UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): November 1, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Corporate Presentation by the Company for November 2016*

_____

* Furnished herewith.

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: November 1, 2016

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

Exhibit 99.1

Investor Presentation

TONIX PHARMACEUTICALS

November 2016

Version P0038 11-01-16

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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.

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Posttraumatic Stress Disorder (PTSD) program

On May 19, 2016, we reported encouraging topline data for TNX-102 SL* 5.6 mg in a military-related PTSD trial ("AtEase")

- PTSD was our "second" clinical program using our proprietary formulation TNX-102 SL
- Prior to the AtEase trial, no other investigational new drugs or approved therapies had demonstrated efficacy in military PTSD in a large adequate well-controlled study

On August 29, 2016, we reported FDA acceptance of the PTSD Phase 3 clinical program at the End-of-Phase 2 meeting

- However, advancing TNX-102 SL for PTSD was not in our budget

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

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Tonix (TNXP): Value proposition

On September 6, 2016 our lead Phase 3 program TNX-102 SL for fibromyalgia narrowly missed its primary endpoint in the first Phase 3 study ("AFFIRM")

- Received strong negative investor market response
- Reassuring safety profile and activity of TNX-102 SL at 2.8 mg for improvement in sleep quality in fibromyalgia sets stage for new clinical direction in PTSD

We simultaneously announced that we discontinued our fibromyalgia program and were re-dedicating our resources to PTSD

- High value Phase 3 clinical asset not well known to the market
- Encouraging evidence of safety and efficacy of TNX-102 SL was demonstrated in Phase 2 AtEase trial
- Regulatory clarity for PTSD based on FDA acceptance of PTSD Phase 3 clinical program at End-of-Phase 2 meeting

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Pivot to PTSD: Rationale

- **Unmet Medical need**
  - PTSD is a serious condition and the prevalence is increasing, especially combat-related
  - Military-related PTSD is not satisfactorily treated by existing FDA approved therapies
  - Two selective serotonin reuptake inhibitors (SSRIs) are approved for PTSD, but have not shown efficacy in military-related PTSD
- **Endpoint**
  - TNX-102 SL 5.6 mg had significant effects on the FDA-recognized primary endpoint, the Clinician Administered PTSD Scale, "CAPS-5"
- **Potential Development and Commercialization Partners**
  - Several companies have U.S. psychiatry-focused specialty sales forces
  - Department of Defense (DoD) is interested in military-related PTSD and has the potential to support basic science and clinical development
- **Important target population**
  - U.S. veterans are in great need of a medicine that works for this indication
- **TNX-102 SL for PTSD has the potential for "Breakthrough Therapy Designation"**

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Highlights of Tonix Pharmaceuticals' Lead Asset

Phase 3 Ready Program

TNX-102 SL (cyclobenzaprine HCl sublingual tablets)

- A unique, innovative product designed for CNS indication(s)
- Targeting a chronic and serious psychiatric disorder: **PTSD**
  - ✓ **Therapeutic dose identified in Phase 2 study**
  - ✓ **Phase 3 clinical and product registration plan accepted by the FDA[3]**
  - ✓ **Phase 3 program expected to start Q1 2017**

Targeting An Attractive Market

PTSD

- High prevalence worldwide and receiving greater attention
- Not well served - high off-label usage[1] with unproven or contraindicated treatments[2]
- Potential opportunity to displace current therapies and expand market

1. Bernardy et al., J Clin Psychiatry, 2012; 73: 297
2. VA/DoD Clinical Practice Guideline for the Management of Post-Traumatic Stress, Version 2, 2010
3. August 2016 FDA End-of-Phase 2 Meeting Minutes

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What is PTSD?

A chronic response to traumatic event(s)

- A majority of people will experience a traumatic event at some point in their lifetime[1]
  - 20% of women and 8% of men in the U.S. who experience significant trauma develop PTSD[1]
  - *Lifetime prevalence:* 6.8%[2] (~ 17 million adults in the U.S.)
    - Persistent - >1/3 fail to recover, even after several years following the trauma[1]
  - *Twelve month prevalence:* *U.S.* 3.5%[3] (~ 8.5 million adults)
    EU 2.3%[4] (~10 million adults)

Most common forms of trauma[1]

- Witnessing someone being badly injured or killed
- Natural disaster
- Life-threatening accident
- Sexual or physical assault

1. Kessler et al, Arch Gen Psychiatry 1995;52:1048.
2. Kessler et al., Arch Gen Psychiatry. 2005;. 62:593
3. Kessler et al., Arch Gen Psychiatry. 2005; 62: 617; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
4. The European Union Market Potential for a New PTSD Drug. Prepared for Tonix Pharmaceuticals by Procela Consultants Ltd September 2016.

