

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): May 1, 2015

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.
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61 Broadway
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 May 2015*

* 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: May 1, 2015

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



NASDAQ: TNXP

May 2015

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Safe harbor statement

2

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 possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development 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, 2014, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 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.



Financial summary

3

NASDAQ: TNXP

Cash reported at December 31, 2014	\$ 38.2 million
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<i>Pro forma</i> for net proceeds from common stock offering in 1Q15	\$ 67.2 million
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Shares outstanding (April 30, 2015)	16.1 million
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Tonix is developing innovative medicines for large markets

4

Common and chronic disorders of the central nervous system (CNS)

Next-generation medicines, novel treatment paradigms

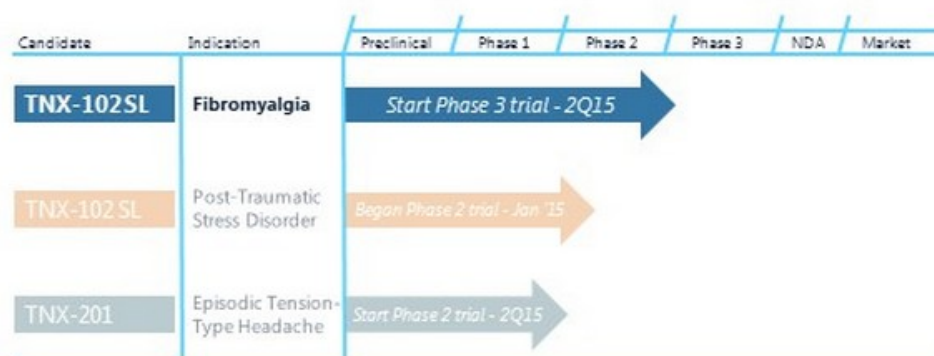
Late stage candidates with mitigated development risk

Capitalized to achieve key readouts in all of our clinical-stage programs



Pipeline led by TNX-102 SL for fibromyalgia (FM)

5



TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 (dexisomethepene muccate) are Investigational New Drugs and are not approved for any indication.

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Fibromyalgia is a large pharmaceutical market

6

Fibromyalgia is a chronic disorder characterized by:

chronic widespread pain
unrefreshed sleep

fatigue
diminished cognition

Believed to result from amplified sensory and pain signaling

Significant disability and impaired quality of life

Estimated to affect ~10 million U.S. adults* and persists for years to decades

FDA-approved drugs achieved 2014 sales of \$1.2 billion

* Lawrence et al, *Arthritis Rheum* 2008;58:26-35; Vincent et al, *Arthritis Care Res* 2013;65:786-792.

Fewer than half of those treated receive sustained benefit from the FDA-approved drugs

7

Overall response rate is ~40%

The majority discontinue therapy due to lack of a response or inability to tolerate



Significant off-label use of prescription painkillers and sleep aids*

ineffective for FM, and carry safety liabilities and addictive potential

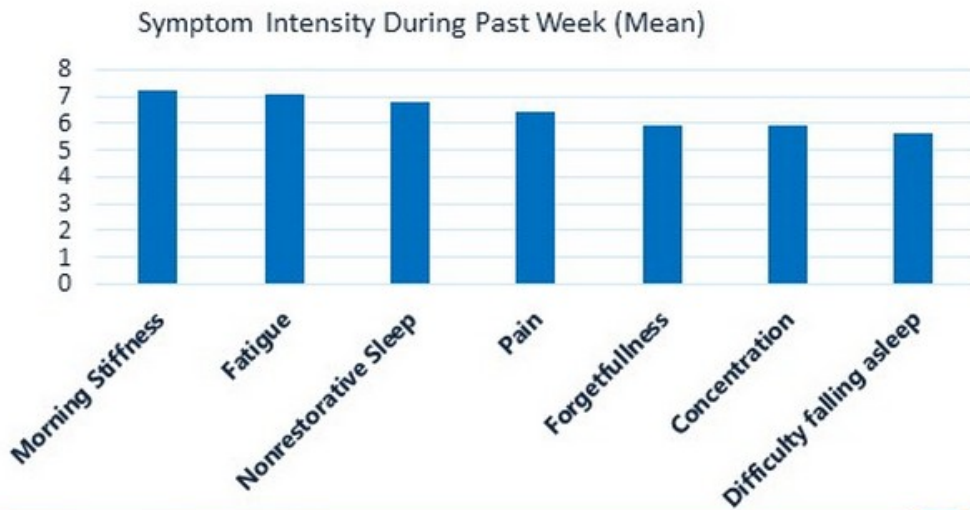
Market research by Frost & Sullivan (commissioned by Tonix).
* Robinson RL et al. Pain Medicine 2012;13:1366-76.

