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): May 25, 2016

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

509 Madison Avenue, Suite 306, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

Copy of correspondence to:

Marc J. Ross, Esq.
James M. Turner, Esq.
Sichenzia Ross Friedman Ference LLP
61 Broadway
New York, New York 10006
Tel: (212) 930-9700 Fax: (212) 930-9725

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") intends to utilize an updated investor presentation to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain non-public information. A copy of the presentation is filed as Exhibit 99.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01, is furnished pursuant to, and shall not be deemed to be "filed" for the purposes of, Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in Item 7.01 of this Current Report shall not be incorporated by reference into any registration statement or any other document filed pursuant to the Securities Act of 1933, as amended, except as otherwise expressly stated in such filing. By filing this Current Report on Form 8-K and furnishing the information contained in this Item 7.01, including Exhibit 99.01, the Company makes no admission as to the materiality of any such information that it is furnishing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Corporate Presentation by the Company for May 2016*

---

* Furnished herewith.

SIGNATURE

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

TONIX PHARMACEUTICALS HOLDING CORP.

Date: May 25, 2016

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

Exhibit 99.1

NASDAQ: TNXP

Investor Presentation

May 2016

Version: P0018-05-23-16

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 possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain U.S Food and Drug Administration clearances or approvals and noncompliance with its regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by the Company on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, and future periodic reports filed with the SEC on or after the date hereof. All of the Company's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

TONIX PHARMACEUTICALS

Developing innovative medicines for large and growing markets

- **Targeting two common central nervous system disorders**
  - One clinical-stage proprietary candidate targeting two indications
  - Differentiated product with potential for sustainable competitive advantages
- **Fibromyalgia – Phase 3 trial to report in 3Q**
  - TNX-102 SL 2.8 mg was active in a Phase 2b study of Fibromyalgia
  - Central pain disorder
  - Phase 3 study (AFFIRM) enrollment complete
- **Post-traumatic stress disorder – Phase 2 trial reported May 2016**
  - TNX-102 SL 5.6 mg was active in treating military-related PTSD
  - Serious mental health problem[1]
  - Planning Phase 3 program in military-related PTSD
- **All intellectual property owned by Tonix**

[1]*Schnurr, PP et al., Contemporary Clinical Trials 2015;41:75.*

TONIX PHARMACEUTICALS

Pipeline led by TNX-102 SL for fibromyalgia

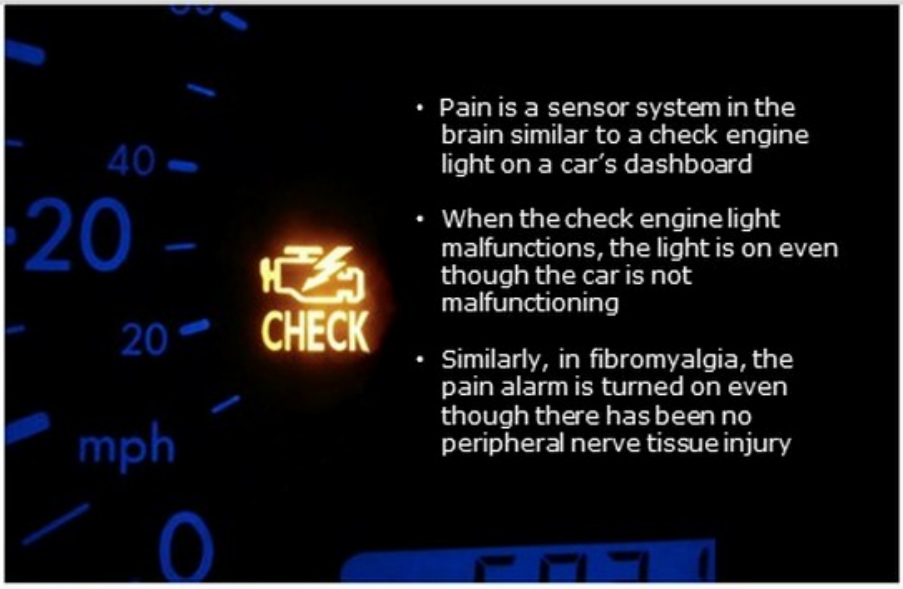
Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
TNX-102 SL 2.8 mg (*Tonmya*®*)	Fibromyalgia							Topline data 3Q 2016
TNX-102 SL 5.6 mg	Post-Traumatic Stress Disorder							Phase 3 starting 1Q 2017

* Tonmya® has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Concept: Fibromyalgia is inappropriate central pain signaling in the absence of peripheral injury



- Pain is a sensor system in the brain similar to a check engine light on a car's dashboard
- When the check engine light malfunctions, the light is on even though the car is not malfunctioning
- Similarly, in fibromyalgia, the pain alarm is turned on even though there has been no peripheral nerve tissue injury