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What Are the Symptoms of PTSD?

Symptoms of PTSD fall into four clusters:

1. Intrusion (aversive memories, nightmares, flashbacks)
2. Avoidance (avoiding persons, places or situations)
3. Mood/cognitions (memory block, emotional numbing, detachment from others)
4. Hyperarousal (anxiety, agitation & **sleep disturbance**)

Symptoms assessed for diagnosis, severity and treatment effect

- **Clinician Administered PTSD Scale ("CAPS-5")**
  - Recognized as the standard for rating PTSD severity in clinical trials
  - Takes into account all four symptom clusters

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What Are the Consequences of PTSD?

Consequences:

- Impaired daily function and substantial interference with work and social interactions
- Reckless or destructive behavior
- Increased heath care utilization and greater medical morbidity

PTSD as a Risk Factor for:

- Depression
- Alcohol or substance abuse
- Absenteeism/unemployment
- Homelessness
- Violent acts
- Suicidal thoughts and suicide

Unmet Needs:

- Effective therapy for populations not well served by current treatment (males, military trauma)
- Alternative therapy for the majority of patients unresponsive or intolerant to current treatments
- Drug therapy compatible and complementary with behavioral therapy

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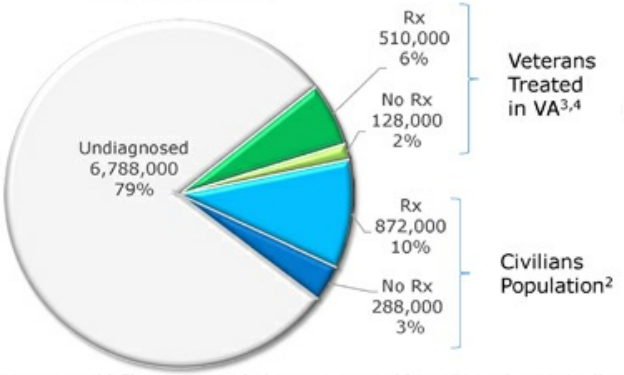
PTSD Prevalence and Market Characteristics

Prevalent Population (U.S.)
~8.6 million[1]



Diagnosed population
- Large population (~1.8 million)
- Majority receive drug treatment
  - Civilians: ~75%[2]
  - Veterans: ~80%[4]

1. Kessler, et al., 2005; ; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
2. IMS Consulting, *Market Sizing & Treatment Dynamics: Post-Traumatic Stress Disorder (PTSD) Patients"*, 2016
3. Bowe and Rosenheck, 2015 ((638,451 veterans diagnosed with PTSD in the VA in fiscal year 2012 across all medical centers)
4. Bernardy et al., 2012 (80% of veterans diagnosed with PTSD had at least one medication from the Clinical Practice Guidelines)

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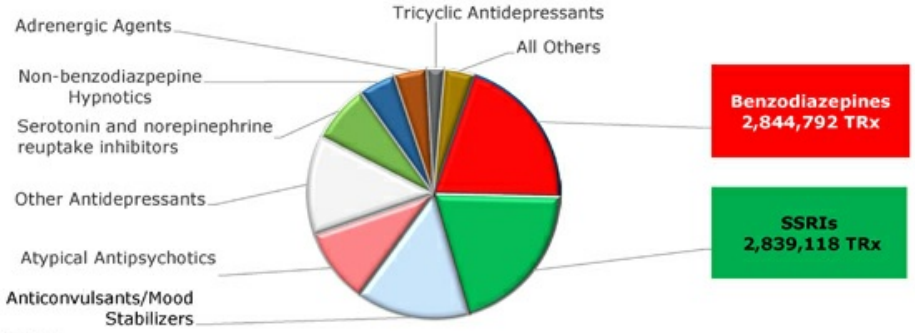
What Drug Classes are Used to Treat PTSD?

