

**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 8, 2016

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:

Marc J. Ross, Esq.
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))
-

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Promotion of Jessica Morris

Effective January 8, 2016, the Board of Directors of Tonix Pharmaceuticals Holding Corp. (the "Company") appointed Ms. Jessica Morris as the Company's Acting Chief Financial Officer.

Ms. Morris, age 37, has worked for the Company since April 2013, as a consultant (April 2013 – September 2013), SVP of Finance (September 2013 – October 2015) and Chief Administrative Officer (October 2015 – January 2016). Between January 2010 and September 2012, Ms. Morris was a Vice President at the family office fund for Zhong Rong Group. Previously, Ms. Morris was a Senior Associate in the Sponsor Finance Group at American Capital, a Vice President of the mezzanine debt fund at Calvert Street Capital Partners, an Associate in the commercial finance department of Silicon Valley Bank and a Financial Analyst in the media and telecommunications investment banking group at Deutsche Bank. Ms. Morris earned a B.S. in Commerce and a B.A. in Music from the University of Virginia.

Resignation of Leland Gershell

Effective January 8, 2016, Dr. Leland Gershell, M.D., Ph.D., resigned as the Company's Chief Financial Officer and Treasurer. Dr. Gershell agreed to stay on as a consultant to the Company.

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 8.01 Other Events.

On January 8, 2016, the Company issued a press release announcing Dr. Gershell's resignation and Ms. Morris' promotion, as discussed in Item 1.01 above. A copy of the press release that discusses these matters is filed as Exhibit 99.02 to, and incorporated by reference in, this report.

The information contained in Item 8.01 of this Current Report on Form 8-K, including Exhibit 99.02, 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 8.01 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

- | | |
|-------|--|
| 99.01 | Corporate Presentation by the Company for January 2016* |
| 99.02 | Press release, dated January 8, 2016, issued by Tonix Pharmaceuticals Holding Corp.* |

* 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 8, 2016

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



NASDAQ: TNXP

Investor Presentation

January 2016

Version: P0003-01-08-16

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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 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and November 6, 2015, respectively, 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.



- **Targeting common pain conditions and a serious psychiatric disorder**
 - Two clinical-stage proprietary candidates targeting three indications
 - Differentiated products with potential for sustainable competitive advantages

- **2016 to reveal results from three clinical trials**
 - Fibromyalgia – Phase 3 to report in 3Q
 - Post-traumatic stress disorder – Phase 2 to report in 2Q
 - Episodic tension-type headache – proof-of-concept Phase 2 to report in 1Q

- **All intellectual property owned by Tonix – from internal R&D**

Pipeline led by TNX-102 SL for fibromyalgia

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Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst	
TNX-102 SL (Tonmya*)	Fibromyalgia								Top line data 3Q 2016
TNX-102 SL	Post-Traumatic Stress Disorder								Top line data 2Q 2016
TNX-201	Episodic Tension-Type Headache								Top line data 1Q 2016

* Tonmya has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) and TNX-201 (dexisometheptene muccate) are Investigational New Drugs and are not approved for any indication.

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Fibromyalgia is a chronic, debilitating disorder that imposes a significant societal and economic burden

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- ⦿ **Fibromyalgia is considered neurobiological disorder characterized by¹:**
 - Chronic widespread pain
 - Nonrestorative sleep
 - Fatigue
 - Diminished cognition

- ⦿ **Believed to result from amplified sensory and pain signaling in central nervous system¹**

- ⦿ **Causes significant impairment in all areas of life²**
 - 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 year³
 - Annual direct medical costs are twice those for non-fibromyalgia individuals⁴

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

² Schaefer et al, *Pain Pract*, 2015, May 16.

³ Robinson et al, *Pain Medicine* 2013;14:1400.

⁴ White et al, *J Occupational Environ Med* 2008;50:13.

