

**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 8, 2014

**TONIX PHARMACEUTICALS HOLDING CORP.**

(Exact name of registrant as specified in its charter)

Nevada  
(State or Other Jurisdiction  
of Incorporation)

001-36019  
(Commission  
File Number)

26-1434750  
(IRS Employer  
Identification No.)

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

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

**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))
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**ITEM 7.01 Regulation FD Disclosure.**

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

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

**ITEM 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

99.01 Corporate Presentation by the Company for July 2014\*

\* Furnished herewith.

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**SIGNATURE**

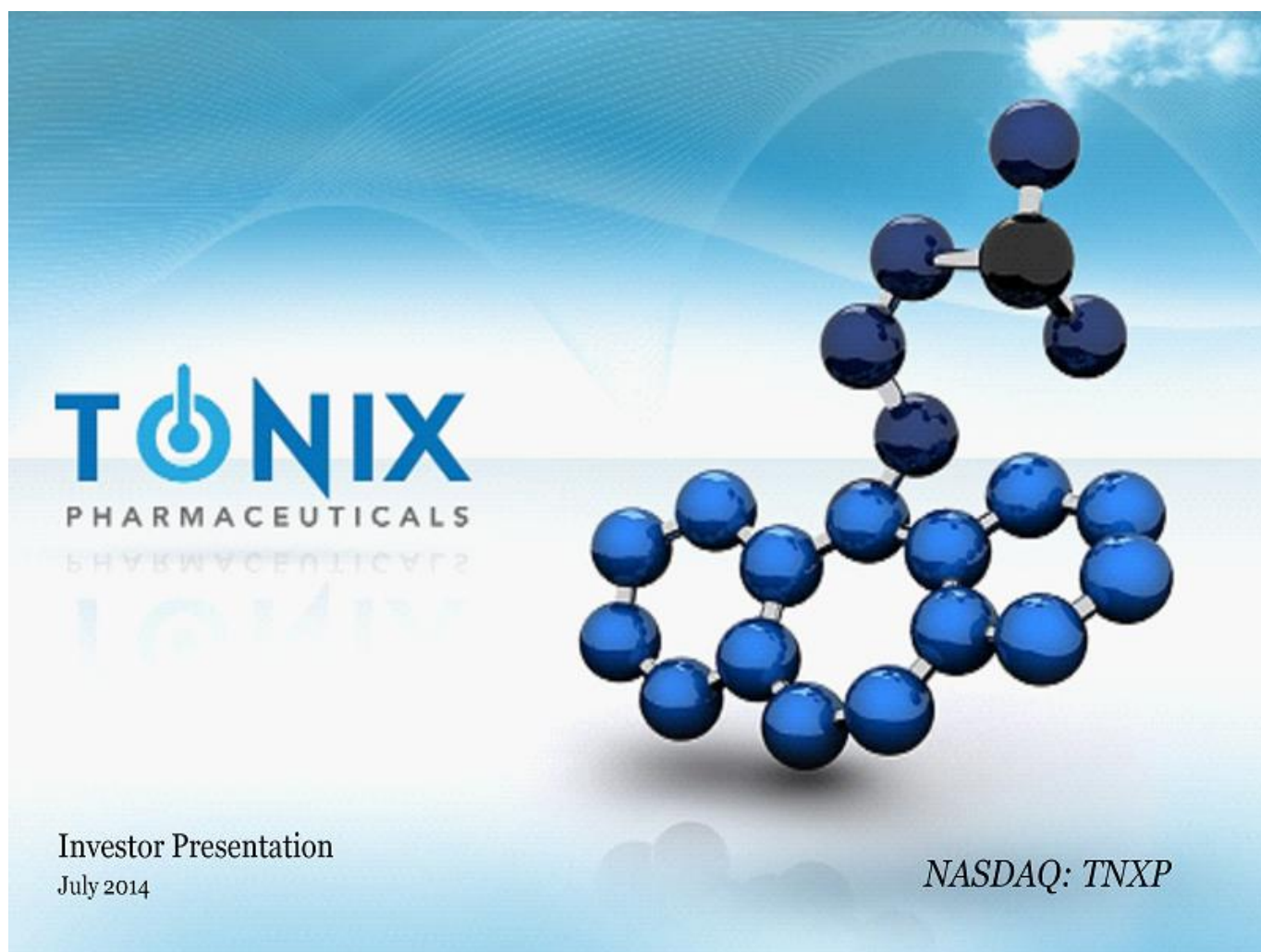
Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**TONIX PHARMACEUTICALS HOLDING CORP.**

Date: July 8, 2014

By: /s/LELAND GERSHELL  
Leland Gershell  
Chief Financial Officer

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# Safe harbor statement

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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 amended Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission (the "SEC") on March 28, 2014 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.

