

**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): January 7, 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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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))
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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 January 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: January 7, 2014

By: /s/LELAND GERSHELL

Leland Gershell

Chief Financial Officer

TONIX
PHARMACEUTICALS

BHVBWVCEDTICVT2

TONIX



Investor Presentation
January 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

Ticker	TNXP
Exchange	NASDAQ Capital Market
Cash at 9/30/13	\$7.4 million
Shares outstanding*	5.8 million
Year Founded	2007
Independent Directors	7

** As of December 30, 2013*

Investment Thesis

Fibromyalgia trial underway for TNX-102 SL (sublingual cyclobenzaprine)

- Top line results of Phase 2b/3 trial to be reported in 2H 2014
- Anticipated to be the first of two pivotal trials required for FDA approval
- Strong evidence of clinical benefit in Phase 2a
- \$1.5B U.S. market; 5M patients in U.S.; large unmet need

Robust pipeline of products

- Post-traumatic stress disorder (PTSD): Phase 2 trial to begin in 3Q 2014
- Tension headache: Pre-IND meeting to be held in 1Q 2014

Repurposing and reformulating strategy

- Capital- and time- efficient FDA approval path
- Reduced development risk

All intellectual property owned by Tonix outright – no royalties

Experienced management and board of directors

- Track record of success in drug approvals and value creation

Advantages of “repurposed/reformulated” 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/Reformulated	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/Reformulated Drugs

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

Product Pipeline

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				505(b)(2)
TNX-102 SL	PTSD	IND in preparation				505(b)(2)
TNX-201	Headache	Pre-IND				505(b)(2)
TNX-301	Alcoholism	Pre-IND				505(b)(2)

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

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***

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	

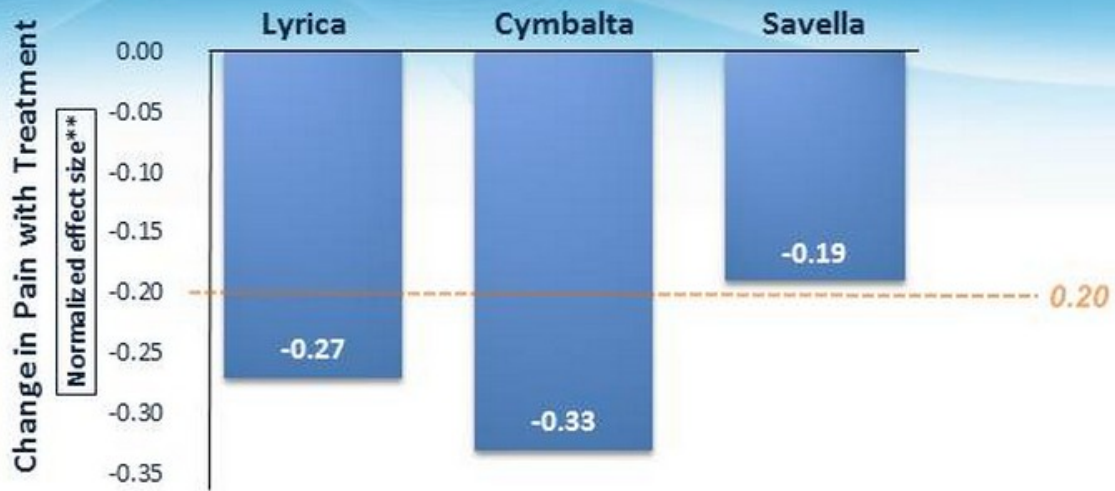
* National Institutes of Health, U.S. Department of Health and Human Services

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

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

† EU only

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

FDA has selected FM as one of 20 conditions for patient input
Patients often take multiple medications ("polypharmacy")
'Off-label' use of opioids and sedative-hypnotics → no sustained benefit

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: 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

