

**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): February 10, 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))
-

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 February 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: February 10, 2014

By: /s/ LELAND GERSHELL

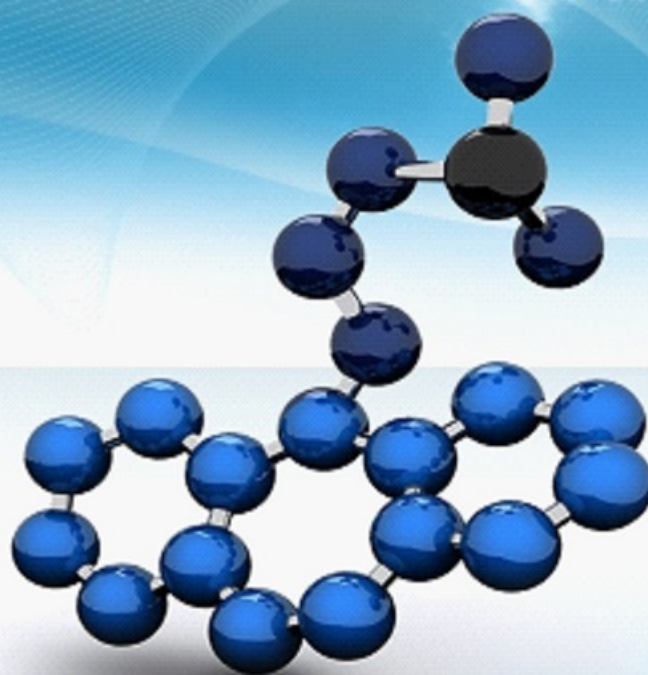
Leland Gershell

Chief Financial Officer

TONIX

PHARMACEUTICALS

5HVBWVCENITCVF2



Investor Presentation
February 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/A for the year ended December 31, 2012, as filed with the Securities and Exchange Commission (the "SEC") on November 22, 2013 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 at-a-glance

NASDAQ: TNXP

Cash reported at September 30, 2013	\$ 7.4 million
Proceeds from warrant exercises*	\$ 8.6 million
Net proceeds from common stock offering**	\$ 40.7 million
Net operating cash burn (January 1 – September 30, 2013)	\$ 5.0 million

Shares outstanding†	9.7 million
---------------------	-------------

* October 1, 2013 – January 29, 2014

** Closed on January 29, 2014

† As of January 29, 2014

Investment thesis

Fibromyalgia: Phase 2b/3 trial of TNX-102 SL underway

- Top line results to be reported in 2H 2014
- Strong evidence of clinical benefit in Phase 2a
- \$1.5B U.S. market; 5M patients in U.S.; large unmet need

Clinical-stage pipeline

- Post-traumatic stress disorder (PTSD)
- Tension headache

High value / low risk strategies: repurposing, reformulating, pure-isomer

- Capital- and time-efficient paths to FDA approval
- Broad human safety experience

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	Phase 2b/3 trial enrolling				2016E	
TNX-102 SL	PTSD	Phase 2 to start 3Q14				2018E	
TNX-201	Headache	Pre-IND				2018E	

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

Advantages of low-risk drug development strategies

Active Ingredient	Safety	Risk to Develop	Cost to Develop	Time to Develop
New	Unknown	Higher	Higher	Longer
Repurposed Reformulated Pure-Isomer	Known	Lower	Lower	Shorter

