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): July 6, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") intends to use 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 July 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: July 6, 2017

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

Exhibit 99.1

Investor Presentation

TONIX PHARMACEUTICALS

July 2017

Version P0072 7-6-17

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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, 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.

Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) for Posttraumatic Stress Disorder (PTSD)

Phase 3 HONOR study of Tonmya[1] in military-related PTSD enrolling

- Encouraging evidence of safety and efficacy was demonstrated in Phase 2

Breakthrough Therapy designation from FDA

- Expedited development and accelerated review are expected
- Potential to file NDA[2] based on one Phase 3 study if data are statistically persuasive

Proposed registration plan agreed by the FDA

- Additional nonclinical safety and clinical abuse potential studies are not required

Patent protection through 2034 in U.S.[3]

- Composition of matter patent for eutectic, required for transmucosal delivery of cyclobenzaprine

Novel mechanism targets sleep quality

- Memory processing during sleep is important to recovery

[1] Tonmya (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication. Tonmya is the proposed proprietary name for TNX-102 SL for the treatment of PTSD. Tonmya has received U.S. Food and Drug Administration (FDA) conditional acceptance.
[2] New Drug Application
[3] U.S. Patent No. 9,636,408 for eutectic proprietary Protectic™ formulation

Phase 3 HONOR Study in PTSD Enrolling

- **To confirm Phase 2 AtEase findings in military-related PTSD:**
  - Larger adaptive design study
  - Enrollment started in 1Q 2017

Tonmya 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% randomized
- IA (N ~275) for efficacy stop, continuation as planned or sample size adjustment
- Potential to enroll 550 participants
- Approximately 35 U.S. clinical sites
- **Primary efficacy endpoint:**
- Mean change from baseline in total CAPS-5 at Week 12 compared between Tonmya 5.6 mg and placebo

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

Breakthrough Therapy Designation

- **FDA granted Tonmya Breakthrough Therapy designation – reported December 19, 2016**
  - PTSD is a serious condition
  - Tonmya has potential advantages over existing therapies in military-related PTSD
- **Benefits of Breakthrough Therapy designation**
  - Eligibility for priority review of the 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
- **NDA filing based on HONOR study is possible if results are statistically persuasive**
  - Discussed at March 9, 2017 Initial Cross-disciplinary Breakthrough Meeting with the FDA

No Recognized Abuse Potential in Clinical Studies

- **Active ingredient is cyclobenzaprine, which is structurally related to tricyclic antidepressants**
  - Cyclobenzaprine interacts with receptors that regulate sleep quality: 5-HT_{2a}; α_1-adrenergic and histamine H_1 receptors
  - Cyclobenzaprine does **NOT** interact with the same receptors as traditional hypnotic sleep drugs, benzodiazepines or non-benzodiazepines that are associated with retrograde amnesia
  - Cyclobenzaprine-containing product was approved 40 years ago and current labeling (May 2016) indicates no abuse and dependence concern
- **Tonmya NDA can be filed without abuse assessment studies**
  - Discussed at March 9, 2017 Initial Cross-disciplinary Breakthrough Meeting with the FDA

Tonmya Intellectual Property – U.S. Protection until 2034

Composition of matter (eutectic)

- U.S. Patent No. 9,636,408 issued May 2, 2017 by U.S. Patent and Trademark Office
  - Protection expected to 2034
- Additional claims and jurisdictions pending