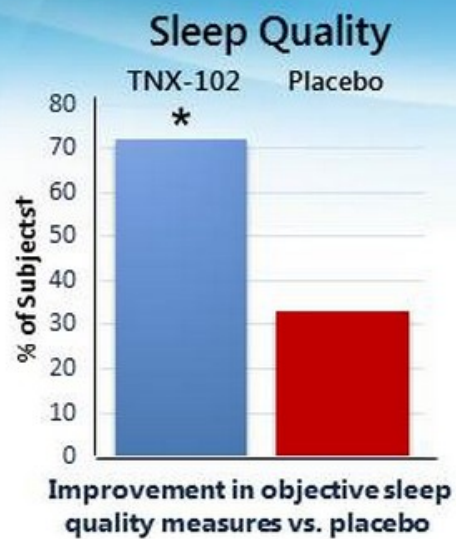
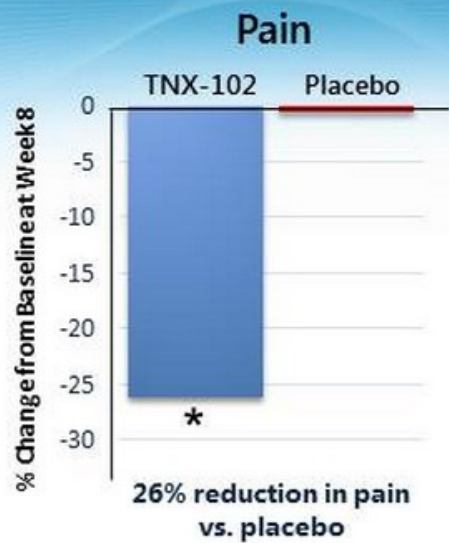
Enrolled 36 subjects with fibromyalgia; 18 per arm

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

Positive efficacy results from Phase 2a trial in FM



* $p < 0.05$

† Improving at least one night of CAP_{A2+A3 (norm)} ≤ 33%

Safety results from Phase 2a trial in FM

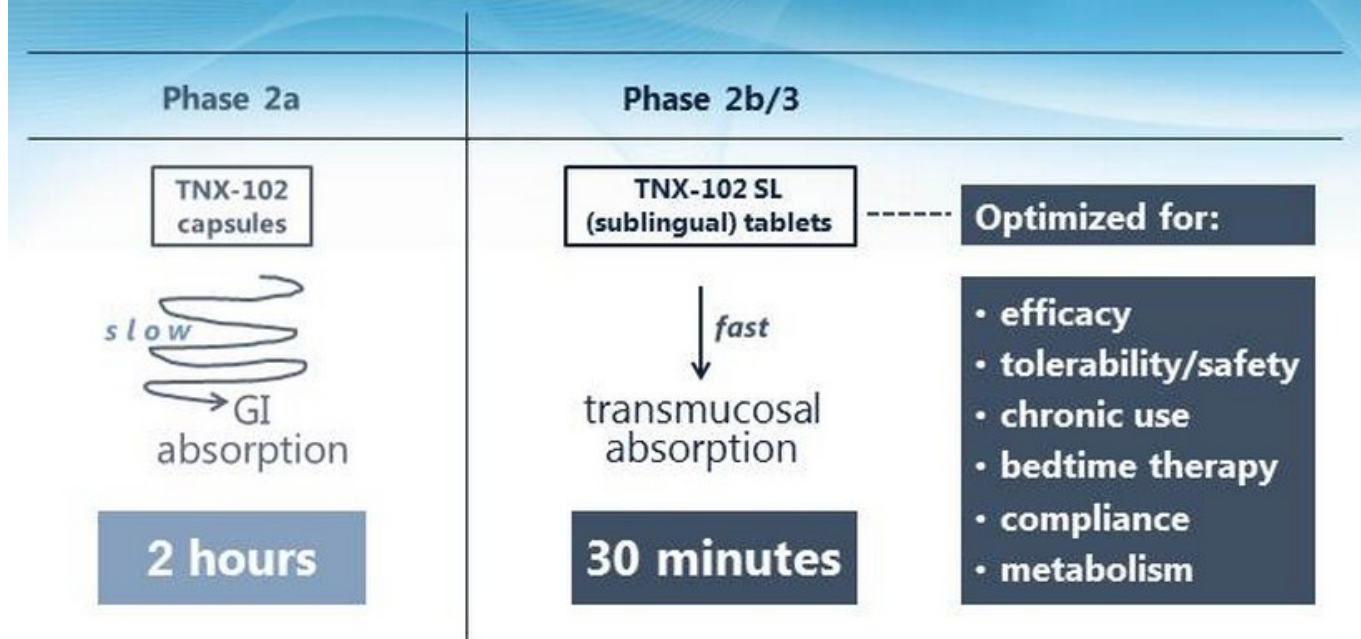
Adverse Event	TNX-102, %	Placebo, %
<i>Any adverse event</i>	83	83
Headache	39	17
Dry mouth	33	6
Somnolence	22	11
Constipation	17	6
Dizziness	17	6
Nausea	11	28
Flu syndrome	11	6
Rhinitis	11	6
Pruritus	11	0

No serious adverse events

No discontinuations due to adverse events in treatment arm

Types of adverse events consistent with approved cyclobenzaprine products

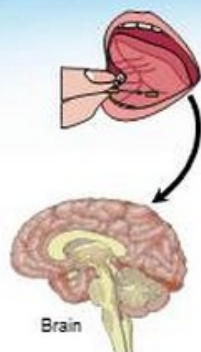
TNX-102 SL is a sublingual tablet formulation optimized for chronic use at bedtime



