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): March 20, 2017

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 two updated investor presentations 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. Copies of the two presentations are filed as Exhibits 99.01 and 99.02.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01 and 99.02, 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 Exhibits 99.01 and 99.02, 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 March 2017*
99.02	Short Corporate Presentation by the Company for March 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: March 20, 2017

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

Exhibit 99.01

Investor Presentation

TONIX PHARMACEUTICALS

March 2017

Version P0054 3-15-17

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 Tonix 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 Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

Tonix (TNXP): Developing Innovative Pharmaceutical Products to Address Current and Emerging Public Health Challenges

Targeting central nervous system conditions

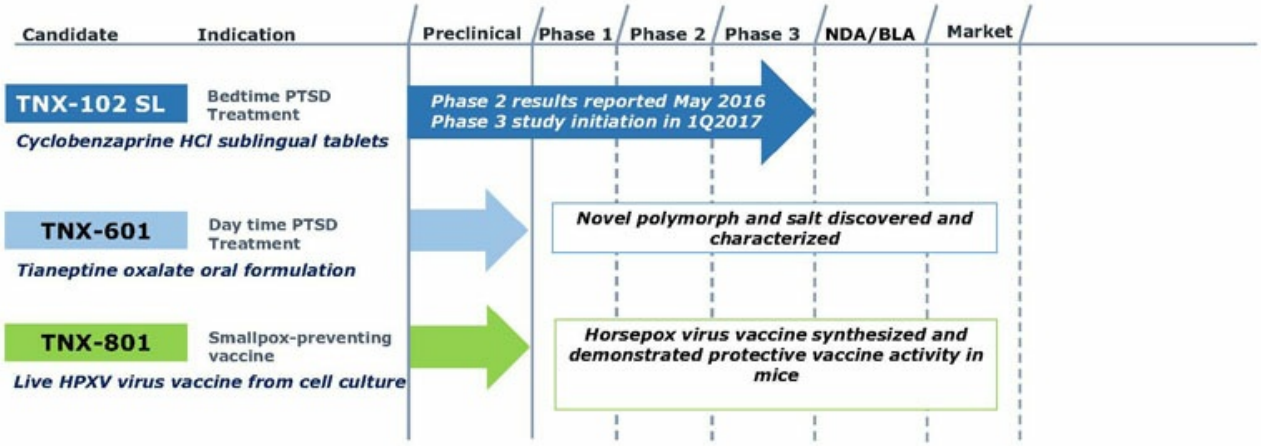
- In Phase 3 development, TNX-102 SL* for posttraumatic stress disorder (PTSD) with **Breakthrough Therapy designation** from the U.S. Food and Drug Administration (FDA)
  - Encouraging evidence of safety and efficacy was demonstrated in Phase 2 AtEase trial of **military-related PTSD** formed the basis of the Breakthrough Therapy designation
  - Regulatory clarity for PTSD based on 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 of action in pre-Investigational New Drug (IND) stage 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

Product Pipeline



Tonix Pharmaceuticals PTSD Program

Phase 3 Development

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 FDA[1]**
  - ✓ **Designated Breakthrough Therapy for expedited development and review**
  - ✓ **Initial Breakthrough Therapy multidisciplinary meeting held with FDA in March 2017**
  - ✓ **Initiation of Phase 3 study in military-related PTSD expected in March 2017**

Targeting a Current and Emerging Public Health Challenge

PTSD

- High prevalence worldwide and receiving greater attention
- Not well served - high off-label usage[2] with unproven or contraindicated treatments[3]
- 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

- **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

- **FDA granted TNX-102 SL Breakthrough Therapy designation – reported December 19, 2016**
  - PTSD is a serious condition
  - TNX-102 SL has potential 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?

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[2]
  - *Twelve month prevalence:* *U.S.* 3.5%[3] (~ 8.6 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

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?

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:

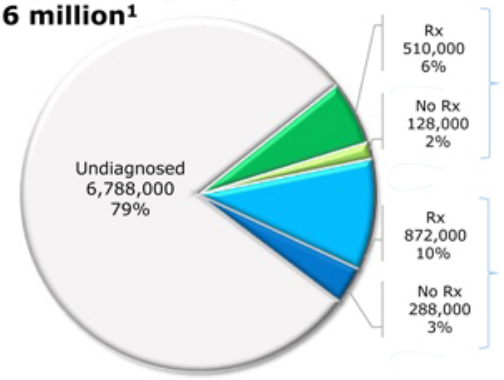
- Depression
- Alcohol or substance abuse
- Absenteeism/unemployment
- Homelessness
- Violent acts
- Suicidal thoughts and suicide

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

PTSD Prevalence and Market Characteristics

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



Veterans Treated in Veterans Administration (VA)[3,4]

Civilian Population[2]

Diagnosed population

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

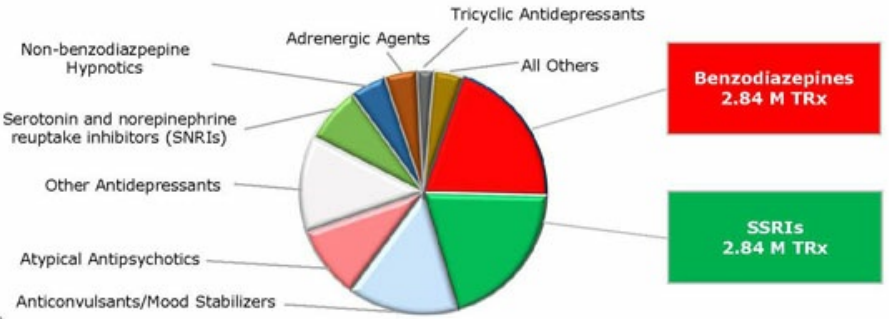
1. Kessler, et al., 2005; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
2. IMS Consulting, *Market Sizing & Treatment Dynamics: "Post-Traumatic Stress Disorder (PTSD) Patients"*, 2016
3. Bowe and 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 indicated)[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