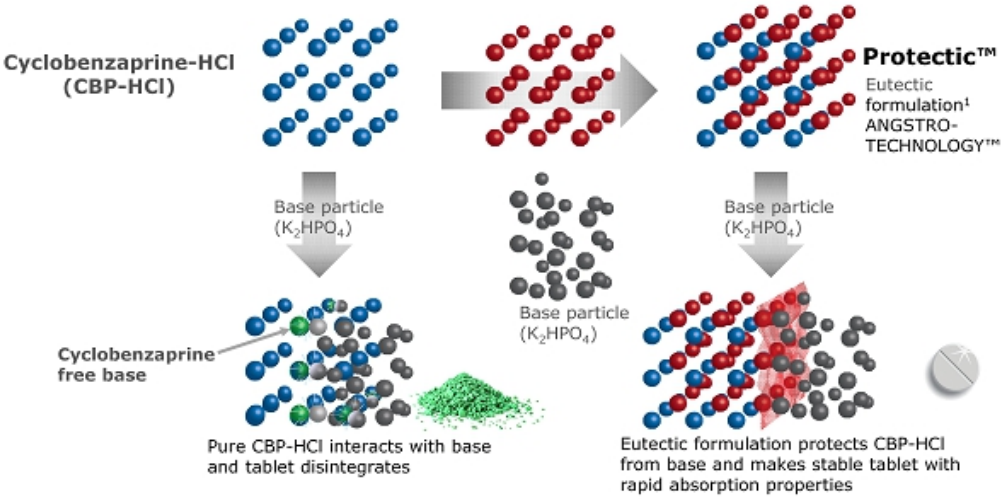
Pharmacokinetics (PK)

- Patents filed
  - Protection expected to 2033

Method of use

- Patents filed

Proprietary Cyclobenzaprine Hydrochloride Eutectic Mixture Stabilizes Sublingual Tablet Formulation



[1] U.S. Patent issued May 2, 2017

Tonmya: Sublingual Formulation is Designed for Bedtime Administration

Tonmya: Proprietary sublingual formulation of CBP with transmucosal absorption

- Innovation by design with patent protected CBP and mannitol eutectic formulation
- Rapid systemic exposure
- Increases bioavailability during sleep
- Avoids first-pass metabolism
- Lowers exposure to long-lived active major metabolite, norcyclobenzaprine (norCBP)

CBP undergoes extensive first-pass hepatic metabolism when orally ingested

- Active major metabolite, norCBP[1]
  - Long half-life (~72 hours)
  - Less selective for target receptors (5-HT_{2A}, α_1-adrenergic, histamine H_1)
  - More selective for norepinephrine transporter

[1] Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015, Toronto Ontario, Canada

Tonmya: Novel Mechanism Targets Sleep Quality for Recovery from PTSD

PTSD is a disorder of recovery

- Most people exposed to extreme trauma recover over a few weeks
- In PTSD, recovery process impeded due to insufficient sleep-dependent memory processing

Memory processing is essential to recovery

- Vulnerability to memory intrusions and trauma triggers remains if no consolidation of new learning (extinction)

Tonmya targets sleep quality[1]

- Cyclobenzaprine interacts with receptors that regulate sleep quality: strongly binds and potently blocks 5-HT_{2A}, a_1-adrenergic and histamine H_1 receptors, permissive to sleep-dependent recovery processes

[1] Daugherty et al., Abstract 728, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015, Toronto Ontario, Canada

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)

Clinician Administered PTSD Scale (CAPS-5) is used to assess symptom severity and treatment effect

- 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

PTSD U.S. Prevalence and Index Traumas

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)

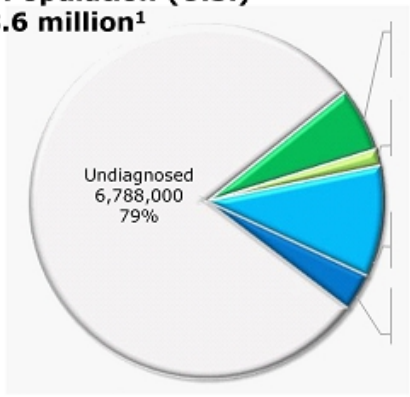
Most common forms of trauma[1]

