

**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): November 14, 2013

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 November 2013*

* 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: November 14, 2013

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

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TONIX



Investor Presentation
November 2013

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 Annual Report on Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission (the "SEC") on March 11, 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

Ticker	TNXP
Exchange	NASDAQ Capital Market
Close on 11/13/13	\$4.18
60-day range*	\$3.55 – \$4.40
Fiscal year end	Dec. 31
Shares outstanding	4.87 M
Market cap	\$20 M
<hr/>	
Year Founded	2007
Independent Directors	7
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* September 14, 2013 – November 13, 2013

Investment Thesis

Fibromyalgia (FM) – first anticipated pivotal trial enrolling

\$1.5B U.S. market; widely recognized; large unmet need
Evidence of clinical benefit, well-tolerated in Phase 2
Top line results of Phase 2b/3 trial expected to be reported in 2H 2014

Post-traumatic stress disorder (PTSD)

7 million U.S. patients, rates are on the rise
Phase 2 trial expected to begin in 2Q 2014

Repurposing/Reformulating known drugs

Capital- and time- efficient FDA strategy
Reduced development risk

Experienced management and board of directors

Track record in drug approvals and value creation
All intellectual property owned by Tonix outright – no royalties

Value proposition

August 2013 - first underwritten institutional financing, NASDAQ listing
Public via reverse merger

Repurposing has created a league of successful, valuable products and companies

Increasing therapeutic options for patients

Tonix Pharmaceuticals

muscle spasm → fibromyalgia

Celgene Corporation

morning sickness → myeloma

Revlimid® sales of \$3.7B in 2012

Medicis

bacterial infection → acne

Acquired by Valeant for \$2.6B

Jazz Pharmaceuticals

→ narcolepsy conditions

Xyrem® sales of \$380M in 2012

Advantages of "repurposed" vs. "new" drugs

Active Ingredient	FDA Term	Safety	Risk to Develop	Cost to Develop	Time to Develop
New	505(b)1	Unknown	Higher	Higher	Longer
Repurposed	505(b)2	Known	Lower	Lower	Shorter

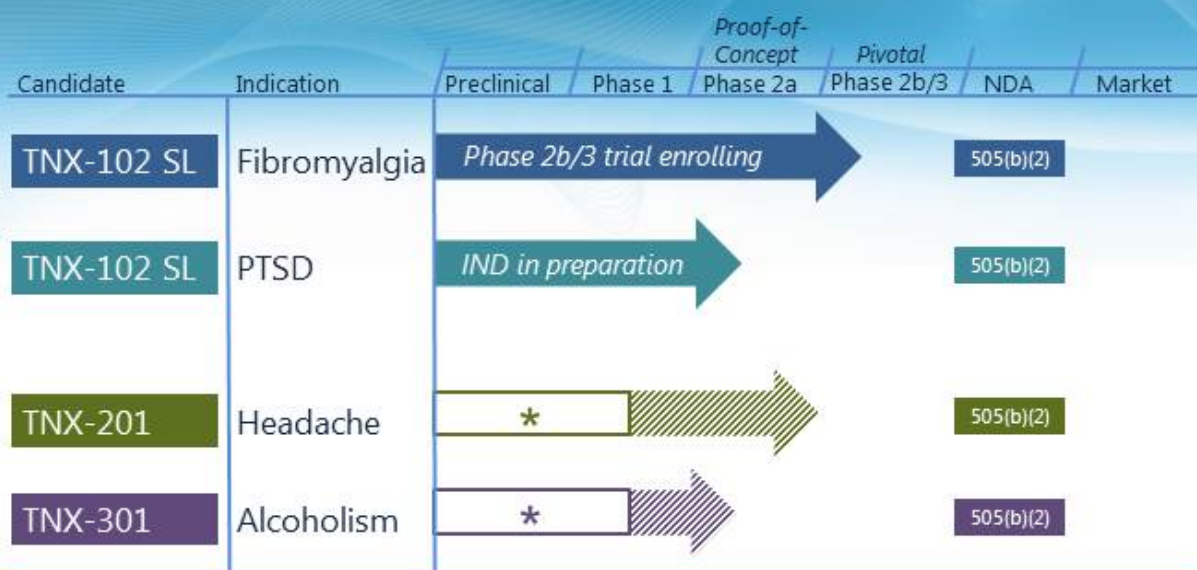
New Drugs

Face high hurdles for showing safety
Many target niche markets like orphan diseases or rare cancers

Repurposed Drugs

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

Product Pipeline



* We expect to be able to enter human clinical studies directly based on existing data.