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Relief of many symptoms is important to patients

8

Patients indicate that the symptom burden is high



Bennett et al. 2007; survey of 2,569 FM patients.

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Opportunity for a new fibromyalgia medicine with a unique profile

9

Tonix approaches the treatment of fibromyalgia by targeting sleep quality

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

Sublingual tablet formulation of low-dose cyclobenzaprine (CBP)

TNX-102 SL is designed for chronic, bedtime administration

505(b)(2) regulatory pathway

TNX-102 SL demonstrated broad activity and was very well-tolerated in Phase 2b trial

Observed statistically-significant improvements across key fibromyalgia symptoms

Systemic tolerability similar to placebo

Administration site reactions more common with TNX-102 SL

2.8 mg daily dose confirmed for future development

* Swick, Ther Adv Musculoskelet Dis 2011;3:167-178

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication



Phase 2b “BESTFIT” trial in fibromyalgia

10

BESTFIT = Bedtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy

Randomized, double-blind, placebo-controlled trial

2010 American College of Rheumatology diagnostic criteria for fibromyalgia

205 participants were randomized 1:1 at 17 U.S. sites

One sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime for twelve weeks

Evaluated measures of pain, sleep quality, and other assessments of fibromyalgia symptoms

First Patient – First Dose
Sept 2013



Last Patient – Last Dose
Aug 2014

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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TNX-102 SL broadly improved fibromyalgia in the BESTFIT study

11

Outcome Measure at Week 12	Declared Secondary Endpoints	p value
Daily Pain Diary, NRS	Proportion Achieving 30% Improvement*	0.033
PROMIS Sleep Disturbance	T-score Change	0.005
Patient Global Impression of Change	Responder Analysis	0.025
FIQ-R Total Score	Mean Change	0.014

NRS = Numeric Rating Scale for pain; PROMIS = Patient-Reported Outcomes Measurement Information System

FIQ-R = Fibromyalgia Impact Questionnaire-Revised

* FDA-accepted primary endpoint in the upcoming Phase 3 study

BESTFIT pre-specified primary endpoint: change in mean pain score p=0.172

Data based on intent-to-treat analysis, N=205 (TNX-102 SL N=103, placebo N=102)

***p < 0.05 → achieved
statistical significance***

Source: Phase 2b BESTFIT study data

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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TNX-102 SL was very well-tolerated in the BESTFIT study

12

Systemic adverse events reported by at least 3.0% of the total study population	TNX-102 SL (N=103)	Placebo (N=101)	Total (N=204)
Somnolence	1.9	6.9	4.4
Dry Mouth	3.9	4.0	3.9
Back Pain	4.9	3.0	3.9

No serious adverse events (SAE) reported with TNX-102 SL

Most frequent local adverse events were administration site reactions

Previously reported in TNX-102 SL Phase 1 studies; no detectable bias on efficacy results

Transient tongue numbness (42% TNX-102 SL vs. 1% placebo)

Abnormal taste (8% TNX-102 SL vs. 0% placebo)