- 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

PTSD Prevalence and Market Characteristics

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



Diagnosed population

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

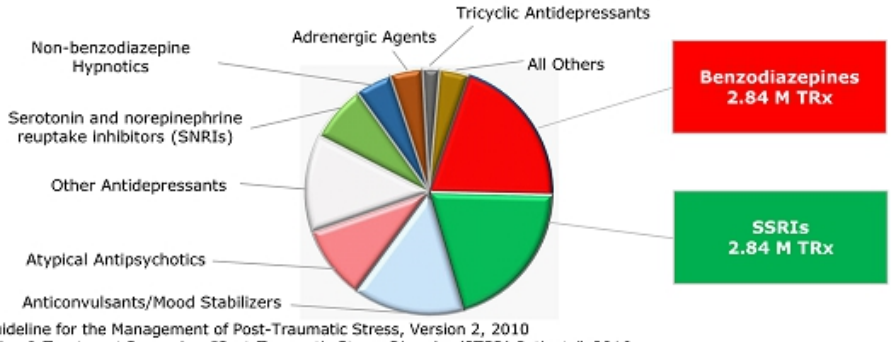
[1] Kessler, et al., 2005; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (≥18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
[2] IMS Consulting, *Market Sizing & Treatment Dynamics: Post-Traumatic Stress Disorder (PTSD) Patients"*, 2016
[3] Bowe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

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

PTSD: Not Well-Served by Approved Treatments

FDA approved selective serotonin reuptake inhibitors (SSRIs), paroxetine and sertraline, have not shown efficacy in military-related PTSD

Majority of patients unresponsive or intolerant to current treatments

- Side effects relating to sexual dysfunction (particularly in males) and sleep are commonly reported

Drug therapy compatible and complementary with behavioral therapy

- Lack of retrograde amnesia (e.g., off-label use benzodiazepines and non-benzodiazepines)
- Lack of interference on sleep (e.g., approved SSRIs)

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

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]

~ 1.9M Veterans out of 2.7M
Service members deployed between 10/1/2001 and 3/31/2015[3]

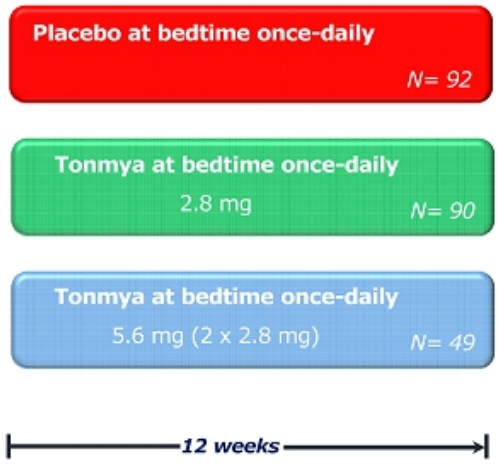
Indirect costs

$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



CAPS-5, Clinician-Administered PTSD Scale for DSM-5

- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- Efficacy analysis from 231 patients; 24 U.S. clinical sites
- Enrolled patients with baseline CAPS-5 score ≥ 29
- **Primary Efficacy Analysis:**
  - Difference in CAPS-5 score change from baseline between Tonmya 2.8 mg and placebo at week 12
- Key Secondary Measures:
  - PROMIS Sleep Disturbance, CGI-I, SDS

Results of Phase 2 AtEase Study in Military-Related PTSD

Tonmya 5.6 mg showed clinical benefit in military-related PTSD

- CAPS-5 scale, was statistically significant by Mixed effect Model Repeated Measures, or MMRM, with Multiple Imputation, or MI, analysis (p-value = 0.031)
- Dose-effect on multiple efficacy and safety measurements in the AtEase study

Well tolerated

- No serious adverse events (AE) related to treatment
- The most common AEs were local site-administration reactions, including mild and transient tongue numbness