Sleep Disturbances Are a Core Feature Of PTSD[1]

Sleep disturbances are a core feature of PTSD and a component of three of the four major symptom clusters:

Diagnostic Criteria for PTSD (DSM-5)[2]
B. Presence of one (or more) intrusion symptoms
C. Persistent avoidance of stimuli associated with traumatic event
D. Negative alterations in cognitions and mood
E. Marked alterations in arousal and reactivity

[1]Germain A. *Am J Psychiatry*. 2013; [2]American Psychiatric Association. *Diagnostic and statistical manual of mental disorders*. 5th ed. Arlington, VA: American Psychiatric Publishing; 2013.

What Is Restorative Sleep?

Restorative Sleep Hypothesis[1]: Sleep is an **active**, necessary state for **processing emotionally charged memories**, replenishing energy, and resetting homeostasis to circuitry in the brain

ENERGY

Homeostasis

Sleep Deprivation
Sleep Disturbances

Depression, Chronic Pain, Anxiety, and PTSD

[1]Germain A. *Am J Psychiatry*. 2013.

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**

TNX-102 SL: Proprietary Patented[1] Formulation

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[2]

Different from other tricyclics

- **CBP is more selective for high affinity sites believed to have a role in sleep quality[3]**
  - 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: Proprietary sublingual formulation of CBP

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

1. Notice of Allowance for Eutectic Proprietary Protectic™ Formulation Patent
2. Rudorfer and Potter, *Cellular and Molecular Neurobiology, 1999 19:373*
3. Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015,Toronto Ontario, Canada

High Prevalence of PTSD Among Combat Veterans

3-9%
General population[1]

19-31%
Vietnam veterans[2]

>19%
Operation Enduring Freedom (OEF; Afghanistan) / Operation Iraqi Freedom (OIF) veterans / Operation New Dawn (OND)[3]

8.6 million American adults affected[1]

Women more likely to develop than men[1]

Susceptibility may **run in families**[1]

[1]Kessler et al., *Arch Gen Psych* 2005; Prevalence rate of 3.5% applied to U.S. Census estimate of 247M U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00); [2]Norris, *PTSD Res Quar.* 2013; [3]*Analysis of VA Health Care Utilization among Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn Veterans, from 1st Qtr FY 2002 through 2nd Qtr FY 2015,* Washington, DC; Among 1.9M separated OEF/OIF/OND Veterans, 1.2M have obtained VA healthcare; 685k evaluated by VA with possible mental disorder, and 379k diagnosed with PTSD.

Growing Economic and Social Burden to Care for Veterans with PTSD

Health care costs associated with PTSD for OEF/OIF/OND veterans:

Direct costs

$3,000-5,000
per patient per year for OEF/OIF Veterans[1]

~ 2.7 million
troops deployed between 10/1/2001 and 3/31/2015[3]

Indirect costs

$2-3 billion
estimated yearly cost to society[2]

Families, social care agencies, schools, employers, welfare system[2]

[1]CBO Report 2012; [2]Tanielan, *Invisible Wounds of War*. 2005; [3]*Analysis of VA Health Care Utilization among Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn Veterans, from 1st Qtr FY 2002 through 2nd Qtr FY 2015,* Washington, DC; OEF/OIF/OND, Operations Enduring Freedom, Iraqi Freedom and New Dawn.

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 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 subgroup[2]
  Paroxetine: no sex-related difference in treatment outcomes[3]

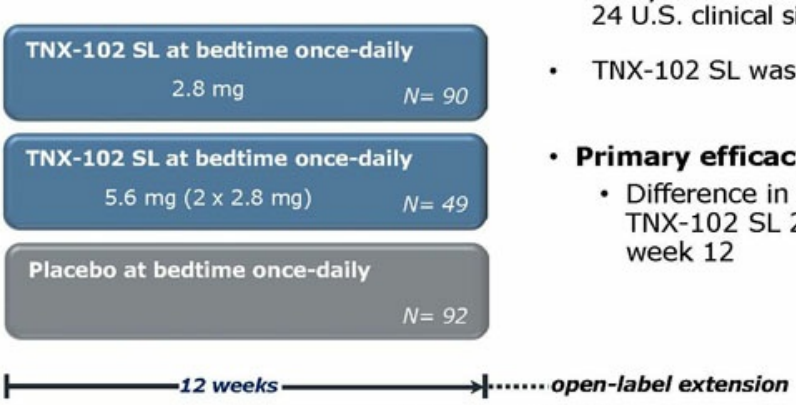
- **Important tolerability issues with SSRIs in this population**

  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

Phase 2 AtEase Study in Military-Related PTSD

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



- 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

- **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

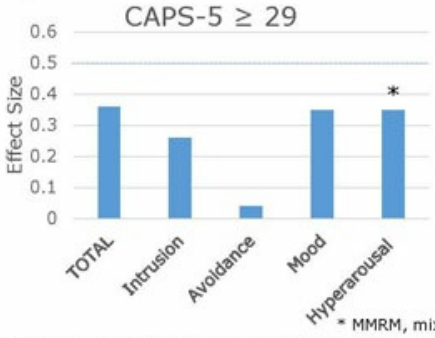
AtEase: Retrospective Analysis for TNX-102 SL 5.6 mg

