher CAPS-5 score (≥ 33) would be similar to the entry criteria used in the registration studies supporting the approval of the marketed PTSD drug products**
  - Same post-hoc analysis revealed a larger separation from placebo in the subset of patients with baseline CAPS-5 ≥ 33 at weeks 2, 4, 8 and 12
  - Phase 3 program will use CAPS-5 ≥ 33 as enrollment threshold

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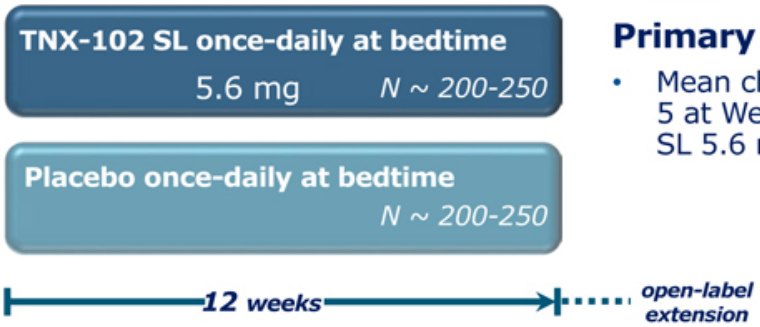
Phase 3 program in PTSD being planned

Planning to confirm AtEase finding in military-related PTSD and in predominantly civilian PTSD:

- **Larger studies**
- **Targeting start in 2017**



General Study Characteristics:

- Randomized, double-blind, placebo-controlled studies in PTSD
- N~400-500; approximately 35 U.S. clinical sites

Primary Efficacy Endpoint:

- Mean change from baseline in total CAPS-5 at Week 12 compared between TNX-102 SL 5.6 mg and placebo

Topline data for Phase 3 in military-related PTSD study anticipated 1H 2018

TONIX PHARMACEUTICALS

Intellectual property

Wholly-owned by Tonix with no obligations to others

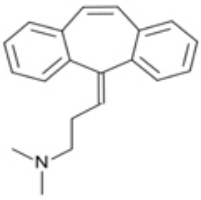
TNX-102 SL

- **Composition-of-matter (eutectic)**
  - Patents filed
  - Protection expected to 2034
- **Pharmacokinetics (PK)**
  - Patents filed
  - Protection expected to 2033
- **Method-of-use**
  - PTSD: patents filed

TONIX PHARMACEUTICALS

TNX-102 SL: active pharmaceutical ingredient

- **Cyclobenzaprine is a tricyclic molecule that binds to a number of central nervous system (CNS) receptor types**



- **Highest affinity for three receptors believed to have a role in treating sleep disturbances**
  - 5-HT_{2A} receptor
  - α_1 adrenergic receptor
  - H_1 receptor

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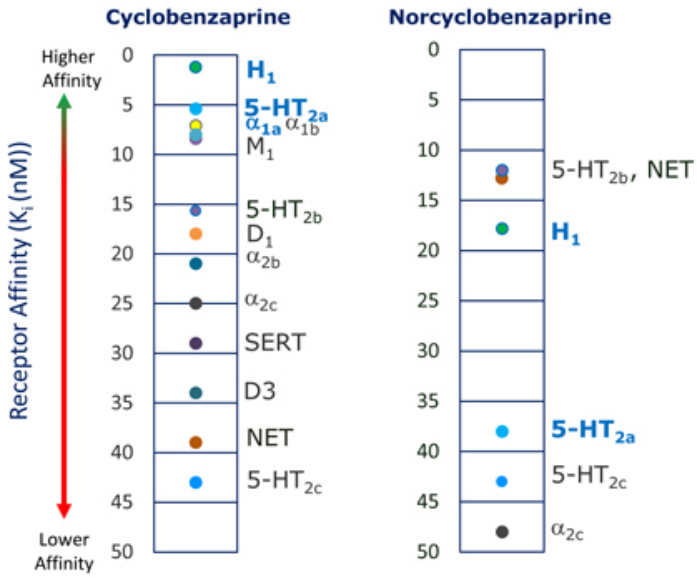
Receptor binding profile: Parent and primary metabolite