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

Fibromyalgia – a significant market opportunity

5 million U.S. patients*

2.6 million diagnosed; 2.4 million receiving treatment**

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

14% CAGR 2007-12

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

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
- Non-restorative sleep linked to hyper-vigilance
- Impairs daily function and productivity: poor quality of life
- Predominantly female
- Prescription drugs approved in U.S., Canada, Japan and Israel

Patients remain unsatisfied despite approved products

- Patients often take multiple medications ("polypharmacy")
- 'Off-label' use of opioids and sedative-hypnotics → no sustained benefit, addiction

Expensive, burdensome condition for healthcare system

- Health utilization and medication costs are substantial
- Managed care / payors recognize need for new therapies

Inter-relationship of pain and poor quality sleep in FM: target for drug therapy

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

Restorative sleep improves FM symptoms

**Poor 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)

Drug therapy that decreases A2, A3 as percent of total CAP also improves FM symptoms**

No evidence for utility of insomnia drugs (e.g., Ambien®) in FM

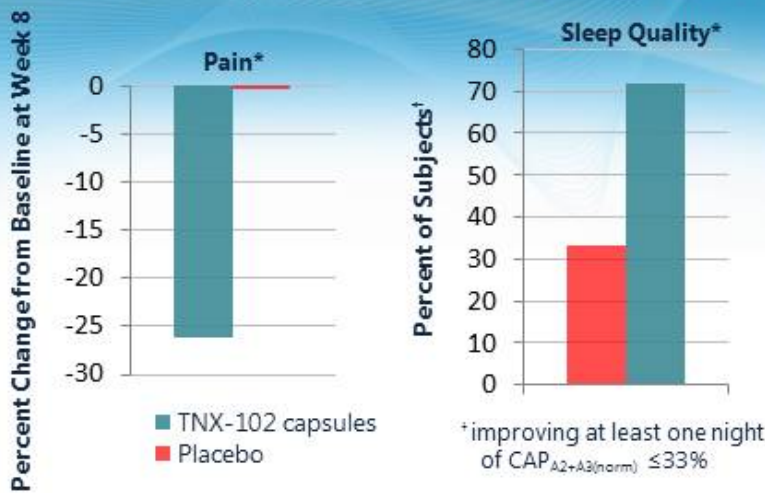
Traditional sedative-hypnotics may disturb sleep architecture

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

** Source: Moldofsky et al., *J. Rheum.* October 2010.

Positive results from Phase 2a trial in FM

TNX-102 capsules (very low dose cyclobenzaprine) taken between dinner and bedtime



Double-blind, randomized
N = 36 (18 each arm)
1 – 4 mg capsules daily x 8 weeks

TNX-102 capsules

- 26% reduction in pain vs. 0% with placebo
- Improvement in sleep quality measures

