

**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): August 29, 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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New York, New York 10006
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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 August 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.

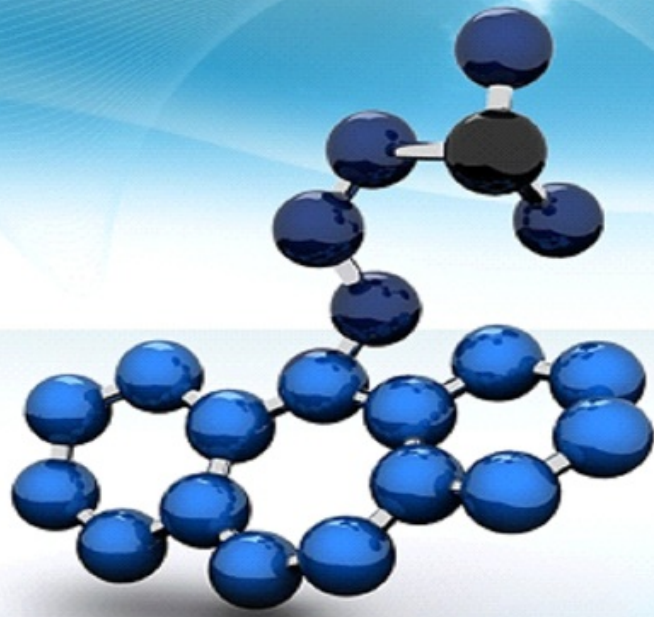
Date: August 29, 2013

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

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Investor Presentation
August 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.

Investment Highlights

Developing novel medications for central pain disorders

Addressing large and unmet needs in the central neuropathic pain market

Fibromyalgia – lead indication

Phase 2b/3 trial of TNX-102 SL to report in 2H 2014

Significant efficacy on core symptoms demonstrated in Phase 2a

Targets pain-sleep 'vicious cycle' – unique, non-addictive treatment approach

Additional market opportunities

Post-traumatic stress disorder (PTSD)

Headache, alcoholism

Capital- and time-efficient FDA strategy

505(b)(2) pathway: faster timeline and reduced risk

Strong market exclusivity

Patent protection on lead candidate expected to extend to 2033

Product Pipeline

Candidate	Indication	Clinical Development Phases					NDA	Market
		Preclinical	Phase 1	Phase 2a	Phase 2b/3			
TNX-102 SL	Fibromyalgia						505(b)(2)	
TNX-102 SL	PTSD						505(b)(2)	
TNX-201	Headache						505(b)(2)	
TNX-301	Alcoholism						505(b)(2)	

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

Fibromyalgia (FM) – Lead Program

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
Typical onset age 20-60; predominantly female
Recognized by health authorities in U.S., Canada, and Japan

Patients desperate for new therapies despite three approved products

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

Expensive, burdensome condition for healthcare system

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

Large opportunity for an effective, well-tolerated, differentiated product

Fibromyalgia 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

Product	Company	Prior Indication	Approval Year in FM	2012 U.S. Sales in FM***
Lyrica®	Pfizer	Pain (neuropathic)	2007	\$475 million
Cymbalta®	Eli Lilly	Depression	2008	\$600 million
Savella®	Forest	Depression†	2009	\$100 million

First FDA approval granted only six years ago

Revenue growth of market driven by converting patients from off-label generics to branded drugs approved specifically for FM†

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

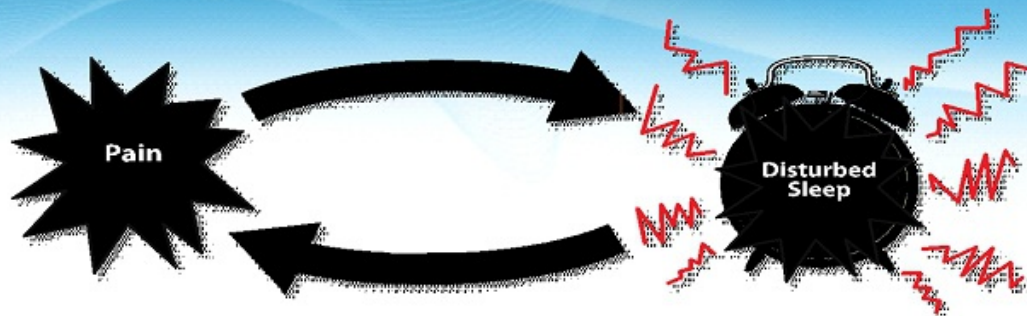
** Robinson et al, Pain 2012; 13: 1366-76.