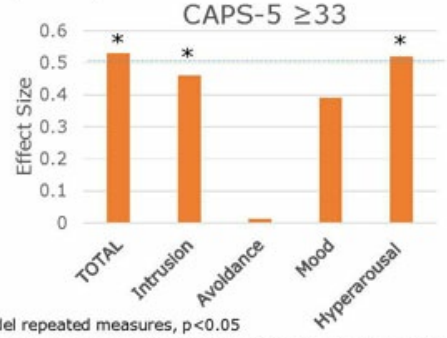
Prior pharmacotherapy trials in PTSD used *earlier versions* of CAPS (e.g. CAPS-2)

- 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

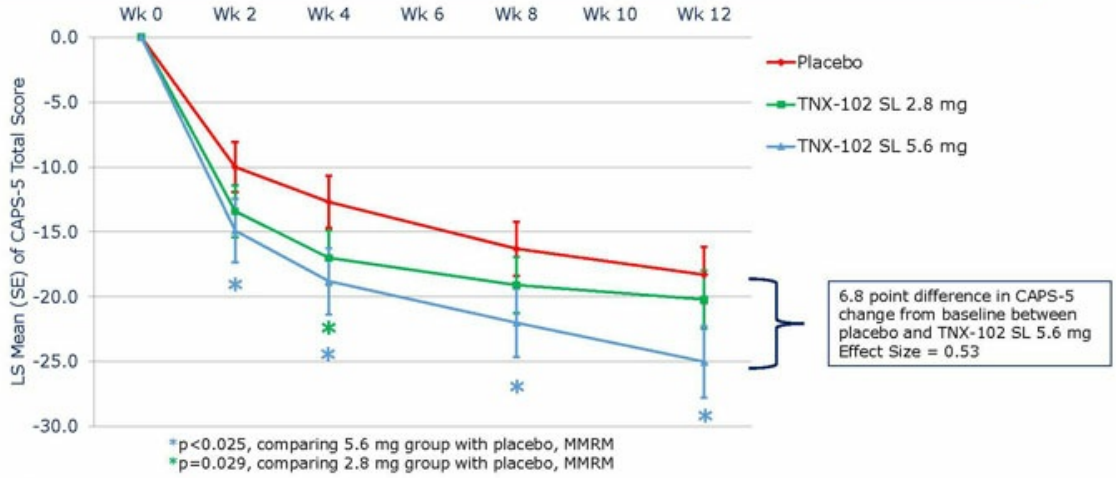




* MMRM, mixed-effects model repeated measures, p<0.05

[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

Retrospective Analysis of CAPS-5 in Patients with Entry CAPS-5 ≥ 33[1]



[1]Primary 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

	Military-related PTSD		Combat PTSD	
CAPS-5 at Baseline	**≥ 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

[1]CAPS-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

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 HONOR Study 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 (140*)*

Placebo once-daily at bedtime
N ~ 275 (140)*

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

* *Interim analysis*

General study characteristics:

- Randomized, double-blind, placebo-controlled, entrance CAPS-5 ≥ 33
- One unblinded interim analysis (IA) by an independent data monitoring committee at 50% recruitment
- IA (N ~275) for efficacy stop, continuation as planned or sample size adjustment
- Potential to enroll 550 patients
- Approximately 35 U.S. clinical sites

Primary efficacy endpoint:

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

1H 2018 - IA outcome anticipated
2H 2018 – topline data anticipated, if 550 patients are studied

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

Intellectual Property

TNX-102 SL

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

Composition-of-matter (eutectic)

- Notice of Allowance issued by U.S. Patent and Trademark Office
- Additional claims and jurisdictions pending
- Protection expected to 2034

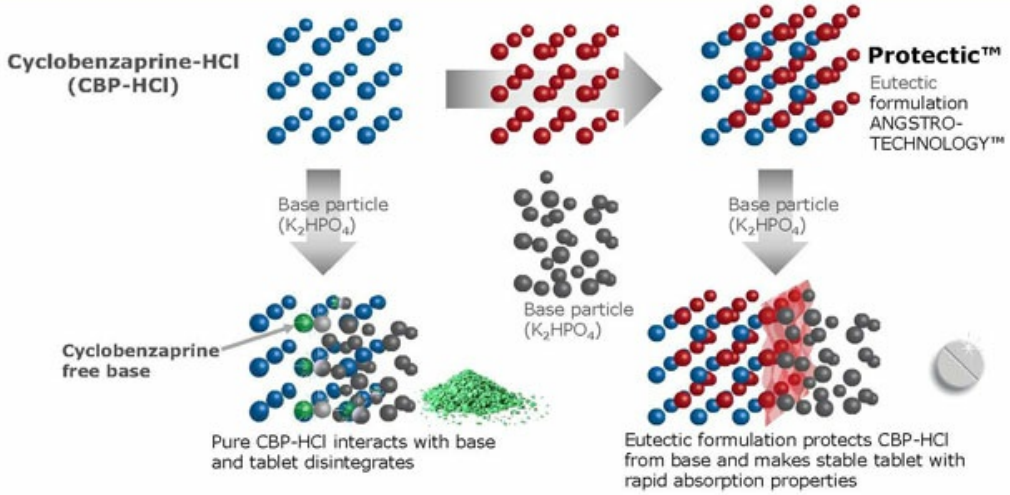
Pharmacokinetics (PK)

