

**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): January 3, 2017

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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Corporate Presentation by the Company for January 2017*

* 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: January 3, 2017

By: /s/ SETH LEDERMAN

Seth Lederman

Chief Executive Officer

 **Investor Presentation**



January 2017

Version P0045 1-3-17

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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.



Tonix (TNXP): Developing Innovative Pharmaceutical Products to Address Emerging Public Health Issues

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Targeting central nervous system conditions

- Phase 3-ready drug, TNX-102 SL* for posttraumatic stress disorder (PTSD) with **Breakthrough Therapy designation**
 - Encouraging evidence of safety and efficacy was demonstrated in Phase 2 AtEase trial of **military-related PTSD** formed the basis of the Breakthrough Therapy designation
 - Regulatory clarity for PTSD based on U.S. Food and Drug Administration (FDA) acceptance of PTSD Phase 3 clinical program at End-of-Phase 2 meeting
 - Expedited development and accelerated review are expected
- Second clinical candidate for PTSD with a different mechanism in pre-clinical development

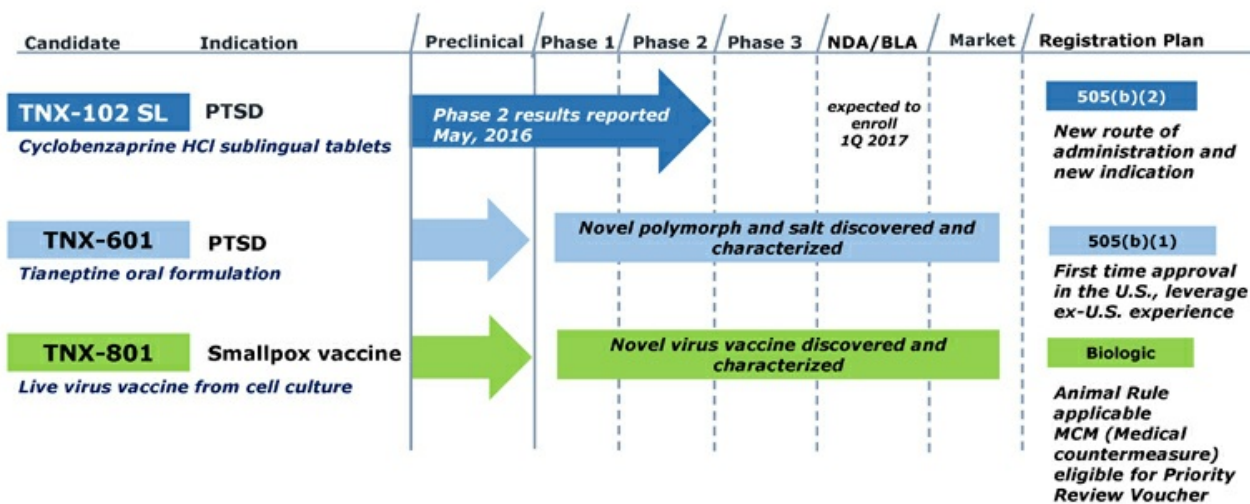
Other development efforts includes a smallpox preventing vaccine program which leverages our government affairs efforts and capabilities

- Development of medical countermeasure drugs and biologics is incentivized with Priority Review Voucher by the recently enacted "21st Century Cures Act"

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

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Product Pipeline





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
 - ✓ Designated Breakthrough Therapy for expedited development and review
 - ✓ Initial Breakthrough Therapy meeting with FDA scheduled 1Q 2017
 - ✓ Targeting commencement of Phase 3 study in military-related PTSD in 1Q 2017

Targeting An Emerging Public Health Issue

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 standard-of-care 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



PTSD characteristics

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- **Unmet medical need**
 - PTSD is a serious condition and the prevalence is increasing, especially combat PTSD
 - 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 for DSM-5, "CAPS-5"
- **Potential development and partners**
 - Several companies have U.S. psychiatry-focused specialty sales forces
 - Department of Defense (DoD) is interested in military-related PTSD and has the capacity to support basic science and clinical development
- **Important target population**
 - U.S. veterans are in great need of a medicine that works for this serious condition



Breakthrough Therapy designation

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- **FDA granted TNX-102 SL Breakthrough Therapy designation – reported December 19, 2016**
 - PTSD is a serious condition
 - TNX-102 SL has the potential to have advantages over existing therapies in military-related PTSD
- **Benefits of Breakthrough Therapy designation**
 - Eligibility for priority review of the New Drug Application (NDA) within 6 months instead of 10 months
 - Option to submit completed portions of the NDA for rolling review
 - An organizational commitment involving FDA's senior managers to accelerate the development and approval process, an opportunity to compress development time



What is PTSD?