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

† EU only

† Frost & Sullivan Fibromyalgia Market Assessment, December 2010

Fibromyalgia: A Vicious Cycle of Pain and Poor Quality Sleep



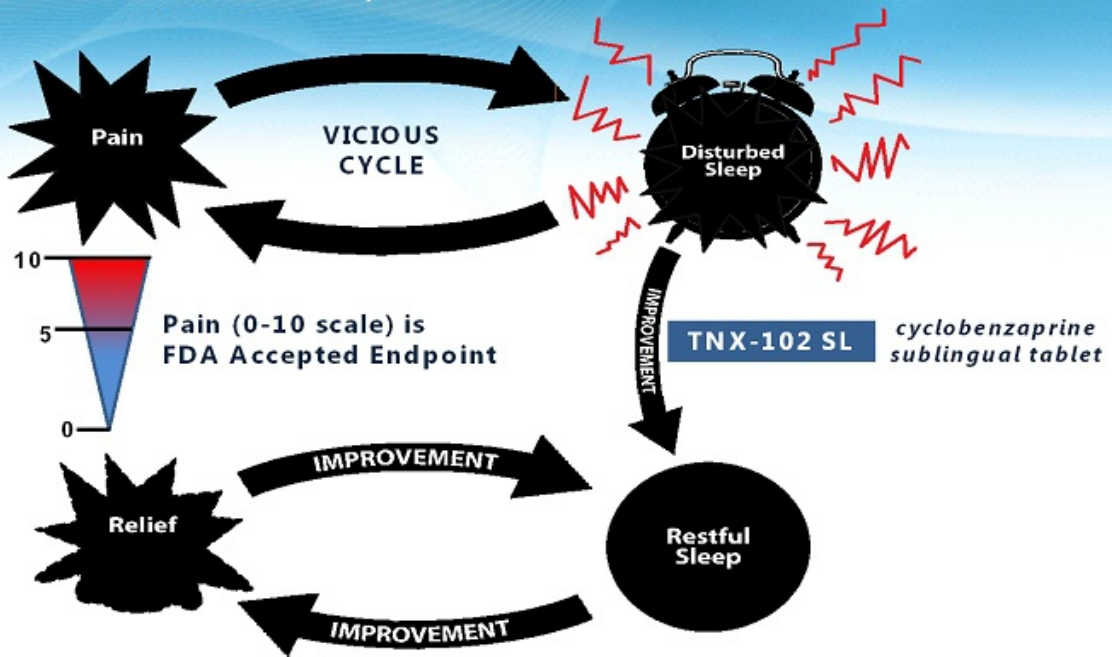
Patient chief complaint: "Hurt all over, can't sleep"

Pain exacerbates poor quality sleep; poor sleep exacerbates pain
No benefit from opiates or prescription sleep drugs

Tonix treatment concept: improving sleep quality can reduce pain and benefit other symptoms

Good quality sleep is "restorative"

TNX-102 SL: Nightly Bedtime Therapy as the Route to Improve FM Pain



Phase 2a Study – Proof-of-Concept

Results published in Journal of Rheumatology*

Harvey Moldofsky, MD – lead investigator (University of Toronto)

Double blind, randomized, placebo controlled study

Conducted at two academic centers in Canada

• under Canadian Clinical Trial Application

36 fibromyalgia patients; 18 per arm

Very low dose cyclobenzaprine (VLD CBP) or placebo

Taken between dinner and bedtime daily

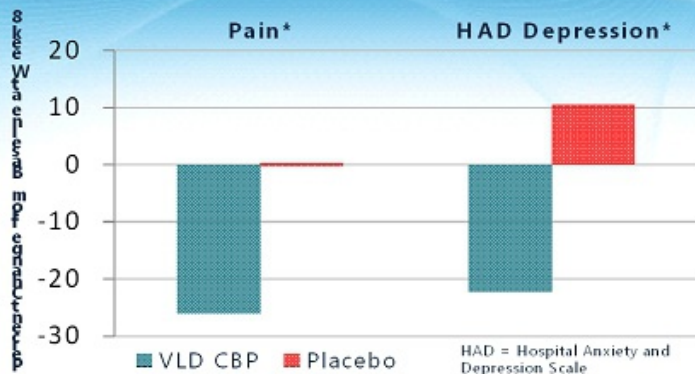
Eight weeks, dose-escalating

1 – 4 mg oral capsules

Average dose at week eight = 3.1 mg

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

Positive Results from Phase 2a VLD CBP in FM



VLD CBP:

- 26% reduction in pain vs. 0% with placebo
- 22% reduction in depressed mood vs. 10% increase with placebo

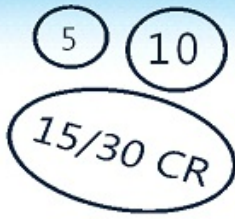



* $p < 0.05$, VLD CBP vs. placebo

No serious adverse events

No discontinuations due to adverse events in treatment arm

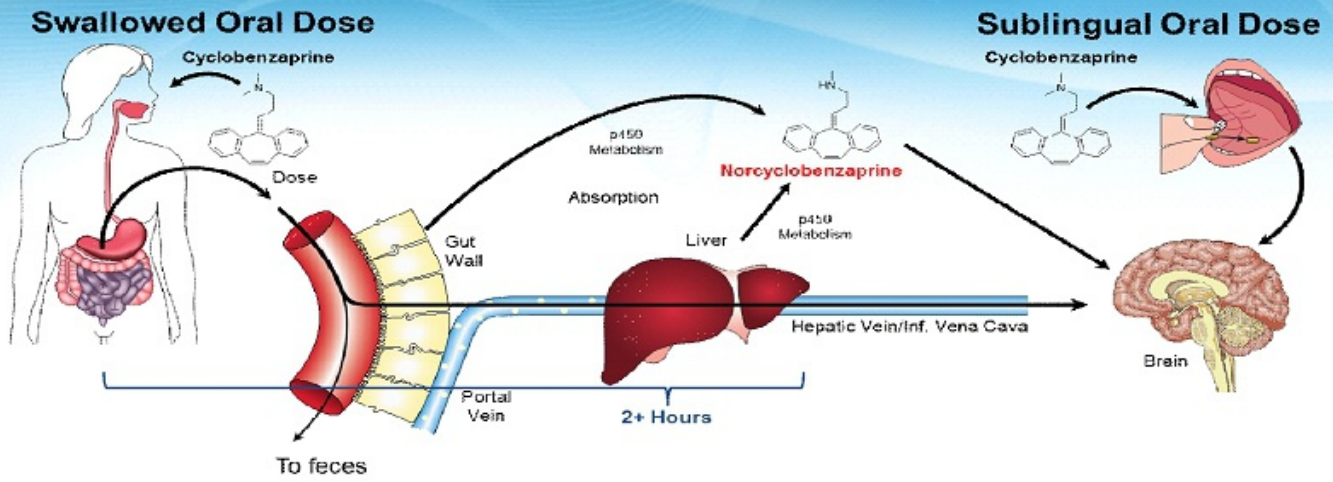
Types of adverse events consistent with approved CBP products (e.g., Flexeril®)

TNX-102 SL Optimizes CBP for FM Therapy

	current CBP products	TNX-102 SL	Optimized for:
Dose	 <p>5 10 15/30 CR</p>	 <p>2.8</p>	<ul style="list-style-type: none">• efficacy• tolerability/safety• chronic use
Delivery	 <p>oral <i>slow</i> GI absorption</p>	 <p>sublingual ↓ <i>fast</i> transmucosal absorption</p>	<ul style="list-style-type: none">• bedtime therapy• compliance• metabolism