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

Registrational 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

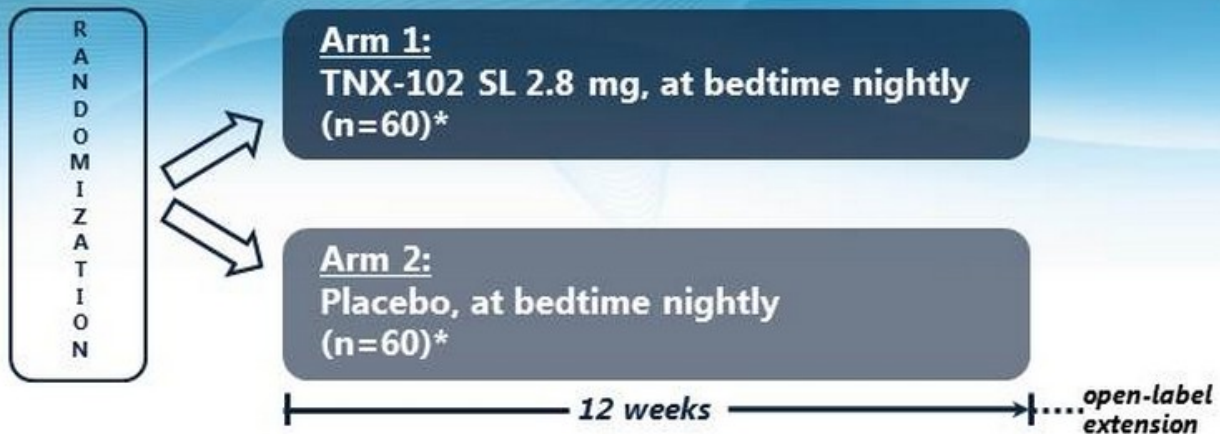
✓ *First trial is enrolling – “BESTFIT”*

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

✓ *Open-label extension study is enrolling*

Definitive repeat dose pharmacokinetic “bridging” study

"BESTFIT" Phase 2b/3 trial in FM is enrolling



BESTFIT: Bedtime **S**ublingual **T**NX-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

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 expected to commence 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

Pipeline

TNX-201 (pure isomer isometheptene) for tension-type headache

Isometheptene has been used in the U.S. for > 50 years as a treatment for headache, but is not FDA approved for any indication*

Limited availability via compounding pharmacies

Over-the-counter medications are inadequate for many patients

- Pre-IND meeting with FDA is scheduled for Q1 2014

TNX-301 (disulfiram/selegiline) for alcoholism

Disulfiram has been used in the U.S. for > 50 years as a treatment for maintaining sobriety

- The addition of selegiline is designed to improved compliance – the major limiting factor to widespread use of disulfiram

* Products containing isometheptene are being marketed as unapproved products in the U.S.; marketing withdrawal has been sanctioned by the FDA since 2012

Intellectual Property

All IP owned by Tonix outright – no royalties / future obligations

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

Corporate

- ✓ 8/9/13 – TNXP stock uplisted to NASDAQ
- ✓ 8/14/13 – Gross proceeds of \$11.4 million from underwritten offering

TNX-102 SL (FM)

- ✓ 3Q 2013 – Began Phase 2b/3 trial in FM
- ✓ 4Q 2013 – Began open-label extension study in FM
- 2H 2014 – Top line results of Phase 2b/3 trial in FM

Pipeline

- 1Q 2014 – Pre-IND meeting for TNX-201 for tension-type headache
- 2Q 2014 – File IND for TNX-102 SL in PTSD
- 3Q 2014 – Begin Phase 2a trial of TNX-102 SL in PTSD