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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 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



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:

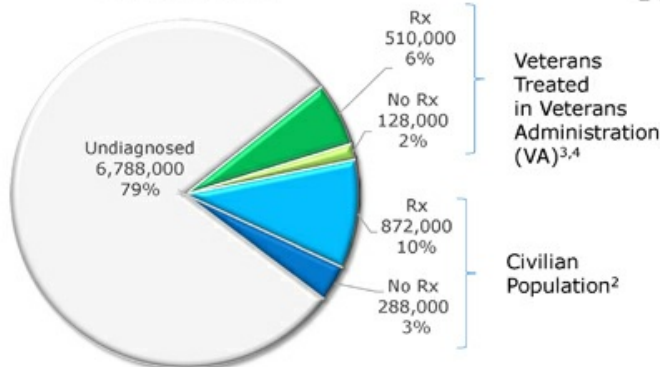
- Effective therapy for populations not well served by current treatment (males, military trauma)
- Alternative therapy for the majority of patients unresponsive or intolerant to current treatments
- Drug therapy compatible and complementary with behavioral therapy

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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)

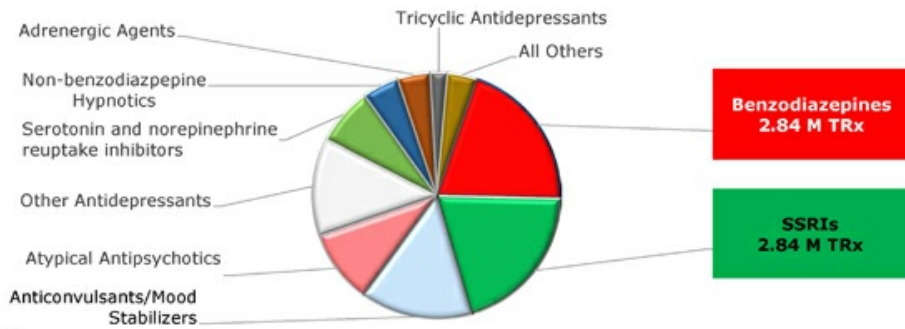


What Drug Classes are Used to Treat PTSD?

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's 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	<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

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}
 - α₁-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}, α₁-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 \geq 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

- 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



AtEase Study: Traumas Associated with PTSD

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



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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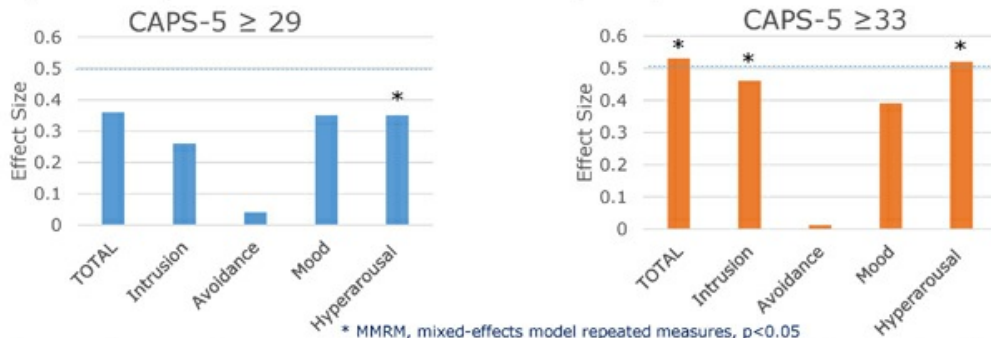
AtEase: Retrospective Analysis for TNX-102 SL 5.6 mg