Receptor Binding Dot Plots for Human Receptors



Undesirable Characteristics of Norcyclobenzaprine (nCBP)

- Half-life ($t_{1/2}$) of 72 hours (will accumulate)
- At steady-state, projected similar exposure day and night
- Distinct receptor binding profile less selective for target receptors
- Potential undesirable off-target functional activities

Bold Blue: Target receptors
Black: Off-target receptors

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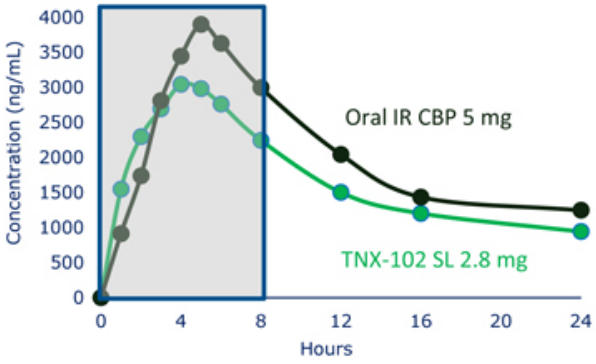
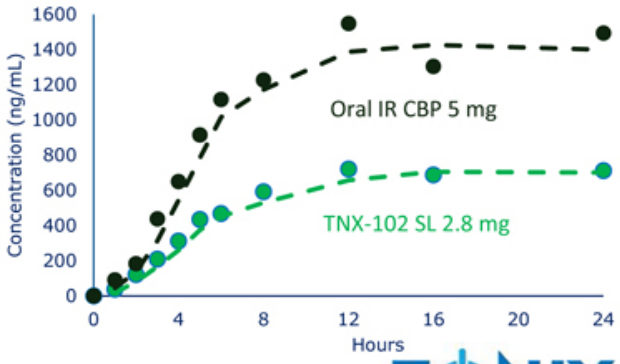
TNX-102 SL single-dose PK study

TNX-102 SL 2.8 mg PK profile relative to 5 mg oral immediate release (IR) CBP:

CBP: ✓ Rapid absorption for bedtime dosing
✓ Peak concentration (C_{max}) reduced by 20%
✓ Maintains t_{max} at ~4 hours



nCBP: ✓ Lower exposure of nCBP by 48%
✓ Higher ratio of CBP relative to nCBP
Ratio of CBP AUC $_{0-48}$ /nCBP AUC $_{0-48}$:
- 1.9 for TNX-102 SL 2.8 mg
- 1.2 for immediate release CBP 5 mg



TONIX PHARMACEUTICALS

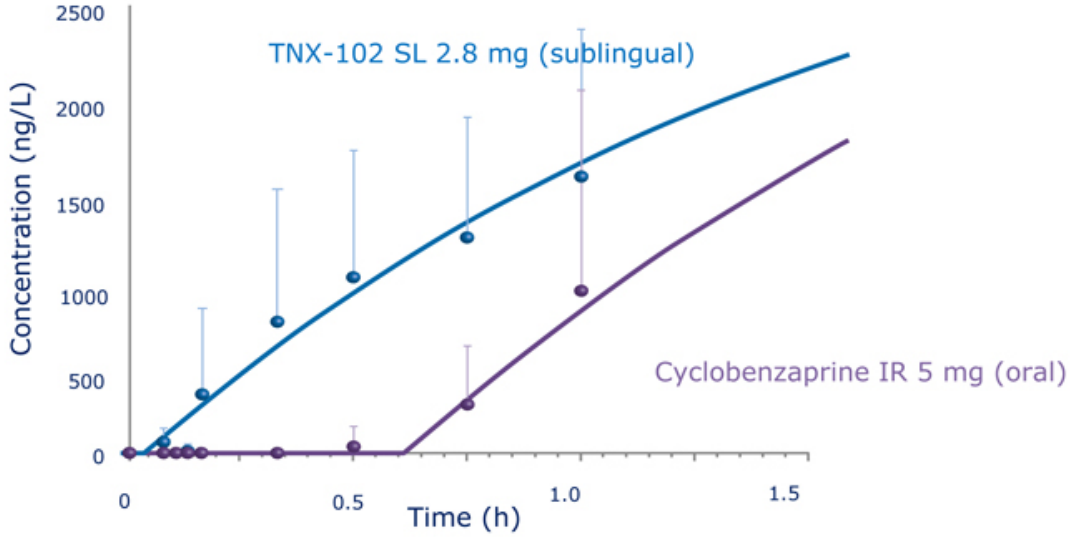
TNX-102 SL: Pharmacokinetic profile after sublingual route of administration