Trial completion rates of 86% with TNX-102 SL vs. 83% with placebo

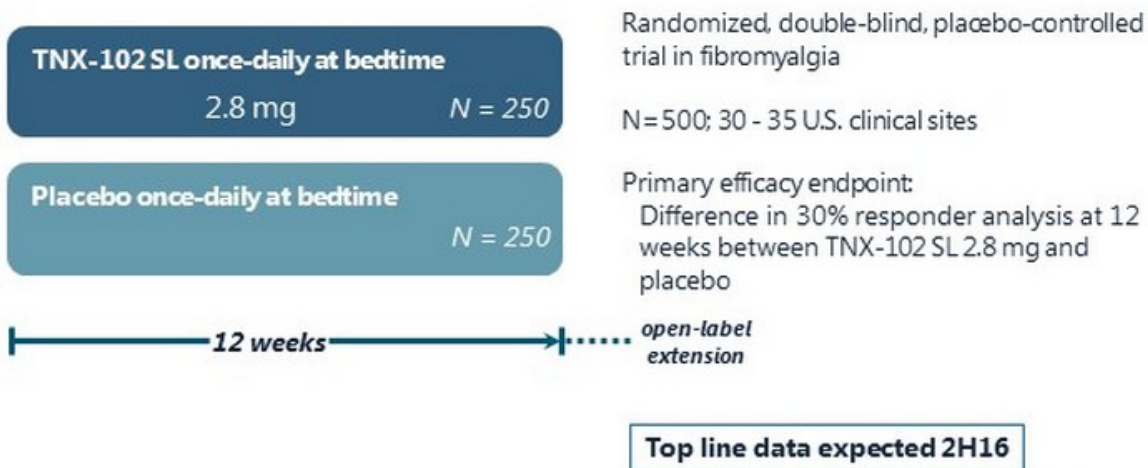
Source: Phase 2b BESTFIT study data

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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Phase 3 "AFFIRM" study of TNX-102 SL in fibromyalgia

13

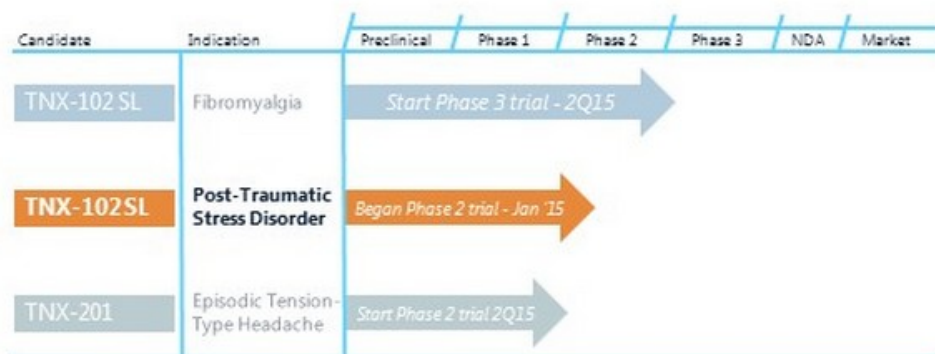


TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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Phase 2 trial of TNX-102 SL for post-traumatic stress disorder (PTSD) is recruiting

14



TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 (dexisometheptene muccate) are Investigational New Drugs and are not approved for any indication.

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Post-traumatic stress disorder is a chronic, debilitating condition

- Experiencing any trauma can lead to PTSD
- High incidence among soldiers and veterans
- Associated with suicide and unpredictable, violent behaviors

8.5 million U.S. patients

- Approximately half are receiving medical treatment*

Limited benefit from the two FDA-approved drugs

- Low rates of response in general
- Lack of efficacy evidence in men or in military populations
- Both are antidepressants, require dose titration, and carry a suicide warning
- No new treatment in > 10 years

* Kessler et al, *Arch Gen Psych* 2005;62:617-627; Wang et al., *Arch Gen Psych* 2005;62:629-640.