* p < 0.05 vs. placebo

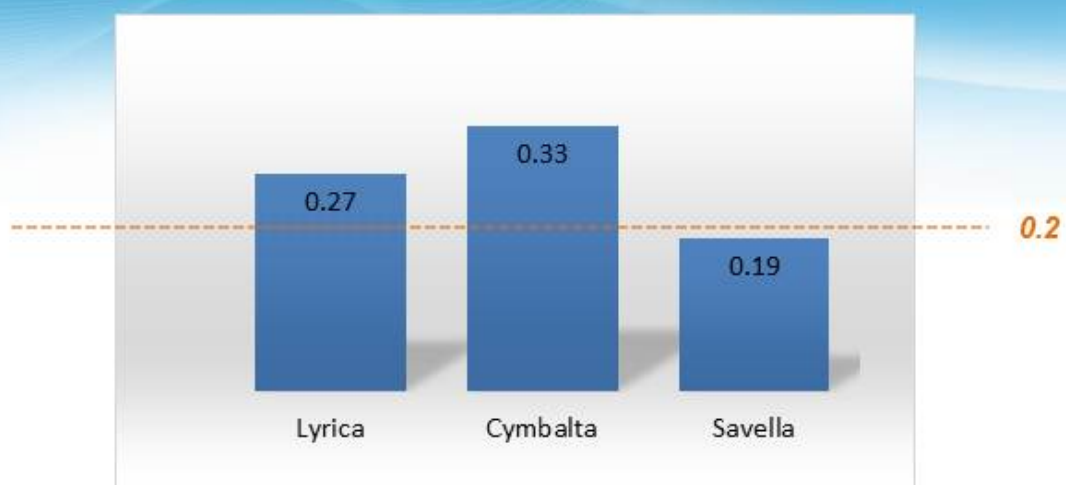
No serious adverse events
No discontinuations due to adverse events in treatment arm
Types of adverse events consistent with approved cyclobenzaprine products

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

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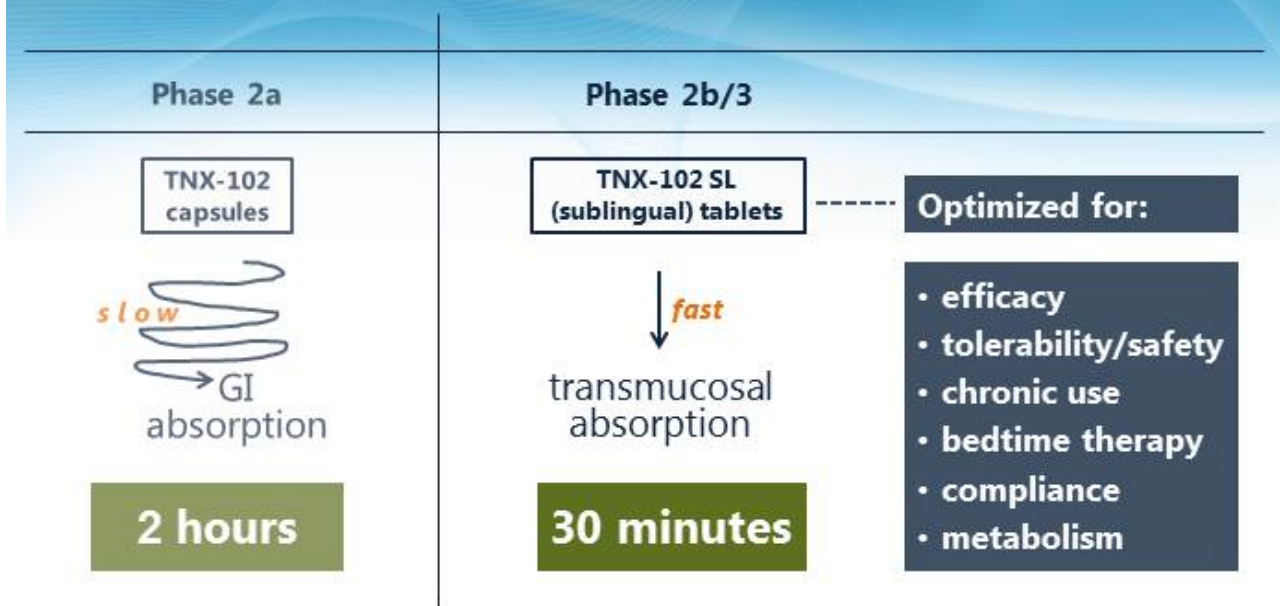
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Normalized ("Cohen") effect sizes of approved FM drugs on pain*



*Hauser et al., *J. Pain*. June 2010; Cohen J, "A power primer". *Psychological Bulletin* 112 (1): 155-159.

