

**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): September 26, 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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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 September 2014*

* 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: September 26, 2014

By: /s/ LELAND GERSHELL

Leland Gershell

Chief Financial Officer



Investor Presentation

September 2014

NASDAQ: TNXP

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Safe harbor statement

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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



Tonix - Overview

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

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

Fibromyalgia – Report top line results from BESTFIT trial by October 15, 2014

Post-traumatic Stress Disorder – Phase 2 trial to begin in 4Q 2014

Episodic Tension-type Headache – To enter clinic in 1Q 2015

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

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Candidate	Indication	Proof-of-Concept					NDA	Market
		Preclinical	Phase 1	Phase 2a	Phase 2b/3			
TNX-102 SL	Fibromyalgia	To report top line results of BESTFIT trial by October 15, 2014						2017E
TNX-102 SL	PTSD	Ph 2 to start 4Q14						2019E
TNX-201	Headache	1Q15*						2019E

*To conduct comparative pharmacokinetic and safety study in 1Q 2015

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.

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New approaches to treating CNS disorders

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Targeting sleep quality in fibromyalgia (FM) and in post-traumatic stress disorder (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

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Fibromyalgia market opportunity

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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

SNRI = Serotonin-Norepinephrine Reuptake Inhibitor



Fibromyalgia: many dissatisfied patients

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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

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Resource utilization over preceding 12 months

Outpatient visits	82.9 %
Any emergency room visit	40.2 %
Mean number of emergency room visits*	2.4

Productivity measures over preceding 12 months

Missed any work due to FM	47.4 %
Mean days of work missed*	58.4
Received disability income benefits	29.9 %
Mean months on disability*	10.6

* Means include only subjects who experienced the event.

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

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Sleep quality is a new target for FM therapy

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>90% of fibromyalgia patients complain of poor sleep quality*

Restorative sleep improves pain and other FM symptoms

Sleep quality of fibromyalgia 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 fibromyalgia severity

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

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

Phase 2a trial of TNX-102 capsules in FM

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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

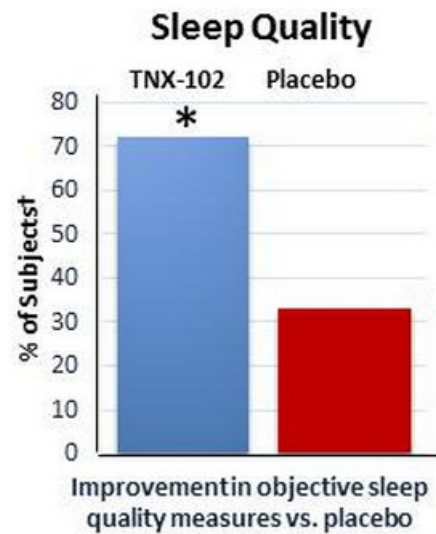
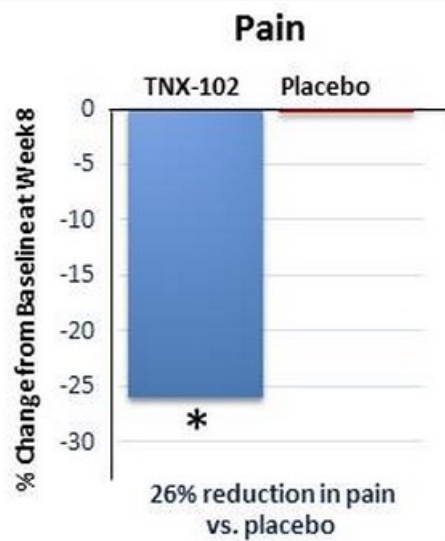
Daily dosing ranged from 1 – 4 mg of TNX-102

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



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

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* $p < 0.05$

+ Improving at least one night of $CAP_{A2+A3(\text{norm})} \leq 33\%$
Mean TNX-102 dose at trial end = 3.5 mg