# Investment thesis

## **First-in-class medicines for common disorders of the central nervous system (CNS)**

- New treatment paradigms
- Late stage candidates
- Large unmet medical needs

**Fibromyalgia (FM)** – Top line results from potential pivotal trial in 4Q 2014

**Post-traumatic Stress Disorder (PTSD)** – Phase 2 trial to begin in 4Q 2014

**Episodic Tension-type Headache (ETTH)** – To enter clinic in 4Q 2014

## **All intellectual property owned by Tonix outright – no royalties**

## **Experienced team, strong balance sheet**

- Track record of success in drug approvals and value creation
- Well-capitalized to execute on key near-term milestones



# Development programs

Candidate	Indication	<div> <div>Preclinical</div> <div>Phase 1</div> <div>Proof-of-Concept Phase 2a</div> <div>Pivotal Phase 2b/3</div> <div>NDA</div> <div>Market</div> </div>					
TNX-102 SL	Fibromyalgia	<div> <div>Top line results 4Q14</div> </div>					2017E
TNX-102 SL	PTSD	<div> <div>Ph 2 to start 4Q14</div> </div>					2019E
TNX-201	Headache	<div> <div>4Q14*</div> </div>					2019E

\* To conduct comparative pharmacokinetic and safety study in 4Q 2014

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.  
 TNX-201 (isometheptene mucate single isomer) is not approved for any indication.

# New approaches to treating CNS disorders

## Targeting sleep quality in FM and PTSD

TNX-102 SL is designed as a chronic therapy for bedtime use

Non-restorative sleep linked to pain, fatigue, hyper-vigilance, and arousals

Restorative sleep improves FM and PTSD symptoms

## Novel molecular target in tension headache

Based on proprietary discoveries by Tonix

Mechanism of action distinct from acetaminophen or barbiturates

**Goal – to introduce non-addictive therapeutics  
with the potential to decrease the use of:**

Opiates

Barbiturates

Benzodiazepines

Non-benzodiazepine sleep drugs



# Fibromyalgia market opportunity

## 5 million U.S. patients\*

2.6 million diagnosed; 2.4 million receiving treatment\*\*

## Three FDA approved prescription medications

Category	Product	Company	Approval Year in FM	2012 U.S. Sales in FM***
Membrane Stabilizer	Lyrica®	Pfizer	2007	\$475 million
SNRI	Cymbalta®	Eli Lilly	2008	\$600 million
	Savella®	Forest	2009	\$100 million
Sleep Quality	TNX-102 SL	Tonix	2017E	

\* National Institutes of Health, U.S. Department of Health and Human Services

\*\* Robinson et al, Pain 2012;13:1366-76.

\*\*\* Estimates based on information from publicly-available sources

† EU only

SNRI = Serotonin-Norepinephrine Reuptake Inhibitor

# Fibromyalgia: many dissatisfied patients

## **Chronic, widespread pain with sleep, fatigue, mood, and memory problems**

Typical patient has onset at 30-40 years of age with persistence for rest of life

Impairs daily function and productivity; poor quality of life

Predominantly female

## **Patients remain unsatisfied despite approved products**

Patients often take multiple medications ("polypharmacy")

'Off-label' use of opioids and sedative-hypnotics despite no sustained benefit

FM featured within FDA's Patient-Focused Drug Development initiative

## **Expensive, burdensome condition for the healthcare system**

Health utilization and medication costs are substantial

Managed care / payers recognize need for new therapies

# Fibromyalgia has a high economic impact

## Resource utilization over preceding 12 months

Outpatient visits	82.9 %
Any emergency room visit	40.2 %
Mean number of emergency room visits <sup>†</sup>	2.4

## Productivity measures over preceding 12 months

Missed any work due to FM	47.4 %
Mean days of work missed <sup>†</sup>	58.4
Received disability income benefits	29.9 %
Mean months on disability <sup>†</sup>	10.6

<sup>†</sup> Means include only subjects who experienced the event.

Robinson et al, *Pain Med.* 2012;13(10):1366-76.

