

**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): March 23, 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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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 March 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: March 23, 2015

By: /s/ SETH LEDERMAN  
Seth Lederman  
Chief Executive Officer



NASDAQ: TNXP

March 2015

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## 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 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.

## New approaches to treating CNS disorders

### First-in-class medicines for common disorders of the central nervous system (CNS)

Innovative treatment paradigms  
Late stage candidates  
Large unmet medical needs

### Entered 2015 with three clinical development programs

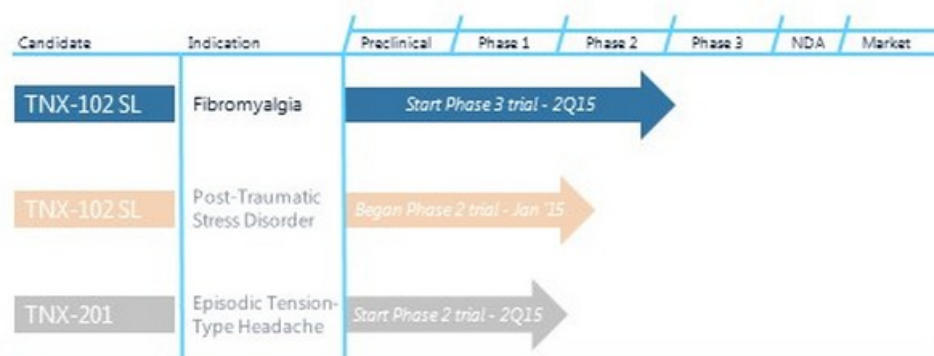


### Capitalized to achieve key clinical readouts in all three programs

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

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## Pipeline led by TNX-102 SL for fibromyalgia



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

# Fibromyalgia market opportunity

Estimated to affect 5 - 15 million U.S. adults\*

## Three FDA approved prescription medications:

Class	Product	Company	Approval Year in FM
Membrane Stabilizer	Lyrica <sup>®</sup>	Pfizer	2007
SNRI	Cymbalta <sup>®</sup>	Eli Lilly	2008
	Savella <sup>®</sup>	Forest	2009

## Tonix is pursuing a different approach:

Sleep Quality	TNX-102 SL	Tonix	1H19E
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\* Lawrence et al, *Arthritis Rheum* 2008;58:26-35; Vincent et al, *Arthritis Care Res* 2013;65:786-792.

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

SNRI = Serotonin Norepinephrine Reuptake Inhibitor





## "AFFIRM" Phase 3 trial of TNX-102 SL in Fibromyalgia

TNX-102 SL at bedtime once-daily

2.8 mg

N = 250

Placebo at bedtime once-daily

N = 250

Randomized, double-blind, placebo-controlled trial in fibromyalgia

N=500; 30 - 35 U.S. clinical sites

Primary efficacy endpoint:

Difference in 30% responder analysis at 12 weeks between TNX-102 SL 2.8 mg and placebo – primary efficacy endpoint based on FDA written acceptance



*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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## Sleep quality is a new target for fibromyalgia therapy

### **Restorative sleep improves pain and other fibromyalgia symptoms**

>90% of fibromyalgia patients complain of poor sleep quality\*  
Sleep quality improvement is not a feature of approved medications

### **Phase 2a study with low-dose cyclobenzaprine (CBP) capsule showed proof-of-concept\*\***

#### **TNX-102 SL is a sublingual tablet formulation of CBP**

Pharmacokinetic profile well-suited to bedtime administration  
Tolerability profile well-suited to chronic use

### **Phase 2b BESTFIT results support Phase 3 program in fibromyalgia**

Contribute to evidence of efficacy to support the planned NDA  
Phase 3 trial to begin in 2Q 2015

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

\*\* Moldofsky et al, *J Rheum* 2011;38:2653-63.

