

**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): December 8, 2016

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(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))
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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 December 8, 2016, the Company issued a press release announcing that the Company presented an updated poster, entitled, "*The AtEase Study: A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL in the Treatment of Military-Related PTSD*" (the "Poster"), at the 55th Annual Meeting of the American College of Neuropsychopharmacology held in Hollywood, Florida. The Poster was presented by Dr. Gregory Sullivan, M.D., the Company's chief medical officer.

A copy of the press release that discusses this matter is filed as Exhibit 99.03 to, and incorporated by reference in, this report. The foregoing description of the Poster is qualified in its entirety by reference to the Poster, a copy of which is deemed filed as Exhibit 99.02 to, and is 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 December 2016*

99.02 *The AtEase Study: A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL in the Treatment of Military-Related PTSD* Poster, filed as an exhibit to the Current Report on Form 8-K, filed with the Securities and Exchange Commission on December 7, 2016 and incorporated herein by reference*

99.03 Press Release, dated December 8, 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: December 8, 2016

By: /s/ BRADLEY SAENGER

Bradley Saenger

Chief Financial Officer



Investor Presentation



December 2016

Version P0043 12-8-16

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Cautionary Note on Forward-Looking Statements

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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.



Posttraumatic Stress Disorder (PTSD) program

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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 drug or approved therapy had demonstrated efficacy in military PTSD in a large adequate well-controlled study

On August 29, 2016, we reported U.S. Food and Drug Administration (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 HCl sublingual tablets) is an Investigational New Drug and has not been approved for any indication



Tonix (TNXP): Value proposition

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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 we are focusing 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



Pivot to PTSD: Rationale

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- **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"**



Tonix Pharmaceuticals Posttraumatic Stress Disorder (PTSD) Program

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Phase 3 Ready Program

TNX-102 SL (cyclobenzaprine HCl sublingual tablets)

- A unique, innovative product designed for bedtime administration
- 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 FDA¹
Targeting commencement of Phase 3 study in military-related PTSD in 1Q 2017

Targeting An Attractive Market

PTSD

- High prevalence worldwide and receiving greater attention
- Not well served - high off-label usage² with unproven or contraindicated treatments³
- Potential opportunity to displace current therapies and expand market

1. August 2016 FDA End-of-Phase 2 Meeting Minutes
2. Bernardy et al., J Clin Psychiatry, 2012; 73: 297

3. VA/DoD Clinical Practice Guideline for the Management of Post-Traumatic Stress, Version 2, 2010



What is PTSD?

A chronic response to traumatic event(s)

- A majority of people will experience a traumatic event at some point in their lifetime¹
 - 20% of women and 8% of men in the U.S. who experience significant trauma develop PTSD¹
- Lifetime prevalence: 6.8%² (~ 17 million adults in the U.S.)
 - Persistent - >1/3 fail to recover, even after several years following the trauma²
- Twelve month prevalence: U.S. 3.5%³ (~ 8.6 million adults)
EU 2.3%⁴ (~10 million adults)

Most common forms of trauma¹

- 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 Procefa 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



What Are the Consequences of PTSD?

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Consequences:

- Impaired daily function and substantial interference with work and social interactions
- Reckless or destructive behavior
- Increased health 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:

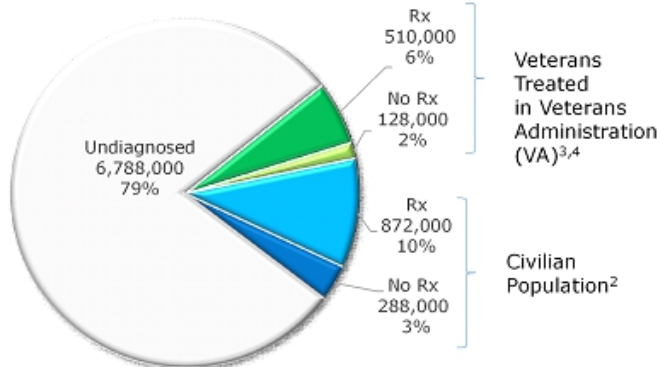
- Effective therapy for populations not well served by current treatment (males, military trauma)
- Alternative therapy for the majority of patients unresponsive or intolerant to current treatments
- Drug therapy compatible and complementary with behavioral therapy

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PTSD Prevalence and Market Characteristics

Prevalent Population (U.S.) ~8.6 million¹



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)



What Drug Classes are Used to Treat PTSD?