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

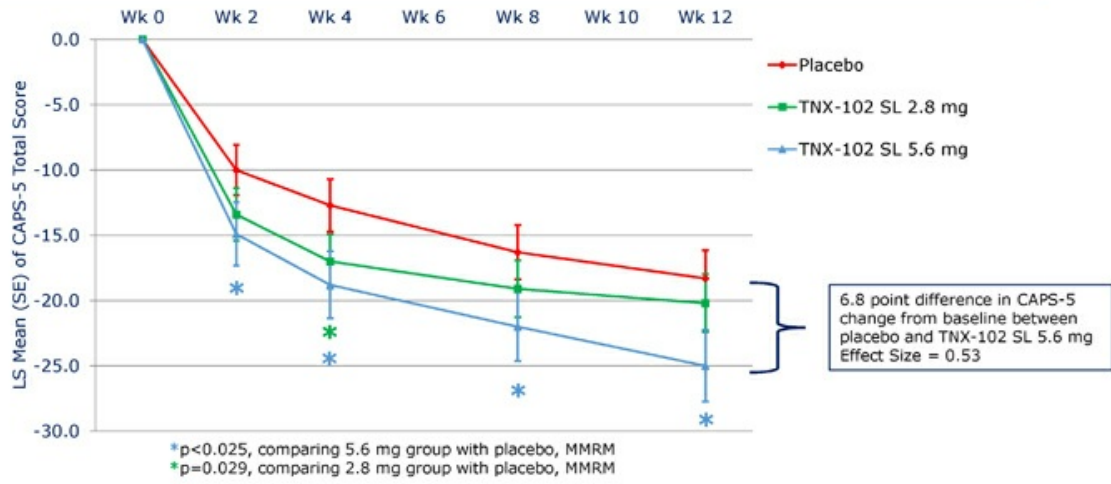


* MMRM, mixed-effects model repeated measures, $p < 0.05$

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/2bFo4mx>



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



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

CAPS-5 at Baseline	Military-related PTSD		Combat PTSD	
	≥ 29	≥ 33	≥ 29	≥ 33
N: PBO/TNX-102 SL 5.6 mg	92/49	77/38	74/46	64/35
Outcome Measure	p-value ¹	p-value ¹	p-value ¹	p-value ¹
CAPS-5				
Total score	0.053	*0.013	*0.037	*0.013
Cluster B (intrusion)	0.161	*0.026	0.183	*0.031
Cluster C (avoidance)	0.963	0.522	0.824	0.570
Cluster D (mood/cognition)	0.062	0.065	*0.035	0.061
Cluster E (arousal and reactivity)	*0.048	*0.012	*0.036	*0.012
E6 (Sleep item)	*0.010	*0.013	*0.003	*0.010
E2 (Reckless/Self Destruct)	0.140	*0.012	0.178	*0.019
CGI-I (responders)	*0.041	*0.042	*0.049	0.082
SDS				
Total Score	0.079	0.093	*0.039	*0.032
Work/School item	0.050	*0.040	*0.026	*0.015
Social/Leisure item	*0.031	0.116	*0.013	*0.028
Family Life/Home Responsibilities item	0.524	0.455	0.328	0.274

¹CAPS-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; N=number of patients; PBO=Placebo; SDS=Sheehan Disability Scale.



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)
- ✓ Evidence of meaningful clinical improvement supports the Breakthrough Therapy designation

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>



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 $N \sim 275$ (90*)

Placebo once-daily at bedtime
 $N \sim 275$ (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 ($N \sim 180$) 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

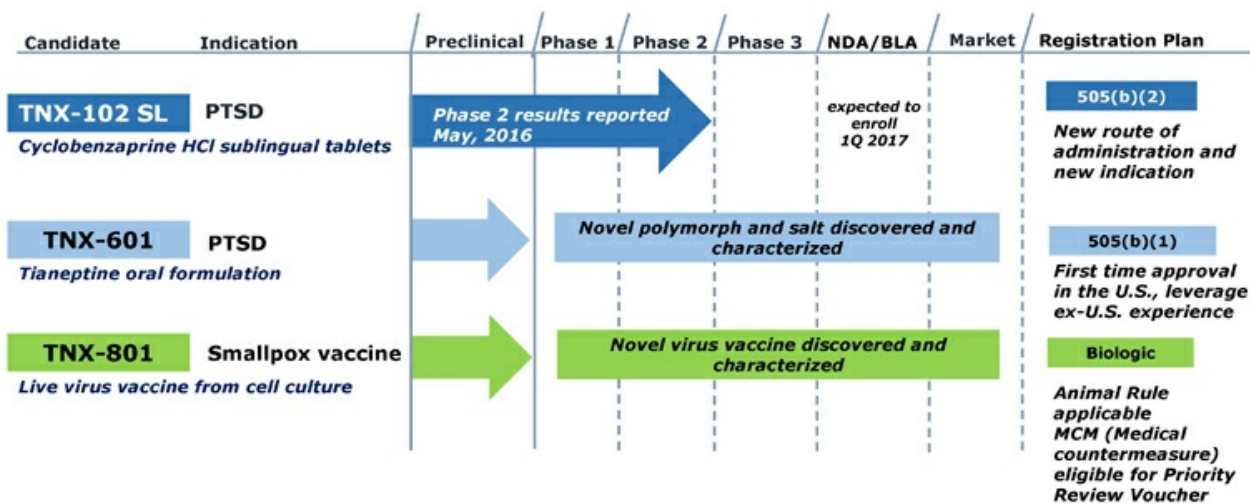
Pharmacokinetics (PK)

