

**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): July 7, 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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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 July 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: July 7, 2015

By: /s/ LELAND GERSHELL

Leland Gershell

Chief Financial Officer



NASDAQ: TNXP

Corporate Presentation

July 2015

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Cautionary note on forward-looking statements

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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.



Developing innovative medicines for large and growing markets

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- Common and chronic disorders of the central nervous system (CNS)
- Next-generation medicines with transformative treatment potential
- Late-stage candidates supported by human experience
- Capitalized to achieve key readouts in all of our clinical-stage programs



Pipeline led by Tonmya™ for fibromyalgia (cyclobenzaprine HCl sublingual tablets, 2.8 mg)

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Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
Tonmya	Fibromyalgia							Top line data H2 2016
TNX-102 SL	PTSD							Top line data H1 2016
TNX-201	Episodic Tension-Type Headache							Top line data Q4 2015

Tonmya / TNX-102 SL (cyclobenzaprine HCl sublingual tablet, 2.8 mg) and TNX-201 (dexisomethopene muate) are Investigational New Drugs and are not approved for any indication.

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Fibromyalgia: a chronic, multi-symptom disorder that generates frustration for patients and physicians

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- ⦿ **Fibromyalgia is characterized by:**
 - Chronic widespread pain
 - Unrefreshing sleep
 - Fatigue
 - Diminished cognition
- ⦿ **Believed to result from amplified sensory and pain signaling in CNS¹**
- ⦿ **Causes significant impairment in all areas of life**
 - Lower levels of health-related quality-of-life – reduced daily functioning
 - Interference with work (loss of productivity, disability)
- ⦿ **Inflicts substantial strain on the healthcare system**
 - Average patient has 20 physician office visits per year²
 - Annual direct medical costs are twice those for non-fibromyalgia individuals³

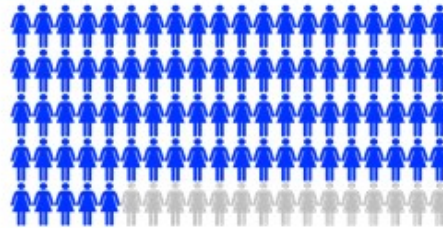
¹ Phillips K & Clauw DJ, *Best Pract Res Clin Rheumatol*. 2011;25:141.

² Robinson et al, *Pain Medicine*. 2013;14:1400.

³ White et al, *J Occupational Environ Med* 2008;50:13.

Fibromyalgia is a large market, but remains under-diagnosed...

Total U.S. market for fibromyalgia (on- and off-label usage) is estimated to be >22 million prescriptions annually^{2,3}



- Chronic condition with onset typically in the 30's-40's, predominantly in females
- **Approved drugs achieved 2014 U.S. sales of \$1.2 billion⁴**
 - Represents about 5.6 million prescriptions³
- Among those diagnosed, 85% receive treatment² = 2.3 million U.S. adults
- Diagnosis rate of 1.1% = 2.7 million U.S. adults → suggests under-diagnosis

¹ Lawrence et al, *Arthritis Rheum* 2008;58:26; Vincent et al, *Arthritis Care Res* 2013;65:786; Jones et al, 2015;67:568.

² Robinson RL et al, *Pain Med* 2012;13:1366.

³ Independent study conducted by IMS Consulting Group, April 2015 using IMS MIDAS (ex-manufacturing price), factored for fibromyalgia based on IMS National Disease and Therapeutic Index (NDTI).

⁴ Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.

...and fewer than half of those treated receive sustained benefit from the three FDA-approved drugs

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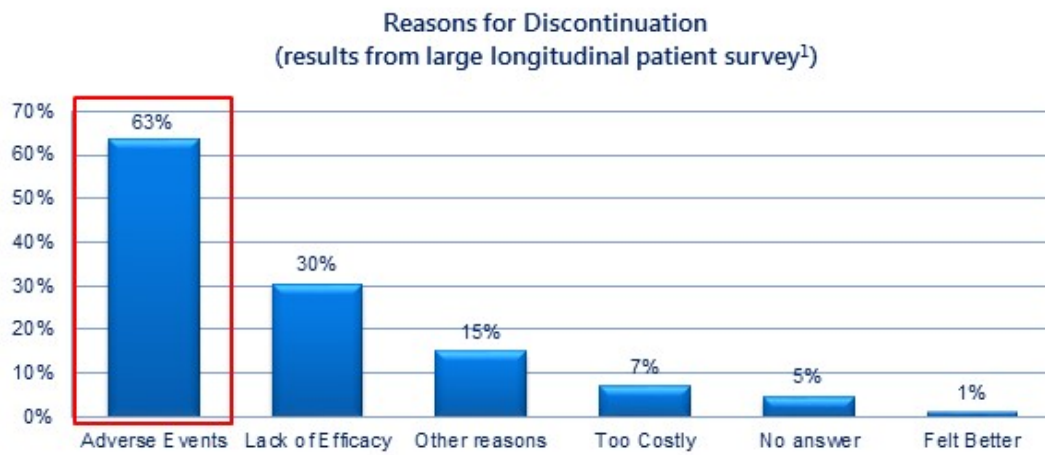
- The treatment objective is to **restore functionality** and **quality of life** by broadly improving symptoms while avoiding significant side effects
- **The majority discontinue therapy** due to lack of a response or poor tolerability:¹



