

**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 22, 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:**

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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 May 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: May 22, 2014

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

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**TONIX**

PHARMACEUTICALS

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TONIX



Investor Presentation  
May 2014

NASDAQ: *TNXP*

## 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

## **High impact prescription drug candidates for common and complex disorders**

- First-in-class medicines
- New treatment paradigms
- Large unmet medical needs

## **Fibromyalgia (FM): BESTFIT trial of TNX-102 SL fully enrolled**

- Top line results to be reported in 4Q 2014
- Strong evidence of clinical benefit in Phase 2a
- Measuring impact on pain relief

## **Additional clinical-stage pipeline**

- Post-traumatic stress disorder (PTSD) – targeting sleep pathology
- Tension-type headache – novel molecular target

## **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	Clinical Development				NDA	Market
		Preclinical	Phase 1	Proof-of-Concept Phase 2a	Pivotal Phase 2b/3		
TNX-102 SL	Fibromyalgia	top line results 4Q14				2016E	
TNX-102 SL	PTSD	→				2018E	
TNX-201	Headache	→				2018E	

TNX-102 SL is an Investigational New Drug and is not approved for any indication

# New approaches, new targets

## **Targeting sleep quality is a new approach to FM**

Non-restorative sleep linked to pain and fatigue

Restorative sleep improves FM symptoms

Goal – to introduce an effective and well-tolerated new therapeutic with the potential to decrease use of opiates

## **Targeting sleep quality is a new approach to PTSD**

Non-restorative sleep linked to hyper-vigilance and arousals

Restorative sleep improves processing of emotionally charged memories

Goal – to introduce an effective and well-tolerated new therapeutic with the potential to decrease use of opiates

## **Novel molecular target in tension headache**

Targets of acetaminophen and barbiturates are not understood

Goal – to introduce an effective and well-tolerated new therapeutic with the potential to decrease use of barbiturates



# Fibromyalgia – a significant therapeutic market

**5 million U.S. patients\***

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

## Three FDA approved prescription medications

Category	Product	Company	Prior Indication	Approval Year in FM	2012 U.S. Sales in FM***
Membrane Stabilizer	Lyrica®	Pfizer	Pain (neuropathic)	2007	\$475 million
SNRI	Cymbalta®	Eli Lilly	Depression	2008	\$600 million
	Savella®	Forest	Depression†	2009	\$100 million
Sleep Quality	TNX-102 SL	Tonix	Muscle Spasm	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: a large opportunity for an effective, well-tolerated, differentiated product

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

Impairs daily function and productivity: poor quality of life

"Central pain" - originates in the brain

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

## Results of fibromyalgia survey – 1,700 subjects\*

### 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.

# Inter-relationship of pain and poor quality sleep: new target for drug therapy

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

Non-restorative sleep linked to hyper-vigilance

Restorative sleep improves 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)

## Drugs that decrease A2, A3 as percent of total CAP also improve FM symptoms\*\*

Sodium oxybate: a potent hypnotic, not approved for FM

TNX-102: low-dose cyclobenzaprine, a drug previously approved at higher doses as a muscle relaxant

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

\*\* Source: Moldofsky et al., *J Rheum.* 2010;37(10):2156-66.



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

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

Conducted at two academic centers in Canada

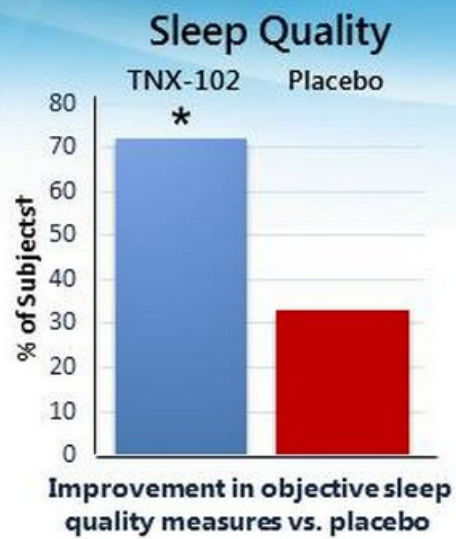
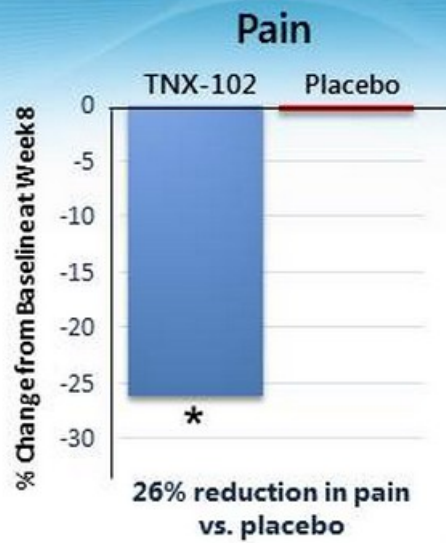
### **Enrolled 36 subjects with fibromyalgia; 18 per arm**