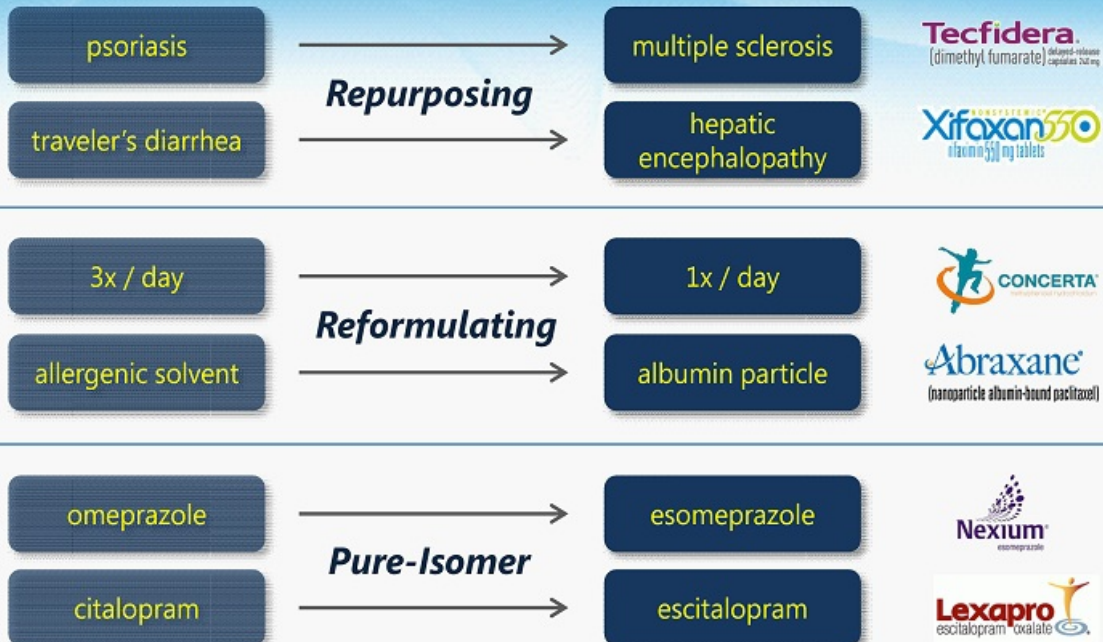
New Drugs

Face high hurdles on demonstrating safety
Many target niche markets like orphan diseases or rare cancers

Repurposed, Reformulated, and Pure-Isomer Drugs

Can address larger, more novel indications than new drugs
Patent strategy can provide significant market exclusivity

New treatment options for important conditions can be created from known drugs



Fibromyalgia – a significant therapeutic market

5 million U.S. patients*

2.6 million diagnosed; 2.4 million receiving treatment**

\$1.5 billion U.S. prescription drug market in 2012***

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

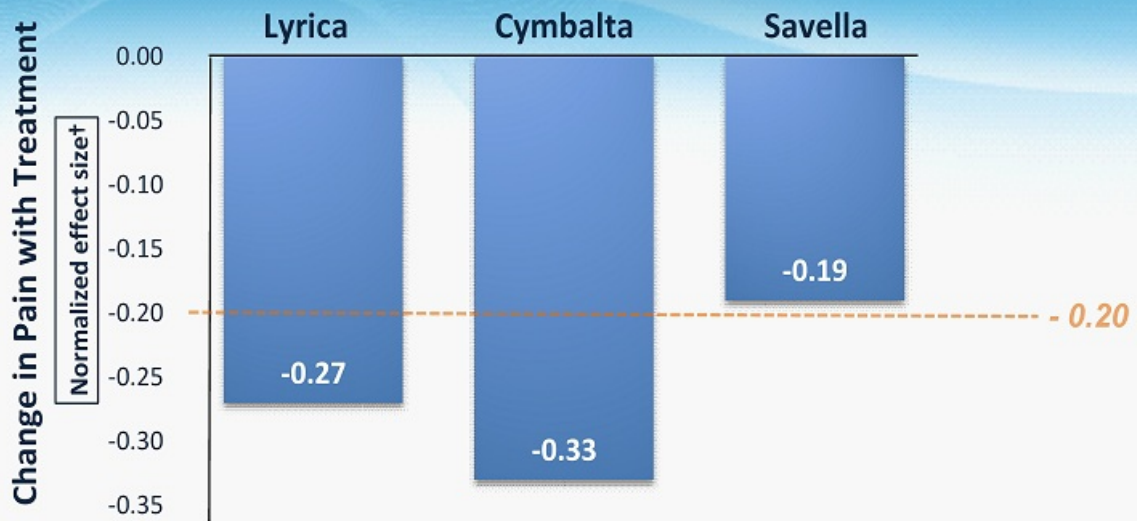
** Robinson et al, Pain 2012;**13**:1366-76.

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

† EU only

SNRI = Serotonin-Norepinephrine Reuptake Inhibitor

Efficacy comparison of approved FM drugs on pain*



* Hauser et al., *J. Pain*. June 2010

† Effect sizes normalized based on Cohen methodology: Cohen J, "A power primer". *Psychological Bulletin* **112**(1):155–159.

Fibromyalgia: a large opportunity for an effective, well-tolerated, differentiated product

Patients feel pain all over the body, but it originates in the brain

Chronic, widespread pain with sleep, fatigue, mood, and memory problems
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
FDA has selected FM as one of 20 conditions for patient input

Expensive, burdensome condition for 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 [†]	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**:1366.