- Patents filed
- Protection expected to 2033

Method-of-use

- PTSD: patents filed

Product Pipeline





TNX-601- A Potential Clinical Candidate for PTSD

TNX-601 (tianeptine oral formulation)

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Preclinical Program

- Targeted as the 1st line monotherapy for **PTSD**: daytime dosing
 - ✓ Leverages expertise in PTSD (clinical and regulatory experience, market analysis, etc.)
 - ✓ Mechanism of Action (MOA) is different from TNX-102 SL
- Active ingredient approved in EU, Russia, Asia and Latin America for depression with established post-marketing experience
- Reformulate using identified a new salt polymorph with improved pharmaceutical properties
 - ✓ Filed patent application on novel salt polymorph
- Issued patent on steroid-induced cognitive impairment and memory loss issues
- GMP synthesis developed
- IND-enabling nonclinical studies and formulation development can proceed simultaneously

Targeting An Important Market

Clinical evidence for PTSD

- Several studies have shown tianeptine to be active in the treatment of PTSD^{1,2,3,4}
- US clinical development benefited from the dose identified and dosing regimen developed ex-U.S.

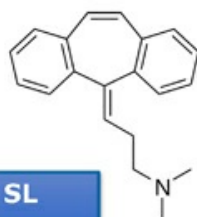
1. Frančičković T, Suković Z, Janović S, Stevanović A, Nemčić-Moro I, Rončević-Gržeta I, Letica-Crepuja M. Tianeptine in the combined treatment of combat related posttraumatic stress disorder. *Psychiatr Danub*. 2011 Sep;23(3):257-63. PMID: 21963693
2. Rumyantseva GM(1), Stepanov AL. Post-traumatic stress disorder in different types of stress (clinical features and treatment). *Neurosci Behav Physiol*. 2008 Jan;38(1):55-61. DOI: 10.1007/s11055-008-0008-0 PMID: 18097761
3. Aleksandrovskii IA, Avedisova AS, Boev IV, Bukhanovskii AO, Voloshin VM, Tsygankov BD, Shamrei BK. Efficacy and tolerability of coamil (tianeptine) in the therapy of posttraumatic stress disorder. *Zh Nevrol Psikhiatr Im S S Korsakova*. 2005;105(11):24-9. PMID: 16329631 [Russian]
4. Onder E, Tural U, Aker T. A comparative study of fluoxetine, moclobemide, and tianeptine in the treatment of posttraumatic stress disorder following an earthquake. *Eur Psychiatry*. 2006 Apr;21(3):174-9. Epub 2005 Jun 17. DOI: 10.1016/j.eurpsy.2005.03.007 PMID: 15964747



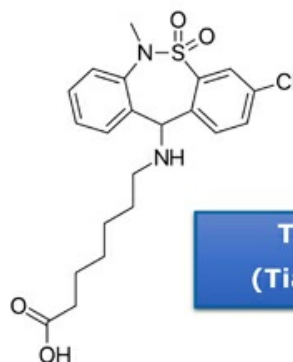
Structural Comparison: TNX-102 SL and TNX-601

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- Cyclobenzaprine and tianeptine share structural similarities with classic tricyclic antidepressants (TCAs) and to each other, but each has unique pharmacological properties
 - Tianeptine has a 3-chlorodibenzothiazepine nucleus with an aminoheptanoic side chain
- Tianeptine leverages Tonix's expertise in pharmacology and pharmaceuticals of tricyclics



TNX-102 SL
(Cyclobenzaprine)



TNX-601
(Tianeptine)