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

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



**\*  $p < 0.05$**

<sup>†</sup> Improving at least one night of  $CAP_{A2+A3(10mm)} \leq 33\%$   
Mean TNX-102 dose at trial end = 3.5 mg



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

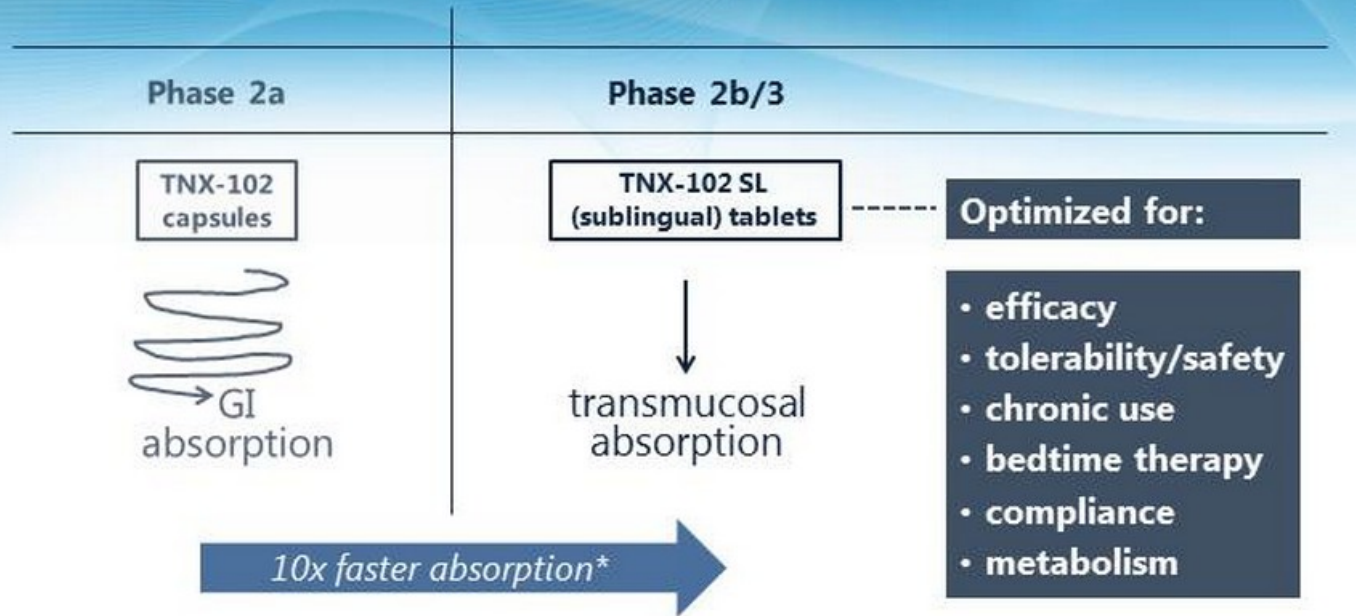
**No serious adverse events**

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

**Types of adverse events consistent with approved cyclobenzaprine products**

Adverse Event	TNX-102, % (N=18)	Placebo, % (N=18)
<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.