¹ Market research by Frost & Sullivan, commissioned by Tonix (2011).
FDA = U.S. Food and Drug Administration

Side effects are the most common driver of treatment discontinuation

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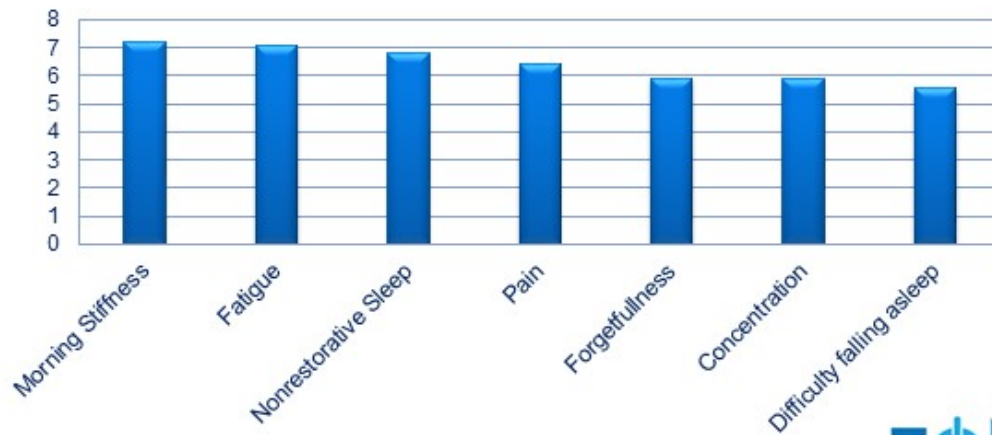


¹ Robinson et al., *Pain Medicine* 2013;14:1400.

Relief of several symptoms is important to patients

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Symptom Intensity During Past Week (Mean)¹



¹ Bennett RM et al, *BMC Musculoskeletal Disord* 2007;8:27.

Pervasive treatment dissatisfaction creates an opportunity for a differentiated therapeutic option

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⦿ High rates of discontinuation, switching and augmentation

- Patients cycle through different medications
- Attempt to treat multiple symptoms and/or avoid intolerable side effects
- Two or more medications are used simultaneously, on average¹
- The typical patient has tried six different medications²

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

Large need for new therapies that provide broad symptom relief without a significant side effect burden

¹ Robinson RL et al, *Pain Medicine* 2012;13:1366

² "Patient Trends: Fibromyalgia", *Decision Resources*, 2011.

- ⦿ **Advanced sublingual tablet containing cyclobenzaprine (CBP) 2.8 mg**
 - Eutectic formulation rapidly delivers a low dose of CBP
 - Avoids first-pass metabolism → reduces exposure to long-lived active metabolite
 - Designed for chronic bedtime administration, no titration

- ⦿ **Tonmya demonstrated broad activity and was very well-tolerated in Phase 2b study**
 - Statistically-significant improvements across core fibromyalgia symptoms
 - Systemic tolerability similar to placebo
 - Transient administration site reactions were more common with Tonmya, no impact on completion rate

- ⦿ **Tonix approaches the treatment of fibromyalgia by targeting sleep quality**
 - Non-restorative sleep is a common clinical and diagnostic feature¹
 - Evolving understanding of the role of sleep in pain control and fibromyalgia development²
 - Tonmya targets CNS receptors believed to play key roles in sleep physiology

¹ Swick TJ, *Ther Adv Musculoskel Dis* 2011;3:167-178

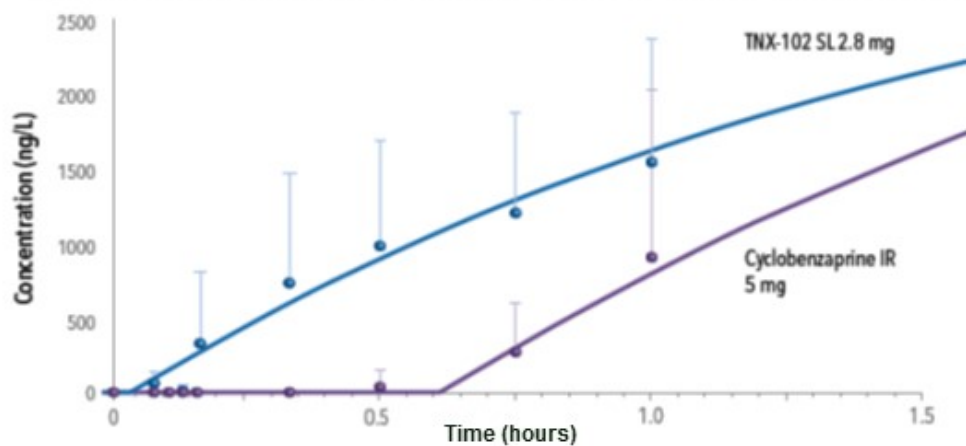
² Choy EHS, *Nat Rev Rheumatol* adv online pub 28 April 2015.