Fibromyalgia is a prevalent disorder but remains underdiagnosed

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- 1.1% diagnosis rate = 2.7 million U.S. adults¹
 - Suggests underdiagnosis
- Approximately 2.3 million U.S. adults receive treatment²
- Approved drugs achieved 2014 U.S. sales of \$1.2 billion³
 - Represent about 5.6 million prescriptions⁴

Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year^{2,4}

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

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

³ Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.

⁴ 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).

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 fail therapy due to **lack of a response** or **poor tolerability**¹



¹ Market research by Frost & Sullivan, commissioned by Tonix (2011).

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Large need for new fibromyalgia therapies that provide broad symptom relief with better tolerability

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- ⦿ **Currently-approved medications may have side effects that limit long-term use¹**
 - Many patients skip doses or discontinue altogether within months of treatment initiation
- ⦿ **Medication-related side effects may be similar to fibromyalgia symptoms**
- ⦿ **High rates of discontinuation, switching and augmentation**
 - Attempt to treat multiple symptoms and/or avoid intolerable side effects
 - Average of 2-3 medications used simultaneously²
 - The typical patient has tried six different medications³
- ⦿ **Substantial off-label use of narcotic painkillers and prescription sleep aids³**

¹ Nuesch et al, *Ann Rheum Dis* 2013;72:955-62.

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

³ "Patient Trends: Fibromyalgia", *Decision Resources*, 2011.

Tonix is developing TNX-102 SL for fibromyalgia

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- **Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP)**
 - Suitable for administration at bedtime due to efficient transmucosal absorption
 - Avoidance of first-pass metabolism reduces formation of long-lived metabolite
 - Designed for daily administration with no titration
- **TNX-102 SL's pharmacologic action is believed to improve sleep quality**
 - Non-restorative sleep is a common clinical and diagnostic feature of fibromyalgia¹
 - Evolving understanding of the role of sleep in pain control and fibromyalgia development²
 - TNX-102 SL targets receptors believed to play key roles in sleep physiology
- **Phase 2b "BESTFIT" study was successfully completed in 3Q14**
- **Top line data from ongoing Phase 3 "AFFIRM" study expected to report in 3Q16**

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

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

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

Phase 2b “BESTFIT” study of TNX-102 SL in fibromyalgia

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⦿ 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 randomized 1:1 at 17 U.S. sites
- Sublingual tablet of 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

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

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BESTFIT results on key clinical endpoints

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Category	Endpoint – week 12 ¹	p value
Pain Relief	30% responder analysis ²	0.033
Sleep Quality	PROMIS Sleep Disturbance	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 (TNX-102 SL N=103, placebo N=102).

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

Source: Phase 2b BESTFIT study data.

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



TNX-102 SL safety and tolerability profile in the BESTFIT study

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- No serious adverse events (SAE) reported with TNX-102 SL
- Systemic adverse events reported by at least 3% of the total BESTFIT population

	TNX 102 SL (N=103)	Placebo (N=101)
Somnolence	1.9	6.9
Dry Mouth	3.9	4.0
Back Pain	4.9	3.0

- Most frequent local adverse events were administration site reactions
 - Previously reported in Phase 1 studies; no detectable bias on efficacy results
 - Transient tongue numbness (44% TNX=102 SL vs. 2% 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 is an Investigational New Drug and is not approved for any indication.



TNX-102 SL in Phase 3 clinical development for fibromyalgia

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Phase 3 AFFIRM Study is underway

TNX-102 SL once-daily at bedtime
2.8 mg *N* = 250

Placebo once-daily at bedtime
N = 250

- 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 TNX-102 SL and placebo

Top line data expected 3Q 2016

12 weeks → open-label extension

Second Phase 3 Study ("REAFFIRM") expected to begin in 2Q 2016

- Expected to be similar to AFFIRM in design and size

Source: Phase 2b BESTFIT study data.
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 post-traumatic stress disorder (PTSD)

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Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst	
TNX-102 SL (Tonmya*)	Fibromyalgia								Top line data 3Q 2016
TNX-102 SL	Post-Traumatic Stress Disorder								Top line data 2Q 2016
TNX-201	Episodic Tension-Type Headache								Top line data 1Q 2016

* Tonmya has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

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PTSD is a chronic stress disorder triggered by a traumatic event

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- ⦿ PTSD 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
 - 20% of women and 8% of men who experience significant trauma develop PTSD¹
- ⦿ 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

PTSD is a prevalent problem for both civilians and the military

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- ~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
- ~638,000 veterans with PTSD in the VA health system (2012)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 Bowe et al, *J Dual Diagnosis* 2015;11:22.