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

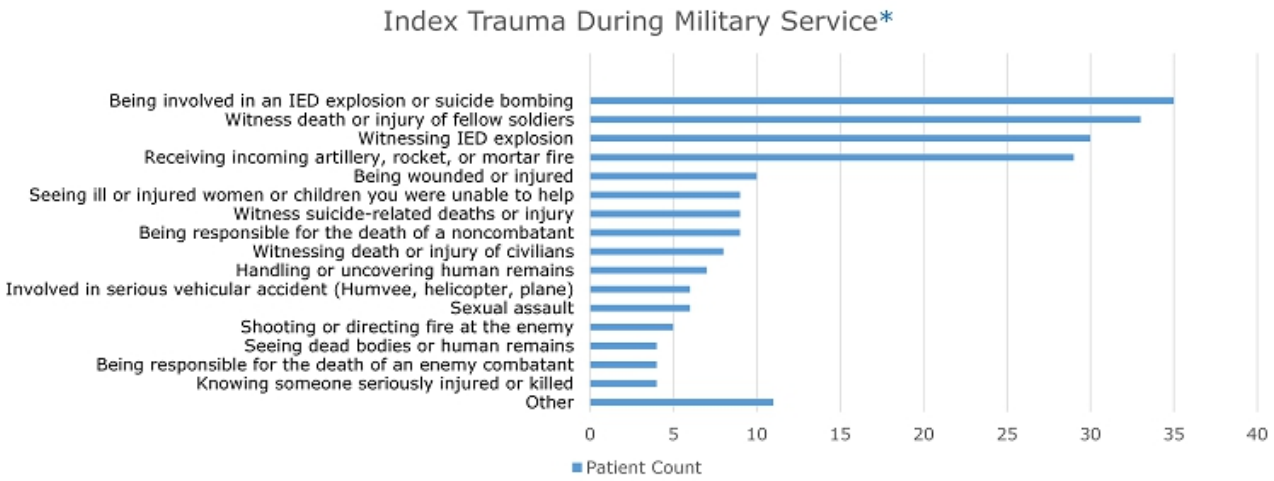
Race and ethnicity generally consistent with U.S. military distribution

Similar baseline CAPS-5 scores and MADRS[1] scores across treatment arms

Current Major Depressive Disorder 14% by MINI 7.0[2]

[1] MADRS, Montgomery-Åsberg Depression Rating Scale
[2] MINI 7.0, Mini-International Neuropsychiatric Interview, Version 7

AtEase Study: Traumas Associated with PTSD



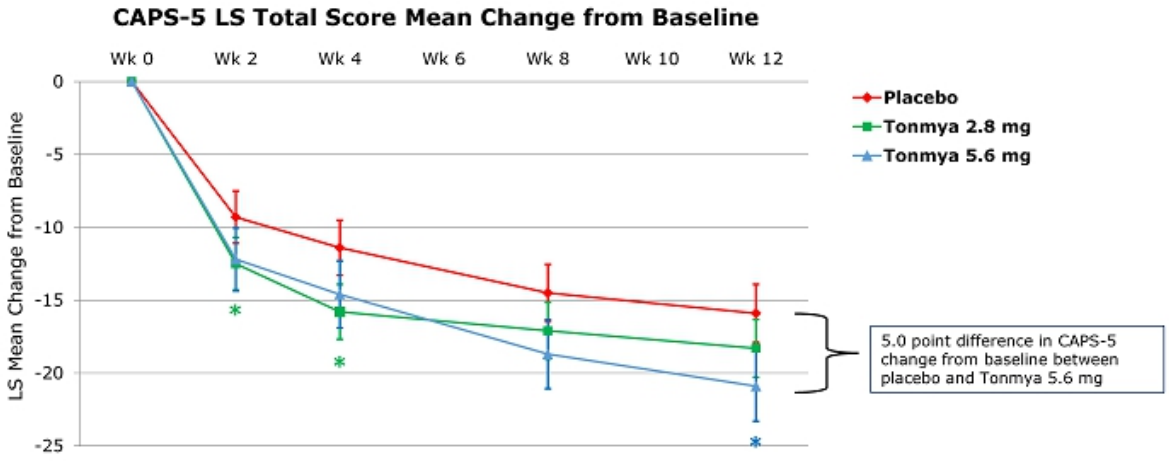
**Some patients experienced more than one trauma*