# TNX-102 SL – registration program in FM

Pre-Phase 3 meeting held with FDA in February 2013

## Remaining clinical work to support New Drug Application:

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*

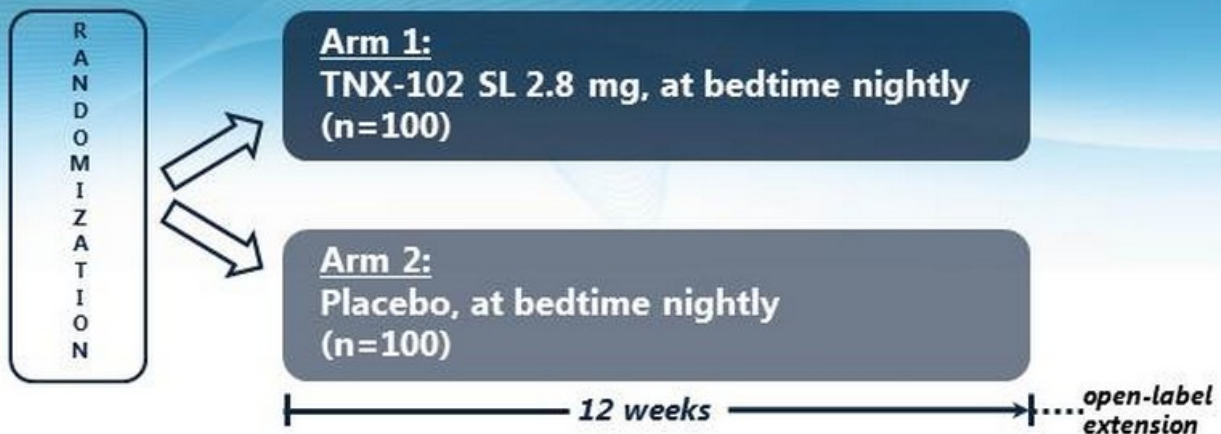
Long-term exposure data to support chronic use label

100 subjects for six months, 50 subjects for one year

- Open-label extension study is underway*

Definitive repeat dose pharmacokinetic “bridging” study

## "BESTFIT" potential pivotal trial – fully enrolled



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

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



# TNX-102 SL – opportunity in PTSD

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

4.2 million receiving medical treatment\*\*

## Two FDA approved prescription medications

Category	Product	Company	Prior Indication	Approval Year in PTSD
SSRI	Paxil®	Glaxo	Depression	2001
	Zoloft®	Pfizer	Depression	1999
Sleep Quality	TNX-102 SL	Tonix	Muscle Spasm	NDA 2018E

## Phase 2 efficacy study of TNX-102 SL to begin in 3Q 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

## 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

Associated with suicide and unpredictable violent behaviors

Patients desperate despite two FDA approved drugs; no new treatment in > 10 years

## 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



# Inter-relationship of PTSD and poor quality sleep: a new clinical target for drug 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

## **Drugs used off-label in PTSD share mechanisms with TNX-102 SL**

Trazodone is an antidepressant used at bedtime

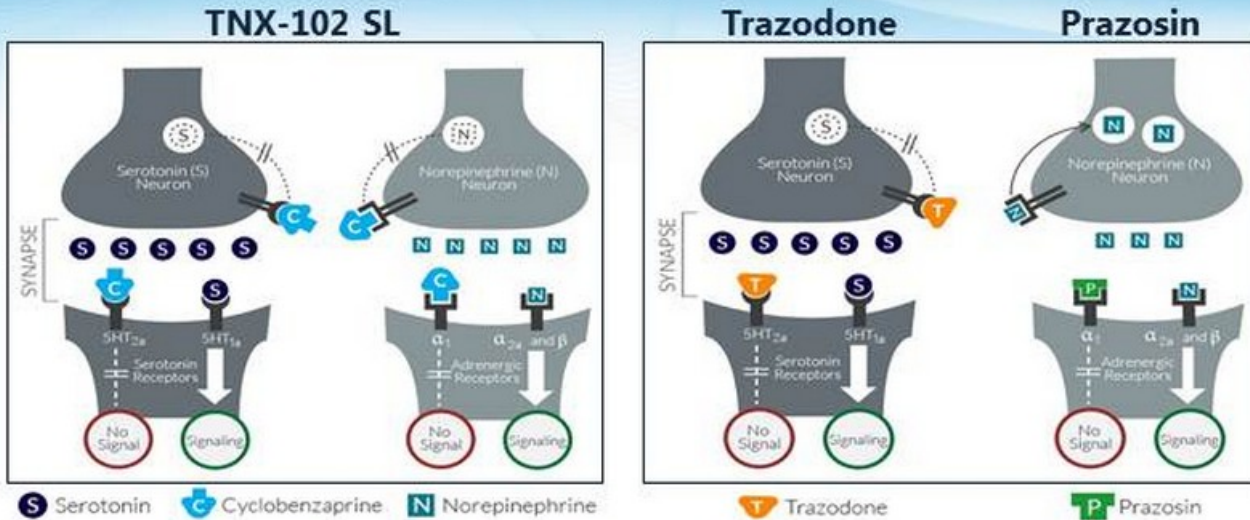
→ *blocks the 5-HT<sub>2A</sub> receptor*