Significant gap in current therapeutic landscape for PTSD

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- ❖ **Medicines approved for PTSD often provide inadequate and/or inconsistent benefit**
 - Limited to two SSRI antidepressants, both of which carry suicidality warnings
 - U.S. Institute of Medicine (IOM) concluded that evidence of treatment effect is low¹
 - Lack of efficacy evidence in those with a history of combat-related trauma²
- ❖ **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
 - Drugs approved for insomnia have been shown to not improve PTSD sleep dysfunction
- ❖ **Off-label use of anxiolytics, sedative-hypnotics, and antipsychotics is common⁵**
 - Limited evidence of effectiveness; may be harmful
 - May interfere with other treatments such as cognitive behavioral therapy (CBT)

SSRI = selective serotonin reuptake inhibitor.

¹ Marshall et al, *Am J Psychiatry* 2001;158:1992.

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.

⁵ Bernardy et al, *J Clin Psychiatry*, 2012, 73:297-303.

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

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- TNX-102 SL is active on receptor sites believed to have treatment potential for sleep problems in PTSD
 - Targeted receptors include 5-HT_{2a}, alpha-1 adrenergic, and histamine-1 receptors
- Efficacy of “tricyclic” drug class in PTSD is supported by clinical data¹
 - Oral tricyclics have side effects that limited their use
- Improvements observed in BESTFIT study relate to PTSD core symptoms²

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

p < 0.05 → statistically significant

¹ Davidson J, *J Psychopharm* 2015;29:264

² 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 fully enrolled

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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=240+; 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 12 weeks

12 weeks → open-label extension

Top line data expected 2Q 2016

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
TNX-102 SL (Tonmya*)	Fibromyalgia						Top line data 3Q 2016	
TNX-102 SL	Post-Traumatic Stress Disorder						Top line data 2Q 2016	
TNX-201	Episodic Tension-Type Headache						Top line data 1Q 2016	

* Tonmya has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

*NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
 TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) and TNX-201 (dexisometheptene muccate) are Investigational New Drugs and are not approved for any indication.*



Episodic tension-type headache (ETTH) – the most common form of headache

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- **More than 75 million adults in the U.S. experience ETTH each year¹**
 - Constant band of pressure on the back/sides of head; "squeezed in a vice" feeling
 - Most are *infrequent* (<1 per month); rarely require medical attention, mainly self-treated
- **21 million experience *frequent* ETTH each year¹**
 - Frequent = one to 14 headaches per month over a three-month period
 - More likely to seek physician care and receive a prescription product^{1,2}
- **ETTH is the major contributor to all 'non-migraine headaches'¹**
 - Non-migraine headaches lead to 9.2 million emergency room or office visits each year^{3,4}

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 Health Care Utilization Project data, 2011.

⁴ IMS National Disease and Therapeutic Index™ 2013.

Many patients do not receive adequate relief from OTC treatments

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⦿ “First-line” treatment - NSAIDs are most common

- Many patients self-medicate with a course of over-the-counter NSAIDs before seeing a physician¹
- Less than 50% of treated patients are pain-free at two hours²
- Some are refractory to NSAIDs when they first seek medical attention¹
- Aspirin- and acetaminophen-containing products also used

OTC = over-the-counter; NSAID = non-steroidal anti-inflammatory drug

¹ Based on independent study commissioned by Tonix, based on physician interviews using IMS National Prescription Audit (8/2013 – 7/14/2014) and IMS National Disease and Therapeutic Index™ Q3 2008 – Q3 2014.