High prevalence of PTSD among combat veterans

16



19-31%
Vietnam veterans¹



10%
Gulf war veterans²



10-21%
Operation Enduring Freedom
(Afghanistan) /
Operation Iraqi Freedom
veterans^{3,4}

1. Norris, PTSD Res Quar 2013.
2. Grady JL, National Center for PTSD.
3. Tanielian, Invisible wounds of war. 2005.
4. CBO Report 2012.

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Military PTSD

Convoy attack on Route Appaloosa: "Ambush Alley"

17



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Sleep quality is a new target for PTSD treatment

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"

Correlated with depression, substance abuse and suicide

Poor sleep quality after trauma may increase the risk of developing PTSD

TNX-102 SL targets mechanisms associated with treating disturbed sleep in PTSD

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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2.8 mg dose supported by BESTFIT study results

Improvements observed in BESTFIT on several metrics that relate to PTSD core symptoms

Outcome Measure at Week 12	<i>p</i> value
PROMIS Sleep Disturbance	0.005
FIQ-R Anxiety Item	0.015
FIQ-R Sensitivity Item	0.017

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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

www.ateasestudy.com

20

TNX-102 SL at bedtime once-daily

2.8 mg *N* = 88

TNX-102 SL at bedtime once-daily

5.6 mg *N* = 44

Placebo at bedtime once-daily

N = 88

Randomized, double-blind, placebo-controlled trial in military-related PTSD

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 at eight weeks

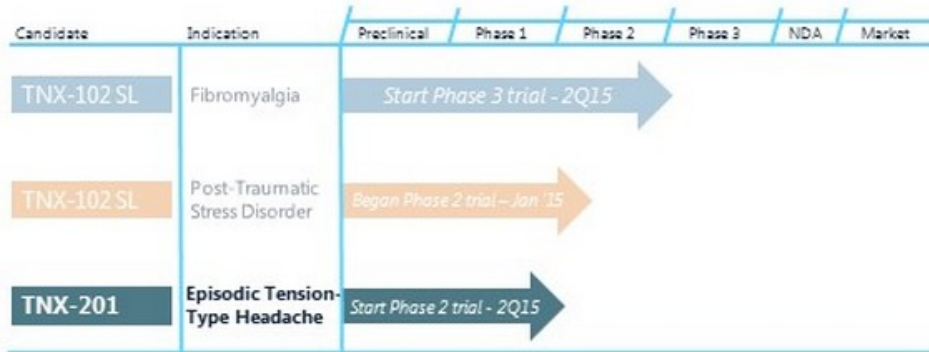
12 weeks → *open-label extension*

Top line data expected 1H16

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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TNX-201 in development for episodic tension-type headache



TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 (dexisometheptere mucate) are Investigational New Drugs and are not approved for any indication.



Episodic tension-type headache (ETTH)

22

75 million adults in the U.S. experience frequent episodic tension-type headaches*

Constant band of pressure on the back/sides of head; "squeezed in a vice" feeling
"Frequent" = one to 15 headaches per month over a three-month period
Approximately 60% receive treatment**

All of the FDA-approved prescription medications contain barbiturates

Over-the-counter medications are inadequate for many
No new medications introduced for >40 years

Class	Product	Company	Regulatory Status	Approval Year in ETTH
Barbiturate	Fiorinal [®]	Actavis	Approved NDA	1976
	Fioricet [®]	Actavis	Approved NDA	1992
Barbiturate + Opiate	Fiorinal with Codeine [®]	Actavis	Approved NDA	1990

* Schwartz et al., JAMA 1998;279:381-383; Chowdhury, Ann Ind Acad Neurol 2012;15:83-88; Tonix analysis of public literature.
** Scher et al., Cephalalgia 2010;30:321-328; company analysis of public literature.