Tonmya is an Investigational New Drug and is not approved for any indication.

CBP is detected in plasma within minutes following sublingual administration of Tonmya in Phase 1 studies

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Plasma Concentration Versus Time of TNX-102 SL Compared to Cyclobenzaprine IR



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

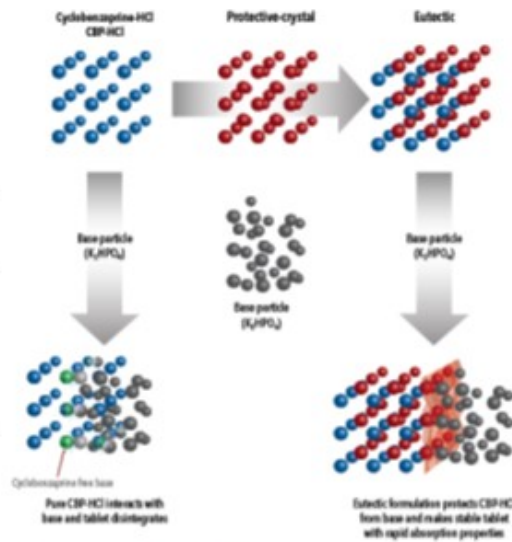
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Tonmya is a proprietary eutectic formulation of low dose CBP engineered for sublingual transmucosal absorption

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1. Transmucosal absorption requires a basic excipient.

2. However, a basic excipient results in an unstable tablet.



3. Eutectic composition protects cyclobenzaprine HCl from degradation caused by the basic excipient.

Tonmya is an Investigational New Drug and is not approved for any indication.

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Phase 2b “BESTFIT” study of Tonmya in fibromyalgia

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- **BESTFIT** = **B**edtime **S**ublingual **T**NX-102 SL as **F**ibromyalgia **I**ntervention **T**herapy
 - 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 Tonmya (TNX-102 SL 2.8 mg) or placebo daily at bedtime for 12 weeks
 - Evaluated measures of pain, sleep quality, and other assessments of fibromyalgia



Tonmya is an Investigational New Drug and is not approved for any indication.

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BESTFIT: Tonmya broadly improved fibromyalgia

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Category	Endpoint – week 12 ¹	p value
Pain	30% responder analysis ²	0.033
Sleep	Daily Sleep Quality PROMIS Sleep Disturbance	<0.001 0.005
Overall response to therapy	PGIC	0.025
Assessment of disease impact	FIQ-R Total score	0.014

p < 0.05 → statistically significant

BESTFIT pre-specified primary endpoint:
change in week 12 mean pain score (p=0.172)

- ◆ PROMIS = Patient-Reported Outcomes Measurement Information System
- ◆ PGIC = Patient Global Impression of Change
- ◆ FIQ-R = Fibromyalgia Impact Questionnaire - Revised

¹ Intent-to-treat analysis, N=205 (Tonmya N=103, placebo N=102)

² FDA-accepted primary endpoint in current Phase 3 AFFIRM study

Source: Phase 2b BESTFIT study data.

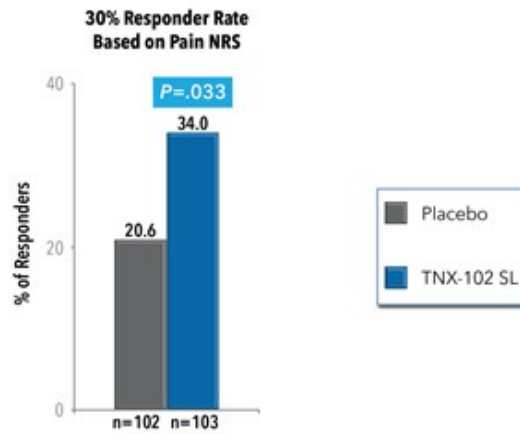
Tonmya is an Investigational New Drug and is not approved for any indication.

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BESTFIT: Tonmya significantly improved the 30% pain responder rate

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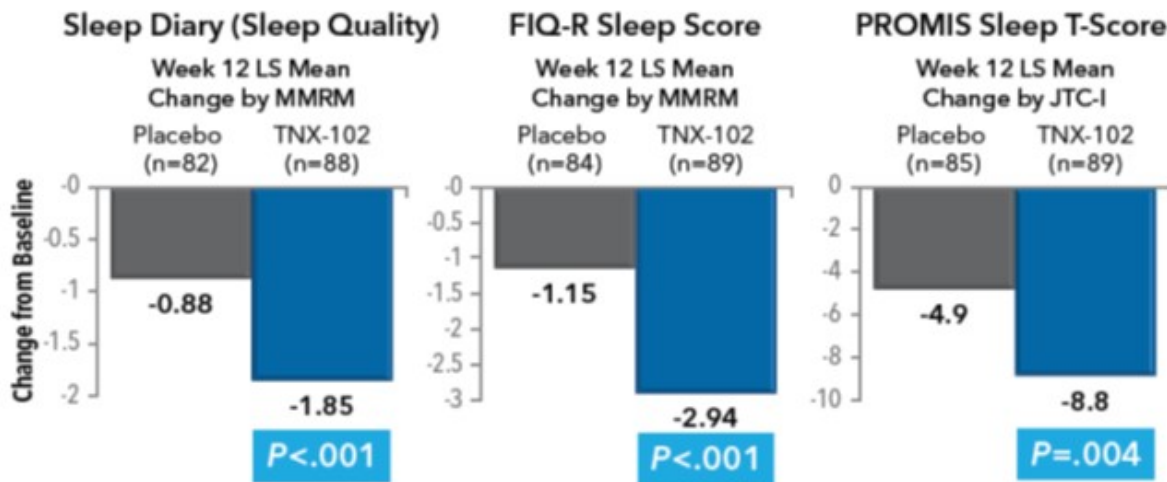
- ⦿ A 30% responder is an individual whose pain has decreased $\geq 30\%$ from baseline to week 12
- ⦿ In a responder analysis each patient "counts once"
- ⦿ 30% pain responder analysis at week 12 is the FDA-accepted primary efficacy endpoint in our Phase 3 registration program



Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.

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BESTFIT: Tonmya significantly improved sleep quality

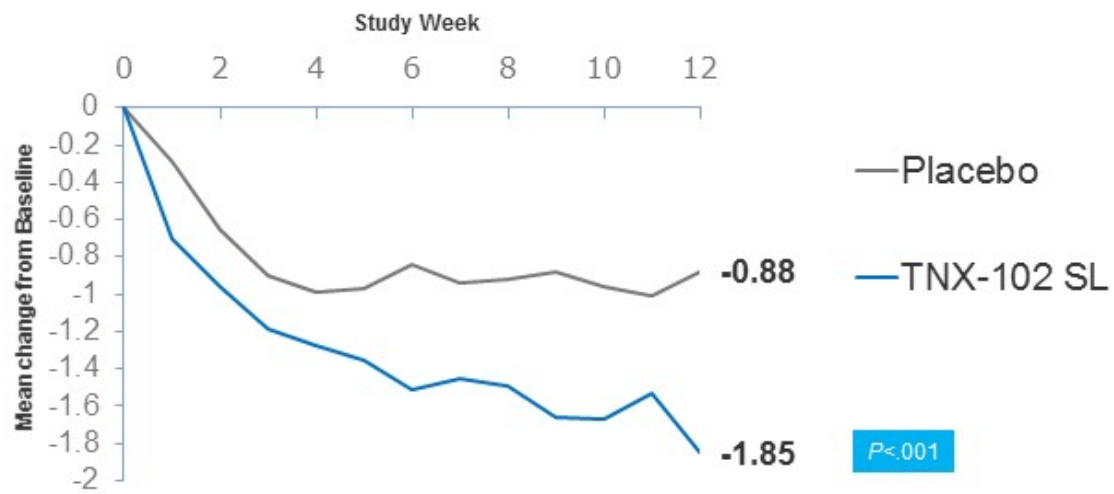


JTC-I = Jump To Control/Multiple Imputations (Intent-to-treat Population)
MMRM = Mixed model for repeated measures

Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.

BESTFIT: Tonmya significantly improved weekly average of Daily Diary Sleep Quality scores

18

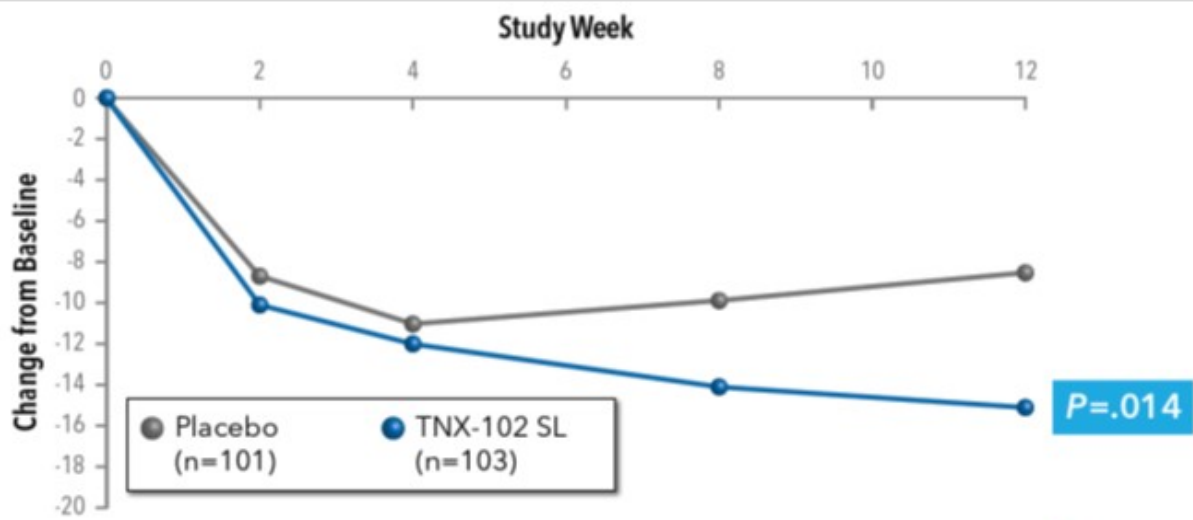


Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.