- Patents filed
- Protection expected to 2033

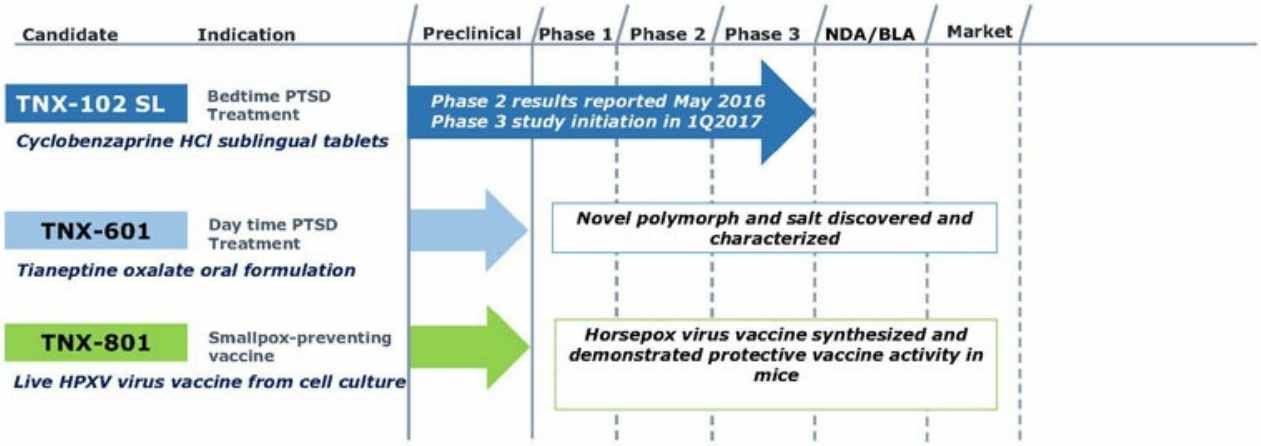
Method-of-use

- PTSD: patents filed

Proprietary Cyclobenzaprine Hydrochloride Eutectic Mixture Stabilizes Tablet Formulation



Product Pipeline



TNX-601 - A Potential Clinical Candidate for PTSD

TNX-601 (tianeptine oxalate oral formulation)

Pre-IND Candidate

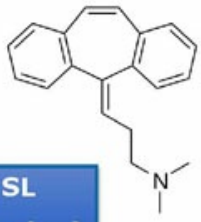
Targeting a Public Health Challenge

- Targeted as a 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**
- Tianeptine sodium (amorphous) has been approved in EU, Russia, Asia and Latin America for depression since 1987 with established post-marketing experience
- Identified new oxalate salt polymorph with improved pharmaceutical properties ideal for reformulation
- **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
- **Clinical evidence for PTSD**
- Several studies have shown tianeptine to be active in the treatment of PTSD[1-4]
- US clinical development benefited from the dose identified and dosing regimen developed ex-U.S.

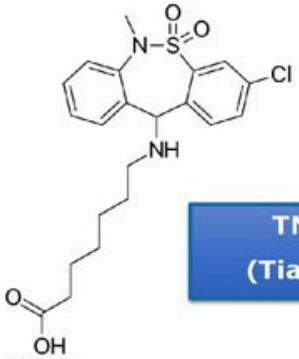
1. Frančišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
2. Rumyantseva GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
3. Aleksandrovskiĭ IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
4. Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747

Structural Comparison: TNX-102 SL and TNX-601

- 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 the pharmacology and development of tricyclics



TNX-102 SL
(Cyclobenzaprine)



TNX-601
(Tianeptine)

TNX-601: A Potential Clinical Candidate for PTSD

- **API is a novel oxalate salt of tianeptine**
  - Shares structural features with tricyclic antidepressants, but has unique pharmacological and neurochemical properties[1]

Mechanism of Action

- **Tianeptine modulates the glutamatergic system indirectly**
  - Does not have significant affinity (K_i>10μM) for NMDA[2] or AMPA[3] receptors
- **Tianeptine is a weak μ-opioid receptor (MOR) agonist**
  - Controlled substance in France, Bahrain and Singapore
- **Tianeptine has been shown to oppose deleterious effects of chronic stress on brain structure and plasticity**

Important Characteristics of TNX-601

- **TNX-601: Novel oxalate salt and polymorph of tianeptine**
  - Improved stability, consistency and manufacturability
  - Benefited from human experience established in ex-U.S. approved countries
  - Potential safety and efficacy evidence in published PTSD studies[4-7]
- **5 year Hatch-Waxman exclusivity for first time approval in the U.S.**
- **Patent filed on novel oxalate 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
4. Frančišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
5. Rumyantseva GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
6. Aleksandrovskiĭ IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
7. Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747

TNX-801: A Potential Smallpox-Preventing Vaccine

Pre-IND Candidate

TNX-801 (live virus vaccine - synthetic Horsepox (HPXV) vaccine)

- Potential improvement over current methods for biodefense against **smallpox**
  - ✓ **Leverages government affairs effort**
- Tonix is developing a new vaccine (TNX-801) with improved properties
  - ✓ **Collaboration with Professor David Evans and Dr. Ryan Noyce at University of Alberta**
  - ✓ **Protective vaccine activity in mice has been demonstrated**
  - ✓ **Patent application on novel vaccine submitted**

Regulatory strategy

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

Targeting a Public Health Issue

Material threat medical countermeasure under 21st Century Cures Act

- Qualifies for receiving **Priority Review Voucher** on approval
  - ✓ **Priority Review Vouchers are transferrable and have sold for ~$125 M**
- ACAM2000 vaccine developed by Acambis was acquired by Sanofi in 2008 for $513 M
  - ✓ **ACAM2000 was sold to U.S. Strategic National Stockpile[1]**

1. Nalca, A et al. Drug design, development and Therapy: 4:71-79 (2010)

TNX-801: Synthetic Live Horsepox Virus (HPXV)

Synthesis from sequence of a 1976 Mongolian isolate[1]

In mice, TNX-801 behaved like attenuated vaccinia virus (vaccinia virus is foundation of current smallpox vaccines)

How is horsepox related to modern vaccines?