ETTH is the most common type of headache

30% of U.S. adults experience frequent ETTH

23



Episodic tension-type headaches account for approximately:

- 63% of all headaches
- 80% of all non-migraine headaches
- "non-migraine" consists primarily of ETTH; >70% female

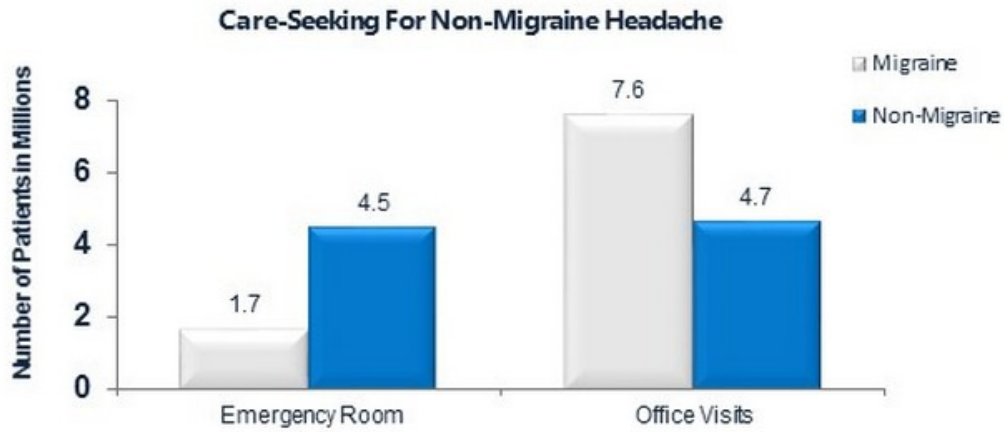
* Estimated from 2013 U.S. Census
Schwartz et al. JAMA 1998;279:381-383 Stovner et al. Cephalalgia 2007;27(3):193-210
Frequent ETTH = one to 15 headaches per month over a three-month period

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Patients with ETTH seek medical attention

Non-migraine headaches lead to 9.2 million emergency room or office visits each year

24



Health Care Utilization Project data, 2011; IMS National Disease and Therapeutic Index™ 2013

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TNX-201 is a modern form of a medicine with a long history of use

25

TNX-201 (dexisometheptene mucate)

a pure optical isomer of isometheptene (IMH)

A mixture of IMH optical isomers had been widely prescribed for many decades

“Racemic isometheptene”

was a single-agent medicine (pre-1962)

was a component of combination drug products

Midrin® – NDA withdrawn

Prodrin® – marketed under “unapproved drug category”

*No product containing any form of isometheptene
is FDA-approved for any indication*

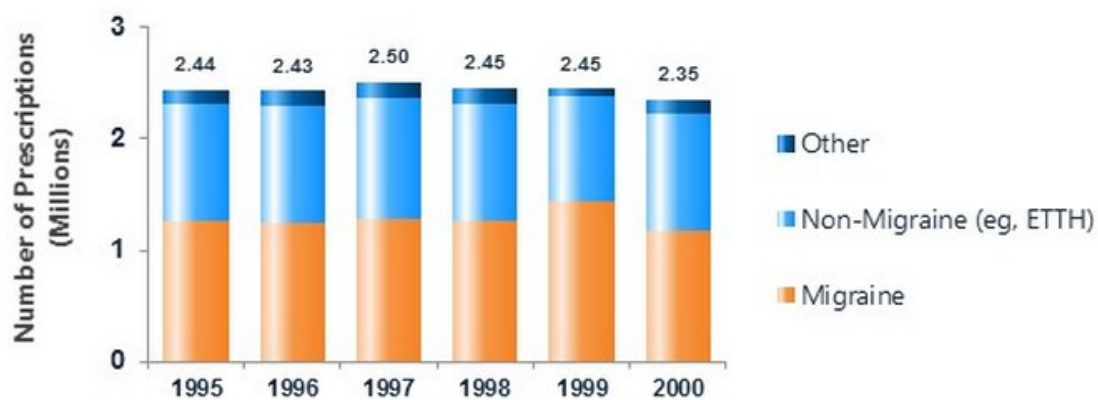
TNX-201 (dexisometheptene mucate) is an Investigational New Drug and is not approved for any indication.