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BESTFIT: Tonmya significantly improved FIQ-R Total scores

19

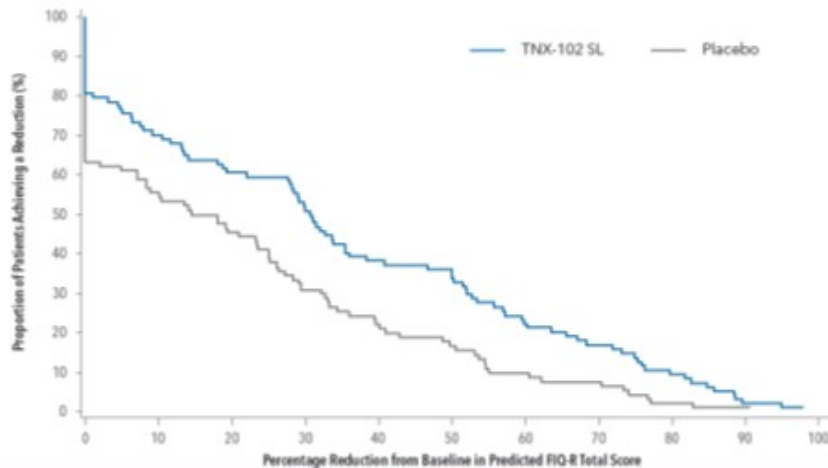


Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.

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BESTFIT: More FIQ-R responders with Tonmya vs. placebo at all levels

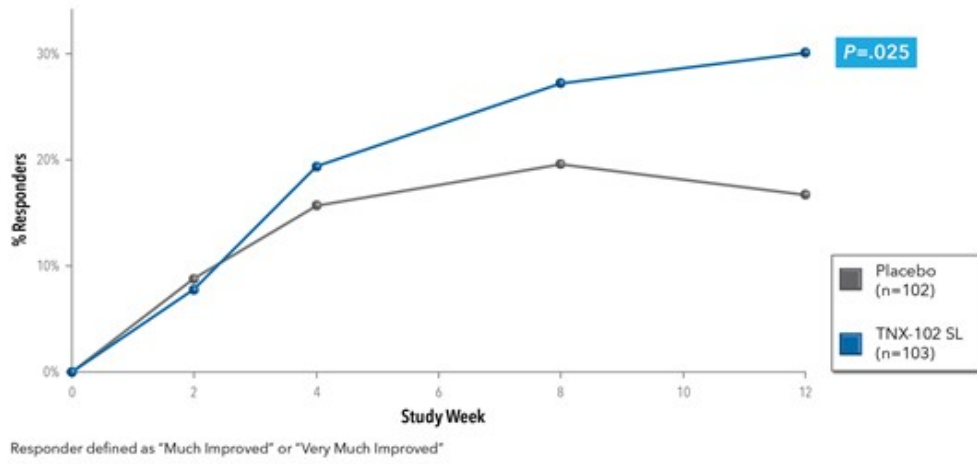
Continuous Responder Analysis on FIQ-R Total Score at Week 12



Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.



BESTFIT: Tonmya improved Week 12 PGIC responder rate



Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.



Tonmya was well tolerated in the BESTFIT study

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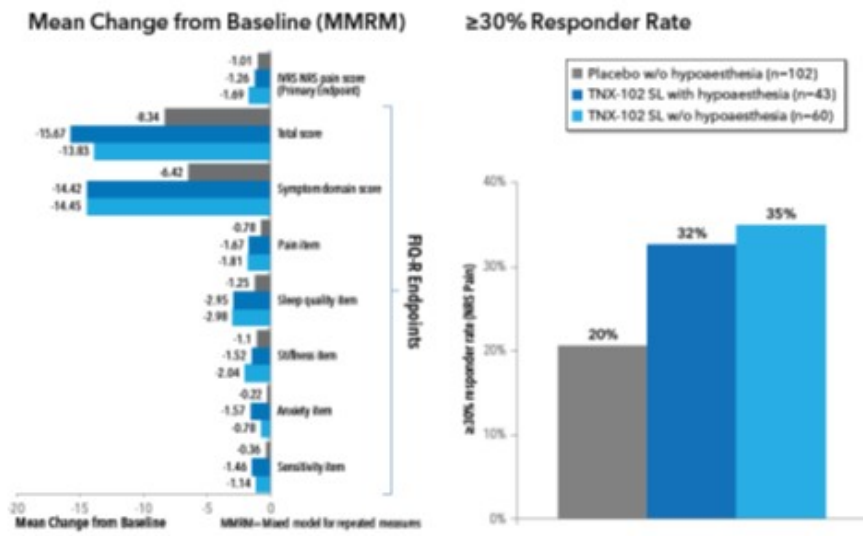
Systemic adverse events reported by at least 3.0% of the total study population	Tonmya (N=103)	Placebo (N=101)	Total (N=204)
Somnolence	1.9	6.9	4.4
Dry Mouth	3.9	4.0	3.9
Back Pain	4.9	3.0	3.9

- No serious adverse events (SAE) reported with Tonmya
- Most frequent local adverse events were administration site reactions
 - Previously reported in Phase 1 studies; no detectable bias on efficacy results
 - Transient tongue numbness (42% Tonmya vs. 1% placebo)
 - Abnormal taste (8% Tonmya vs. 0% placebo)
- Trial completion rates of 86% with Tonmya vs. 83% with placebo

Source: Phase 2b BESTFIT study data.
Tonmya is an Investigational New Drug and is not approved for any indication.