² Moore et al, Pain 2014;155:2220-2228



Prescription options for acute therapy are limited and potentially addictive

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- **Butalbital combinations are the only FDA-approved prescription products for ETTH**
 - ~3.5 million prescriptions for these products are written per year for non-migraine headaches¹
 - Butalbital is a barbiturate – and frequently combined with codeine, an opiate
 - Not recommended for extended use because of addiction, tolerance and abuse potential²
- **Opioid narcotic combination products are used off-label to treat non-migraine headaches**
 - Include products that contain hydrocodone, codeine, and tramadol¹
 - ~5.3 million prescriptions for these products issued annually for the treatment of non-migraine headaches¹

¹ Based on independent study commissioned by Tonix, based on physician interviews using IMS National Prescription Audit (8/2013 – 7/14/2014) and IMS National Disease and Therapeutic Index™ Q3 2008 – Q3 2014.

² Fioricet package insert.

- **Isometheptene (IMH) had been marketed for tension-type headache**
 - Single agent product for migraine was voluntarily withdrawn by Knoll Pharma in 1981
 - IMH-containing combination products remained on the market without approved NDAs
 - Original product labeling for Prodrin® indicates that FDA classified as "possibly" effective for migraine¹

- **2.5 million prescriptions of IMH-containing combination products were filled in 1997²**
 - Midrin® – NDA withdrawn (2011)
 - Prodrin® – now marketed under "Unapproved Drug Other" category

¹ PRODRIN package insert (revised 8/13): <http://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1d157217-d307-423c-8f50-965b23881330&type=display>

² 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).

Scientific rationale for development of TNX-201

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⦿ TNX-201 (dexisometheptene mucate) contains the (R) isomer of isometheptene

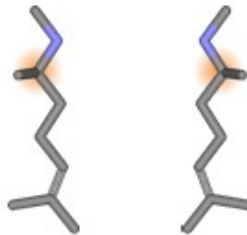
- Pharmacologic profile is distinct from (S) isomer per preclinical studies
- Represents a new class of analgesics (selective imidazoline-1 receptor agonists)

(R) isomer ✓

- Analgesic in two rat models of headache¹
- Binds to imidazoline-1 receptor
- Inactive on adrenergic receptors



TNX-201



(S) isomer ✗

- Sympathomimetic

¹ Fried et al, *Headache* 2015;55:184.
TNX-201 is an Investigational New Drug and is not approved for any indication.

⦿ Key attributes

- Unique analgesic mechanism of action (imidazoline-1 receptor agonist)
- Differentiated pharmacology as a single isomer of isometheptene
- May offer a non-addictive treatment option for ETTH

⦿ May serve patients who:

- Do not adequately respond to an NSAID
- Would be candidates for treatment with butalbital and/or opioid narcotics
- Suffer from medication overuse headaches
 - May be caused by NSAIDs, butalbital, or opioid narcotics

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

Phase 2 proof-of-concept trial of TNX-201 in ETT is fully enrolled

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TNX-201

140 mg

N = 100

Placebo

N = 100

- Randomized, double-blind, placebo-controlled trial in episodic tension-type headache
- Goal is to assess treatment of approx. 150 headaches
- ~10 U.S. clinical sites

Top line data expected 1Q 2016

- **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 hour post-dose period
- Change from baseline in pain severity score at several intervals post-dose

- **Results will be used to support discussion with FDA on Phase 3 study design**

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

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Wholly-owned by Tonix with no 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, 2020 expiry
 - PTSD: patents filed

TNX-201

Headache

- **Composition-of-matter (isomer)**
 - Patents filed
 - Protection expected to 2033

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

Financial overview

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NASDAQ: TNPX

Cash, cash equivalents, and marketable securities reported at September 30, 2015 **\$ 55.0 million**