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 (Primary Analysis)	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 Tonmya 2.8 mg versus placebo
*p<0.05

AtEase Study Results: Primary Endpoint
CAPS-5 Total Score by MMRM with MI#



#Primary analysis MMRM, *p=0.031, comparing placebo and Tonmya 5.6 mg, *p<0.05, comparing placebo and Tonmya 2.8 mg, by MMRM with MI, mixed-effect model repeated measures with multiple imputation; CAPS-5, Clinician Administered PTSD Scale for DSM-5; LS Mean, least squares mean

AtEase Study: Safety and Tolerability Profile

No serious adverse events reported with Tonmya deemed related to treatment

Systemic Adverse Events*	Placebo (N=94)	Tonmya 2.8 mg (N=93)	Tonmya 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% Tonmya 2.8 mg; 84% Tonmya 5.6 mg

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

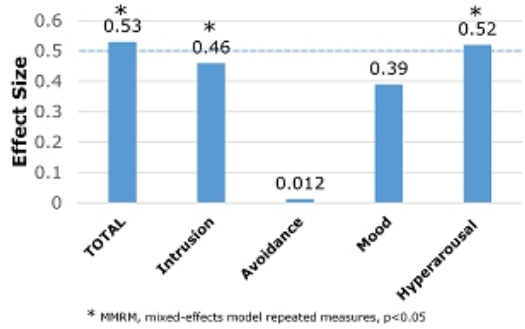
Assessing CAPS-5 Entry Threshold in AtEase

- **Score of ≥29 on CAPS-5 (20 items) required at screening and baseline**
  - >50 on prior versions of CAPS (17 items) typical in previous drug registration trials
  - Extrapolation from prior versions of CAPS: ((50/17 items)/2) x 20 items = 29.4
- ***Post-hoc* analysis to impute CAPS for DSM-IV (iCAPS-IV) scores for each subject**
  - Baseline iCAPS-IV score calculated by summing 17 items in common with CAPS-5 and multiplying by two (for 0-8 intensity + frequency rather than 0-4)
  - 4.3% of the sample had baseline iCAPS-IV of ≤ 50
  - Choosing CAPS-5 ≥33 results in all iCAPS-IV > 50
  - 80% of mITT had baseline CAPS-5 of ≥ 33
- **Primary analysis of AtEase was run for subgroup with baseline CAPS-5 ≥ 33**

AtEase Retrospective Analysis:
Effect Sizes for Total CAPS-5 and Cluster Scores

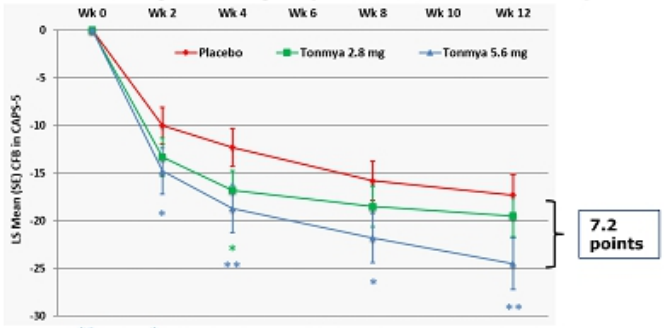
- **Effect sizes calculated for total CAPS-5 and clusters for patients with entry CAPS-5 ≥33**
  - Larger effect size, in moderate range of 0.5, for total CAPS-5 and intrusion and hyperarousal clusters