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BESTFIT: Presence of oral adverse events did not lead to meaningful differences in outcome measures



Source: Phase 2b BESTFIT study data.
 Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.



Tonmya in Phase 3 registration program in fibromyalgia

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Phase 3 AFFIRM Study is underway

Tonmya once-daily at bedtime

2.8 mg

N = 250

Placebo once-daily at bedtime

N = 250

12 weeks

..... *open-label extension*

- Randomized, double-blind, placebo-controlled study in fibromyalgia
- N*=500; approximately 35 U.S. clinical sites
- Primary efficacy endpoint:
 - Difference in 30% pain responder analysis at Week 12 between Tonmya and placebo

Top line data expected 2H16

Second Phase 3 clinical trial expected to begin in 2Q 2016

- Currently expected to be similar to AFFIRM in design and size

Source: Phase 2b BESTFIT study data.
Tonmya / TNX-102 SL is an Investigational New Drug and is not approved for any indication.

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TNX-102 SL in Phase 2 development for PTSD

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Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
Tonmya	Fibromyalgia							Top line data H2 2016
TNX-102 SL	PTSD							Top line data H1 2016
TNX-201	Episodic Tension-Type Headache							Top line data Q4 2015

*PTSD = post-traumatic stress disorder
Tonmya / TNX-102 SL and TNX-201 are Investigational New Drugs and are not approved for any indication.*

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PTSD: An important and growing public health problem

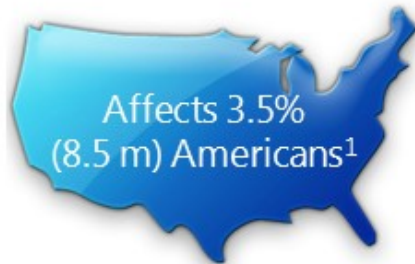
26

- ⦿ PTSD is a chronic disorder following a traumatic event and is characterized by:
 - re-experiencing the triggering event
 - situation/stimulus avoidance
 - negative alterations in mood/cognition
 - hypervigilance (anxiety, difficulty sleeping)

- ⦿ Considered a stress response, but prolonged and does not resolve with time
 - Of those who experience significant trauma, ~15% develop PTSD (20% of women, 8% of men)¹

- ⦿ Associated with significant life disruption
 - Social isolation, inability to maintain employment, loss of independent living
 - Unpredictable acts of violence, suicidal thoughts

¹ Kessler et al. *Arch Gen Psychiatry* 1995;52:1048



- ~70% are considered to have moderate to severe symptoms
- Of those diagnosed, ~50% utilize professional healthcare (psycho/pharmacotherapy)²

• Higher prevalence in military population

- 20% of veterans from recent conflicts will have potential/provisional PTSD³
- ~500,000 veterans are receiving treatment for PTSD in the VA health system (2009)⁴
- Majority are male
- Alcohol and substance abuse are common

¹ Kessler RC et al, *Arch Gen Psychiatry* 2013;62:617; U.S. Census Bureau, 2013 Projection.

² Wang et al, *Arch Gen Psychiatry* 2005;62:629.

³ Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND)

Veterans Diagnosed with Potential or Provisional PTSD.

⁴ Berndary et al, *J Clin Psychiatry* 2012;73:297.

Significant gap in current therapeutic landscape for PTSD

28

- ⦿ **Medicines for PTSD often provide inadequate and/or inconsistent benefit**
 - FDA-approved medications are limited to two SSRIs, approved >10 years ago
 - Weak evidence of treatment effect in men¹
 - Lack of evidence of efficacy in those with a history of combat-related trauma²
 - Carry suicidality warnings, require dose titration
- ⦿ **Sleep dysfunction in PTSD is resistant to currently-approved options**
 - 95%+ report insomnia, 83% report recurrent dreams of the trauma³
 - Correlated with disease severity, depression, substance abuse and suicide⁴
 - Poor sleep quality after trauma may increase the risk of developing PTSD
 - Off-label use of anxiolytics, sedative-hypnotics, opiates, and antipsychotics

SSRI = selective serotonin reuptake inhibitor

¹ Marshall et al, *Am J Psychiatry* 2001;158:1982.

² Jonathan Davidson, personal communications, 2014.

³ Green B. Post-traumatic stress disorder: Symptom profiles in men and women. *Curr Med Res Opin* 2003;19:200-4.

⁴ Germain et al, *J Anxiety Disord* 2005;19:233; Krakow et al, *J Nerv Ment Dis* 2002;190:442.