# Sleep quality is a new target for FM therapy

## **>90% of FM patients complain of poor sleep quality\***

Restorative sleep improves pain and other FM symptoms

## **Sleep quality of FM patients can be objectively measured: Cyclic Alternating Pattern (CAP)**

A1 patterns indicate sleep stability

A2, A3 patterns indicate sleep instability (poor sleep quality)

## **Pain is the measure of FM severity**

By improving sleep quality, chronic TNX-102 SL therapy is designed to decrease pain

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\* Source: Swick, Ther. Adv. Musculoskel. Dis. 2011;3(4):167-178.



# Phase 2a trial of TNX-102 capsules in FM

## **Double-blind, randomized, placebo-controlled**

Conducted at two academic centers in Canada

## **Enrolled 36 subjects with fibromyalgia; 18 per arm**

TNX-102 capsules or placebo taken between dinner and bedtime daily

## **Eight-week, dose-escalating study**

Daily dosing ranged from 1 – 4 mg of TNX-102

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Source: Moldofsky et al., J Rheum. 2011;38(12):2653-63 - <http://jrheum.org/content/early/2011/08/30/jrheum.110194.full.pdf+html>

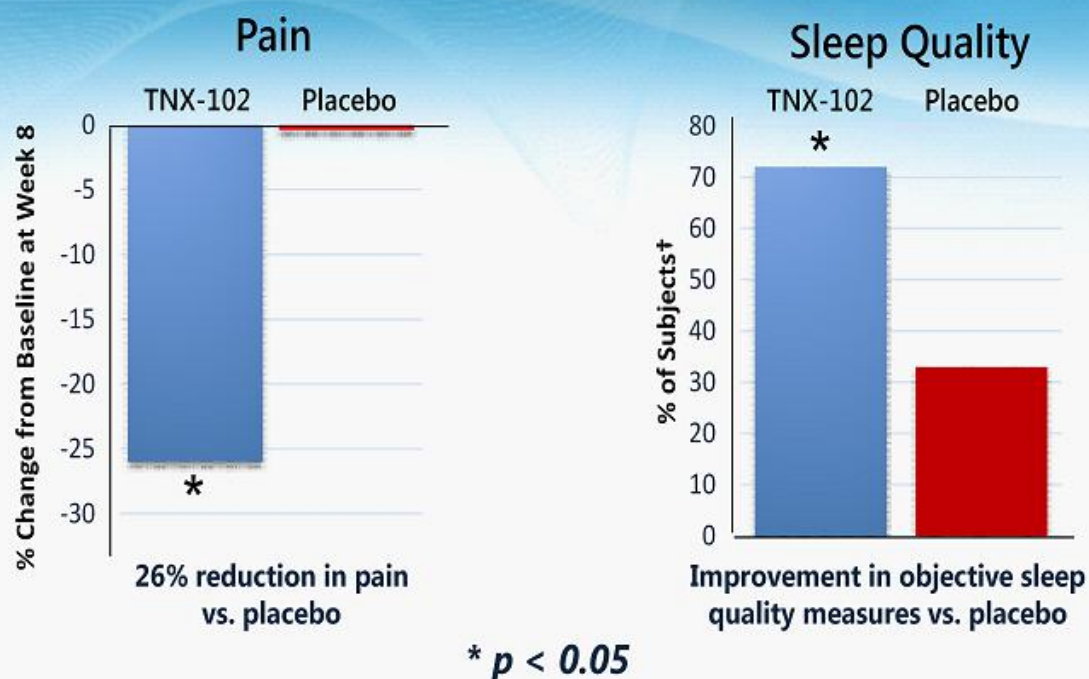
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TONIX PHARMACEUTICALS

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## Positive efficacy results from Phase 2a trial of TNX-102 capsules in FM



† Improving at least one night of CAP<sub>A2+A3(norm)</sub> ≤ 33%  
Mean TNX-102 dose at trial end = 3.5 mg