Volkswagen Check Engine [Photograph]. (2011, October 14). Wikipedia

TONIX PHARMACEUTICALS

Fibromyalgia is a chronic, debilitating disorder that imposes a significant societal and economic burden

- **Fibromyalgia is considered neurobiological disorder characterized by[1]:**
  - Chronic widespread pain
  - Nonrestorative sleep
  - Fatigue
  - Diminished cognition
- **Believed to result from amplified sensory and pain signaling in central nervous system[1]**
- **Causes significant impairment in all areas of life[2]**
  - Lower levels of health-related quality of life – reduced daily functioning
  - Interference with work (loss of productivity, disability)
- **Inflicts substantial strain on the healthcare system**
  - Average patient has 20 physician office visits per year[3]
  - Annual direct medical costs are twice those for non-fibromyalgia individuals[4]

[1]*Phillips K & Clauw DJ, Best Pract Res Clin Rheumatol 2011;25:141.*
[2]*Schaefer et al., Pain Pract, 2015.*
[3]*Robinson et al, Pain Medicine 2013;14:1400.*
[4]*White et al, J Occupational Environ Med 2008;50:13.*

TONIX PHARMACEUTICALS

Fibromyalgia is a prevalent disorder but remains underdiagnosed

Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year[2,3]

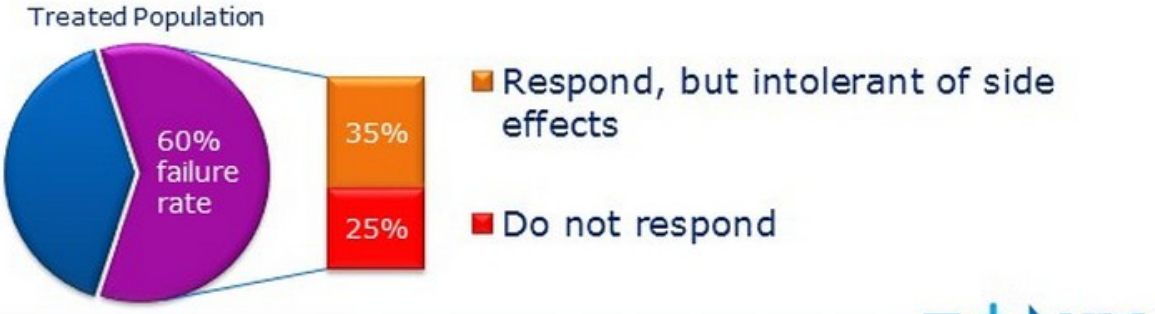
- **1.1% diagnosis rate = 2.7 million U.S. adults[1]**
  - Suggests under-diagnosis
- **Approximately 2.3 million U.S. adults receive treatment[2]**
- **<u>Approved</u> drugs achieved 2014 U.S. sales of $1.2 billion[4]**
  - Represent about 5.6 million prescriptions[3]

[1]Lawrence et al, Arthritis Rheum 2008;58:26; Vincent et al, Arthritis Care Res 2013;65:786; Jones et al, Arthritis Rheum 2015;67:568; U.S. Census Bureau, 2013 Projection.
[2]Robinson RL et al, Pain Med 2012;13:1366.
[3]Independent study conducted by IMS Consulting Group, April 2015 using IMS MIDAS (ex-manufacturing price), factored for fibromyalgia based on IMS National Disease and Therapeutic Index (NDTI).
[4]Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.

TONIX PHARMACEUTICALS

Fewer than half of those treated for fibromyalgia receive sustained benefit from the three currently marketed drugs

- **The treatment objective is to restore functionality and quality of life by broadly improving symptoms while avoiding significant side effects**
- The majority fail therapy due to **lack of a response** or **poor tolerability**[1]



[1]*Market research by Frost & Sullivan, commissioned by Tonix (2011).*

Large need for new fibromyalgia therapies that provide broad symptom improvement with better tolerability

- **Currently-approved medications may have side effects that limit long-term use[1]**
  - Many patients skip doses or discontinue altogether within months of treatment initiation
- **Medication-related side effects may be similar to fibromyalgia symptoms**
- **High rates of discontinuation, switching and augmentation**
  - Attempt to treat multiple symptoms and/or avoid intolerable side effects
  - Average of 2-3 medications used simultaneously[2]
  - The typical patient has tried six different medications[3]
- **Substantial off-label use of narcotic painkillers and prescription sleep aids[3]**

[1]Nuesch et al, Ann Rheum Dis 2013;72:955-62.
[2]Robinson RL et al, Pain Medicine 2012;13:1366.
[3]"Patient Trends: Fibromyalgia", Decision Resources, 2011.