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TNX-102 SL's potential as a treatment for PTSD is supported by clinical evidence and nonclinical activities

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- ⦿ **TNX-102 SL targets mechanisms associated with treating disturbed sleep in PTSD**
 - 5-HT_{2A} receptor antagonist and reuptake inhibitor (like trazodone)
 - Alpha-1 adrenergic receptor antagonist (like prazosin)
 - Trazodone and prazosin receive off-label use to treat sleep dysfunction in PTSD
- ⦿ **Fibromyalgia program informs development of TNX-102 SL in PTSD**
 - Improvements observed in Phase 2b BESTFIT study relate to PTSD core symptoms

Outcome Measure at Week 12 in BESTFIT ¹	<i>p</i> value
PROMIS Sleep Disturbance	0.005
FIQ-R Anxiety Item	0.015
FIQ-R Sensitivity Item	0.017

p < 0.05 → statistically significant

¹ Phase 2b BESTFIT study data.
TNX-102 SL is an Investigational New Drug and is not approved for any indication.

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

www.ateasestudy.com

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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 is an Investigational New Drug and is not approved for any indication.

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TNX-201 in Phase 2 development for episodic tension-type headache

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
Tonmya	Fibromyalgia							Top line data H2 2016
TNX-102 SL	PTSD							Top line data H1 2016
TNX-201	Episodic Tension-Type Headache							Top line data Q4 2015

Tonmya / TNX-102 SL and TNX-201 are Investigational New Drugs and are not approved for any indication.



Episodic tension-type headache (ETTH)

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- **75 million adults in the U.S. experience frequent episodic tension-type headaches¹**
 - 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 treatment²
- **Over-the-counter medications are inadequate for many**
 - 10 million prescriptions per year for 'non-migraine' headaches in the U.S.³
- **All of the FDA-approved prescription medications contain a barbiturate (butalbital)**
 - Impairs alertness, carries risks of dependence; physically and psychologically addictive
 - Increases the risk that episodic headaches will become chronic
 - "Extended use not recommended" warning in product labels

No new medications introduced for >40 years

¹ Schwartz et al., JAMA 1998;279:381-383; Chowdhury, Ann Ind Acad Neurol 2012;15:83-88; Tonix analysis of public literature.

² Scher et al., Cephalalgia 2010;30:321-328; Tonix analysis of public literature.

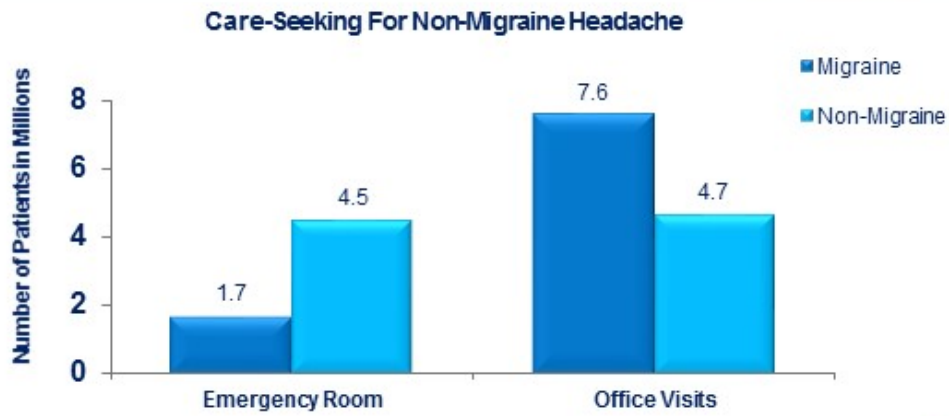
³ Based on independent study conducted by Trinity Partners using IMS National Prescription Audit (8/2013 – 7/14/2014) and IMS National Disease and Therapeutic Index™ Q3 2008 – Q3 2014.

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Patients with ETTH seek medical attention

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

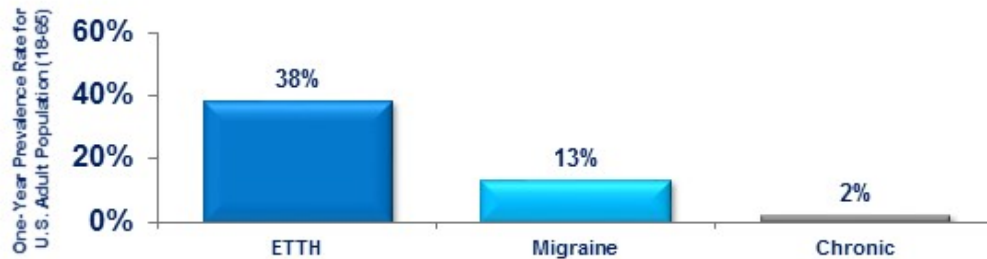


Health Care Utilization Project data, 2011; IMS National Disease and Therapeutic Index™ 2013

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ETTH is the most common type of headache

More than one-third of U.S. adults experience frequent ETTH¹



Adults (18-65)² ~198 M ~75 M ~26 M ~4.4 M

¹ Schwartz et al, JAMA 1998;279:381
² U.S. Census Bureau, 2013 Projection.