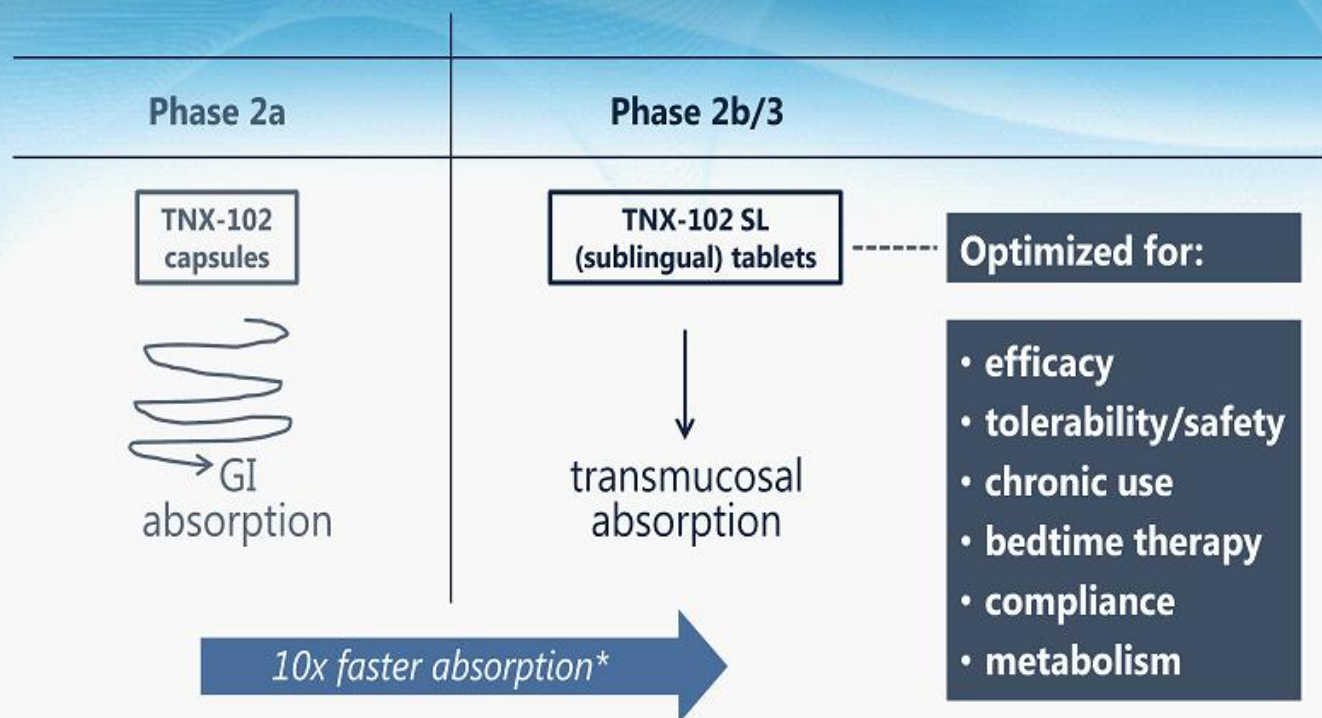
# Safety results from Phase 2a trial of TNX-102 capsules in FM

**No serious adverse events**

**No discontinuations due to adverse events in treatment arm**

<b>Adverse Event</b>	<b>TNX-102, % (N=18)</b>	<b>Placebo, % (N=18)</b>
<i>Any adverse event</i>	83	83
Headache	39	17
Dry mouth	33	6
Somnolence	22	11
Constipation	17	6
Dizziness	17	6
Nausea	11	28
Flu syndrome	11	6
Rhinitis	11	6
Pruritus	11	0

# TNX-102 SL is a sublingual tablet formulation optimized for chronic use at bedtime



\* Absorption lag time ( $t_{lag}$ ) based on clinical pharmacokinetic data

# Registration program for TNX-102 SL in FM

## Two adequate and well-controlled efficacy and safety trials in FM patients

Primary efficacy endpoint = pain

- ✓ First trial has completed enrollment – “BESTFIT”\*
- Top line BESTFIT data expected in Q4 2014