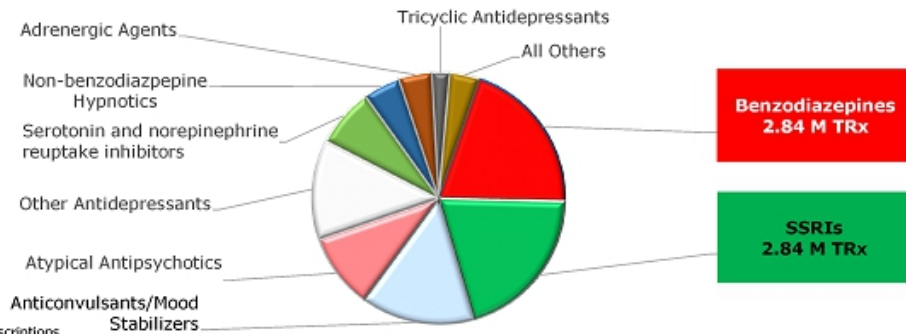
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Market highly fragmented, with benzodiazepines being widely prescribed (but not indicated¹)

- Multiple medications per patient (or "Polypharmacy") is the norm
 - Approximately 55% of patients receive a benzodiazepine, and 53% receive an selective serotonin reuptake inhibitor (SSRI)

- SSRI is 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 ^o Clinical Endpoint	Therapeutic Benefit 1 ^o Clinical Endpoint
PTSD	<ul style="list-style-type: none">• 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



TNX-102 SL: Innovative and Unique By Design

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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 profiles¹

Different from other tricyclics

- **CBP is more selective for high affinity sites believed to have a role in sleep quality²**
 - 5-HT_{2A}
 - α_1 -adrenergic
 - histamine H₁
- **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 H₁)
 - 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



Why Initially Target Military-Related PTSD?

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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 a 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 subgroup²
Paroxetine: no sex-related difference in treatment outcomes³

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

Sexual dysfunction^{2,3}
Insomnia^{2,3}
SSRI withdrawal syndrome⁴

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



Phase 2 AtEase Study in Military PTSD

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

- Enrolled patients with baseline CAPS-5 ≥ 29
- Analysis from 231 patients; 24 U.S. clinical sites
- TNX-102 SL was active at 5.6 mg dose

- **Primary efficacy analysis:**
 - Difference in CAPS-5 score between TNX-102 SL 2.8 mg and placebo at week 12





AtEase Study Demographics and Characteristics

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- 93% of the randomized patients were 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 U.S. military distribution
- Current Major Depressive Disorder 14% by MINI 7.0
- Similar baseline CAPS-5 scores and MADRS scores across treatment arms

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 7.0, Mini-International Neuropsychiatric Interview, version 7
SD, standard deviation

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AtEase Study: Traumas Associated with PTSD

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Index Trauma During Military Service	Patient Count*
Being involved in an IED explosion or suicide bombing	35
Witness death or injury of fellow soldiers	33
Witnessing IED explosion	30
Receiving incoming artillery, rocket, or mortar fire	29
Being wounded or injured	10
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	9
Witnessing death or injury of civilians	8
Handling or uncovering human remains	7
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
Other	11

*Some patients experienced more than one trauma

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AtEase Study – Summary of Primary and Secondary Analyses (week 12)

Assessment	Domain	Analysis	p-Values	
			2.8 mg (N=90)	5.6 mg (N=49)
CAPS-5	Total	MMRM	0.259 [^]	0.053
	Total	MMRM with Multiple Imputation	0.211	0.031*
	Total	MMRM w/ Hybrid LOCF/BOCF	0.172	0.037*
	Total	ANCOVA	0.090	0.038*
CAPS-5 clusters/items	Arousal & Reactivity cluster (E)	MMRM	0.141	0.048*
	Sleep item (E6)	MMRM	0.185	0.010*
	Exaggerated Startle item (E4)	MMRM	0.336	0.015*
CGI-I	Responders	Logistic Regression	0.240	0.041*
PGIC	Mean score	MMRM	0.075	0.035*
Sheehan Disability Scale	Work/school item	MMRM	0.123	0.050*
	Social/leisure item	MMRM	0.198	0.031*