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 (CBP), 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. October 2010.

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

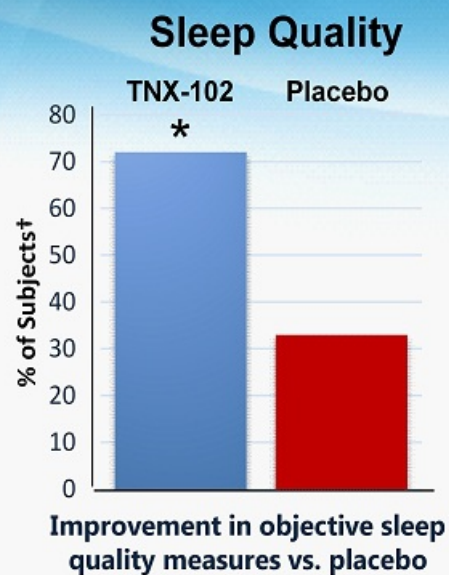
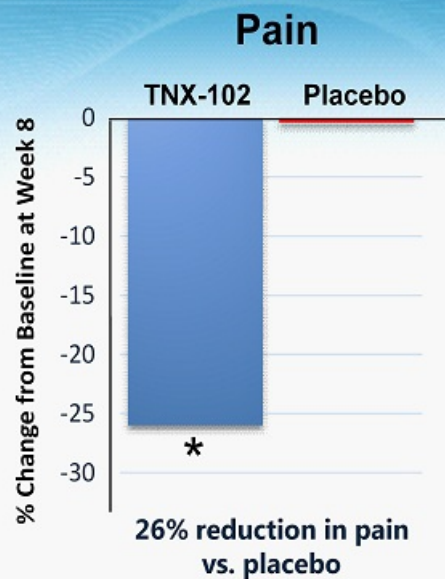
TNX-102 capsules or placebo taken between dinner and bedtime daily

Eight-week, dose-escalating study

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

Source: Moldofsky et al., *J. Rheum.* December 2011: <http://jrheum.org/content/early/2011/08/30/jrheum.110194.full.pdf+html>

Positive efficacy results from Phase 2a trial in FM



* $p < 0.05$

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

Safety results from Phase 2a trial in FM

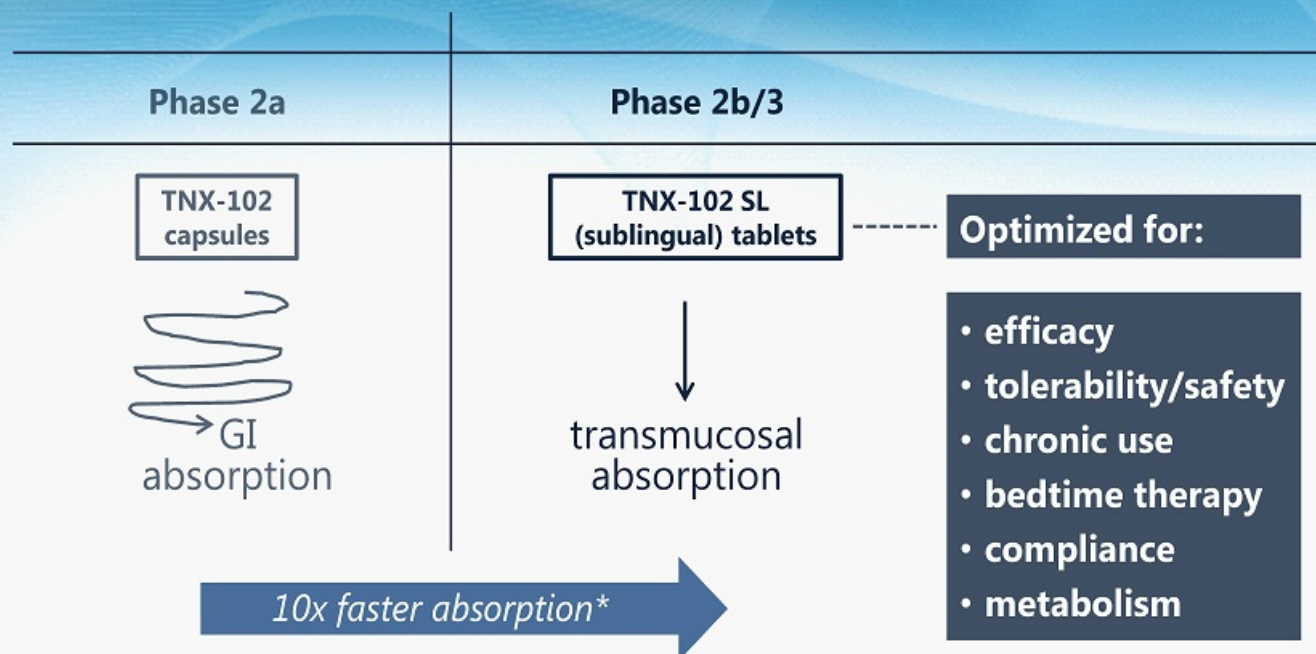
Adverse Event	TNX-102, % (N=18)	Placebo, % (N=18)
<i>Any adverse event</i>	83	83
Headache	39	17
Dry mouth	33	6
Somnolence	22	11
Constipation	17	6
Dizziness	17	6
Nausea	11	28
Flu syndrome	11	6
Rhinitis	11	6
Pruritus	11	0