## Long-term exposure data to support chronic use label

100 subjects for six months, 50 subjects for one year

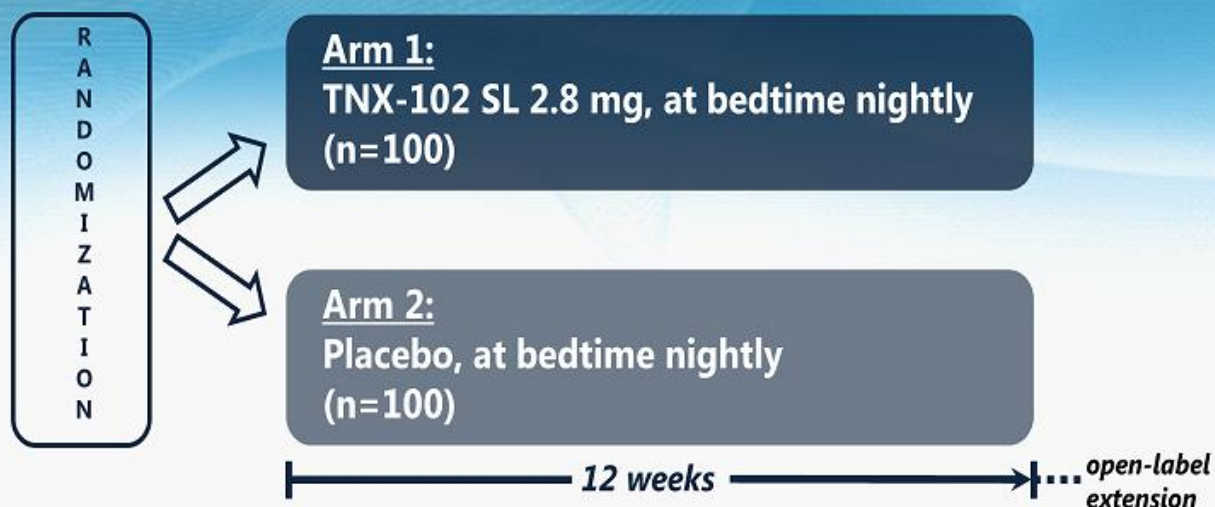
- ✓ Open-label extension study is underway

## Definitive repeat dose pharmacokinetic “bridging” study

\***BESTFIT**: **BE**dtime **S**ublingual **TNX-102 SL** as **F**ibromyalgia **I**ntervention **T**herapy



## "BESTFIT" potential pivotal trial – fully enrolled



**BESTFIT:** BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy

Randomized, double-blind, placebo-controlled; 17 U.S. sites

Primary efficacy endpoint = change in pain at week 12 vs. baseline (Numeric Rating Scale)

Top-line results expected in 4Q 2014

If successful, will serve as first of two pivotal studies to support TNX-102 SL approval in FM



# PTSD market opportunity

**8.4 million U.S. patients\***

4.2 million receiving medical treatment\*\*

## Two FDA approved prescription medications

Category	Product	Company	Approval Year in PTSD
SSRI	Paxil®	Glaxo	2001
	Zoloft®	Pfizer	1999
Sleep Quality	TNX-102 SL	Tonix	2019E

## Phase 2 efficacy study of TNX-102 SL to begin in 4Q 2014

Leverage fibromyalgia formulation, clinical experience, manufacturing know-how

\* National Institutes of Health, U.S. Department of Health and Human Services

\*\* Wang et al., Arch Gen Psych. 2005;62(6):167-78.

SSRI = Selective Serotonin Reuptake Inhibitor

# PTSD is an important public health problem

## **Post-traumatic stress disorder (PTSD) is a chronic debilitating condition**

Patients desperate despite two FDA approved drugs; no new treatment in >10 years  
Associated with suicide and unpredictable, violent behaviors

## **3.5% of U.S. adult population has suffered from PTSD in past 12 months\***

Experiencing any trauma can lead to PTSD  
High incidence among U.S. soldiers and veterans

## **Overlap between PTSD and FM**

~50% of FM or PTSD patients meet criteria for the other disorder  
Patients experience disturbed sleep  
Widespread pain is considered "co-morbid" with PTSD  
Opioid and sedative-hypnotic drug misuse common

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\* National Institutes of Mental Health & National Institutes of Health 2010

# Sleep quality is a new target for PTSD therapy

## **PTSD patients complain of poor sleep quality as a core symptom**

Distressing dreams (nightmares) are part of "re-experiencing"

Restless sleep is part of "hyper-arousal"