Market highly fragmented, with benzodiazepines being the largest class (but contraindicated[1])

- Multiple medications per patient (or "Polypharmacy") is the norm
  - Approximately 55% of patients receive a benzodiazepine, and 53% receive an SSRI
- SSRIs are the only FDA approved drug class

Estimated PTSD Market Volume (Civilian Population Only) ~14.1 million TRx*[2]



* TRx = Total prescriptions

1. VA/DoD Clinical Practice Guideline for the Management of Post-Traumatic Stress, Version 2, 2010
2. IMS Consulting, *Market Sizing & Treatment Dynamics: Post-Traumatic Stress Disorder (PTSD) Patients*", 2016

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Relevance of Sleep Disturbances for PTSD

Sleep Disturbances:

- Core symptom of PTSD (component of intrusion and hyperarousal symptom clusters)
- Believed to play roles in the pathophysiology of PTSD

	Sleep As a Core Symptom	Pathophysiology	Pharmacological Action 2° Clinical Endpoint	Therapeutic Benefit 1° Clinical Endpoint
PTSD	• **Nightmares** • **Hyperarousal**	**Stress ≈ Hyperarousal ≈ Sleep Disturbances** Hyperarousal and hypervigilance interfere with sleep and emotional memory processing during sleep	**Reduced hyperarousal**	**Reduced PTSD symptoms and disability**

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TNX-102 SL: Innovative and Unique By Design

Active Pharmaceutical Ingredient (API) is cyclobenzaprine (CBP), is structurally related to tricyclic antidepressants (TCAs)

- TCAs and their metabolites differ widely in their receptor binding and pharmacokinetic profiles[1]

Different from other tricyclics

- **CBP is more selective for high affinity sites believed to have a role in sleep quality[2]**
  - 5-HT_{2A}
  - α_1-adrenergic
  - histamine H_1
- **CBP undergoes extensive first-pass hepatic metabolism when administered orally**
  - Major metabolite, norcyclobenzaprine (nCBP)
    - Long half-life (~72 hours)
    - Less selective for target receptors (5-HT_{2A}, α_1-adrenergic, histamine H_1)
    - More selective for norepinephrine transporter

Different from oral CBP formulation

TNX-102 SL: Innovative sublingual formulation of CBP

- Rapid systemic exposure
- Increased bioavailability
- Avoids first-pass metabolism
  - Lowers exposure to long-lived active major metabolite, nCBP

1. Rudorfer and Potter, *Cellular and Molecular Neurobiology, 1999 19:373*
2. Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015,Toronto, Ontario, Canada

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Why Initially Target Military-Related PTSD?

Military-related PTSD not well-served by existing FDA-approved therapies

- ***No clear treatment response observed in U.S. military population***

  Sertraline: failed to show efficacy in large multicenter trial in U.S. military (placebo numerically better)[1]
  Paroxetine: no large trials conducted with predominantly military trauma

- **Inconsistent treatment response observed in males**

  Sertraline: FDA-conducted post-hoc analysis concluded no effect for male civilian subgroup[2]
  Paroxetine: no sex-related difference in treatment outcomes[3]

- **Important tolerability issues with SSRIs in this population**

  Sexual dysfunction[2,3]
  Insomnia[2,3]
  SSRI withdrawal syndrome[4]

1. Friedman et al., J Clin Psychiatry 2007; 68:711, 2. Zoloft Package Insert, August, 2014, 3. Paxil Package Insert, June, 2014,
4. Fava et al., Psychother Psychosom 84:72-81, 2015

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Phase 2 AtEase Study in Military PTSD

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

TNX-102 SL at bedtime once-daily
5.6 mg (2 x 2.8 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 analysis:**
  - Difference in CAPS-5 score between TNX-102 SL 2.8 mg and placebo at week 12

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

TNX-102 SL was active at 5.6 mg dose

Enrolled patients with baseline CAPS-5 ≥ 29

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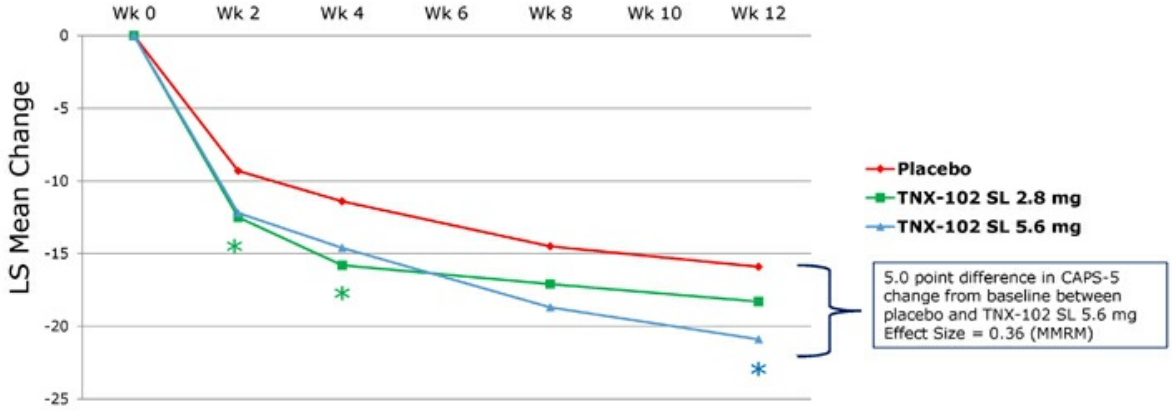
AtEase Study Results CAPS-5 Total Score