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

Sublingual vs. Oral Delivery of CBP

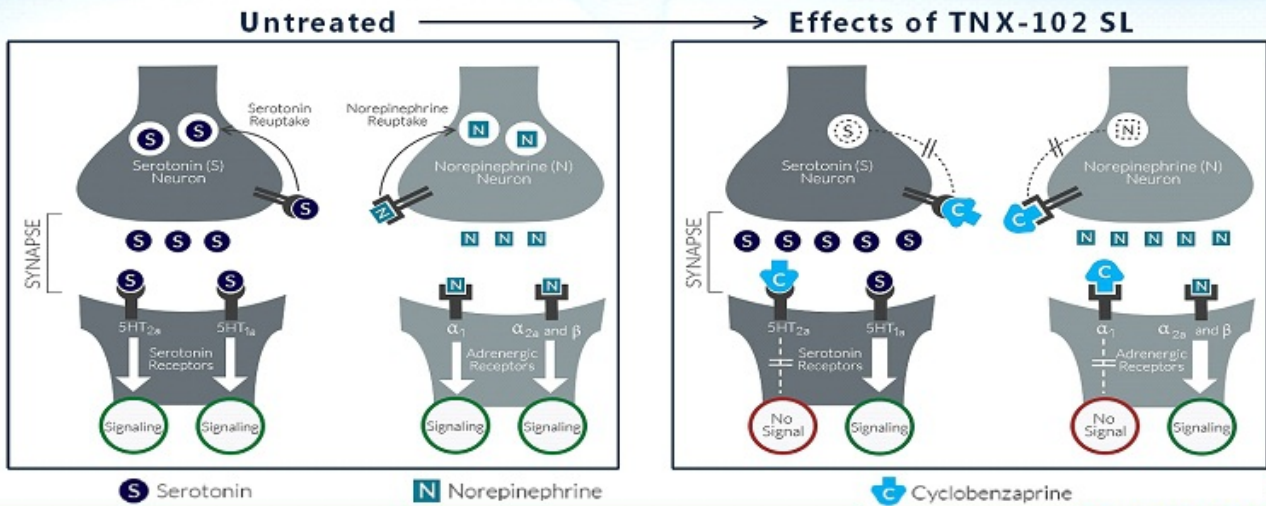


CBP Effects on Nerve Cell Signaling

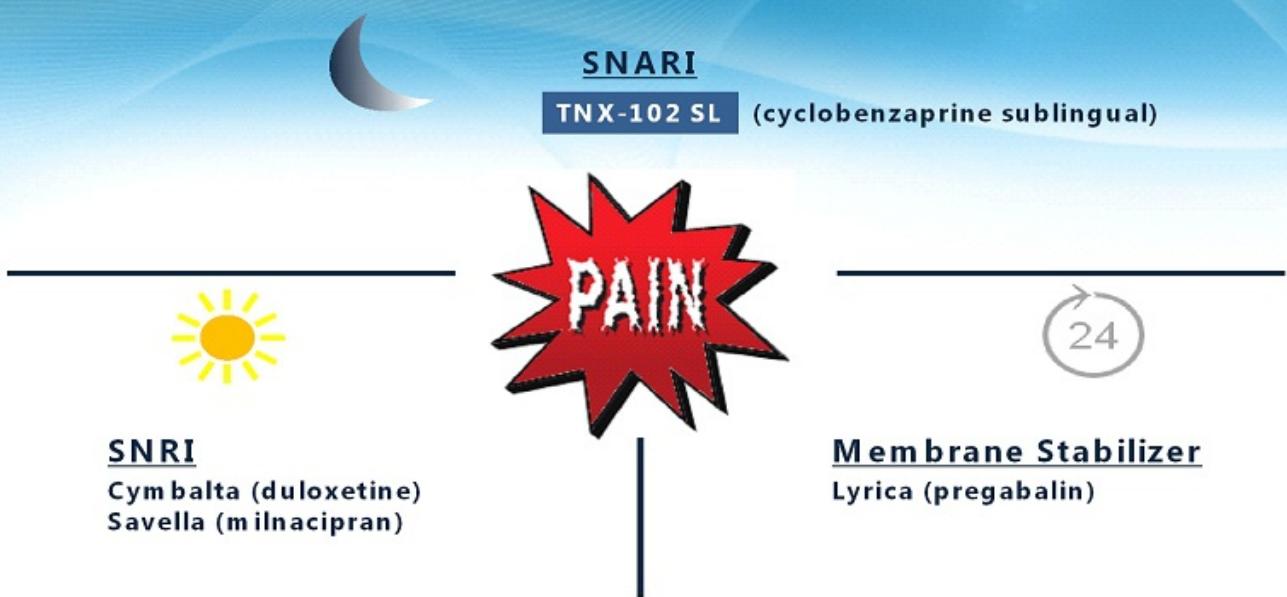
CBP is a multi-functional drug

- inhibits Serotonin and Norepinephrine reuptake
- blocks Serotonin 5HT_{2a} and Norepinephrine α₁ receptors