## **Poor sleep quality after trauma is linked to onset of PTSD**

Poor sleep correlates with depression, substance abuse and suicide

## **TNX-102 SL targets two different mechanisms, each of which is associated with treating disturbed sleep in PTSD**

Trazodone is an antidepressant used at bedtime off-label

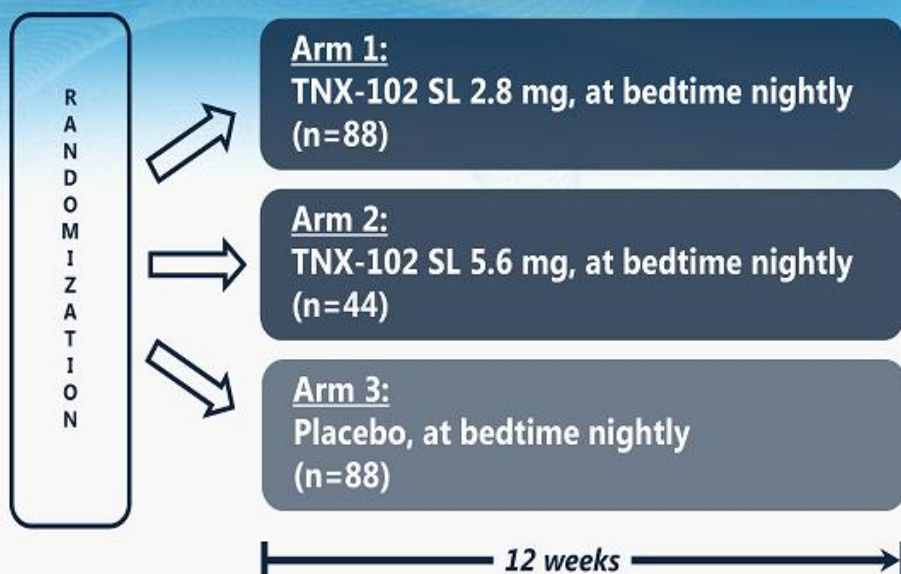
→ blocks the 5-HT<sub>2A</sub> receptor

Prazosin is a high blood pressure medicine used at bedtime off-label

→ blocks the  $\alpha$ -1 adrenergic receptor

TNX-102 SL blocks both the 5-HT <sub>2A</sub> and $\alpha$ -1 adrenergic receptors
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## "AtEase" Phase 2 trial of TNX-102 SL in PTSD



Randomized, double-blind, placebo-controlled; to begin enrollment in 4Q14

N=220; approximately 30 U.S. clinical sites

Primary efficacy endpoint = difference in Clinician-Administered PTSD Scale (CAPS) score  
between TNX-102 SL 2.8 mg and placebo



# TNX-201 – Episodic tension-type headache (ETTH)

## 92 million adults in the U.S. experience tension-type headaches\*

Constant band of pressure on the back/sides of head; “squeezed in a vice” feeling

Projected that 34 million experience frequent episodes\*\*, 12 million seek a medical consult\*\*\*

## Three FDA approved prescription medications – all contain barbiturates

Over-the-counter medications are inadequate for many

Category	Product	Company	Regulatory Status	Approval Year in ETTH
Barbiturate	Fiorinal®	Actavis	Approved NDA	1990
	Fioricet®	Actavis	Approved NDA	1992
Barbiturate + Opiate	Fioricet with Codeine®	Actavis	Approved NDA	1992
New molecular target	TNX-201	Tonix	Pre-IND	2019E

\* Schwartz et al., JAMA 1998;279(5):381-3; Chowdhury, Ann Ind Acad Neurol 2012;15(5):83-88.

\*\* Russell, J Headache Pain 2005;6(6):441-47.

\*\*\* Scher et al., 2010; due to the lack of prescription products for tension-type headache, most patients self-treat



# TNX-201 to enter clinical development in 2014

## **Novel molecular mechanism**

Based on proprietary discoveries by Tonix

Non-barbiturate, non-opioid

Mechanism of action distinct from acetaminophen and barbiturates

## **Comparative pharmacokinetic and safety study to be conducted in 4Q 2014**

Pre-IND meeting with FDA held in January 2014

# Intellectual property

*All IP wholly-owned by Tonix – no royalties / future obligations*

## **TNX-102 SL**

Fibromyalgia, PTSD

### **Composition-of-matter**

Patents filed

Protection expected to 2034

### **Pharmacokinetics (PK)**

Patents filed

Protection expected to 2033

### **Method-of-use**

FM: patents issued, 3Q 2020 expiry

PTSD: patents filed

## **TNX-201**

Headache

### **Composition-of-matter**

Patents filed

Protection expected to 2033

# Milestones – recent and upcoming

## Corporate

- ✓ Jan 2014 – \$40.7 million net proceeds from common stock offering

## TNX-102 SL - FM

- ✓ 3Q 2013 – Began BESTFIT trial in FM
- ✓ 4Q 2013 – Began open-label extension study in FM
- 4Q 2014 – Report top line results of BESTFIT trial in FM