Prazosin is a high blood pressure medicine used at bedtime

→ *blocks the  $\alpha$ -1 adrenergic receptor*

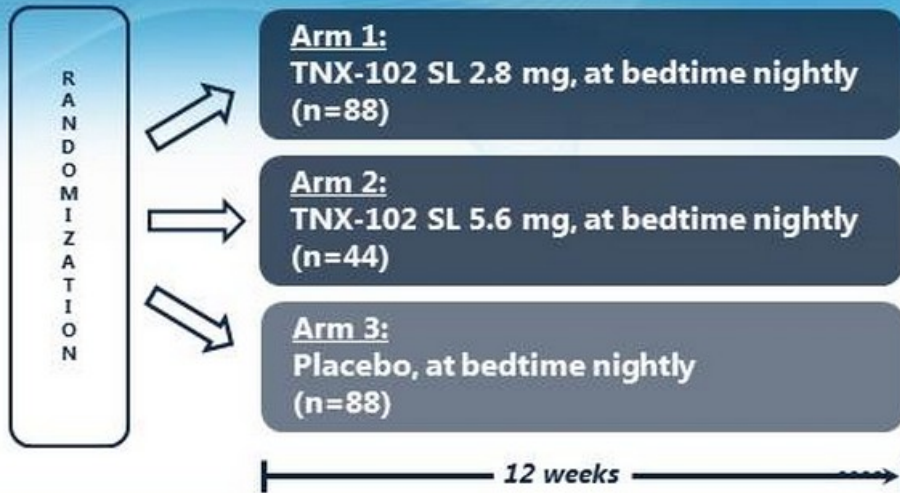
# TNX-102 SL shares activity with drugs used off-label in PTSD

- Trazodone inhibits serotonin 5HT<sub>2a</sub> receptors and serotonin reuptake (SARI)
- Prazosin blocks norepinephrine α<sub>1</sub> receptors



SARI = Serotonin Receptor Antagonist & Reuptake Inhibitor (Stahl SM, CNS Spectrums, 2009;14(10):536-46).  
 TNX-102 SL is an Investigational New Drug and is not approved for any indication.

# Phase 2 trial of TNX-102 SL to begin in 3Q 2014



Randomized, double-blind, placebo-controlled

N=220; approximately 25 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 <sup>®</sup>	Actavis	Approved NDA	1990
	Fioricet <sup>®</sup>	Actavis	Approved NDA	1992
Barbiturate + Opiate	Fioricet with Codeine <sup>®</sup>	Actavis	Approved NDA	1992
New molecular target	TNX-201	Tonix	Pre-IND	NDA 2018E

\* 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

## **TNX-201 (single isomer isometheptene)**

Non-barbiturate, non-opioid

Racemic mixture > 50 years of use in combination products for headache in the U.S.

Not FDA approved for any indication\*

Limited availability, quality concerns via compounding pharmacies

## **Tonix non-clinical research supports the rationale for single isomer development**

Pre-IND meeting with FDA held in January 2014

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

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\* Products containing racemic isometheptene are marketed as unapproved products in the U.S.; marketing withdrawal has been sanctioned by the FDA since 2010.

# Intellectual property

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

## TNX-102 SL

Fibromyalgia, PTSD

### Pharmacokinetics (PK)

Patents filed around unique PK profile  
Protection expected to 2033

### Composition-of-matter

Patent filed - "Eutectic"  
Protection expected to 2034

### Method-of-use

FM: patent issued, 3Q 2020 expiry  
PTSD: patent filed in 2010

## TNX-201

Headache

### Composition-of-matter

Patent filed – single isomer  
Protection expected to 2033



## Milestones – recent and upcoming

### Corporate

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

### TNX-102 SL

- 3Q 2013 – Began BESTFIT trial in FM
- 4Q 2013 – Began open-label extension study in FM
- 3Q 2014 – Start Phase 2 efficacy study in PTSD
- 4Q 2014 – Report top line results of BESTFIT trial in FM

### TNX-201

- Jan 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**

**Fusilev**  
(levoleucovorin) for injection

**vela**  
Vela Pharmaceuticals, Inc.

**Leland Gershell, MD, PhD**  
CFO

**COWEN**  
AND COMPANY

**ATON**  
PHARMA

**Zolinza**  
[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

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 May 16, 2014

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TONIX PHARMACEUTICALS

## 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**



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