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Racemic isometheptene combination (RIC) prescriptions had been commonly written

26

Usage of RIC Prescriptions for All Diagnoses



Source: IMS Health, National Prescription Audit, 01/1995 - 12/2000 (extracted 8/2014);
IMS Health, IMS National Disease and Therapeutic Index™, 01/1995 - 12/2000 (extracted 8/2014).

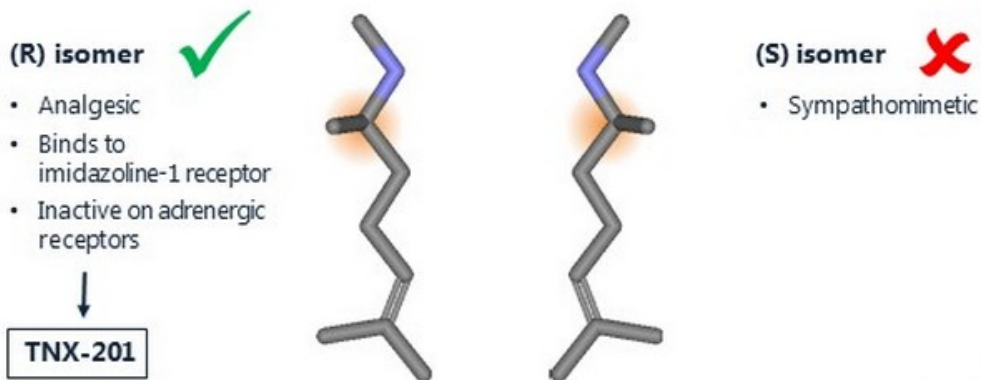
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Optical isomers of IMH have distinct pharmacological activities

27

Previously marketed IMH drugs contained a mixture of two mirror-image isomers (racemic IMH)

Tonix is developing a single IMH isomer for ETTH, supported by proprietary research



TNX-201 (dexisomethepene muccate) is an Investigational New Drug and is not approved for any indication.

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TNX-201 was well-tolerated in Phase 1 study

28

Phase 1 study in healthy volunteers

Single ascending dose study (N=45) – three cohorts of 15 subjects
Randomized to TNX-201, racemic IMH, or placebo (3:1:1 ratio, resp.)

	TNX-201 35 mg (N=9)	TNX-201 70 mg (N=9)	TNX-201 140 mg (N=9)	Racemic IMH 70 mg (N=9)	Placebo (N=9)
Subjects reporting ≥1 adverse event, %	22	11	0	11	33

Adverse events reported by TNX-201 subjects all rated as "mild" and most are not study drug-related
No subject discontinued due to treatment-emergent adverse events
Dose-related increase in TNX-201 plasma levels (C_{max} , AUC)
No evidence of isomer interconversion

TNX-201 (dexisometheptene muccate) is an Investigational New Drug and is not approved for any indication.

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Proof-of-concept Phase 2 trial of TNX-201 in ETTT

29

TNX-201

140 mg

N = 100

Randomized, double-blind, placebo-controlled trial in episodic tension-type headache

Placebo

N = 100

N=200; approximately 10 U.S. clinical sites

A proof-of-concept study to evaluate:

- Proportion of subjects who report "pain free" at several intervals post-dose
- Proportion of subjects who use rescue medication during the 24 hours post-dose
- Change from baseline in pain severity score at several intervals post-dose

Top line data expected 4Q15

TNX-201 (dexisometheptene muccate) is an Investigational New Drug and is not approved for any indication.