Effect Sizes in Tonmya 5.6 mg Subgroup with ≥ 33 CAPS-5 Entry Score



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

CAPS-5 Change in Subgroup with ≥ 33 CAPS-5 Entry Score

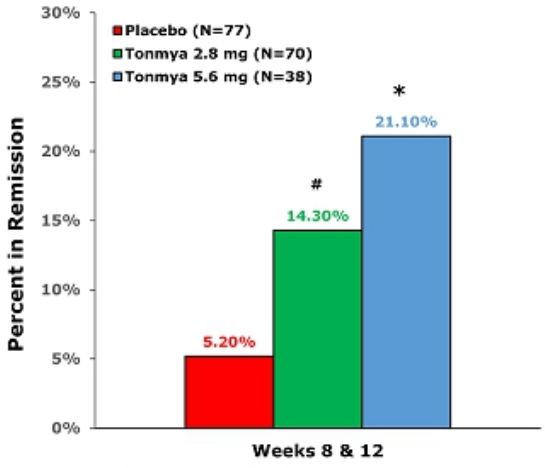


** p<0.01, + p<0.025, Tonmya 5.6 group with placebo, MMRM with multiple imputation (MI); *p=0.018, Tonmya 2.8 mg group with placebo, MMRM with MI

- **Based on findings of post-hoc imputed CAPS, a baseline CAPS-5 score ≥33 was set as PTSD severity inclusion criterion in Phase 3 HONOR trial**

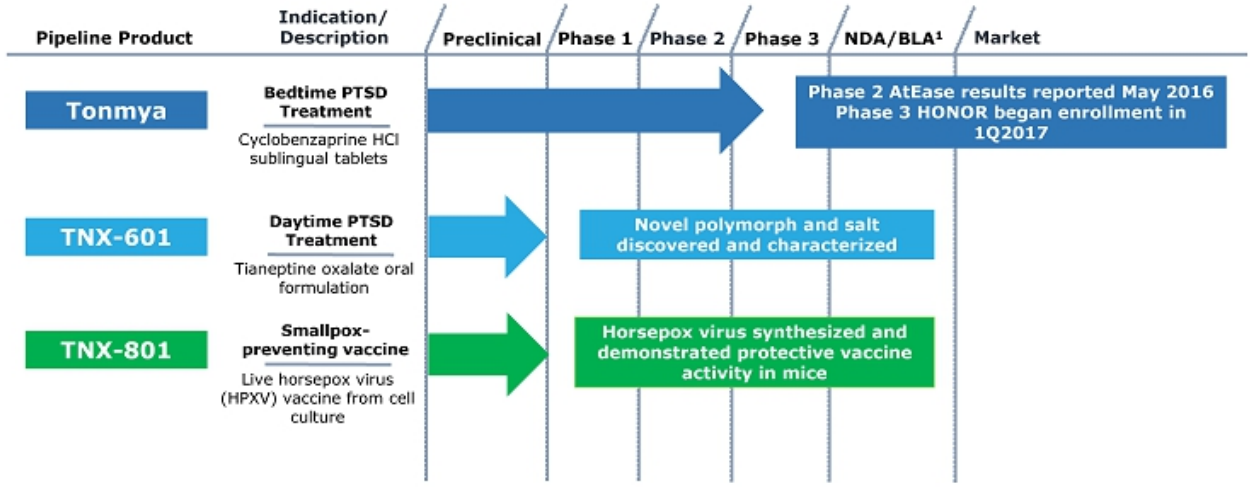
AtEase Study Retrospective Analysis:
Sustained Remission in CAPS-5 Baseline ≥33 Subgroup

- **Remission is more clinically meaningful if it is sustained**
- **In order to look at sustained remission in AtEase:**
  - Determined rates of participants who met remission status at *both* Week 8 and Week 12
- **21% of the Tonmya 5.6 mg participants met for sustained remission v. 5% of placebo (p=0.02)**



Remission = Loss of Diagnosis and CAPS-5 < 11
Asterisk and hashmark represent pairwise comparisons between Tonmya and Placebo; #p=0.08, Odds Ratio 3.01 (0.89, 10.18)
*p=0.02, Odds Ratio 4.60 (1.27, 16.66); logistic regression