- **Very rapid absorption after dosing (measurable in plasma within 3 minutes of administration)**
  - Reaching t_{max} at ~4 hours after dosing
  - Approximately 50% of exposure to cyclobenzaprine occurs during first 8 hours
- **Avoids first-pass hepatic metabolism to long-lived major metabolite, norcyclobenzaprine**
  - Large reduction in exposure to norcyclobenzaprine (↓ 48% AUC_{0-48})
  - Decreased potential for adverse events

TONIX PHARMACEUTICALS

Cyclobenzaprine is detected in plasma within minutes following sublingual TNX-102 SL

Plasma Concentration Versus Time of TNX-102 SL Compared to Oral Cyclobenzaprine IR



Source: U.S. Patent applications 13/918,692 – Transmucosal absorption.

TONIX PHARMACEUTICALS

Management team

Seth Lederman, MD President & CEO	TARGENT, Fusilev (levoleucovorin) for injection, vela pharm
Bruce Daugherty, PhD, MBA Chief Scientific Officer	MERCK, Roche
Gregory Sullivan, MD Chief Medical Officer	Columbia University Department of Psychiatry, New York State Psychiatric Institute
Bradley Saenger, CPA Chief Financial Officer	Shire, VERTEX, Steward, pwc
Jessica Edgar Morris EVP, Operations	Deutsche Bank, svb Silicon Valley Bank, American Capital
Ronald Notvest, PhD EVP, Commercial Planning & Development	Wyeth, Rapamune sirolimus, Evidec

Board of directors

Seth Lederman, MD Chairman	**Ernest Mario, PhD** ALZA, Glaxo, Reliant Pharma
Stuart Davidson Labrador Ventures, Alkermes, Combion	**Charles Mather** BTIG, Janney, Jefferies, Cowen, Smith Barney
Patrick Grace Apollo Philanthropy, WR Grace, Chemed	**John Rhodes** NYSERDA, NRDC, Booz Allen Hamilton
Donald Landry, MD, PhD Chair of Medicine, Columbia University	**Samuel Saks, MD** Jazz Pharma, ALZA, Johnson & Johnson

TONIX PHARMACEUTICALS

Financial overview

NASDAQ: TNXP	
Cash, cash equivalents, and marketable securities reported at June 30, 2016	$ 31.2 million
Net proceeds from overallotment in 3Q16	$1.4 million
Shares outstanding (September 6, 2016)	25.9 million

TONIX PHARMACEUTICALS

Milestones – recent and upcoming

TNX-102 SL – Posttraumatic Stress Disorder

☑	December 2015	Entered into Collaborative Research and Development Agreement (CRADA) with the United States Army Medical Materiel Development Activity (USAMMDA)
☑	May 2016	Report results from AtEase study
☑	August 2016	End of Phase 2 meeting with FDA - Proposed Phase 3 and NDA plan accepted - Breakthrough Therapy Designation Request can be submitted for review
☐	Q1 2017	Target commencement of Phase 3 study in military-related PTSD
☐	Q2 2017	Target commencement of Phase 3 study in predominantly civilian PTSD