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TNX-201 is active on the imidazoline-1 receptor (I₁-R): a novel target for the treatment of pain

30

Characteristics

- Transmembrane receptor
- Distinct from α_2 AR and MAO receptor subtypes
- No sequence similarity to GPCRs or ATP-sensitive K⁺ channels
- Shares similarities to ryanodine and cytokine receptors

Mouse studies

- I₁-R null mice show **no difference** in systolic blood pressure or heart rate compared to wild type
- I₁-R null mice show a **reduction in pain threshold** compared to wild type in both the hot plate and tail flick tests



Hot Plate Test

Piletz JE et al, DNA Cell Biol 2000;19:319-329.
Zhang L et al, CNS Neurosci Ther 2013;19:978-981.

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Intellectual property

All IP wholly-owned by Tonix with no obligations to others

31

TNX-102 SL

Fibromyalgia, PTSD

Composition-of-matter (eutectic)

Patents filed
Protection expected to 2034

Pharmacokinetics (PK)

Patents filed
Protection expected to 2033

Method-of-use

Fibromyalgia: patents issued, 3Q 2020 expiry
PTSD: patents filed

TNX-201

Headache

Composition-of-matter (isomer)

Patents filed
Protection expected to 2033

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 (dexisomethepene mucate) are Investigational New Drugs and are not approved for any indication.

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Management team

32

Seth Lederman, MD
President & CEO

TARGET
X

Fusilev
(evoleucovirin) for injection

vela
PHARMA
VEVA PHARMACEUTICALS, INC.

Leland Gershell, MD, PhD
Chief Financial Officer

COWEN
AND COMPANY

ATON
PHARMA

Zolinza
[vorinostat] capsules

Bruce Daugherty, PhD
Chief Scientific Officer

 **MERCK**

 **Roche**

Gregory Sullivan, MD
Chief Medical Officer

 **COLUMBIA UNIVERSITY**
Department of Psychiatry

New York State
Psychiatric Institute

Ronald Notvest, PhD
SVP, Commercial Planning & Development

Wyeth

Rapamune
sirolimus
0.5mg 1mg
2mg Tablets

 **Eviduc**

Board of directors

33

Seth Lederman, MD

Chairman

Ernest Mario, PhD

ALZA, Glaxo, Reliant Pharma

Stuart Davidson

Labrador Ventures, Alkermes, Combion

Charles Mather

BTIG, Janney, Jefferies, Cowen, Smith Barney

Patrick Grace

Apollo Philanthropy, WR Grace, Chemed

John Rhodes

NYSERDA, Booz Allen Hamilton

Donald Landry, MD, PhD

Chair of Medicine, Columbia University

Samuel Saks, MD

Jazz Pharma, ALZA, Johnson & Johnson

5%+ holders

Broadfin Capital

Deerfield Special Situations Fund

Technology Partners Fund VIII

Franklin Templeton Investments

Kingdon Capital Management

Lombard Odier Investment Management

Wall Street Associates

Based on public filings as of April 30, 2015.

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Milestones – recent and upcoming

35

TNX-102 SL – Fibromyalgia

- September 2014 – Reported top line results from Phase 2b BESTFIT study
- January 2015 – Reported FDA acceptance of 30% responder analysis as Phase 3 primary endpoint
- 2Q 2015 – Begin Phase 3 AFFIRM study
- 2H 2016 – Report top-line results from AFFIRM study

TNX-102 SL – Post-Traumatic Stress Disorder

- December 2014 – Began recruiting Phase 2 AtEase study in military-related PTSD
- 2Q 2015 – Provide update on enrollment and timing of results from AtEase
- 1H 2016 – Report top-line results from AtEase study

TNX-201 – Episodic Tension-Type Headache

- December 2014 – Completed Phase 1 clinical pharmacology study
- 2Q 2015 – Begin proof-of-concept Phase 2 study in ETTH
- 4Q 2015 – Report top-line results from proof-of-concept Phase 2 study

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