TNX-102 SL optimized for use at bedtime



Drug reformulations have generated significant value



Acquired by Allergan - \$958 MM



Acquired by Shire - \$2.6 B



Acquired by Johnson & Johnson - \$11 B



Acquired by Celgene - \$2.9 B

TNX-102 SL – registration program in FM

Held Pre-Phase 3 meeting with FDA in February 2013

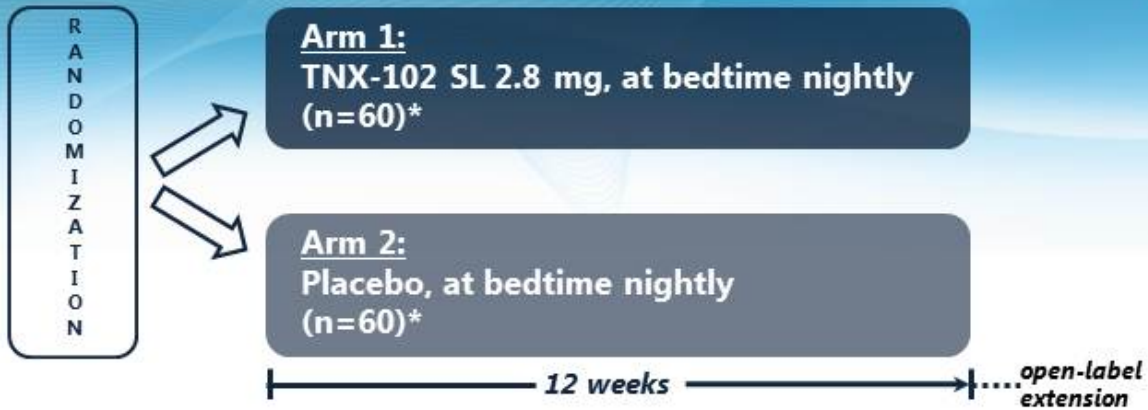
Remaining clinical work to support New Drug Application:

Two adequate and well-controlled safety and efficacy trials in FM patients
Primary efficacy endpoint = pain

Long-term exposure data to support chronic use label
100 subjects for six months, 50 subjects for one year

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; 12-15 sites, all in U.S.

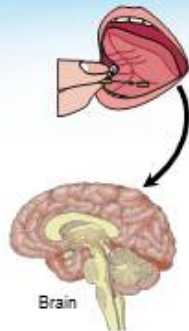
Primary efficacy endpoint = change in pain at week 12 vs. baseline (Numeric Rating Scale)

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 200 patients.

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

Phase 2b/3 BESTFIT study underway

Post-Traumatic Stress Disorder

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, that 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 expected to commence in 2Q 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

Intellectual Property

TNX-102 SL

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

Milestones – Recent and Upcoming

- ✔ 8/9/13 – TNXP stock uplisted to NASDAQ
- ✔ 8/14/13 – Gross proceeds of \$11.4 million from underwritten offering
- ✔ 3Q 2013 – Began Phase 2b/3 trial of TNX-102 SL in FM

- ❑ 4Q 2013 – Begin open-label extension study of TNX-102 SL in FM
- ❑ 1Q 2014 – File IND for TNX-102 SL in PTSD
- ❑ 1Q 2014 – Pre-IND meeting for TNX-201 for headache indications
- ❑ 2Q 2014 – Begin Phase 2a trial of TNX-102 SL in PTSD
- ❑ 2H 2014 – Top line results of Phase 2b/3 trial of TNX-102 SL in FM

Management Team

Seth Lederman, MD
CEO



Leland Gershell, MD PhD
CFO



Bruce Daugherty, PhD
CSO



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

Booz Allen Hamilton
NYSERDA

Why Invest in Tonix?

- **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**
- **FDA 505(b)(2) regulatory pathway offers risk/reward advantage**
- **Multiple opportunities (fibromyalgia, PTSD, headache, alcoholism)**
- **Team distinguished by track record of drug development success**
- **Well-capitalized to execute on key near-term milestones**

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NASDAQ: TNXP