TONIX PHARMACEUTICALS

NASDAQ: TNXP

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Exhibit 99.02

Tonix Pharmaceuticals Reports Topline Results from Phase 3 AFFIRM Study of TNX-102 SL in Fibromyalgia and Provides Corporate Update

Following Completion of AFFIRM, Tonix to Prioritize Resources for Advancing Posttraumatic Stress Disorder (PTSD) Program into Phase 3

TNX-102 SL Generally Well Tolerated; No New Safety Signals Observed

NEW YORK, Sept. 6, 2016 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix) announced preliminary topline results from its Phase 3 clinical study, AFFIRM, designed to evaluate the safety and efficacy of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, in patients with fibromyalgia. AFFIRM was a 12-week randomized, double-blind, placebo-controlled trial of TNX-102 SL taken daily at bedtime, in which 519 participants were enrolled at 35 centers in the U.S. Fibromyalgia is a multi-symptom disorder that originates in the central nervous system and is characterized by widespread pain, non-restorative sleep, fatigue, and disability.

The AFFIRM data did not achieve statistical significance in the primary efficacy endpoint: the proportion of patients who reported a 30 percent or greater reduction in pain from baseline to the end of the 12-week treatment period based on the pre-specified primary analysis (p=0.095, Table 1). However, TNX-102 SL did show statistically significant effects on pain when analyzed by other standard statistical approaches (Table 1). TNX-102 SL activity in fibromyalgia was cross-validated by two additional endpoints, Patient Global Impression of Change (PGIC) and Fibromyalgia Impact Questionnaire-Revised (FIQ-R) (Table 2). These endpoints assess global improvement and a range of fibromyalgia symptoms and function. TNX-102 SL showed strong effects on improving sleep quality by the daily diary and the PROMIS sleep disturbance scale (Table 2). The internal consistency of these results provides clear evidence of beneficial effect of TNX-102 SL for the treatment of fibromyalgia.

Seth Lederman, M.D., president and chief executive officer of Tonix, commented, "TNX-102 SL showed broad beneficial effects across key fibromyalgia symptoms and was well-tolerated in the AFFIRM study. Despite achieving clinically meaningful results from AFFIRM, we have greater clarity on the regulatory path forward in our PTSD program. We will therefore discontinue the fibromyalgia program in order to fully focus Tonix's resources on advancing our potential breakthrough PTSD program to Phase 3. We owe it to our investors, and to patients who are waiting for meaningful clinical innovation, to steward our resources effectively." Dr. Lederman continued, "We thank those who contributed to the AFFIRM trial, from the clinical teams to the patients and their families. They helped us evaluate this potential new therapy and their involvement provided valuable clinical and scientific information."

An unexpected imbalance in patient discontinuations for reasons unrelated to efficacy or tolerability (for example, a patient relocating away from the clinical site) (Table 3), created a negative bias in the primary responder analysis because any patient who left the study, for any reason prior to completion, was labeled a non-responder despite their results up to that point. Another standard statistical method for assessing the 30 percent responder analysis that considers the reason for discontinuation showed statistical significance in the primary pain data (Table 1, P=0.012).

Overall, TNX-102 SL was well-tolerated in the AFFIRM study and the adverse events reported were similar to those seen in other TNX-102 SL clinical studies (Table 4). There were seven serious adverse events (SAEs) reported during the study: four in the placebo group and three in the active group. No new safety signals were observed; multiple causal factors were involved in each SAE, and all were resolved quickly and without sequelae.