TNX-201 has evolved from popular headache medications with a long history of use

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- ⦿ **TNX-201 (dexisometheptene mucate)**
 - Single optical isomer of isometheptene (IMH)
- ⦿ **A mixture of IMH optical isomers had been widely prescribed for many decades**
 - “Racemic isometheptene”
 - Single-agent medicine (pre-1962)
 - Component of combination drug product
 - Midrin® – NDA withdrawn
 - Prodrin® – marketed under “unapproved drug category”

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

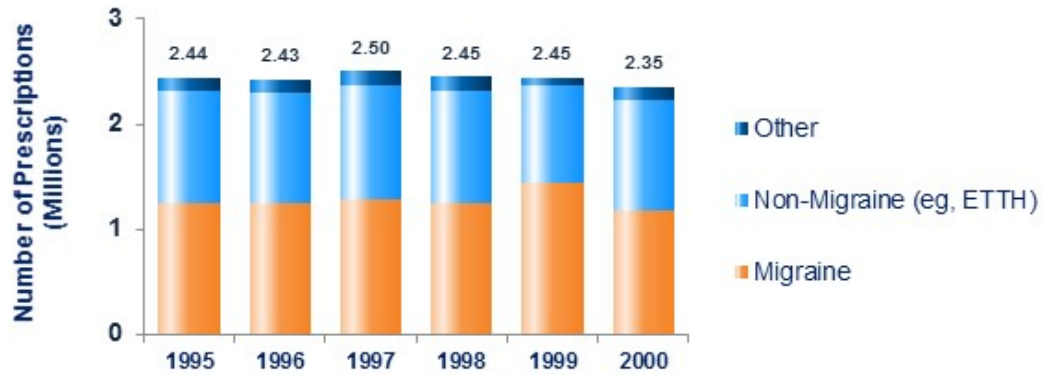
TNX-201 is an Investigational New Drug and is not approved for any indication.

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Racemic isometheptene combination (RIC) prescriptions had been commonly written

36

Usage of RIC Prescriptions for All Diagnoses¹



¹ 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).

Optical isomers of IMH have distinct pharmacological activities

37

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

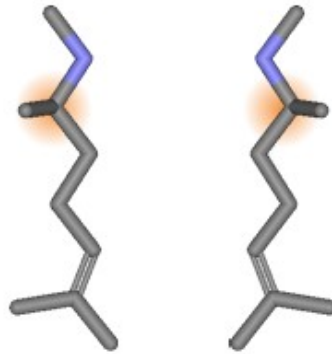
Tonix is developing a single IMH isomer for ETT, supported by proprietary research

(R) isomer ✓

- Analgesic
- Binds to imidazoline-1 receptor
- Inactive on adrenergic receptors



TNX-201



(S) isomer ✗

- Sympathomimetic

TNX-201 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

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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”; most were 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 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 ETTH

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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

Top line data expected Q4 2015

- **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
- **No FDA clinical guidelines on tension-type headache**
- **No ETTH drug approved in over four decades**
 - Expect to discuss Phase 3 program design with FDA at End-of-Phase 2 meeting

TNX-201 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

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Characteristics¹

- 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 studies²

- 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

¹ Piletz JE et al. *DNA Cell Biol* 2000;19:319

² Zhang L et al. *CNS Neurosci Ther* 2013;19:978.

TNX-201 is an Investigational New Drug and is not approved for any indication.

Wholly-owned by Tonix with no obligations to others

Tonmya / 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

Tonmya, TNX-102 SL and TNX-201 are Investigational New Drugs and are not approved for any indication.

Financial overview

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NASDAQ: TNXP

Cash reported at March 31, 2015	\$ 58.2 million
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Shares outstanding (July 7, 2015)	16.2 million
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Management team

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Seth Lederman, MD
President & CEO

TARGET

Fusilev[®]
(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

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

44

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, NRDC, Booz Allen Hamilton

Donald Landry, MD, PhD

Chair of Medicine, Columbia University

Samuel Saks, MD

Jazz Pharma, ALZA, Johnson & Johnson



Milestones – recent and upcoming

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Tonmya – Fibromyalgia

- May 2015 Began Phase 3 AFFIRM study
- June 2015 Presented additional data from Phase 2b BESTFIT study at EULAR
- 2H 2016 Report top-line results from AFFIRM study

TNX-102 SL – Post-Traumatic Stress Disorder

- January 2015 Began Phase 2 AtEase study in military-related PTSD
- 1H 2016 Report top-line results from AtEase study

TNX-201 – Episodic Tension-Type Headache

- June 2015 Began randomization in proof-of-concept Phase 2 study
- June 2015 Presented non-clinical data at AHS (receptor, migraine models)
- 4Q 2015 Report top-line results from proof-of-concept Phase 2 study

Tonmya / TNX-102 SL and TNX-201 are Investigational New Drugs and are not approved for any indication.

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Developing innovative medicines for large and growing markets

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- Common and chronic disorders of the CNS
- Next-generation medicines with transformative treatment potential
- Late-stage candidates supported by human experience
- Capitalized to achieve key readouts in all of our clinical-stage programs





NASDAQ: TNXP

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