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

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No serious adverse events

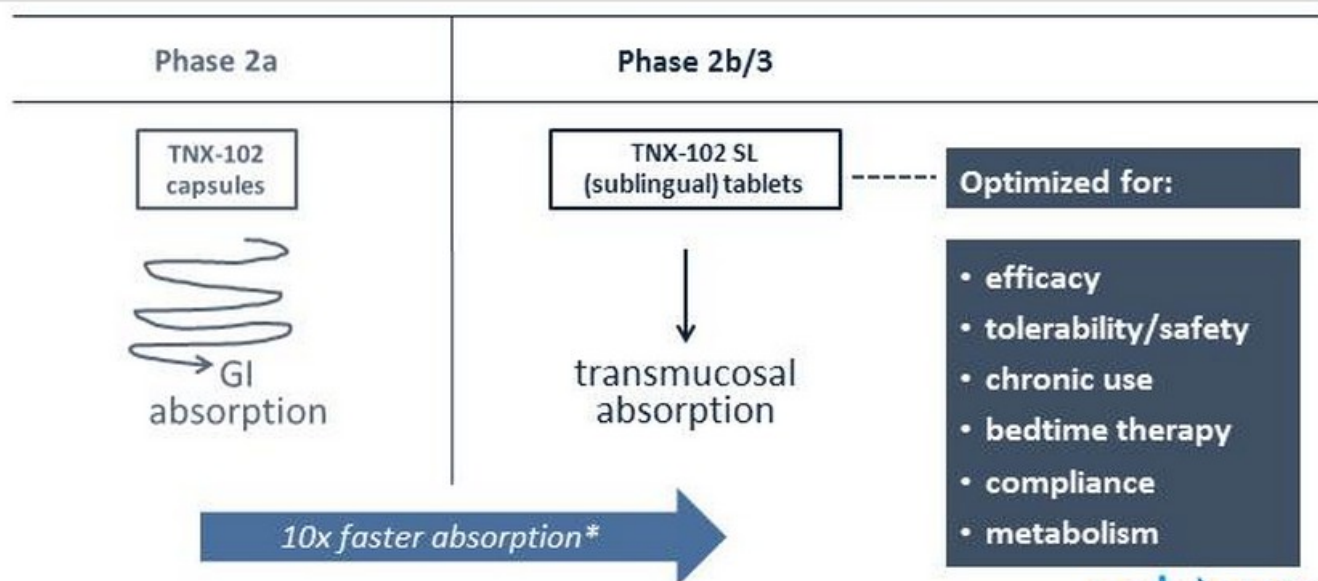
No discontinuations due to adverse
events in treatment arm

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

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

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

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Registration program for TNX-102 SL in FM

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Two adequate and well-controlled efficacy and safety trials in fibromyalgia patients

Primary efficacy endpoint = pain

- ☒ First trial has completed – “BESTFIT”*
- ☐ Report top line results from BESTFIT by October 15, 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

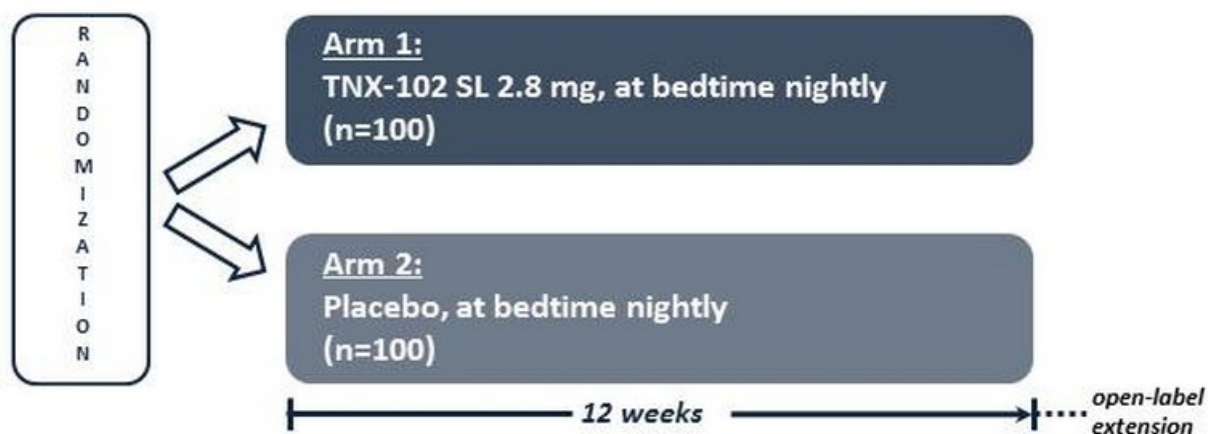
Definitive repeat dose pharmacokinetic “bridging” study