CAPS-5 LS 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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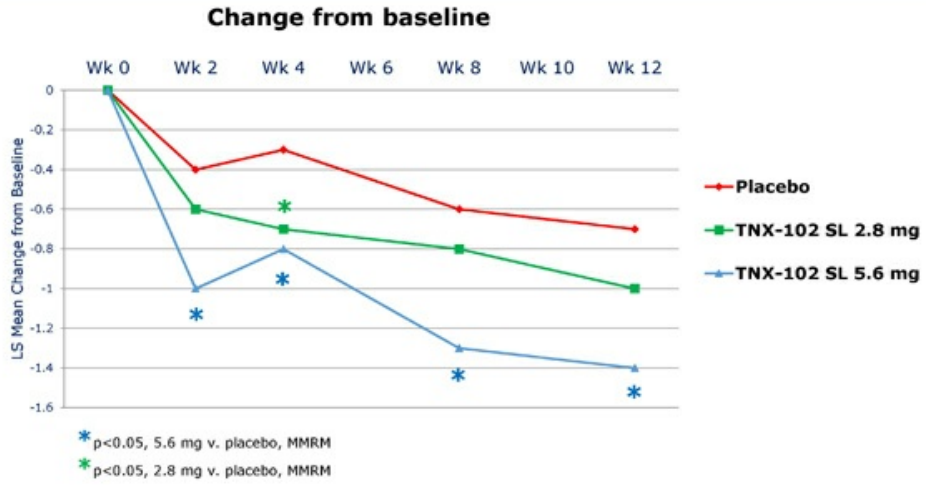
AtEase Study Results CAPS-5 Sleep Disturbance



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AtEase Study: Safety and Tolerability Profile

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

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

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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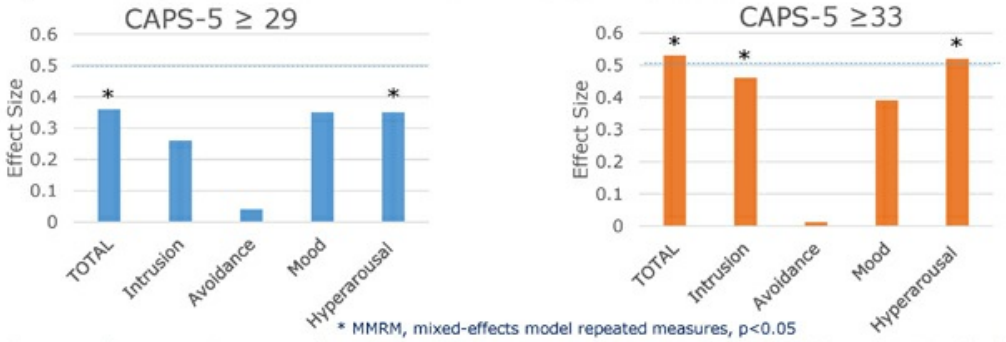
AtEase: Retrospective Analysis

Prior pharmacotherapy trials in PTSD used *earlier versions* of CAPS (e.g. CAPS-2)

- Different scoring range from CAPS-5
- Most frequently used a score of ≥ 50 for entry (similar to CAPS-5 ≥ 33[1])
- FDA has accepted this higher entry criteria (CAPS-5 ≥ 33) for Phase 3 program

Compared CAPS-5 Severity Entry Criteria ≥ 29 versus ≥ 33 on Effect Size for AtEase