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

## BESTFIT Phase 2b trial in fibromyalgia

### **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

### **Primary efficacy endpoint**

Mean change from baseline in the daily diary pain score during week 12  
11-point (0-10) Numerical Rating Scale (NRS) to assess prior 24-hour average pain intensity

First Patient – First Dose  
September 2013



Last Patient – Last Dose  
August 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 improved pain in fibromyalgia in the BESTFIT study

Outcome Measure at Week 12	Intent-to-Treat Population <sup>†</sup>	p value	Method
Daily Pain Diary, NRS	Mean Change**	0.086	MMRM
		0.172	JTC-MI
Daily Pain Diary, NRS	Proportion Achieving 30% Improvement*	0.033	LR
Clinic NRS 7-day pain recall	Mean Change	0.029	MMRM
FIQ-R Pain Item	Mean Change	0.004	MMRM

NRS = Numeric Rating Scale for pain; FIQ-R = Fibromyalgia Impact Questionnaire-Revised  
 MMRM = Mixed-Effect Model of Repeated Measure; JTC-MI = Jump to Control-Multiple Imputation (FDA-preferred analysis); LR = Logistic Regression

\*\* Declared primary endpoint; was primary endpoint for FDA approvals of Lyrica and Cymbalta

\* Declared secondary endpoint; will be the primary endpoint in the upcoming Phase 3 study

† N=205 (TNX-102 SL N=103, placebo N=102)

$p < 0.05 \rightarrow$  achieved statistical significance

Source: Phase 2b BESTFIT study preliminary 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 improved sleep quality in fibromyalgia in the BESTFIT study

Outcome Measure at Week 12	Intent-to-Treat Population	p value	Method
Daily Sleep Quality Diary, NRS	Mean Change*	<0.001	MMRM
PROMIS Sleep Disturbance	T-score Change*	0.005	MMRM
FIQ-R Sleep Quality Item	Mean Change	<0.001	MMRM

PROMIS = Patient-Reported Outcomes Measurement Information System

\* Declared secondary endpoint

$p < 0.05 \rightarrow$  achieved statistical significance

Source: Phase 2b BESTFIT study preliminary 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 broadly improved fibromyalgia symptoms in the BESTFIT study

Outcome Measure at Week 12	Intent-to-Treat Population	p value	Method
Patient Global Impression of Change	Responder Analysis*	0.025	LR
FIQ-R Total Score	Mean Change*	0.014	MMRM
FIQ-R Symptom Domain	Mean Change	0.004	MMRM
FIQ-R Function Domain	Mean Change	0.060	MMRM
FIQ-R Anxiety Item	Mean Change	0.015	MMRM
FIQ-R Sensitivity Item	Mean Change	0.017	MMRM
FIQ-R Stiffness Item	Mean Change	0.039	MMRM

\* Declared secondary endpoint

$p < 0.05 \rightarrow$  achieved statistical significance

Source: Phase 2b BESTFIT study preliminary 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 well-tolerated in the BESTFIT Study

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

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

### 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 preliminary 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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## Registration program for TNX-102 SL in fibromyalgia

### Phase 2b BESTFIT study confirmed activity and tolerability

Statistically-significant improvements across key fibromyalgia symptoms were observed  
Systemic tolerability similar to placebo  
2.8 mg daily dose confirmed for future development

### Phase 3 AFFIRM study to commence in 2Q 2015

Randomized, double-blind, parallel-group, placebo-controlled  
N=500; 30-35 U.S. sites; 1:1 randomization  
12-week study similar to the BESTFIT design  
One sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime

**30% responder analysis at 12 weeks\*** – primary efficacy endpoint based on FDA written acceptance

*\* TNX-102 SL demonstrated  $p=0.03$  in BESTFIT 30% pain responder analysis (pre-specified secondary endpoint)*

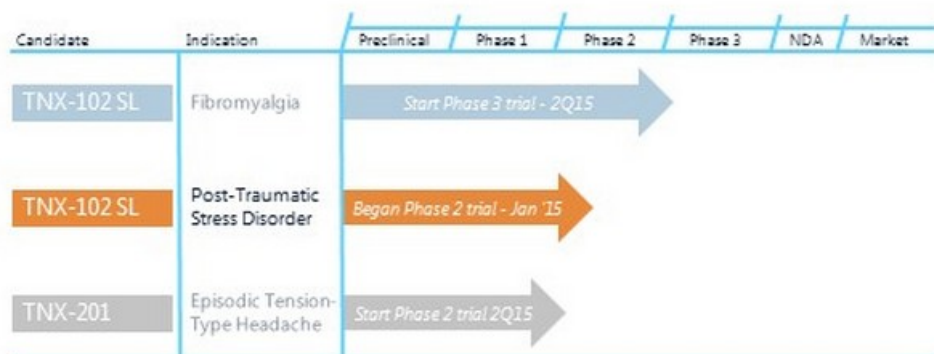
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TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