## TNX-102 SL - PTSD

- 4Q 2014 – Start Phase 2 AtEase efficacy study in PTSD

## TNX-201

- ✓ 1Q 2014 – Held Pre-IND meeting for tension-type headache
- 3Q 2014 – File IND for tension-type headache
- 4Q 2014 – Conduct clinical pharmacology study

# Management team

**Seth Lederman, MD**  
CEO

**TARGET**  
X

**Fusilev<sup>®</sup>**  
(levoleucovorin) for injection

**vela**  
PHARM  
VELA PHARMACEUTICALS, INC.

**Leland Gershell, MD, PhD**  
CFO

**COWEN**  
AND COMPANY

**ATON<sup>™</sup>**  
PHARMA

**Zolinza<sup>®</sup>**  
[vorinostat] capsules

**Bruce Daugherty, PhD**  
CSO

 **MERCK**

 **Roche**

**Don Kellerman, PharmD**  
SVP, Clinical Development  
& Regulatory Affairs

 **MAP**  
PHARMACEUTICALS, INC.

**GlaxoWellcome**

**INSPIRE**  
PHARMACEUTICALS, INC.

 **SEPRACOR**

# Board of directors

## Seth Lederman, MD (Chair)

Targent Pharmaceuticals  
Vela Pharmaceuticals

## Ernest Mario, PhD

Glaxo, ALZA  
Reliant Pharmaceuticals

## Stuart Davidson

Alkermes  
Combion

## Charles Mather

Janney Montgomery Scott  
Cowen, Smith Barney

## Patrick Grace

WR Grace  
Chemed

## John Rhodes

NYSERDA, NRDC  
Booz Allen Hamilton

## Donald Landry, MD, PhD

Chair, Department of Medicine  
Columbia University

## Samuel Saks, MD

ALZA  
Jazz Pharmaceuticals



# Financial summary

## NASDAQ: TNXP

Cash reported at March 31, 2014	\$ 49.5 million
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Net cash used in operations in 1Q14	\$ 4.0 million
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Shares outstanding <sup>†</sup>	9.9 million
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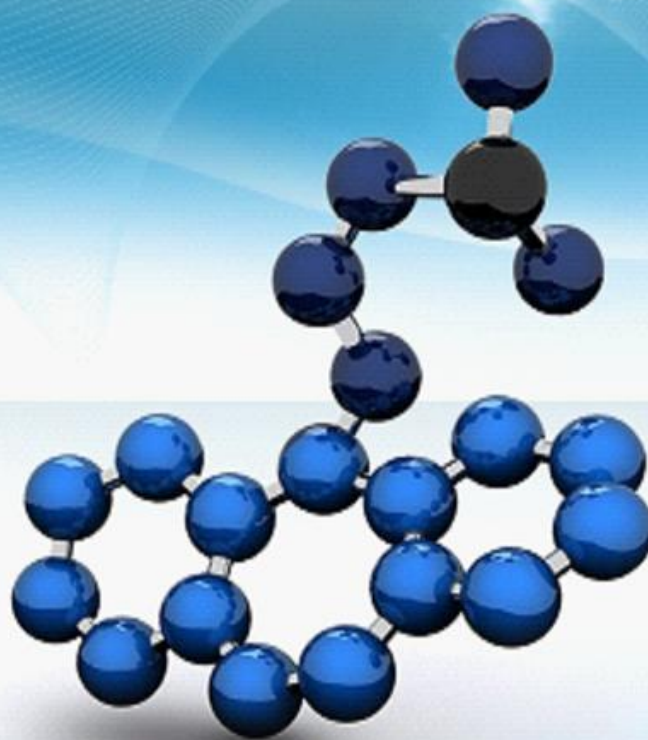
<sup>†</sup> As of July 7, 2014

# Why invest in Tonix now?

- **TNX-102 SL: late-stage clinical program in large market indication**
  - Strong evidence of clinical benefit in Phase 2a
  - Current FM treatment options leave many patients unsatisfied
  - Fibromyalgia is a current focus of the FDA
- **Multiple opportunities (fibromyalgia, PTSD, headache)**
- **Team distinguished by track record of drug development success**
- **Well-capitalized to execute on key near-term milestones**

**TONIX**  
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*NASDAQ: TNXP*