BOCF, baseline observation carried forward; CGI-I, Clinical Global Impression - Improvement scale; LOCF, last observation carried forward; MMRM, mixed model repeated measures; PGIC, Patient Global Impression of Change

[^]Primary analysis p-value not significant comparing TNX-102 SL 2.8 mg versus placebo

*p<0.05



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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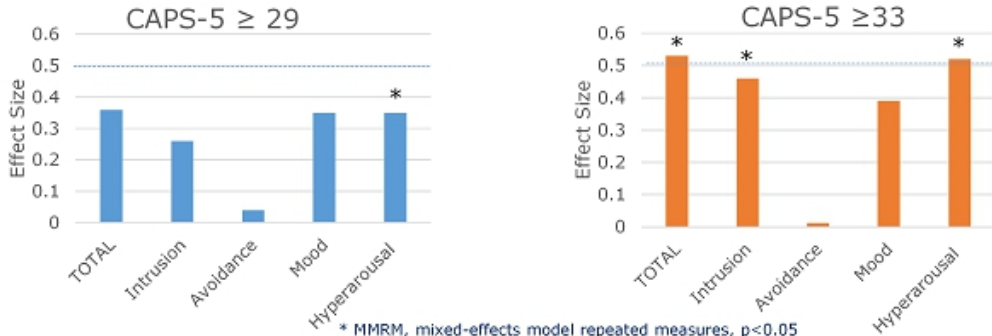
AtEase: Retrospective Analysis for TNX-102 SL 5.6 mg

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

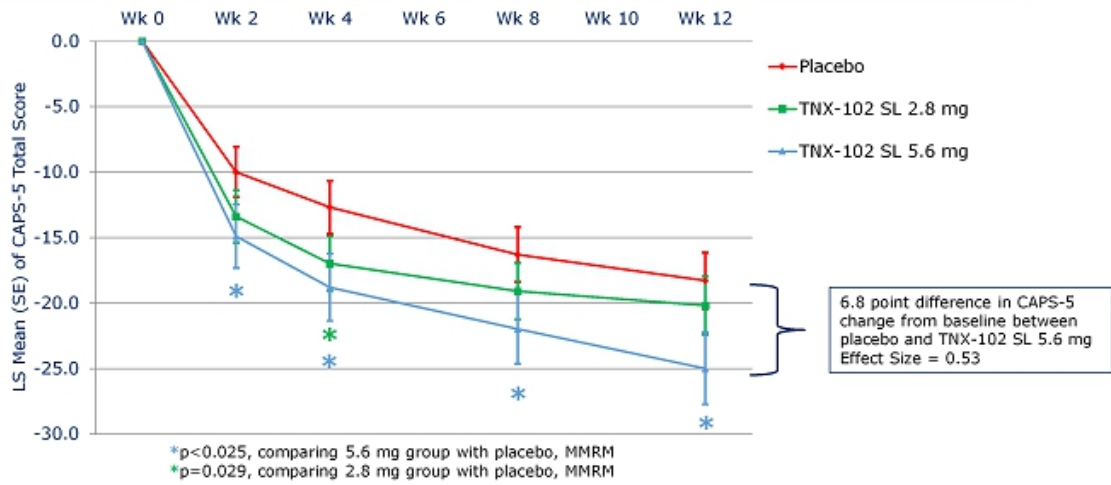


* MMRM, mixed-effects model repeated measures, $p < 0.05$

¹Sullivan, 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/2bF04mx>



Retrospective Analysis of CAPS-5 in patients with entry CAPS-5 ≥ 33 ¹



¹Primary analysis was TNX-102 SL 2.8 mg with entry CAPS-5 ≥ 29



Week 12 outcome measures for TNX-102 SL 5.6 mg vs. placebo in military-related PTSD for CAPS-5 ≥ 29 and CAPS-5 ≥ 33 at baseline