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## Phase 2 trial of TNX-102 SL for PTSD is recruiting



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

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## PTSD: A significant and growing public health problem

### Post-traumatic stress disorder is a chronic, debilitating condition

High incidence among soldiers and veterans, but experiencing any trauma can lead to PTSD  
Associated with suicide and unpredictable, violent behaviors  
Patients desperate despite two FDA approved drugs; no new treatment in > 10 years

**Among 8.5 million U.S. patients, approximately half are receiving medical treatment\***

### FDA approved prescription medications:

Class	Product	Company	Approval Year in PTSD
SSRI	Paxil®	Glaxo	2001
	Zoloft®	Pfizer	1999

### Tonix is pursuing a different approach:

Sleep Quality	TNX-102 SL	Tonix	2H19E
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\* Kessler et al, *Arch Gen Psych* 2005;62:617-627; Wang et al., *Arch Gen Psych* 2005;62:629-640.  
SSRI = Selective Serotonin Reuptake Inhibitor

# Sleep quality is a new target for PTSD treatment

## **Poor sleep quality after trauma is linked to onset of PTSD**

### **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

### **Military-related PTSD is an unmet need**

Evidence suggests that SSRIs may be ineffective in military-related PTSD

### **Response of PTSD in men to SSRIs has not been adequately studied**

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

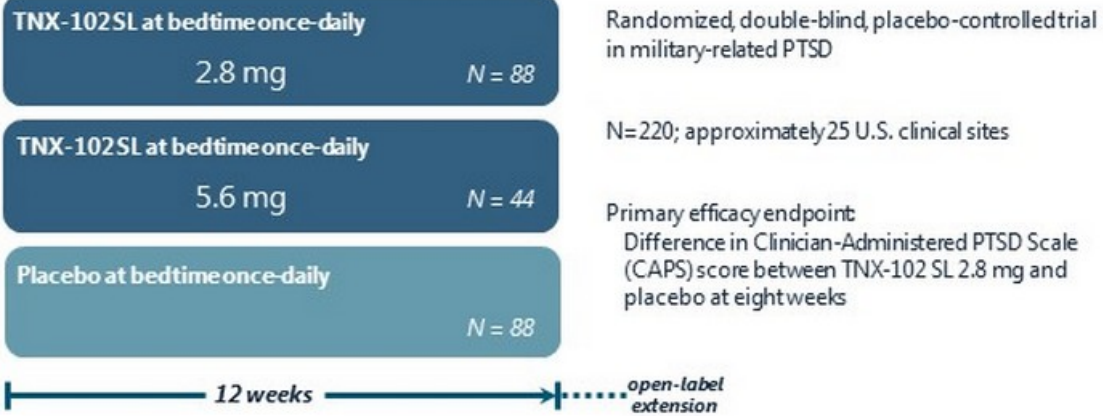
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## "AtEase" Phase 2 trial of TNX-102 SL in PTSD

[www.ateasestudy.com](http://www.ateasestudy.com)



*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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## PTSD program with TNX-102 SL

### **Fibromyalgia program informs development of TNX-102 SL in PTSD**

Safety data from fibromyalgia studies are potentially supportive for PTSD program

Efficacy data support potential for activity in PTSD

Improvements in several outcomes analyses of BESTFIT that relate to PTSD core symptoms: sleep; FIQ-R sensitivity; and FIQ-R anxiety

2.8 mg dose supported by BESTFIT study results

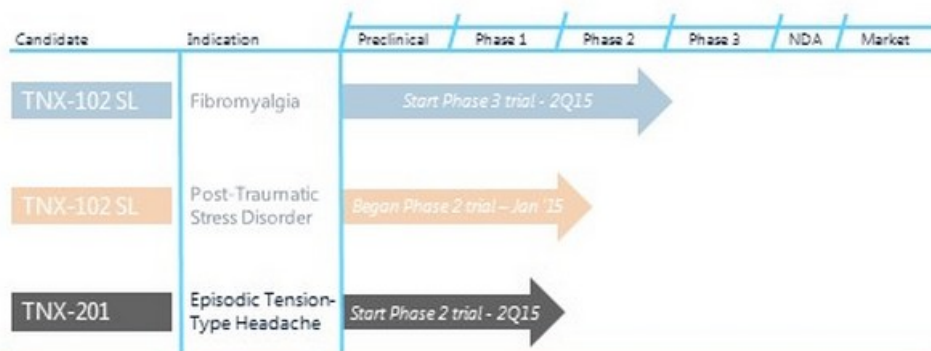
### **Phase 2 study of TNX-102 SL in military-related PTSD ("AtEase") is enrolling**