Products in Development



¹BLA –Biologic Licensing Application

TNX-601 (Tianeptine Oxalate): A Potential Clinical Candidate for PTSD

Pre-IND Candidate

- Targeted as a 1st line monotherapy for **PTSD**: oral formulation for **daytime dosing**
  - ✓ **Leverages expertise in PTSD (clinical and regulatory experience, market analysis, etc.)**
  - ✓ **Mechanism of Action (MOA) is different from Tonmya**
- 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

Targeting a Public Health Challenge

- **Clinical evidence for PTSD**
- Several studies have shown tianeptine to be active in the treatment of PTSD[1-4]

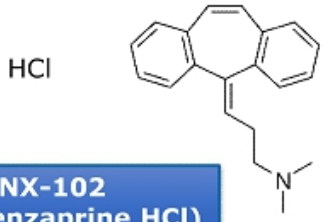
[1] Frančišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
[2] Rumyantseva GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
[3] Aleksandrovskiĭ IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
[4] Onder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

Structural Comparison: TNX-102 and TNX-601

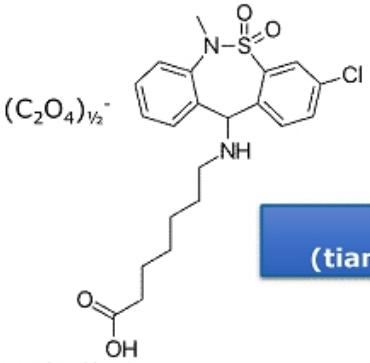
Cyclobenzaprine and tianeptine share structural similarities with classic tricyclic antidepressants (TCAs) and to each other, but each has unique pharmacological properties

- 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 (cyclobenzaprine HCl)



TNX-601 (tianeptine oxalate)

TNX-601: A Potential Clinical Candidate for PTSD

The active pharmaceutical ingredient (API) is a novel oxalate salt of tianeptine

- Shares structural features with tricyclic antidepressants, but has unique pharmacological and neurochemical properties[1]
- GMP synthesis developed

Mechanism of Action

- **Tianeptine modulates the glutamatergic system indirectly**
  - Does not have significant affinity (K_i>10μM) for NMDA or AMPA 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[2-5]
- **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] Frančišković T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
[3] Rumyantseva GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
[4] Aleksandrovskiĭ IA, et al. Zh Nevrol Psikhiatr Im S S Korsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
[5] Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747
NMDA; N-methyl-D-aspartate, AMPA; α-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid

TNX-801 (Synthesized Live Horsepox Virus): A Potential Smallpox-Preventing Vaccine

Pre-IND Candidate

Potential improvement over current methods for biodefense against smallpox

- ✓ Leverages government affairs effort
- ✓ 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 have no expiration date, 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 (Synthesized Live Horsepox Virus): A Potential Smallpox-Preventing Vaccine

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 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 (Synthesized Live Horsepox Virus): A Potential Smallpox-Preventing Vaccine

Synthesized 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 X | Fusilev (levoleucovorin) 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

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Milestones – Recently Completed and Upcoming

Tonmya – Posttraumatic Stress Disorder

☑	May 2016	Reported results from Phase 2 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 Phase 3 HONOR study design in military-related PTSD
☑	1Q 2017	Initial Cross-disciplinary Breakthrough Meeting with FDA
☑	1Q 2017	Commenced enrollment of HONOR study
☑	2Q 2017	U.S. Patent No. 9,636,408 issued for eutectic formulation of Tonmya
☐	1H 2018	Anticipated interim analysis of HONOR study in ~275 randomized participants
☐	2H 2018	Anticipated topline results of 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

- PTSD is an important public health issue

Tonmya for PTSD is designated as a Breakthrough Therapy by FDA

- Accelerated development and approval process is expected

Phase 3 HONOR study in military-related PTSD began enrollment in 1Q 2017

- Outcome of the interim analysis on ~275 randomized participants (50% efficacy evaluable) expected to be available 1H 2018
- Fully funded through the 100% completion of the 550-participant trial, if needed, and announcement of topline results expected in 2H 2018

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!