Cash used in operations in 2015 through September 30 **\$ 30.6 million**

Shares outstanding (January 8, 2016) **18.8 million**



Management team

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Seth Lederman, MD

President & CEO



Bruce Daugherty, PhD, MBA

Chief Scientific Officer



Gregory Sullivan, MD

Chief Medical Officer



COLUMBIA UNIVERSITY
Department of Psychiatry

New York State
Psychiatric Institute

Jessica Edgar Morris

Acting CFO, Chief Administrative Officer

Deutsche Bank



Ronald Notvest, PhD

SVP, Commercial Planning & Development



Board of directors

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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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TNX-102 SL – Fibromyalgia

- May 2015 Began Phase 3 AFFIRM study
- November 2015 Presented additional data from Phase 2b BESTFIT study at ACR Annual Meeting
- 3Q 2016 Report top-line results from AFFIRM study

TNX-102 SL – Post-Traumatic Stress Disorder

- December 2015 Entered into CRADA with USAMMDA
- December 2015 Reported completion of enrollment in Phase 2 AtEase study
- 2Q 2016 Report top-line results from AtEase study

TNX-201 – Episodic Tension-Type Headache

- June 2015 Presented non-clinical data at AHS Annual Meeting (receptor, animal models)
- December 2015 Reported completion of enrollment in proof-of-concept Phase 2 study
- 1Q 2016 Report top-line results from Phase 2 study

ACR = American College of Rheumatology; AHS = American Headache Society
CRADA = Cooperative Research & Development Agreement
USAMMDA = U.S. Army Medical Material Development Activity
TNX-102 SL and TNX-201 are Investigational New Drugs and are not approved for any indication.

TONIX
PHARMACEUTICALS



NASDAQ: TNXP

509 Madison Avenue
New York, NY 10022
(212) 980-9155

www.tonixpharma.com



Tonix Pharmaceuticals Announces Management Change

New York, NY – January 8, 2016 – [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ: TNPX) (“Tonix”), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, today announced that Jessica Edgar Morris, Chief Administrative Officer, has been appointed Acting Chief Financial Officer, effective immediately. Ms. Morris replaces Leland J. Gershell, M.D., Ph.D., who resigned from his position at the company to pursue new opportunities.

“On behalf of the management team and board of directors, I thank Leland for his contributions to Tonix over the past four years,” said Seth Lederman, M.D., Tonix’s president and CEO. “We wish him continued success in his future endeavors.”

Ms. Morris is an accomplished finance and investment executive with more than fifteen years of experience at both private and publicly-traded companies. She began working at Tonix in April 2013, was appointed Senior Vice President of Finance in September 2013 and became the Chief Administrative Officer in October 2015.

Dr. Lederman added, “Jessica has been an integral part of our company’s successful evolution, and over the past two and a half years, she has greatly contributed to our finance, investor relations and human resources departments. Her expertise in financial reporting, compliance, valuation and capital raising will continue to be invaluable as she expands her role on the leadership team as Acting Chief Financial Officer.”

Prior to joining Tonix, Ms. Morris served as a vice president at Zhong Rong Group, where she oversaw its U.S. family office investment strategy and asset allocation. Previously, she worked at American Capital, a publicly-traded private equity firm and global asset manager, where she sourced and underwrote investments in companies across a range of industries, including healthcare. Ms. Morris also served as a vice president at Calvert Street Capital Partners, a private equity firm, and as an associate at Silicon Valley Bank, a senior debt lender to technology and life science companies. Ms. Morris began her career at Deutsche Bank, as an investment banking financial analyst, and earned a B.S. in Commerce and B.A. in Music from the University of Virginia where she was an Echols Scholar.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

Safe Harbor / Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of 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,” “expect,” 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 FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on February 27, 2015 and November 6, 2015, respectively, and future periodic reports filed with the SEC on or after the date hereof. All of Tonix’s forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.

Contact:

Jessica Edgar Morris
Chief Administrative Officer and Acting Chief Financial Officer
(212) 980-9155 x106
jessica.morris@tonixpharma.com

Jenene Thomas Communications (investors)
Jenene Thomas
(908) 938-1475
jenene@jenenethomascommunications.com

Dian Griesel Int'l. (media)
Susan Forman / Laura Radocaj
(212) 825-3210
sforman@dgicomm.com
lradocaj@dgicomm.com

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