SNARI = Serotonin and Norepinephrine receptor Antagonist and Reuptake Inhibitor

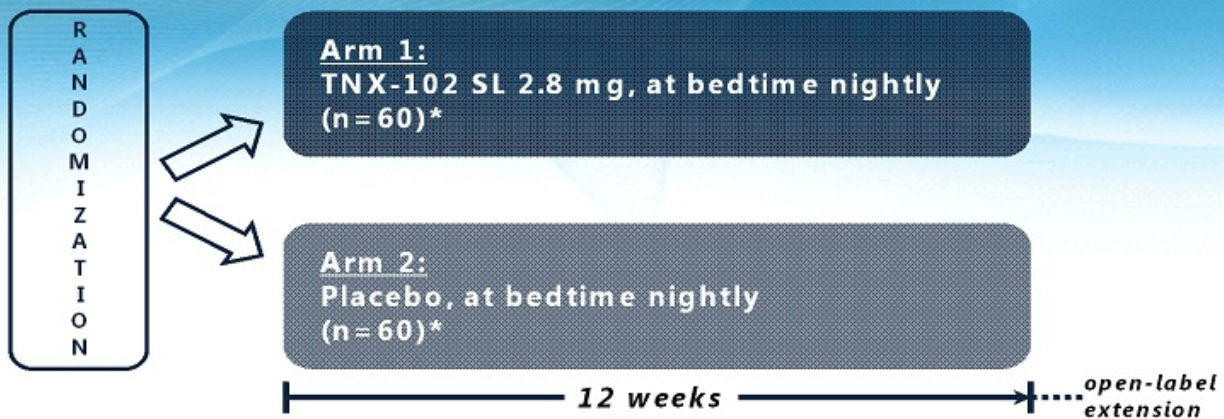


FM Treatments: Central Pain Inhibitors



SNRI - Serotonin & Norepinephrine Reuptake Inhibitor
SNARI - Serotonin & Norepinephrine receptor Antagonist and Reuptake Inhibitor

TNX-102 SL: "BESTFIT" Phase 2b/3 trial in FM



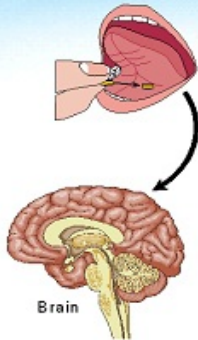
BESTFIT: BEdtime **S**ublingual **TNX-102 SL** as **F**ibromyalgia **I**ntervention **T**herapy
Randomized, double-blind, placebo-controlled; 12-15 sites, all in U.S.
Primary efficacy endpoint = change in pain at week 12 vs. baseline (Numeric Rating Scale)
Top-line results expected in 2H 2014
If successful, to serve as first of two pivotal studies to support TNX-102 SL approval in FM

* Target enrollment; may enroll up to 200 patients.

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TNX-102 SL: First-in-Class Fibromyalgia Medicine



Targets pain and poor sleep

SNARI – 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

Daytime tolerability
Developed for long-term use

Significant treatment effect

Positive clinical experience with VLD CBP

Starting potential registration study in 3Q 2013

TNX-102 SL: 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 night terrors, a form of sleep disturbance

Painkiller abuse and addiction are common

Patients desperate despite two FDA approved drugs

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

Phase 2a proof-of-concept study expected to commence in 1Q 2014

Pre-IND meeting held with FDA

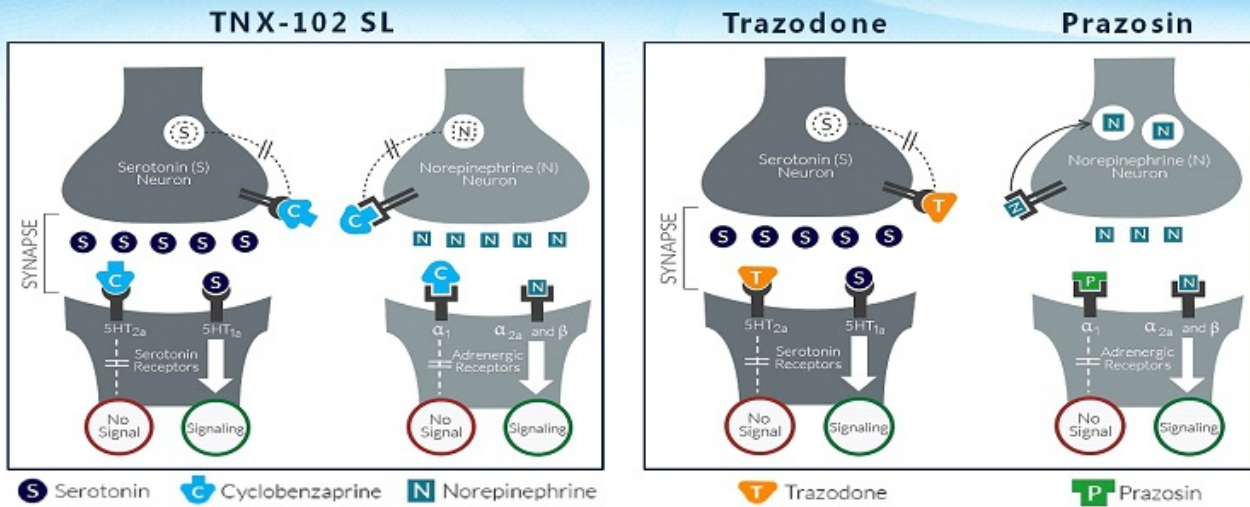
Leverage fibromyalgia formulation, clinical experience, manufacturing know-how