- Retrospective analysis showed more robust effect with high entry criteria



* MMRM, mixed-effects model repeated measures, p<0.05

[1]Sullivan, Gregory, et al. 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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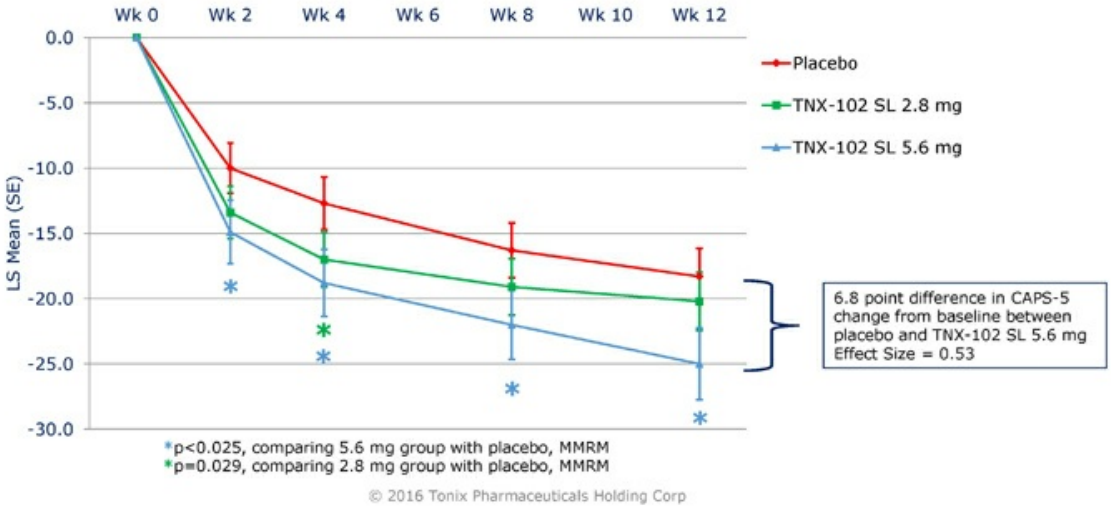
Analysis Using CAPS-5 ≥ 33 As Entry Criteria

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



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Phase 2 AtEase Study Conclusions

First large multi-center trial demonstrating efficacy of an Investigational New Drug (IND) in military-related PTSD

- ✓ TNX-102 SL therapeutic dose (5.6 mg) identified
- ✓ Symptom reduction (CAPS-5)
- ✓ Functional improvement (Sheehan Disability Scale domains)
- ✓ Clinical global impression of improvement (CGI-I)

Effects on sleep and hyperarousal

- ✓ Consistent with mechanistic hypothesis

Well-tolerated; side effects include:

Systemic: somnolence, dry mouth, headache and sedation
Local administration site reactions: transient tongue numbness

Comprehensive AtEase study results from scientific presentations available at:
http://www.tonixpharma.com/research-development/scientific-presentations

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Planned Phase 3 program in PTSD

To confirm AtEase finding in military-related PTSD:

- **Larger adaptive design study**
- **Targeting start in 1Q 2017**

TNX-102 SL once-daily at bedtime
5.6 mg *N ~ 275 (90*)*

Placebo once-daily at bedtime
N ~ 275 (90)*

12 weeks

** First interim analysis*

General Study Characteristics:

- Randomized, double-blind, placebo-controlled, entrance CAPS-5 ≥ 33
- One to two planned unblinded interim analyses (IAs)
- First IA (N ~180) for efficacy stop or sample size adjustment
- Potential to enroll 550 patients
- Approximately 30 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

First IA topline data anticipated 2H 2017

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Commercialization Options

Tonix is exploring a variety of options to commercialize TNX-102 SL, including commercializing on our own or partnering all or some indications in specific regions of the world.

Commercial Considerations:

- Primary physician audience is well defined: psychiatrists (~30,000 in U.S.)
  - Small specialty sales force sufficient for coverage
- Primary market research with psychiatrists indicate strong interest in new therapeutic options

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Intellectual Property

TNX-102 SL
PTSD

Portfolio of international patents filed under the Patent Cooperation Treaty (PCT)

Composition-of-matter (eutectic)
- Patents filed
- Protection expected to 2034

Pharmacokinetics (PK)
- Patents filed
- Protection expected to 2033

Method-of-use
- PTSD: patents filed

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Management Team

Seth Lederman, MD President & CEO	TARGENT, Fusilev (levoleucovorin) for injection, vela
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 Morris EVP, Operations	Deutsche Bank, svb Silicon Valley Bank, American Capital

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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
Net Proceeds from At-the-market offering (ATM) in 3Q16	$2.5 million
Net proceeds from underwritten offering in 4Q16	$4.6 million
Shares outstanding (November 1, 2016)	39.2 million

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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 clinical and NDA plan accepted - Breakthrough Therapy Designation Request can be submitted for review
☐	1Q 2017	Target commencement of Phase 3 study in military-related PTSD
☐	2H 2017	Topline data from interim analysis of Phase 3 study in ~180 military-related PTSD patients

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Summary

Strong position for value growth with Phase 3 trial in a major medical indication: PTSD

- Phase 3 asset not previously well-known to the investor marketplace

Funded through 1st interim analysis (180 patients) of Phase 3 PTSD trial initiating in 1Q2017

- Topline data from 1st interim analysis expected to be available 2H2017

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NASDAQ: TNXP

Thank you!

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