TONIX PHARMACEUTICALS

Tonix is developing TNX-102 SL for fibromyalgia

- **Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP)**
  - Designed for daily bedtime administration with no titration
  - Efficient transmucosal absorption
  - Avoidance of first-pass metabolism reduces formation of long-lived metabolite
- **TNX-102 SL's pharmacologic action is believed to improve sleep quality**
  - Non-restorative sleep is a common clinical and diagnostic feature of fibromyalgia[1]
  - Evolving understanding of the role of sleep in pain control and fibromyalgia development[2]
  - TNX-102 SL targets receptors believed to play key roles in sleep physiology
- **Phase 2b "BESTFIT" study was successfully completed in 3Q14**
- **Topline data from ongoing Phase 3 "AFFIRM" study expected to report in 3Q16**

[1]Swick TJ, Ther Adv Musculoskel Dis 2011;3:167-178.
[2]Choy EH, Nat Rev Rheumatol; 2015: 11:513-520.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Phase 2b "BESTFIT" study of TNX-102 SL in fibromyalgia

- **BESTFIT = BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy**
  - Randomized, double-blind, placebo-controlled trial
  - 2010 American College of Rheumatology diagnostic criteria for fibromyalgia
  - 205 participants randomized 1:1 at 17 U.S. sites
  - Sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime for 12 weeks
  - Evaluated measures of pain, sleep quality, and other assessments of fibromyalgia

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

BESTFIT results on key clinical endpoints

Category	Endpoint – week 12[1]	*p* value
Pain Relief	30% responder analysis[2]	**0.033**
Sleep Quality	PROMIS Sleep Disturbance	0.005
Overall response to therapy	PGIC	0.025
Assessment of disease impact	FIQ-R Total score	0.014

$p < 0.05$ → statistically significant

BESTFIT pre-specified primary endpoint: change in week 12 mean pain score (p=0.172)

- PROMIS = Patient-Reported Outcomes Measurement Information System
- PGIC = Patient Global Impression of Change
- FIQ-R = Fibromyalgia Impact Questionnaire - Revised

[1]Intent-to-treat analysis, N=205 (TNX-102 SL N=103, placebo N=102).
[2]FDA-accepted primary endpoint in current Phase 3 AFFIRM study.
Source: Phase 2b BESTFIT study data.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL safety and tolerability profile in the BESTFIT study

- **No serious adverse events (SAE) reported with TNX-102 SL**
- **Systemic adverse events reported by at least 3% of the total BESTFIT population**

	TNX-102 SL *(N=103)*	Placebo *(N=101)*	Total *(N=204)*
Somnolence	1.9	6.9	4.4
Dry Mouth	3.9	4.0	3.9
Back Pain	4.9	3.0	3.9
Nausea	4.9	2.0	3.4
Sinusitis	3.9	3.0	3.4

- **Most frequent local adverse events were administration site reactions**
  - Previously reported in Phase 1 studies; no detectable bias on efficacy results
  - Transient tongue numbness (44% TNX-102 SL vs. 2% placebo)
  - Abnormal taste (8% TNX-102 SL vs. 0% placebo)
- **Trial completion rates of 86% with TNX-102 SL vs. 83% with placebo**

Source: Lederman et al., poster at American College of Rheumatology, 2015.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Enrollment completed in TNX-102 SL in Phase 3 trial for fibromyalgia

- Phase 3 AFFIRM Study is fully enrolled

- Randomized, double-blind, placebo-controlled study in fibromyalgia
- N=500; approximately 35 U.S. clinical sites
- **Primary efficacy endpoint:**
  - Difference in 30% pain responder analysis at Week 12 between TNX-102 SL and placebo

Topline data expected 3Q 2016

- Second Phase 3 Study ("REAFFIRM") expected to begin in 2Q 2016
  - Expected to be similar to AFFIRM in design and sample size

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL in Phase 2 development for post-traumatic stress disorder (PTSD)

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
TNX-102 SL (*Tonmya*®*) 2.8 mg	Fibromyalgia							Topline data 3Q 2016
TNX-102 SL 5.6 mg	**Post-Traumatic Stress Disorder**							**Phase 3 Starting 1Q 2017**

* *Tonmya® has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.*

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

PTSD is a chronic stress disorder triggered by a traumatic event

- **PTSD is characterized by:**
  - re-experiencing the triggering event
  - negative alterations in mood/cognition
  - situation/stimulus avoidance
  - hyperarousal (anxiety, agitation & sleep disturbance)
- **Considered a stress response, but prolonged and does not resolve with time**
  - 20% of women and 8% of men who experience significant trauma develop PTSD[1]
- **Associated with significant life disruption**
  - Social isolation, inability to maintain employment, loss of independent living
  - Unpredictable acts of violence, suicidal thoughts

[1] *Kessler et al, Arch Gen Psychiatry 1995;52:1048.*

TONIX PHARMACEUTICALS

PTSD is a prevalent problem for both civilians and the military

- **~70% are considered to have moderate to severe symptoms**
- **Of those diagnosed, ~50% utilize professional healthcare (psychotherapy/pharmacotherapy)[2]**