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Outcome Measure	PBO N=92, 5.6mg N=49; CAPS-5 ≥ 29		PBO N=77, 5.6mg N=38; CAPS-5 ≥ 33	
	ES ¹	p-value ²	ES ¹	p-value ²
CAPS-5				
Total score	0.36	0.053	0.53	*0.013
Cluster B (intrusion)	0.26	0.161	0.46	*0.026
Cluster C (avoidance)	0.04	0.963	0.12	0.522
Cluster D (mood/cognition)	0.35	0.062	0.39	0.065
Cluster E (arousal and reactivity)	0.35	*0.048	0.52	*0.012
E6 (Sleep item)	0.51	*0.010	0.51	*0.013
E2 (Reckless/Self Destruct)	0.15	0.140	0.30	*0.012
CGI-I (responders)	2.11	*0.041	2.29	*0.042
SDS				
Total Score	0.33	0.079	0.35	0.093
Work/School item	0.34	0.050	0.41	*0.040
Social/Leisure item	0.38	*0.031	0.35	0.116
Family Life/Home Responsibilities item	0.12	0.524	0.15	0.455

¹Cohen's d for CAPS-5 and Sheehan Disability Scale outcome measures; odds ratio from logistic regression for CGI-I.

²CAPS-5 and Sheehan Disability Scale outcome measures: p-values from mixed-effects model repeated measures statistical test on the mean change from baseline difference between TNX-102 SL 5.6 mg and placebo; CGI-I: p-values from a repeated measure logistic regression (Responder defined as a patient who was rated as "1" very much improved, or "2" much improved at week 12). *denotes statistical significance difference with $p < 0.05$, not adjusted for multiple comparisons; Abbreviations: 5.6 mg=TNX-102 SL 5.6 mg; CAPS-5=Clinician-Administered PTSD Scale for DSM-5; ES=Effect Size; N=number of patients; PBO=Placebo; SDS=Sheehan Disability Scale.



Week 12 outcome measures for TNX-102 SL 5.6 mg vs. placebo in combat PTSD subset for CAPS-5 ≥ 29 and CAPS-5 ≥ 33 at baseline

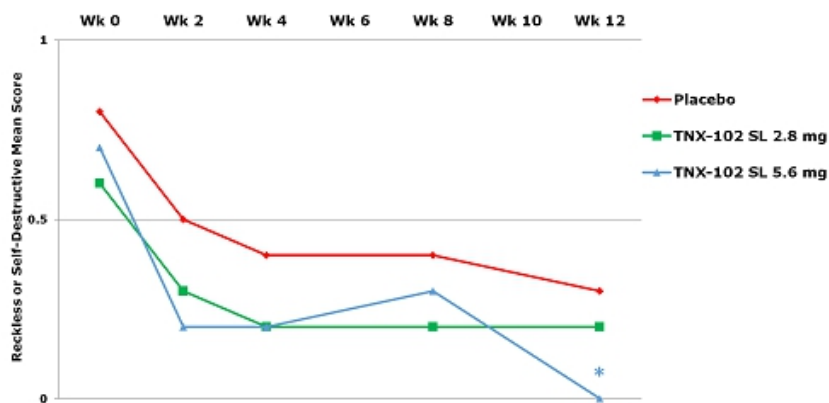
Outcome Measure	PBO N=74, 5.6mg N=46; CAPS-5 ≥ 29		PBO N= 64, 5.6mg N=35; CAPS-5 ≥ 33	
	ES ¹	p-value ²	ES ¹	p-value ²
CAPS-5				
Total score	0.42	*0.037	0.57	*0.013
Cluster B (intrusion)	0.26	0.183	0.50	*0.031
Cluster C (avoidance)	0.04	0.824	0.11	0.570
Cluster D (mood/cognition)	0.41	*0.035	0.42	0.061
Cluster E (arousal and reactivity)	0.40	*0.036	0.57	*0.012
E6 (Sleep item)	0.58	*0.003	0.58	*0.010
E2 (Reckless/Self Destruct)	0.15	0.178	0.30	*0.019
CGI-I (responders)	2.15	*0.049	2.12	0.082
SDS				
Total Score	0.41	*0.039	0.47	*0.032
Work/School item	0.40	*0.026	0.40	*0.015
Social/Leisure item	0.50	*0.013	0.51	*0.028
Family Life/Home Responsibilities item	0.19	0.328	0.22	0.274