- Multiple sources[2-4] indicate that the smallpox vaccine discovered by Dr. Edward Jenner in the early 19th century was likely a horsepox virus
- Evidence indicates that modern smallpox vaccines descend from a HPXV-like ancestral strain
- Horsepox is now believed to be extinct[4]

1. Tulman et al., Journal of Virology, 2006; 80(18): 9244-9258.
2. Qin et al., Journal of Virology, 2011; 85(24):13049-13060.
3. Medaglia et al., Journal of Virology, 2015; 89(23):11909-11925.
4. Esparza J. Veterinary Record. 2013; 173: 272-273.

Horsepox - Better Tolerability as a Vaccine?

- Horsepox is caused by HPXV and is characterized by mouth and skin eruptions
- HXPV isolate from the 1976 outbreak later sequenced
- Modern vaccinia virus smallpox vaccines are associated with cardiotoxicity; may have acquired undesirable properties not present in an ancestral virus (likely HPXV)
- Horsepox has potential for slower proliferation or decreased toxicity

A Better Smallpox-preventing Vaccine is Important and Necessary Today

- Smallpox was eradicated as a result of global public health campaigns
- No cases of naturally-occurring smallpox have been reported since 1977
- Accidental or intentional transmission of smallpox does not require a natural disease reservoir
- Stockpiles of smallpox-preventing vaccines are currently maintained and refreshed in case of need

TNX-801: A Potential Medical Countermeasure

- **21st Century Cures Act (2016), Section 3086**
  - Encouraging treatments for agents that present a national security threat
- **Medical countermeasures are drugs or vaccines intended to treat:**
  - Biological, chemical, radiological, or nuclear agents that present a national security threat
  - Harm from a condition that may be caused by administering a drug or biological product against such an agent
- **New priority review voucher program for "material threat medical countermeasures"**
- **Priority review voucher may be transferred or sold**

TNX-801: A Potential Smallpox-Preventing Vaccine

Synthetic live virus HPXV TNX-801

- Shares structural characteristics with vaccinia-based vaccines
- Unique properties that suggest lower toxicity
- Smallpox has a ~30% mortality rate in vaccine-naïve populations

Mechanism of Action

Live virus vaccines stimulate cross-reactive immunity

- Protects from consequences of infection with smallpox agent
- Renders recipient "immune"
- Provides additional protection of non-immunized population

Important Characteristics of TNX-801

Potential safety advantage over existing vaccines

- Cardiotoxicity limits use of existing vaccines

Exclusivity

- Patent filed on novel virus composition
- Anticipate 12 years exclusivity

Management Team

Seth Lederman, MD President & CEO	TARGENT, Fusilev (evoleucovorin) for injection, vela
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

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

TNX-102 SL – Posttraumatic Stress Disorder

☑	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 design for Phase 3 HONOR study in military-related PTSD
☑	1Q 2017	Initial Multidisciplinary Breakthrough Therapy Meeting with FDA
☑	1Q 2017	Notice of Allowance for Eutectic Proprietary Protectic™ Formulation Patent
☐	1Q 2017	Target commencement of Phase 3 HONOR study
☐	1H 2018	Anticipated interim analysis of Phase 3 HONOR study in ~275 participants
☐	2H 2018	Anticipated topline results of Phase 3 HONOR study in 550 participants (if needed)

Summary

Strong position for value growth with Phase 3 development 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

Phase 3 HONOR study in military-PTSD expected to initiate in 1Q 2017

- Outcome of the interim analysis on ~275 participants expected to be available 1H 2018
- Topline results from 550 participants, if needed, expected to be available 2H 2018

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!

Exhibit 99.02

Investor Presentation

TONIX PHARMACEUTICALS

March 2017
Oral Presentation

Version P0055 3-15-17

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 Tonix 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 Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

Tonix (TNXP): Developing Innovative Pharmaceutical Products to Address Current and Emerging Public Health Challenges