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*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 ((R)-isometheptene mucate) are Investigational New Drugs and are not approved for any indication.*

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## Episodic tension-type headache (ETTH)

### 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 <sup>®</sup>	Actavis	Approved NDA	1976
	Fioricet <sup>®</sup>	Actavis	Approved NDA	1992
Barbiturate + Opiate	Fiorinal with Codeine <sup>®</sup>	Actavis	Approved NDA	1990

\* Schwartz et al., JAMA 1998;279:381-383; Chowdhury, Ann Ind Acad Neuro 2012;15:83-88; company analysis of public literature.

\*\* Scher et al., Cephalalgia 2010;30:321-328; company analysis of public literature.



## TNX-201 in clinical development for ETTH

### **TNX-201 is (R)-isometheptene mucate**

Tonix is developing TNX-201 for ETTH  
Phase 2 study to begin in 2Q 2015

### **Racemic isometheptene mucate is a mixture of (R) and (S) isomers**

Had been widely prescribed for many decades in the U.S. as:  
a single-agent medicine (pre-1962)  
a component of combination drug products  
Midrin® – NDA withdrawn  
Prodrin® – marketed under "unapproved drug category"

*No product containing isometheptene mucate is currently FDA approved for any indication*

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

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## Phase 2 trial of TNX-201 in ETTH to begin in 2Q15

TNX-201

140 mg

N = 100

Placebo

N = 100

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

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

### Primary efficacy endpoint:

Number of subjects who report "pain free" at two hours following one dose of study medication (upon first ETTH episode experienced)

**To report top-line results in 4Q 2015**

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

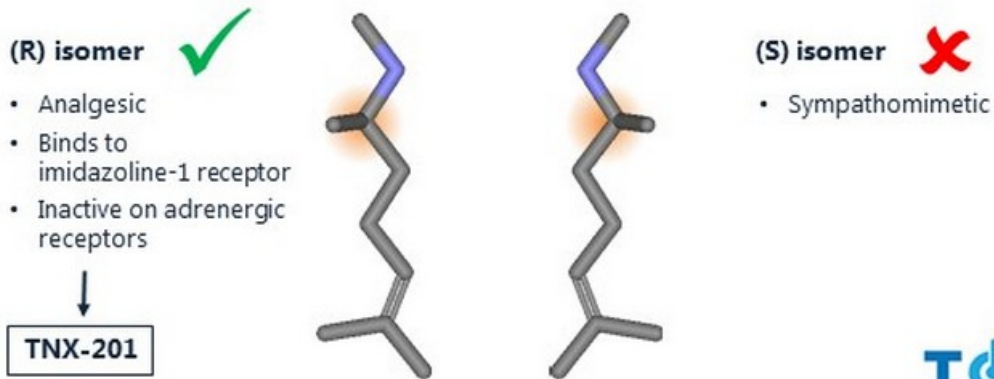
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# Isometheptene (IMH) isomers have distinct pharmacological activities

*TNX-201 is a single isomer of IMH*

## The (R) and (S) isomers of IMH have different pharmacologies

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



## Phase 1 study of TNX-201 completed

### 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

### Results support the advancement of TNX-201 into Phase 2 development

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

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# The imidazoline-1 receptor ( $I_1$ -R) is a novel target for the treatment of pain

## Characteristics

- Transmembrane receptor
- Distinct from  $\alpha_2$ AR and MAO receptor subtypes
- No sequence similarity to GPCRs or ATP-sensitive K<sup>+</sup> channels
- Shares similarities to ryanodine and cytokine receptors

## Mouse studies

- $I_1$ -R null mice show **no difference** in systolic blood pressure or heart rate compared to wild type
- $I_1$ -R null mice show a **reduction in pain threshold** compared to wild type in both the hot plate and tail flick tests