No serious adverse events

No discontinuations due to adverse events in treatment arm

Types of adverse events consistent with approved cyclobenzaprine products

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

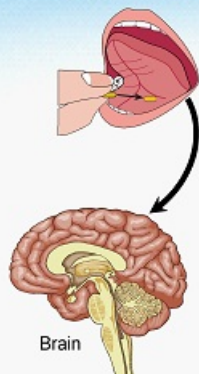


* Absorption lag time (t_{lag}) based on clinical pharmacokinetic data.

TNX-102 SL: first-in-class fibromyalgia medicine

Targets pain and poor sleep

Unique mechanism of action among marketed FM products



Sublingual tablet at bedtime

Fast onset aligns exposure with sleeping period
Designed to optimize ease-of-use, compliance

Very low dose – 2.8 mg per day

Daytime tolerability
Developed for long-term use

Evidence of clinical benefit

Positive clinical experience with TNX-102 capsules

Registration program underway

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 is underway– “BESTFIT”*

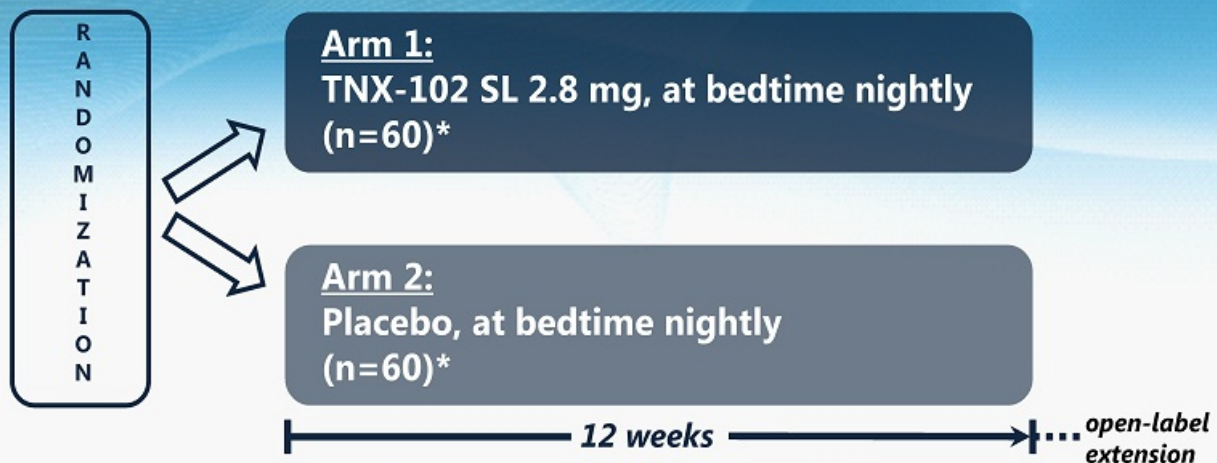
Long-term exposure data to support chronic use label

100 subjects for six months, 50 subjects for one year

✓ *Open-label extension study is underway*

Definitive repeat dose pharmacokinetic “bridging” study

“BESTFIT” Phase 2b/3 trial in FM is enrolling



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

Randomized, double-blind, placebo-controlled; 13-15 U.S. sites

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

Top-line results expected in 2H 2014

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

* Target enrollment; may enroll up to 100 subjects per arm.