Targeting central nervous system conditions

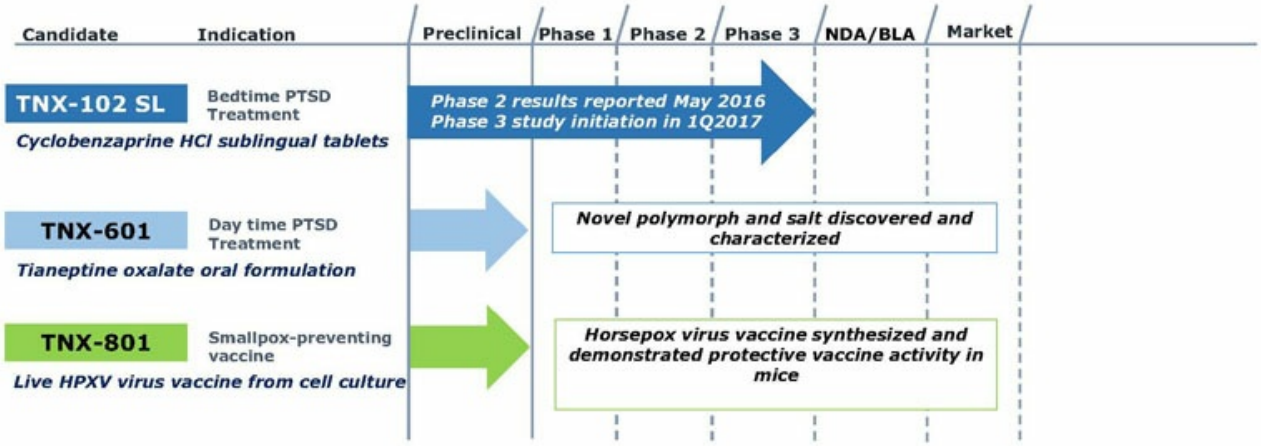
- In Phase 3 development, TNX-102 SL* for posttraumatic stress disorder (PTSD) with **Breakthrough Therapy designation** from the U.S. Food and Drug Administration (FDA)
  - Encouraging evidence of safety and efficacy was demonstrated in Phase 2 AtEase trial of **military-related PTSD** formed the basis of the Breakthrough Therapy designation
  - Regulatory clarity for PTSD based on 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 of action in pre-Investigational New Drug (IND) stage 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

Product Pipeline



Tonix Pharmaceuticals PTSD Program

Phase 3 Development

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 FDA[1]**
  - ✓ **Designated Breakthrough Therapy for expedited development and review**
  - ✓ **Initial Breakthrough Therapy multidisciplinary meeting held with FDA in March 2017**
  - ✓ **Initiation of Phase 3 study in military-related PTSD expected in March 2017**

Targeting a Current and Emerging Public Health Challenge

PTSD

- High prevalence worldwide and receiving greater attention
- Not well served - high off-label usage[2] with unproven or contraindicated treatments[3]
- 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

- **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

- **FDA granted TNX-102 SL Breakthrough Therapy designation – reported December 19, 2016**
  - PTSD is a serious condition
  - TNX-102 SL has potential 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 Are the Consequences of PTSD?

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

TNX-102 SL: Proprietary Patented[1] Formulation

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[2]

Different from other tricyclics

- **CBP is more selective for high affinity sites believed to have a role in sleep quality[3]**
  - 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: Proprietary sublingual formulation of CBP

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

1. Notice of Allowance for Eutectic Proprietary Protectic™ Formulation Patent
2. Rudorfer and Potter, *Cellular and Molecular Neurobiology, 1999 19:373*
3. Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015,Toronto Ontario, Canada

High Prevalence of PTSD Among Combat Veterans

3-9%
General population[1]

19-31%
Vietnam veterans[2]

>19%
Operation Enduring Freedom (OEF; Afghanistan) / Operation Iraqi Freedom (OIF) veterans / Operation New Dawn (OND)[3]

8.6 million American adults affected[1]

Women more likely to develop than men[1]

Susceptibility may **run in families**[1]

[1]Kessler et al., *Arch Gen Psych* 2005; Prevalence rate of 3.5% applied to U.S. Census estimate of 247M U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00); [2]Norris, *PTSD Res Quar.* 2013; [3]*Analysis of VA Health Care Utilization among Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn Veterans, from 1st Qtr FY 2002 through 2nd Qtr FY 2015,* Washington, DC; Among 1.9M separated OEF/OIF/OND Veterans, 1.2M have obtained VA healthcare; 685k evaluated by VA with possible mental disorder, and 379k diagnosed with PTSD.

Growing Economic and Social Burden to Care for Veterans with PTSD

Health care costs associated with PTSD for OEF/OIF/OND veterans:

Direct costs

$3,000-5,000
per patient per year for OEF/OIF Veterans[1]

~ 2.7 million
troops deployed between 10/1/2001 and 3/31/2015[3]

Indirect costs

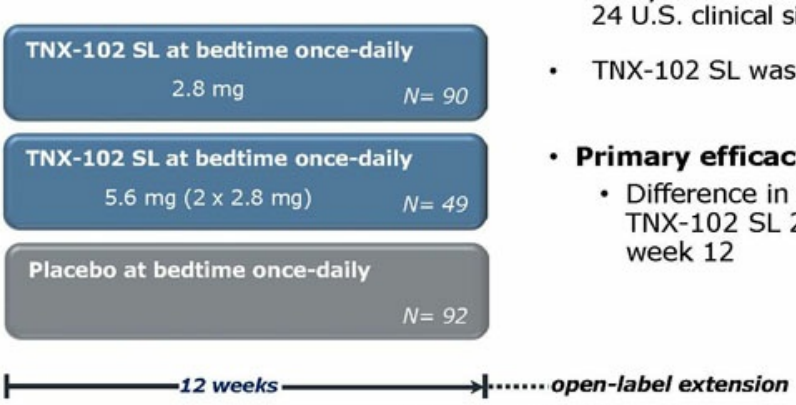
$2-3 billion
estimated yearly cost to society[2]

Families, social care agencies, schools, employers, welfare system[2]

[1]CBO Report 2012; [2]Tanielan, *Invisible Wounds of War*. 2005; [3]*Analysis of VA Health Care Utilization among Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn Veterans, from 1st Qtr FY 2002 through 2nd Qtr FY 2015,* Washington, DC; OEF/OIF/OND, Operations Enduring Freedom, Iraqi Freedom and New Dawn.