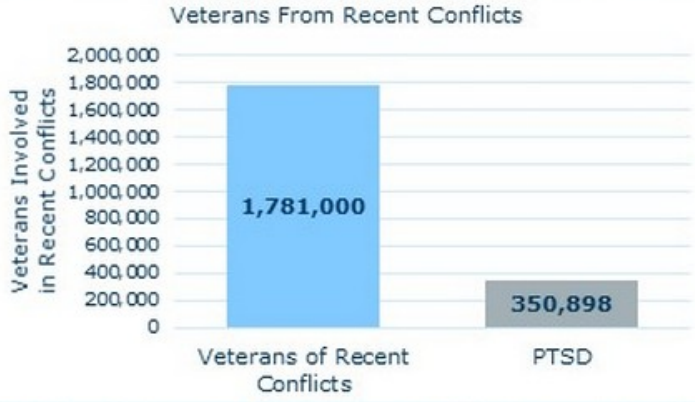
- **Higher prevalence in military population**
  - 20% of veterans from recent conflicts will have potential/provisional PTSD[3]
  - ~638,000 veterans with PTSD in the VA health system (2012)[4]
  - Majority are male
  - Alcohol and substance abuse are common

[1]Kessler RC at al, Arch Gen Psychiatry 2013;62:617; U.S. Census Bureau, 2013 Projection.
[2]Wang et al, Arch Gen Psychiatry 2005;62:629.
[3]Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD.
[4]Bowe et al, J Dual Diagnosis 2015;11:22.

TONIX PHARMACEUTICALS

PTSD veteran population: recent conflicts only

Veteran Administration (VA) records indicate that 20% of veterans from recent conflicts will have potential or provisional PTSD

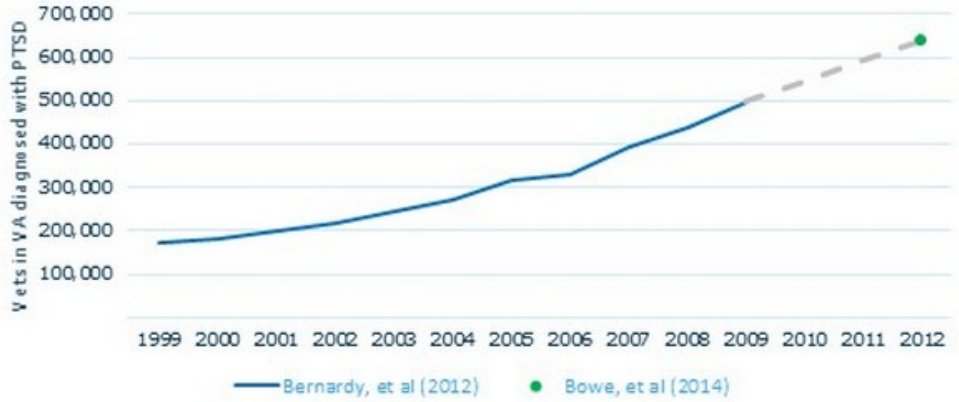


Source: Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD. Cumulative from 1st Qtr FY 2002 through 1st Qtr FY 2014 (October 1, 2001 – March 31, 2014).

PTSD veteran population: all conflicts

The number of veterans in the VA system and diagnosed with PTSD has been rising[1,2]

- Does not include veterans with PTSD not treated or diagnosed in the VA system



[1]*Bernardy et al., J Clin Psychiatry, 2012, 73:297-303.*
[2]*Bowe et al, J Dual Diagnosis, 2014, 11:22-32.*

TONIX PHARMACEUTICALS

Significant gap in current therapeutic landscape for PTSD

- **Medicines approved for PTSD often provide inadequate and/or inconsistent benefit**
  - Limited to two SSRI antidepressants, both of which carry suicidality warnings
  - U.S. Institute of Medicine (IOM) concluded that evidence of treatment effect is low[1]
  - Lack of efficacy evidence in those with a history of combat-related trauma[2]
  - No new therapy since 2001
- **Sleep dysfunction in PTSD is resistant to currently-approved options**
  - 95%+ report insomnia, 83% report recurrent dreams of the trauma[3]
  - Correlated with disease severity, depression, substance abuse and suicide[4]
  - Drugs approved for insomnia have been shown to not improve PTSD sleep dysfunction
- **Off-label use of anxiolytics, sedative-hypnotics, and antipsychotics is common[5]**
  - Limited evidence of effectiveness; may be harmful
  - May interfere with other treatments such as cognitive behavioral therapy (CBT)

SSRI = selective serotonin reuptake inhibitor.

[1] Marshall et al, Am J Psychiatry 2001;158:1982.

[2] Jonathan Davidson, personal communications, 2014.

[3] Green B. Post-traumatic stress disorder: Symptom profiles in men and women. Curr Med Res Opin 2003;19:200–4.