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

Drugs Used Off-Label in PTSD

Trazodone (disordered sleep), Prazosin (night terrors)

- Trazodone inhibits serotonin 5HT_{2a} receptors and serotonin reuptake (SARI)
- Prazosin blocks norepinephrine α_1 receptors



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

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

TNX-201

Composition-of-matter

Patent filed – pure isomer
Protection expected to 2033

TNX-301

Method-of-use


Alcoholism: patent allowed, 4Q 2021 expiry

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 – Begin Phase 2b/3 trial of TNX-102 SL in FM
- 4Q 2013 – File IND for TNX-102 SL in PTSD
- 1Q 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

	Selected Previous Corporate Affiliations	Selected Previous Product Affiliations
Seth Lederman, MD CEO & Chairman	<ul style="list-style-type: none"> • Vela • Targent • Validus • Fontus 	
Leland Gershell, MD, PhD CFO	<ul style="list-style-type: none"> • Cowen • Apothecary Capital • Madison Williams 	
Bruce Daugherty, PhD, MBA CSO	<ul style="list-style-type: none"> • Merck • Roche Institute 	

Board of Directors

	Selected Current & Previous Affiliations	Selected Previous Product Affiliations
Seth Lederman, MD Chairman	<ul style="list-style-type: none"> • Vela • Targent • Validus/Fontus 	
Stuart Davidson	<ul style="list-style-type: none"> • Alkermes • Combion 	
Patrick Grace	<ul style="list-style-type: none"> • WR Grace • Chemed • Grace Institute 	
Donald Landry, MD, PhD	<ul style="list-style-type: none"> • Columbia University <i>Chair, Dept. of Medicine</i> • Vela 	
Ernest Mario, PhD	<ul style="list-style-type: none"> • Glaxo • Alza • Reliant 	
Charles Mather	<ul style="list-style-type: none"> • Janney Montgomery Scott • Cowen • Smith Barney 	
John Rhodes	<ul style="list-style-type: none"> • Booz Allen Hamilton • NRDC 	
Samuel Saks, MD	<ul style="list-style-type: none"> • Jazz • Alza • Cougar 	

Why Invest in Tonix

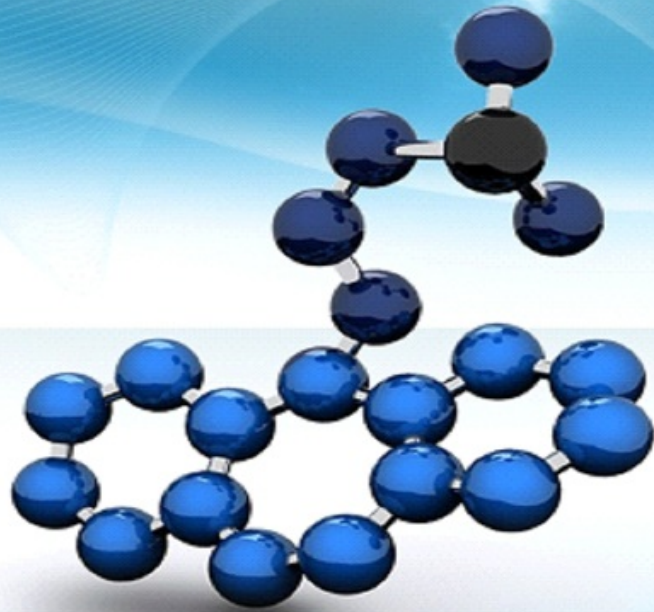
- **Late stage clinical program in large market indication**
- **Strong evidence of desired treatment effect in Phase 2a**
- **Active ingredient has established safety profile at higher doses**
- **Team distinguished by track record of drug development success**
- **Well-capitalized to execute on key near-term milestones**

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БНУКВУСЕНТИСУТЗ

LOWIV



NASDAQ: TNXP