Phase 2 AtEase Study in Military-Related PTSD

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



- 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

- **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 – 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

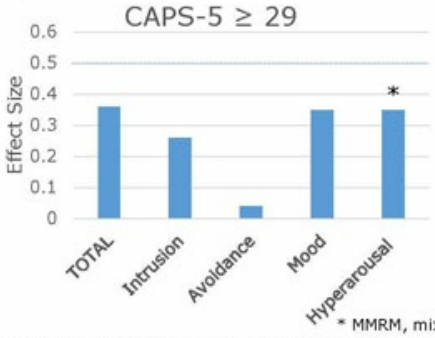
AtEase: Retrospective Analysis for TNX-102 SL 5.6 mg

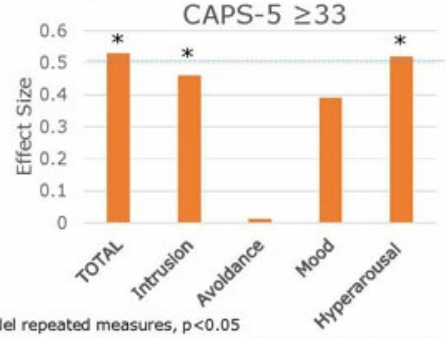
Prior pharmacotherapy trials in PTSD used *earlier versions* of CAPS (e.g. CAPS-2)

- 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

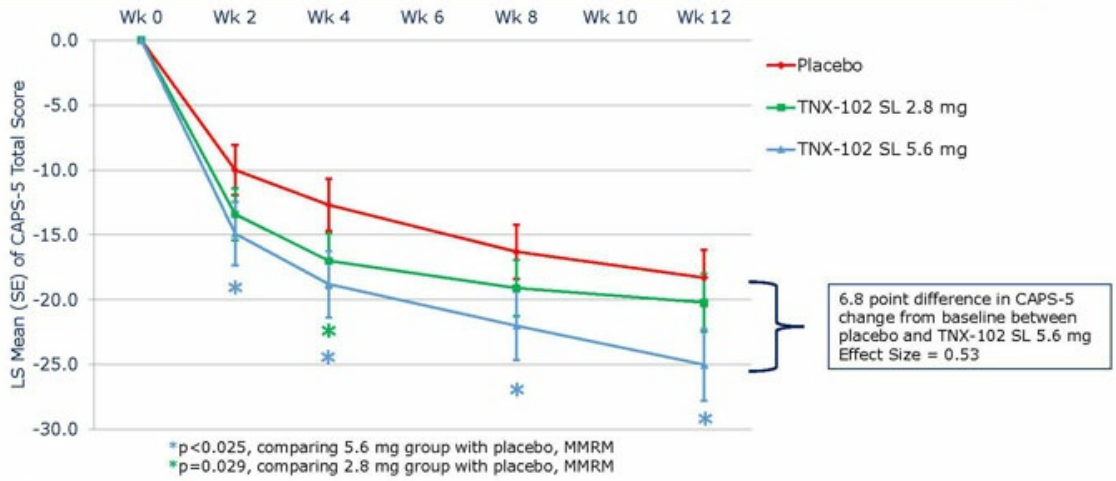




* MMRM, mixed-effects model repeated measures, p<0.05

[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

Retrospective Analysis of CAPS-5 in Patients with Entry CAPS-5 ≥ 33[1]



[1]Primary 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

	Military-related PTSD		Combat PTSD	
CAPS-5 at Baseline	**≥ 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

[1]CAPS-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

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 HONOR Study 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 (140*)*

Placebo once-daily at bedtime
N ~ 275 (140)*

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

* *Interim analysis*

General study characteristics:

- Randomized, double-blind, placebo-controlled, entrance CAPS-5 ≥ 33
- One unblinded interim analysis (IA) by an independent data monitoring committee at 50% recruitment
- IA (N ~275) for efficacy stop, continuation as planned or sample size adjustment
- Potential to enroll 550 patients
- Approximately 35 U.S. clinical sites

Primary efficacy endpoint:

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

1H 2018 - IA outcome anticipated
2H 2018 – topline data anticipated, if 550 patients are studied

Intellectual Property

TNX-102 SL

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

Composition-of-matter (eutectic)

- Notice of Allowance issued by U.S. Patent and Trademark Office
- Additional claims and jurisdictions pending
- Protection expected to 2034

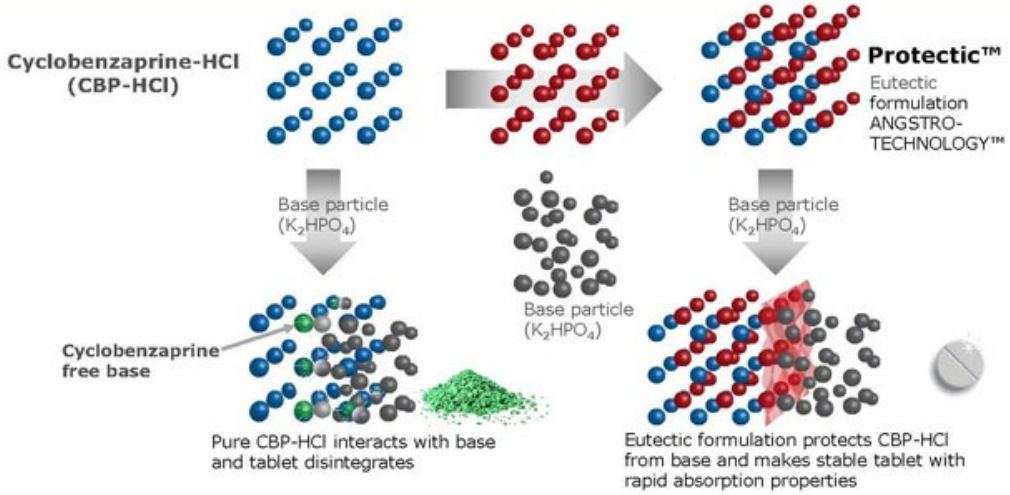
Pharmacokinetics (PK)