[4] Germain et al, J Anxiety Disord 2005;19:233; Krakow et al, J Nerv Ment Dis 2002;190:442.

[5] Bernardy et al., J Clin Psychiatry, 2012, 73:297-303.

TONIX PHARMACEUTICALS

Targeting sleep quality is a novel mechanism of action in PTSD therapy

- **PTSD patients complain of sleep disturbance as a core symptom[1]**
  - Distressing dreams (nightmares) are part of "re-experiencing"
  - Avoidance can be of bed/sleep due to fear of nightmares
  - Restless sleep is part of the "hyper-arousal" cluster of PTSD diagnostic criteria
- **Sleep disturbance after trauma is linked to onset of PTSD[2]**
- **Sleep disturbance also correlates with depression, substance abuse and suicidal behaviors in PTSD[3]**
- **TNX-102 SL is a tricyclic molecule that potently targets three molecular mechanisms[4], each of which is associated with treating aspects of disturbed sleep, enhancing sleep quality**
  - Blocks the 5-HT_{2A} receptor (like trazodone)
  - Blocks the α_1 adrenergic receptor (like prazosin)
  - Blocks the H_1 receptor (like low-dose doxepin)

---

[1] *American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, 2013.*
[2] *Koren et al, AJP 159:855-857, 2002; Mellman et al, AJP 159:1969-1701, 2002.*
[3] *Germain, AJP 170:372-382, 2013; McHugh et al, J Traumatic Stress 27:82-89, 2014 Betts et al, Journal of Anxiety Disorders 27:735-41, 2013.*
[4] *Daugherty et al, Society of Biological Psychiatry 70th Annual Scientific Convention, May 14-16, 2015 Toronto, Ontario, Canada.*
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Tonix's AtEase study in military-related PTSD: primary endpoint

- **Primary endpoint is the change from baseline of the Clinician Administered PTSD Scale for DSM-5 (CAPS-5)**
  - Gold standard for assessment of PTSD severity
  - Endpoint used in prior pivotal studies for FDA approved therapies
  - Raters were trained, certified, and monitored for reliability throughout the study

TONIX PHARMACEUTICALS

Limitations of current FDA-approved pharmacotherapies for PTSD

- **No treatment response observed in U.S. military population**
  - Sertraline: negative large multicenter trial in U.S. military veterans[1]
    - Placebo numerically superior on CAPS-2
  - Paroxetine: not studied in military population
- **Inconsistent treatment response observed in males**
  - Sertraline: FDA-conducted post-hoc analysis concluded no effect for male civilian subgroup[2]
  - Paroxetine: no gender-related difference in treatment outcome[3]
- **Important tolerability issues with SSRIs in this population**
  - Sexual dysfunction
  - Insomnia

[1]Friedman MJ et al. J Clin Psychiatry 2007;68:711-20.
[2]Zoloft® Package Insert, Pfizer, August 2014.
[3] Paxil® Package Insert, Glaxo, June 2014.

TONIX PHARMACEUTICALS

Phase 2 AtEase trial of TNX-102 SL in PTSD

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

TNX-102 SL at bedtime once-daily
5.6 mg *N= 49*

Placebo at bedtime once-daily
N= 92

- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- Analysis from 231 patients; 24 U.S. clinical sites
- **Primary efficacy endpoint:**
  - Difference in Clinician-Administered PTSD Scale (CAPS) score between TNX-102 SL 2.8 mg and placebo at week 12

12 weeks → *open-label extension*

TNX-102 SL was active at 5.6 mg dose

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Phase 2 AtEase study of TNX-102 SL in PTSD

- **AtEase Study**
  - Randomized, double-blind, placebo-controlled trial
  - DSM-5 diagnostic criteria for PTSD
  - 231 participants studied 2:1:2 at 25 U.S. sites
    - 1 x TNX-102 SL 2.8 mg: 2 x TNX-102 SL 2.8 mg: placebo
  - Evaluated CAPS-5 as primary endpoint
    - Pre-specified primary analysis was 2.8 mg dose

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

AtEase results on key clinical endpoints

TNX-102 SL 5.6 mg subgroup compared to placebo

Category	Endpoint – week 12[1]	*p* value
PTSD Symptoms	CAPS-5 (MMRM with MI)	**0.031**
Global improvement	CGI-I	0.041
Arousal and reactivity	CAPS-5 cluster	0.048
Sleep Quality	CAPS-5 sleep	0.010

p < 0.05 → statistically significant

AtEase pre-specified primary analysis: change from baseline at week 12 mean CAPS-5 score on 2.8 mg (p=0.211)

- MMRM with MI: Mixed-effect Model Repeated Measures with Multiple Imputation
- CAPS-5: Clinician Administered PTSD Scale-5
- CGI-I: Clinician Global Impression- Improvement

[1]Intent-to-treat analysis, N=231 (TNX-102 SL 2.8 mg N=90, TNX-102 SL 5.6 mg N= 49, placebo N=92).