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

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

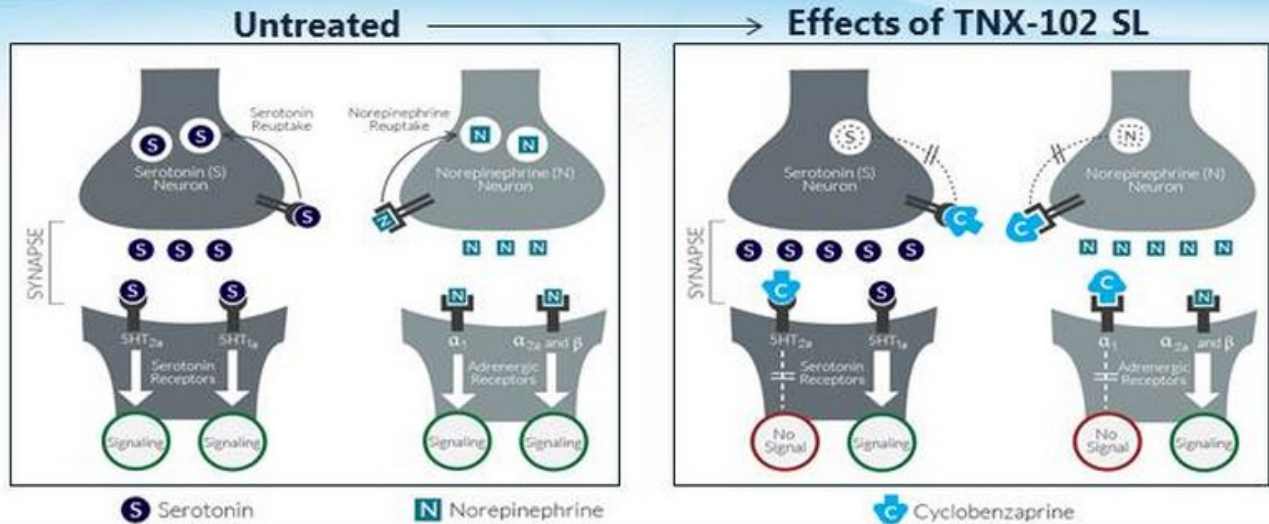


Appendix

Cyclobenzaprine Effects on Nerve Cell Signaling

Cyclobenzaprine is a multi-functional drug

- inhibits serotonin and norepinephrine reuptake
- blocks serotonin 5HT_{2a} and norepinephrine α_1 receptors



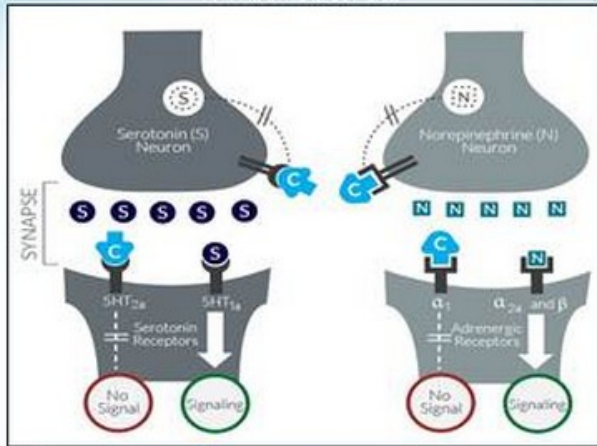
SNARI = Serotonin and Norepinephrine receptor Antagonist and Reuptake Inhibitor

Drugs Used Off-Label in PTSD

Trazodone (disordered sleep), Prazosin (night terrors)

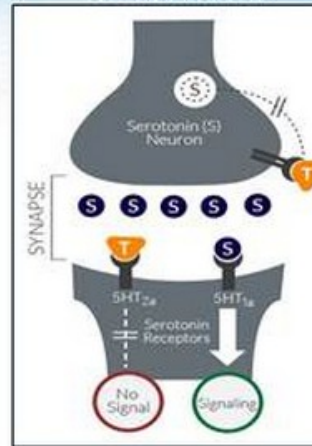
- Trazodone inhibits serotonin 5HT_{2a} receptors and serotonin reuptake (SARI)
- Prazosin blocks norepinephrine α_1 receptors

TNX-102 SL



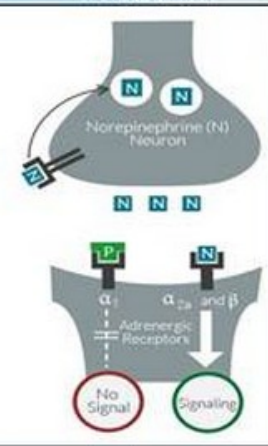
S Serotonin **C** Cyclobenzaprine **N** Norepinephrine

Trazodone



T Trazodone

Prazosin



P Prazosin

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

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

Known drugs can be developed to treat new medical conditions and create important new treatment 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

Drug reformulations have generated significant value

Known drugs can be reformulated into new products to treat new medical conditions and create important new treatment options for patients

Tonix Pharmaceuticals

Flexeril® → TNX-102 SL

MAP Pharmaceuticals

Migranal® → Levadex®

Acquired by
Allergan - \$958 M

Alza Corporation

Ritalin® → Concerta®

Acquired by J&J
- \$11 B

New River Pharmaceuticals

Dexedrine® → Vyvanse®

Acquired by
Shire - \$2.6 B

TONIX
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БНУВWVCEDTICVTZ

TONIX



NASDAQ: TNXP