Post-traumatic stress disorder: TNX-102 SL

Overlap between PTSD and FM

~50% of FM or PTSD patients meet criteria for the other disorder

Patients experience disturbed sleep and widespread pain

Core defining feature is hyper-vigilance – can disturb sleep

Painkiller abuse and addiction are common

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

Phase 2 study of TNX-102 SL to be initiated in 3Q 2014

Pre-IND meeting held with FDA

Leverage fibromyalgia formulation, clinical experience, manufacturing know-how

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

Tension-type headache: TNX-201

Tension-type Headache

Constant band of pressure on the back/sides of head; "squeezed in a vice" feeling
Frequent episodic type affects >20% of the adult population*
Over-the-counter medications are inadequate for many
The only prescription medications approved for tension headache contain a barbiturate

TNX-201 (pure isomer isometheptene)

Racemic form used in the U.S. for >50 years as oral treatment for headache
Not FDA approved for any indication**
Limited availability, quality concerns via compounding pharmacies
Tonix non-clinical research supports single isomer development strategy

Clinical pharmacology study planned for Q4 2014

Pre-IND meeting with FDA held in January 2014

* Russell et al, *Eur. J. Epidemiol.*, 2006;**21**(2):153-60.

** 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 owned by Tonix outright – 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 – pure 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 2a trial in PTSD
- 2H 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
X

Fusilev[®]
(levoleucovorin) for injection

vela
PHARM
VELA PHARMACEUTICALS INC.

Leland Gershell, MD, PhD
CFO

COWEN
AND COMPANY

ATON[™]
PHARMA

Zolinza[®]
[vorinostat] capsules

Bruce Daugherty, PhD
CSO

 **MERCK**

 **Roche**

Board of directors

Ernest Mario, PhD

Glaxo



Samuel Saks, MD



Johnson & Johnson



Jazz Pharmaceuticals®



Stuart Davidson

Alkermes
Combion

Seth Lederman, MD

Targent Pharmaceuticals
Vela Pharmaceuticals

Patrick Grace

WR Grace
Chemed

Charles Mather

Janney Montgomery Scott
Cowen, Smith Barney

Donald Landry, MD, PhD

Chair, Department of Medicine
Columbia University

John Rhodes

NYSERDA, NRDC
Booz Allen Hamilton

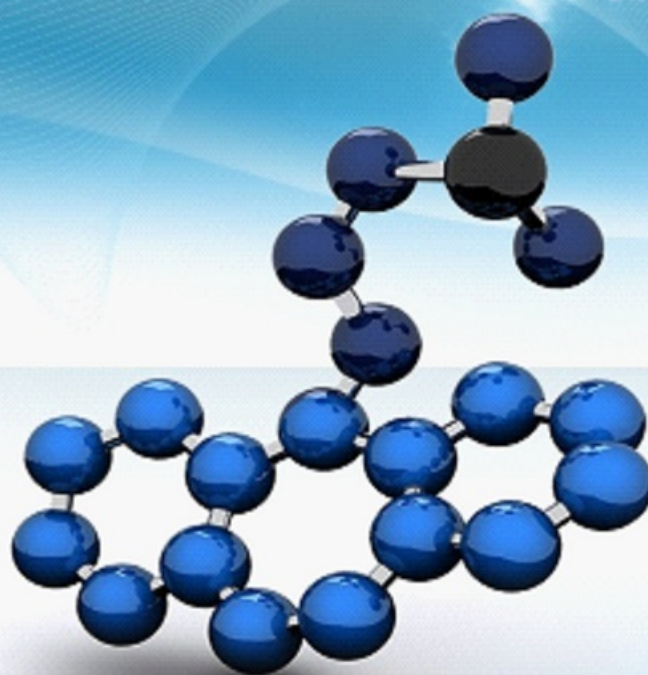
Why invest in Tonix?

- **TNX-102 SL: late-stage clinical program in large market indication**
 - Strong evidence of clinical benefit in Phase 2a
 - Active ingredient has established safety profile at higher doses
- **Multiple opportunities (fibromyalgia, PTSD, headache)**
 - Repurposing, reformulating, pure-isomer strategies offer risk/reward advantage
- **Team distinguished by track record of drug development success**
- **Well-capitalized to execute on key near-term milestones**

TONIX

PHARMACEUTICALS

BIOPHARMACEUTICALS



NASDAQ: TNXP