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL safety and tolerability profile in the AtEase study

No serious adverse events reported with TNX-102 SL deemed related to treatment 27

Administration Site Reactions	Placebo (N=94)	TNX-102 SL 2.8 mg (N=93)	TNX-102 SL 5.6 mg (N=50)	Total TNX-102 SL (N=143)
Hypoaesthesia oral	2.1%	38.7%	36.0%	37.8%
Paraesthesia	3.2%	16.1%	4.0%	11.9%
Glossodynia	1.1%	3.2%	6.0%	4.2%
Systemic Adverse Events				
Somnolence	6.4%	11.8%	16.0%	13.3%
Dry Mouth	10.6%	4.3%	16.0%	8.4%
Headache	4.3%	5.4%	12.0%	7.7%
Insomnia	8.5%	7.5%	6.5%	7.0%
Sedation	1.1%	2.2%	12.0%	5.6%

Trial completion rates: 73% placebo; 79% TNX-102 SL 2.8 mg; 84% TNX-102 SL 5.6 mg

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Phase 3 program in PTSD being planned

Two Phase 3 studies:

- **Military-related PTSD**
  - Repeat AtEase
- **Civilian PTSD**

Targeting to start 1Q 2017

TNX-102 SL once-daily at bedtime
5.6 mg *N ~ 225*

Placebo once-daily at bedtime
N ~ 225

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

General Study Characteristics:

- Randomized, double-blind, placebo-controlled study in PTSD
- N~450; approximately 35 U.S. clinical sites

Primary Efficacy Endpoint:

- Difference in total CAPS-5 analysis at Week 12 between TNX-102 SL 5.6 mg and placebo

Topline data anticipated 1H 2018

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Intellectual property

Wholly-owned by Tonix with no obligations to others

TNX-102 SL
Fibromyalgia, PTSD

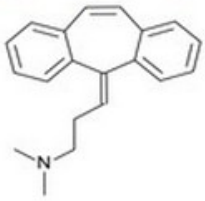
- **Composition-of-matter (eutectic)**
  - Patents filed
  - Protection expected to 2034
- **Pharmacokinetics (PK)**
  - Patents filed
  - Protection expected to 2033
- **Method-of-use**
  - Fibromyalgia: patents issued, 2020 expiry
  - PTSD: patents filed

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL: active pharmaceutical ingredient

- **Cyclobenzaprine is a tricyclic molecule that binds to a number of central nervous system (CNS) receptor types**



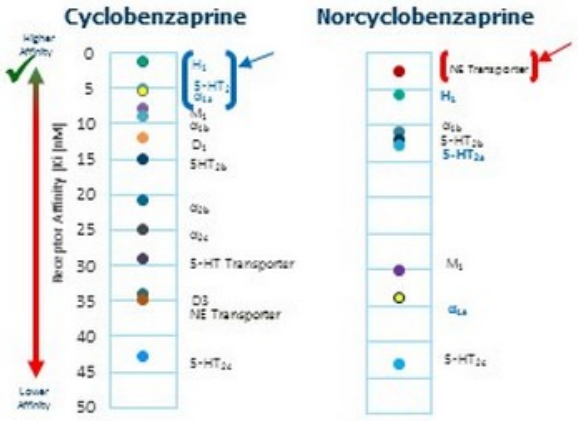
- **Highest affinity for three receptors believed to have a role in treating sleep disturbances**
  - 5-HT_{2A} receptor
  - α_1 adrenergic receptor
  - H_1 receptor

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Properties of cyclobenzaprine and its metabolite norcyclobenzaprine: opportunity to modify pharmacokinetic profile

Receptor Binding Dot Plots for Human Receptors



Cyclobenzaprine Properties:

- High affinity for 3 receptors believed to have a role in sleep quality
  - $5\text{-}HT_{2a}$
  - H_1
  - α_{1a}
- Functional assays ≈ antagonism