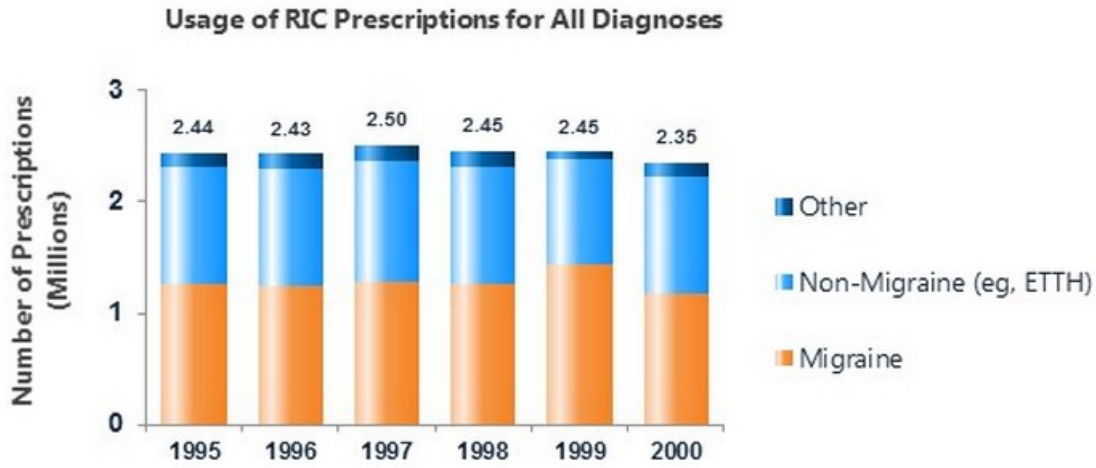


Hot Plate Test

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

## Racemic isometheptene combination (RIC) prescriptions had been commonly written

Number of RIC prescriptions peaked at 2.5 million



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).

## ETTH is the most common type of headache

30% of U.S. adults experience frequent ETTH



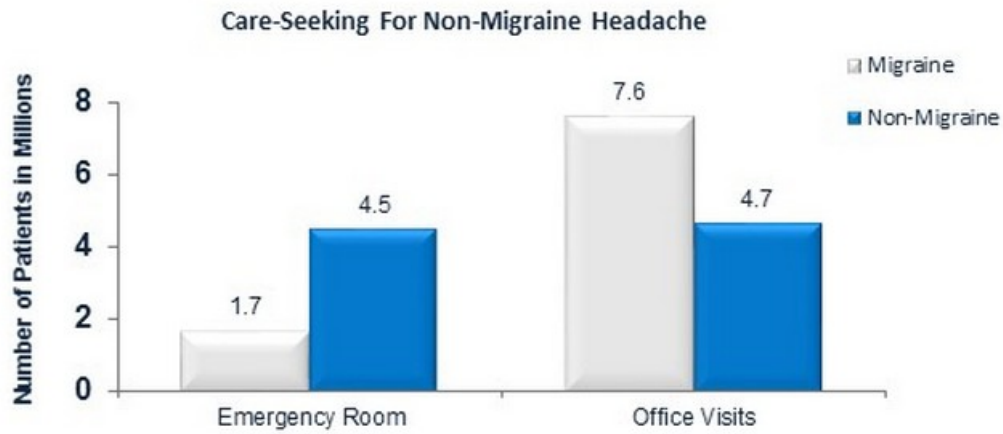
Episodic tension-type headaches account for approximately:

- 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

## Patients with ETTH seek medical attention

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



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



## Intellectual property

All IP wholly-owned by Tonix without obligations to others

### 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

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## Financial summary

### NASDAQ: TNXP

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Cash reported at December 31, 2014	\$ 38.2 million
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Net proceeds from common stock offering in 1Q15	\$ 29.0 million
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Shares outstanding (Feb 27, 2015)	16.1 million
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## Management team

**Seth Lederman, MD**  
Chief Executive Officer

**TARGENT**

**Fusilev<sup>®</sup>**  
(levoleucovorin) for injection

**vela**  
PHARMA

**Leland Gershell, MD, PhD**  
Chief Financial Officer

**COWEN**  
AND COMPANY

**ATON**  
PHARMA

**Zolinza**  
[vorinostat] capsules

**Bruce Daugherty, PhD**  
Chief Scientific Officer

 **MERCK**

 **Roche**

## Milestones – recent and upcoming

### **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
- ☐ 1H 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 Phase 2 study in ETTH
- ☐ 4Q 2015 – Report top-line results from Phase 2 study

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





NASDAQ: TNXP

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[www.tonixpharma.com](http://www.tonixpharma.com)

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