Table 1. Primary and Other Standard Analyses of Pain

Analysis Method	Imputation	Result
30% Responder Analysis Pre-specified	BOCF all discontinuations	P=0.095
30% Responder Analysis	BOCF for LOE and AE; LOCF for others	P=0.012
ANCOVA; MCFB	Multiple imputation; LOE, AE and ID considered MNAR	P=0.009
ANCOVA; MCFB	Multiple imputation; all MNAR except LTF	P=0.042
MMRM of MCFB	None	P<0.001
50% Responder Analysis	BOCF all discontinuations	P=0.035

AE- Adverse Event; ANCOVA- Analysis of Covariance; BOCF- Baseline Observation Carried Forward; ID- Investigator Decision; LOCF- Last Observation Carried Forward; LOE- Lack of Efficacy; LTF- Lost to Follow-up; MCFB- Mean Change from Baseline; MMRM- Mixed Models Repeated Measures; MNAR- Missing Not at Random

Table 2. Key Secondary Efficacy Data

Measure	Analysis Method	Imputation	Result
PGIC	Responder Analysis	BOCF	0.038
FIQ-R Total Score	MMRM of MCFB	None	<0.001
FIQ-R Symptom Domain	MMRM of MCFB	None	<0.001
FIQ-R Function Domain	MMRM of MCFB	None	<0.001
Clinic 7-day pain recall	MMRM of MCFB	None	0.003
FIQ-R Pain Item	MMRM of MCFB	None	<0.001
PROMIS Fatigue	MMRM of MCFB	None	<0.001
Daily Sleep Quality Diary	MMRM of MCFB	None	<0.001
PROMIS Sleep Disturbance	MMRM of MCFB	None	<0.001
FIQ-R Sleep Quality Item	MMRM of MCFB	None	<0.001

Table 3. Reasons for Patient Dropouts/Discontinuations

Reason	TNX-102 SL	Placebo
Occurrence of an Adverse Event	20 (7.6%)	11 (4.3%)
Withdrawal of Consent	15 (5.7%)	3 (1.2%)
Investigator Decision	6 (2.3%)	0 (0%)
Lack of Efficacy	6 (2.3%)	5 (1.9%)
Lost to Follow-up	11 (4.2%)	15 (5.8%)
Other	1 (0.4%)	1 (0.4%)
Total	59 (22.5%)	35 (13.6%)

Among subjects randomized to the TNX-102 SL and control arms, 77.5 percent and 86.4 percent, respectively, completed the 12-week dosing period. As observed in other TNX-102 SL clinical studies, the rate of tongue numbness was higher in the active treatment group (40.2 percent vs. 0.8 percent). Transient tongue numbness, the most frequent adverse reaction, is a local effect related to TNX-102 SL sublingual administration and it did not appear to bias efficacy results. The most common systemic adverse reactions occurring in greater than or equal to 3 percent of patients in TNX-102 SL group and greater than placebo, are listed in Table 4.

Table 4. Most Common Systemic Adverse Reactions Occurring in ≥ 3% of Patients in the TNX-102 SL Group and Greater than Placebo

Preferred term	TNX-102 SL (N = 261)*	Placebo (N=257)*
Fatigue	15 (5.7%)	6 (2.3%)
Somnolence	8 (3.1%)	4 (1.6%)

*Safety Population = 518 patients

About PTSD

PTSD affects approximately 8.5 million Americans and is a chronic and debilitating condition, in which patients experience nightmares and disturbed sleep, and which is associated with depression and suicide. Individuals who suffer from PTSD experience impaired social functioning, occupational disability, intense anxiety and avoidance, emotional numbness, intense guilt or worry, agitation and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable or violent behaviors, additional reasons that make it a critical public health concern. PTSD can develop from witnessing or experiencing a traumatic event in which there was the threat or actual occurrence of grave physical harm.

About TNX-102 SL

TNX-102 SL is an Investigational New Drug and has not been approved for any indication. 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 quality and the stress response. Tonix is developing 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, with its lead program focusing on PTSD. This disorder is characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

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