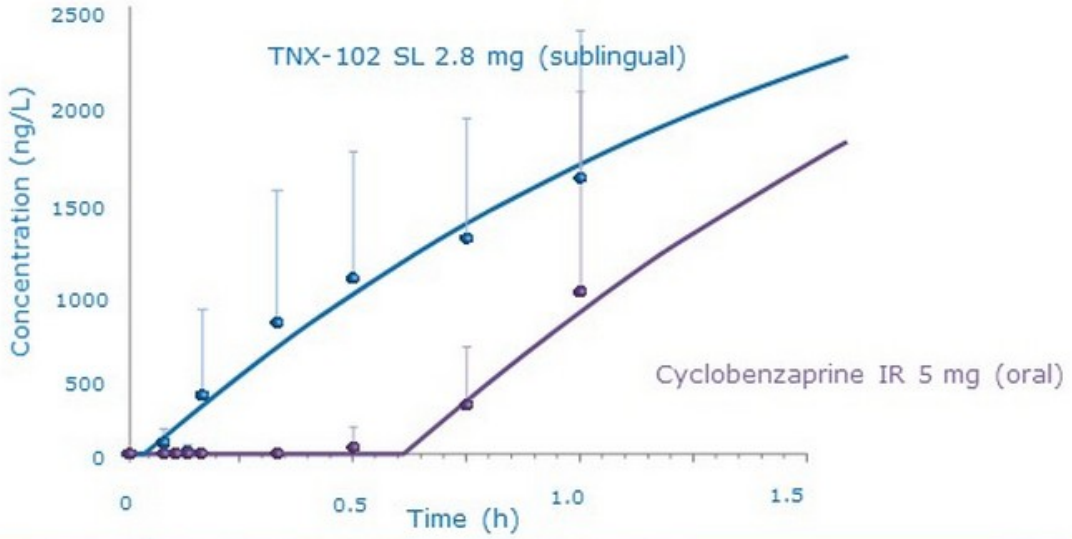
Norcyclobenzaprine Properties:

- Product of first-pass hepatic metabolism
- Persistent - half-life ($t_{1/2}$) ~72 hours
- Less selective for target receptors
- Contributes equally to daytime and nighttime exposure
- Potential for adverse events

TONIX PHARMACEUTICALS

Cyclobenzaprine is detected in plasma within minutes following sublingual TNX-102 SL

Plasma Concentration Versus Time of TNX-102 SL Compared to oral Cyclobenzaprine IR 32



Source: U.S. Patent applications 13/918,692 – Transmucosal absorption.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL: Pharmacokinetic profile after sublingual route of administration

- **Very rapid absorption after dosing (measurable in plasma within 3 minutes of administration)**
  - Maintains T_{max} at ~4 hours after administration
  - Approximately 50% of exposure to cyclobenzaprine occurs during first 8 hours
- **Avoids first-pass hepatic metabolism to persistent metabolite, norcyclobenzaprine**
  - Large reduction in exposure to norcyclobenzaprine (-48% AUC_{0-48})
  - Should equally reduce both daytime and nighttime exposure to norcyclobenzaprine at steady-state
  - Decreased potential for adverse events

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Somnolence and dry mouth with oral and sublingual cyclobenzaprine in fibromyalgia patients

- **ORAL – Phase 2a[1]:**
  - Dose TNX-102 (CBP capsules, 1 mg)
  - Dosing regimen
    - titrated from 1 mg to a range of 2 to 4 mg
    - average of 3.1 mg per day
    - Administered once daily for 8 weeks
    - Administered between dinner and bedtime

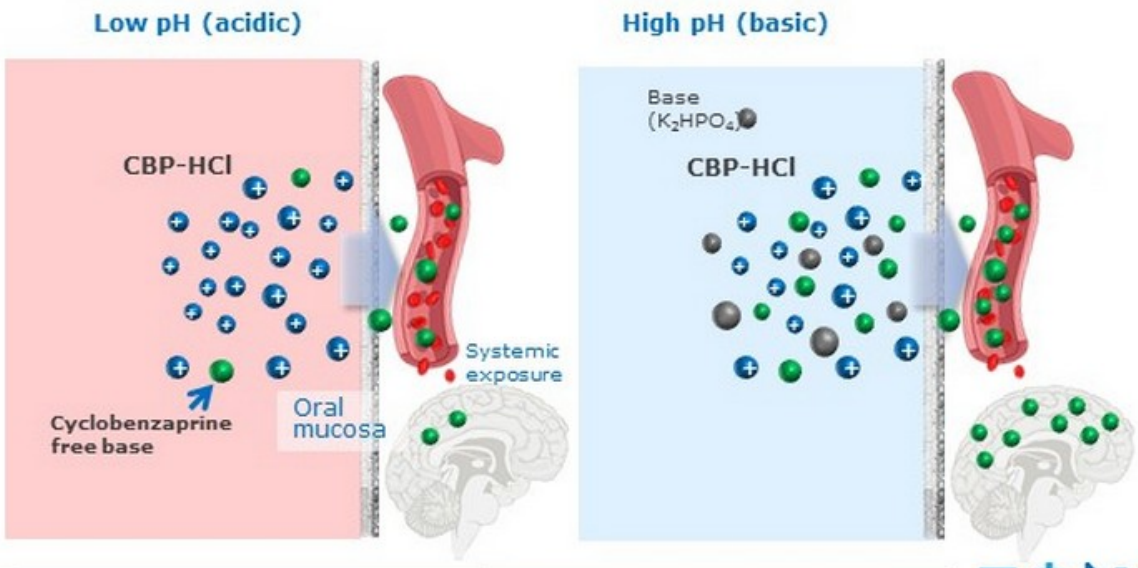
- **SUBLINGUAL – Phase 2b (BESTFIT)[2]:**
  - Dose TNX-102 SL (CBP sublingual tablets, 2.8 mg)
  - Dosing regimen
    - 2.8 mg per day
    - Administered once daily for 12 weeks
    - Administered at bedtime

[1]Moldofsky H, et al "Effects of bedtime very low dose cyclobenzaprine..." J. Rheumatol 2011 38:2653.
[2]Lederman, S et al., Arthritis Rheumatol. 2015; 67 (suppl 10).
TNX-102 (CBP HCl capsules, 1 mg) and TNX-102 SL (CBP HCl sublingual tablets, 2.8 mg) are Investigational New Drugs and are not approved for any indication.