¹Cohen's d for CAPS-5 and Sheehan Disability Scale outcome measures; odds ratio from logistic regression for CGI-I.

²CAPS-5 and Sheehan Disability Scale outcome measures; p-values from mixed-effects model repeated measures statistical test on the mean change from baseline difference between TNX-102 SL 5.6 mg and placebo; CGI-I: p-values from a repeated measure logistic regression (Responder defined as a patient who was rated as "1" very much improved, or "2" much improved at week 12). *denotes statistical significance difference with $p < 0.05$, not adjusted for multiple comparisons; Abbreviations: 5.6 mg=TNX-102 SL 5.6 mg; CAPS-5=Clinician-Administered PTSD Scale for DSM-5; ES=Effect Size; N=number of patients; PBO=Placebo; SDS=Sheehan Disability Scale.



Reckless or Self-Destructive Behavior Item on CAPS-5



Reckless or self-destructive behavior can include dangerous driving, high-risk thrill-seeking, excessive alcohol or drug use, injurious behaviors to self or others, or suicidal behaviors.

*p=0.012, TNX-102 SL 5.6 mg v. placebo, mixed model repeated measures



Phase 2 AtEase Study Conclusions

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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

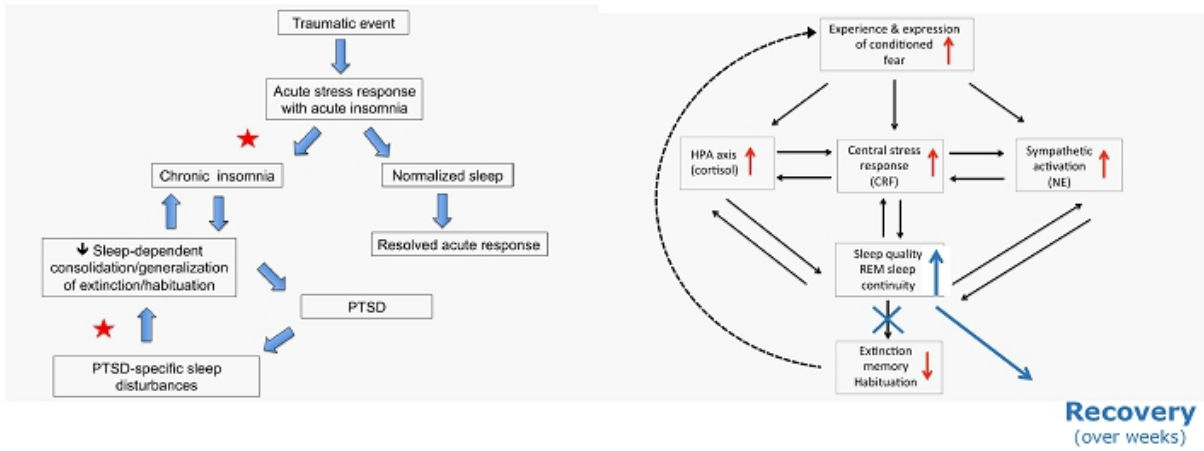
Comprehensive AtEase study results from scientific presentations available at:

<http://www.tonixpharma.com/research-development/scientific-presentations>



Hypothesized mechanism of action in PTSD

Attenuation of Sleep Disruption by TNX-102 SL Leads to Recovery



Diagrams adapted from Pace-Schott et al. Biol Mood Anxiety Disord 2015;5:3



Planned Phase 3 Program in PTSD

To confirm AtEase findings 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



Commercialization Options

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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