TNX-601 - A Potential Clinical Candidate for PTSD

- **Active Pharmaceutical Ingredient (API) is a novel salt of tianeptine**

- Shares structural features with tricyclic antidepressants, but has unique pharmacological and neurochemical properties¹
- Tianeptine sodium (amorphous) is marketed for depression in Europe, Asia, Latin America – first approved in France in 1987

Mechanism of Action

- **Tianeptine modulates the glutamatergic system indirectly**
 - Does not have significant affinity ($K_i > 10\mu\text{M}$) for NMDA² or AMPA³ receptors
- **Tianeptine is a weak μ -opioid receptor (MOR) agonist**
 - Controlled substance in France, Belgium and Singapore
- **Tianeptine has been shown to oppose deleterious effects of chronic stress on brain structure and plasticity**
- **Established profile of safety from ex-U.S. use**

Unique Characteristics of TNX-601

- **TNX-601: Novel salt and polymorph of tianeptine**
 - Improved stability, consistency and manufacturability
 - Benefited from human experience established in ex-U.S. approved countries
- **5 year Hatch-Waxman exclusivity for first time approval in the U.S.**
- **Patent filed on novel salt and polymorph**

1. McEwen, Bruce S., et al. The neurobiological properties of tianeptine (Stablon): from monoamine hypothesis to glutamatergic modulation. *Molecular psychiatry*. 2010; 15.3: 237-249.
2. N-methyl-D-aspartate,
3. α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid



TNX-801 - A Potential Smallpox Preventing Vaccine

Pre-IND
Candidate

TNX-801 (live virus vaccine)

- Targeting a biological warfare threat: **smallpox**
 - ✓ Leverages government affairs effort
- Tonix has identified a new vaccine with improved properties
 - ✓ Patent application on novel vaccine submitted

Regulatory strategy

- FDA's "Animal Rule" can be applied to establish human efficacy
- GMP virus in development for human safety study

Targeting An
Important
Market

Material threat medical countermeasure (MCM) – under 21st Century Cures Act

- Qualifies for receiving **Priority Review Voucher** on approval
 - ✓ Priority Review Vouchers are transferrable and have sold for >\$300 M
- ACAM2000 developed by Acambis was acquired by Sanofi in 2008 for \$513 M
 - ✓ ACAM2000 was sold to U.S. Strategic National Stockpile¹

1. Nalca, A et al. ACAM2000: the new smallpox vaccine for the U.S. Strategic National Stockpile/ Drug design, development and Therapy: 4:71-79 (2010)
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TNX-801 - A Potential Smallpox Preventing Vaccine

- **Active biological ingredient is live virus**
 - Shares structural characteristics to vaccinia-based vaccines, but has unique virulence properties that suggest lower toxicity¹
 - Smallpox has a ~30% mortality rate in naïve populations – vaccination discontinued in U.S. in 1970's

Mechanism of Action

- **Live virus vaccines stimulate cross-reactive immunity**
 - Protects from consequences of infection with variola virus (smallpox agent)
 - Renders recipient "immune" and protects population (even un-immunized) by decreasing spread of infection

Unique Characteristics of TNX-801

- **Potential safety advantage over existing vaccinia vaccines**
 - Cardiotoxicity limits use of existing vaccines
- **Exclusivity**
 - Patent filed on novel virus composition
 - 12 years exclusivity under the Patient Protection and Affordable Care Act

1. Tonix, unpublished data



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 (January 3, 2017)	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

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ALZA, Glaxo, Reliant Pharma

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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 Reported results from AtEase study
- August 2016 End-of-Phase 2 meeting with FDA
 - Proposed Phase 3 clinical and NDA plan accepted
- December 2016 Breakthrough Therapy designation granted by FDA
- January 2017 FDA concurrence with protocol for Phase 3 study in military-related PTSD
- 1Q 2017 FDA Initial Comprehensive Interdisciplinary Breakthrough Therapy Meeting
- 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 including military-related PTSD

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

TNX-102 SL for PTSD is designated as a Breakthrough Therapy by FDA

- Accelerated development and approval process is expected

Funded through 1st interim analysis (180 patients) of Phase 3 PTSD trial expected to initiate in 1Q 2017

- Topline data from 1st interim analysis expected to be available 2H 2017



TONIX
PHARMACEUTICALS
NASDAQ: TNXP

Thank you!

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