TONIX PHARMACEUTICALS

Formulation with base increases systemic absorption of sublingual cyclobenzaprine[1]

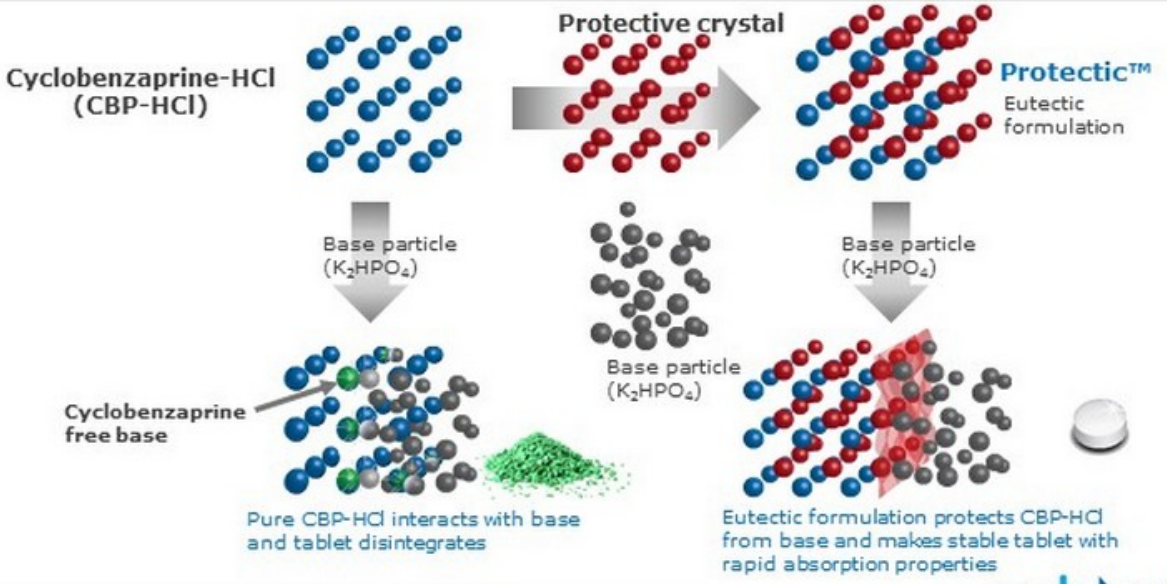
Concentration gradient increases diffusion of free base across oral mucosa (Le Chatelier's Principle) 35



[1]U.S. Patent applications 13/918,692, 14/214,433 and 14/776,624 - Eutectic Formulations.

TONIX PHARMACEUTICALS

Proprietary cyclobenzaprine hydrochloride eutectic mixture stabilizes tablet formulation[1]



[1]U.S. Patent applications 14/214,433 and 14/776,624 - Eutectic Formulations.

TONIX PHARMACEUTICALS

Financial overview

NASDAQ: TNXP	
Cash, cash equivalents, and marketable securities reported at March 31, 2016	$ 27.5 million
Shares outstanding (May 25, 2016)	18.9 million

TONIX PHARMACEUTICALS

Management team

Seth Lederman, MD
President & CEO

Bruce Daugherty, PhD, MBA
Chief Scientific Officer

Gregory Sullivan, MD
Chief Medical Officer

Bradley Saenger, CPA
Chief Financial Officer

Jessica Edgar Morris
EVP, Administration

Ronald Notvest, PhD
EVP, Commercial Planning & Development

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 – Fibromyalgia

☑	May 2015	Began Phase 3 AFFIRM study
☑	November 2015	Presented additional data from Phase 2b BESTFIT study at ACR Meeting
☑	May 2016	Reported completion of enrollment in P3 AFFIRM study
☐	Q3 2016	Report results from P3 AFFIRM study

TNX-102 SL – Post-Traumatic Stress Disorder

☑	December 2015	Entered into Collaborative Research and Development Agreement (CRADA) with the United States Army Medical Materiel Development Activity (USAMMDA)
☑	December 2015	Reported completion of enrollment in Phase 2 AtEase study
☑	2nd Half May 2016	Report results from AtEase study

TONIX PHARMACEUTICALS

NASDAQ: TNXP

509 Madison Avenue
New York, NY 10022
(212) 980-9155

www.tonixpharma.com