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

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"BESTFIT" potential pivotal trial - completed

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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)

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

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PTSD market opportunity

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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

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Post-traumatic stress disorder 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

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

Sleep quality is a new target for PTSD therapy ¹⁸

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_{2A} receptor*

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

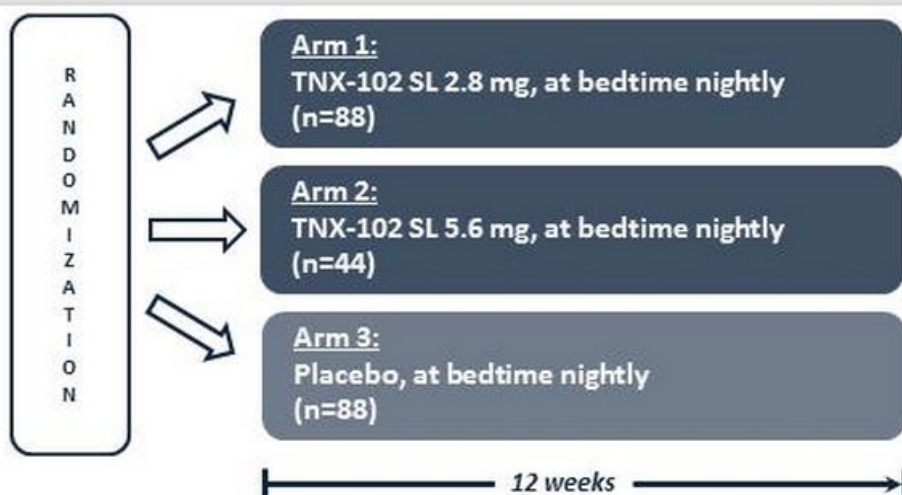
→ *blocks the α -1 adrenergic receptor*

TNX-102 SL blocks both the 5-HT_{2A} and α -1 adrenergic receptors

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"AtEase" Phase 2 trial of TNX-102 SL in PTSD

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

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

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

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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 Neural 2012;15(5):83-88.

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

*** Scher et al., Cephalalgia 2010;30(3):321-328; due to the lack of prescription products for tension-type headache, most patients self-treat

TNX-201 to enter clinical development in 2015

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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 1Q 2015

Pre-IND meeting with FDA held in January 2014



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

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Corporate

- ✓ July 2014 – \$7.2 million in net proceeds from common stock offering

TNX-102 SL - Fibromyalgia

- ✓ August 2014 – Completed BESTFIT trial
- Report top line results from BESTFIT by October 15, 2014

TNX-102 SL - PTSD

- ✓ June 2014 – Received IND clearance
- 4Q 2014 – Start Phase 2 AtEase efficacy study

TNX-201 – Episodic Tension-type Headache

- ✓ January 2014 – Held Pre-IND meeting
- 1Q 2015 – Conduct clinical pharmacology study



Management team

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Seth Lederman, MD
CEO



Leland Gershell, MD, PhD
CFO



Bruce Daugherty, PhD
CSO



Don Kellerman, PharmD
SVP, Clinical Development
& Regulatory Affairs



Board of directors

25

Seth Lederman, MD (Chair)

Targent Pharmaceuticals
Vela Pharmaceuticals

Stuart Davidson

Alkermes
Combion

Patrick Grace

WR Grace
Chemed

Donald Landry, MD, PhD

Chair, Department of Medicine
Columbia University

Ernest Mario, PhD

Glaxo, ALZA
Reliant Pharmaceuticals

Charles Mather

Janney Montgomery Scott
Cowen, Smith Barney

John Rhodes

NYSERDA, NRDC
Booz Allen Hamilton

Samuel Saks, MD

ALZA
Jazz Pharmaceuticals



Financial summary

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NASDAQ: TNXP

Cash reported at June 30, 2014*	\$ 43.9 million
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Net cash used in operations in 2Q14	\$ 5.7 million
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Shares outstanding [†]	10.6 million
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** Does not include \$7.2 million in net proceeds from stock offering in July 2014.*

† As of September 24, 2014



Why invest in Tonix now?

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- **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**





Thank you

NASDAQ: TNXP

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