TNX-102 SL

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



Financial overview

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NASDAQ: TNXP

Cash, cash equivalents, and marketable securities reported at September 30, 2016	\$26.7 million
Net proceeds from underwritten offering in 4Q16	\$4.6 million
Shares outstanding (December 1, 2016)	39.2 million



Management Team

Seth Lederman, MD
President & CEO



Gregory Sullivan, MD
Chief Medical Officer



Bradley Saenger, CPA
Chief Financial Officer



Jessica Morris
EVP, Operations





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



Milestones – recent and upcoming

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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 Anticipated topline data from interim analysis of Phase 3 study in ~180 military-related PTSD patients



Summary

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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 expected to initiate in 1Q2017

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



TONIX
PHARMACEUTICALS
NASDAQ: TNXP

Thank you!

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Tonix Pharmaceuticals Presented New Clinical Results from Sub-Group Analysis of Phase 2 AtEase Study in Military-Related Posttraumatic Stress Disorder (PTSD)

Sub-Group Analysis of the Phase 2 AtEase Clinical Study Confirms TNX-102 SL's Potential Efficacy in Combat-Related PTSD Patients Who are the Most Difficult to Treat

New Results Presented in Poster Session at the American College of Neuropsychopharmacology (ACNP) Annual Meeting

NEW YORK, Dec. 8, 2016 – **Tonix Pharmaceuticals Holding Corp.** (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for PTSD, recently presented new results from a sub-group analysis of the data from the AtEase study, a 12-week, randomized, double-blind, placebo-controlled Phase 2 study evaluating TNX-102 SL*, 5.6 mg, in military-related PTSD.

The sub-group analysis focused on those patients whose index trauma in the AtEase study was directly related to combat. Patients were enrolled in the trial with military-related PTSD, which was defined by trauma during military service and included combat trauma, but also included non-combat trauma such as sex trauma. Combat-related PTSD represented the majority of index traumas in the AtEase study (85%; N=197). The combat-related PTSD sub-group was analyzed for those with baseline scores of the Clinician Administered PTSD Scale for the Diagnostic and Statistical Manual for Mental Illness, Edition 5, or CAPS-5, at baseline of ≥ 33 , as well as for the whole population with entry CAPS-5 ≥ 29 . The sub-group analysis confirmed that patients with combat-related PTSD and entry CAPS-5 ≥ 33 , treated with TNX-102 SL, 5.6 mg, showed improvement on total CAPS-5 severity, in addition to certain items in CAPS-5 cluster scores, such as reckless and self-destructive behavior. Functional improvement by the Sheehan Disability Scale total score, work and social items was also observed in the sub-group with CAPS-5 ≥ 33 , treated with TNX-102 SL, 5.6 mg.

Gregory Sullivan, M.D., chief medical officer of Tonix, presented these findings at the 55th Annual Meeting of the American College of Neuropsychopharmacology on December 7, 2016 in Hollywood, FL, in a poster session. The poster showcasing this new data, and titled “The AtEase Study: A Phase 2 Multicenter Randomized Clinical Trial of the Safety and Efficacy of TNX-102 SL* in the Treatment of Military-Related PTSD,” can be found on [Tonix's website](#) on the [Scientific Presentations](#) page.

Dr. Sullivan commented, “The data from this sub-group analysis is very exciting and reassuring since, typically, combat-related PTSD is the most difficult to treat, and TNX-102 SL can be an important treatment option for this group based on this sub-group analysis. The retrospective analysis of the CAPS-5 ≥ 33 subset is relevant to our Phase 3 plan, because CAPS-5 ≥ 33 will be the enrollment criteria for future registration studies.”

Seth Lederman, M.D., president and chief executive officer of Tonix, added, “This combat-related PTSD sub-group analysis confirms that TNX-102 SL has the potential to improve the health and function of military veterans suffering from PTSD, including those whose trauma directly resulted from events experienced in the combat theater. We are committed to developing a treatment solution for military-related PTSD, and Tonix remains on target to initiate the first of the two 12-week, randomized, double-blind, placebo-controlled Phase 3 studies in military-related PTSD in the first quarter of 2017.”

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

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 posttraumatic stress disorder. This disorder is a serious condition 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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