- Patents filed
- Protection expected to 2033

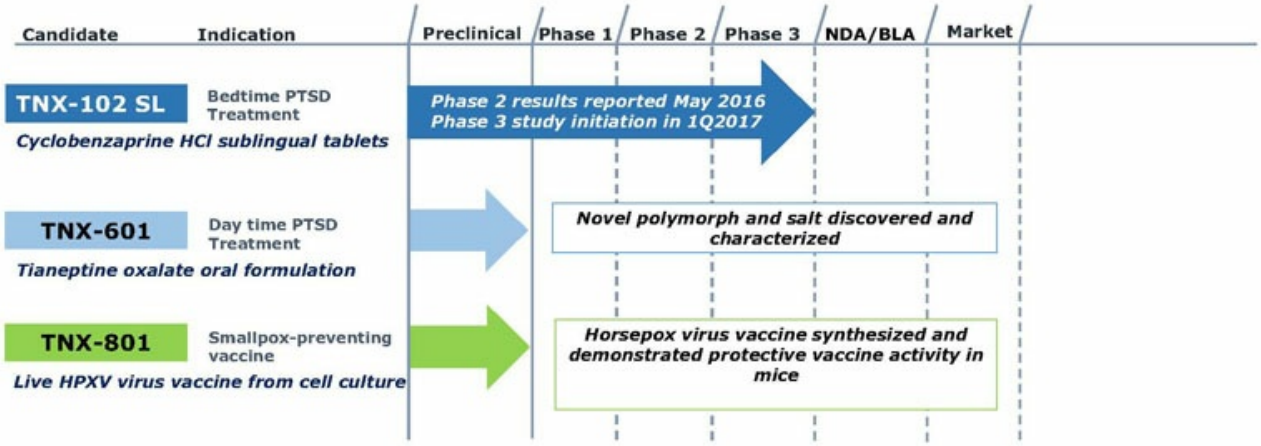
Method-of-use

- PTSD: patents filed

Proprietary Cyclobenzaprine Hydrochloride Eutectic Mixture Stabilizes Tablet Formulation



Product Pipeline



TNX-601 - A Potential Clinical Candidate for PTSD

TNX-601 (tianeptine oxalate oral formulation)

Pre-IND Candidate

Targeting a Public Health Challenge

- Targeted as a 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**
- Tianeptine sodium (amorphous) has been approved in EU, Russia, Asia and Latin America for depression since 1987 with established post-marketing experience
- Identified new oxalate salt polymorph with improved pharmaceutical properties ideal for reformulation
- **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
- **Clinical evidence for PTSD**
- Several studies have shown tianeptine to be active in the treatment of PTSD[1-4]
- US clinical development benefited from the dose identified and dosing regimen developed ex-U.S.

1. Frančišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
2. Rumyantseva GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
3. Aleksandrovskiĭ IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
4. Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747

TNX-801: A Potential Smallpox-Preventing Vaccine

Pre-IND Candidate

TNX-801 (live virus vaccine - synthetic Horsepox (HPXV) vaccine)

- Potential improvement over current methods for biodefense against **smallpox**
  - ✓ **Leverages government affairs effort**
- Tonix is developing a new vaccine (TNX-801) with improved properties
  - ✓ **Collaboration with Professor David Evans and Dr. Ryan Noyce at University of Alberta**
  - ✓ **Protective vaccine activity in mice has been demonstrated**
  - ✓ **Patent application on novel vaccine submitted**

Regulatory strategy

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

Targeting a Public Health Issue

Material threat medical countermeasure under 21st Century Cures Act

- Qualifies for receiving **Priority Review Voucher** on approval
  - ✓ **Priority Review Vouchers are transferrable and have sold for ~$125 M**
- ACAM2000 vaccine developed by Acambis was acquired by Sanofi in 2008 for $513 M
  - ✓ **ACAM2000 was sold to U.S. Strategic National Stockpile[1]**

1. Nalca, A et al. Drug design, development and Therapy: 4:71-79 (2010)

Management Team

Seth Lederman, MD President & CEO	TARGENT X · Fusilev (evoleucovorin) for injection · vela
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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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

TNX-102 SL – Posttraumatic Stress Disorder

☑	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 design for Phase 3 HONOR study in military-related PTSD
☑	1Q 2017	Initial Multidisciplinary Breakthrough Therapy Meeting with FDA
☑	1Q 2017	Notice of Allowance for Eutectic Proprietary Protectic™ Formulation Patent
☐	1Q 2017	Target commencement of Phase 3 HONOR study
☐	1H 2018	Anticipated interim analysis of Phase 3 HONOR study in ~275 participants
☐	2H 2018	Anticipated topline results of Phase 3 HONOR study in 550 participants (if needed)

Summary

Strong position for value growth with Phase 3 development 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

Phase 3 HONOR study in military-PTSD expected to initiate in 1Q 2017

- Outcome of the interim analysis on ~275 participants expected to be available 1H 2018
- Topline results from 550 participants, if needed, expected to be available 2H 2018

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!