

**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): October 9, 2014

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(IRS Employer
Identification No.)

509 Madison Avenue, Suite 306, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

Copy of correspondence to:

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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 October 2014*

* Furnished herewith.

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: October 9, 2014

By: /s/ LELAND GERSHELL

Leland Gershell

Chief Financial Officer



NASDAQ: TNXP

October 2014

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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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing efforts and dependence upon third parties; and risks related to failure to obtain U.S. Food and Drug Administration clearances or approvals and noncompliance with its regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by the Company on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the amended Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission (the "SEC") on March 28, 2014 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.



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

- Innovative treatment paradigms
- Late stage candidates
- Large unmet medical needs

Fibromyalgia

Post-traumatic Stress Disorder

Episodic Tension-type Headache

Unencumbered intellectual property portfolio

Strong balance sheet, experienced team

- Multiple successes in drug approvals and value creation
- Well-capitalized to execute on key near-term milestones



Development programs

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Candidate	Indication						NDA	Market
		Preclinical	Phase 1	Phase 2	Phase 3			
TNX-102 SL	Fibromyalgia							2017E
TNX-102 SL	Post-traumatic Stress Disorder							2019E
TNX-201	Episodic Tension-type Headache							2019E

*TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 28 mg is an Investigational New Drug and is not approved for any indication.
TNX-201 (isometheptene mucate single isomer) is not approved for any indication.*

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Targeting sleep quality in fibromyalgia (FM) and post-traumatic stress disorder (PTSD)

Non-restorative sleep linked to pain, fatigue, hyper-vigilance, and arousals

Restorative sleep improves symptoms of fibromyalgia and PTSD

TNX-102 SL is designed as a chronic therapy for bedtime use

Novel molecular target for tension-type headache

Based on proprietary discoveries by Tonix

Mechanism of action distinct from acetaminophen or barbiturates



Fibromyalgia market opportunity

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

Three FDA approved prescription medications:

Class	Product	Company	Approval Year in FM	2012 U.S. Sales in FM**
Membrane Stabilizer	Lyrica [®]	Pfizer	2007	\$475 million
SNRI	Cymbalta [®]	Eli Lilly	2008	\$600 million
	Savella [®]	Forest	2009	\$100 million

Tonix is pursuing a different approach:

Sleep Quality	TNX-102 SL	Tonix	2017E	
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* Lawrence et al. *Arthritis Rheum* 2008;59:26-35; Vincent et al. *Arthritis Care Res* 2013;65:786-792.

** Estimates based on information from publicly-available sources

SNRI = Serotonin Norepinephrine Reuptake Inhibitor



Chronic, widespread pain with sleep, fatigue, mood, and memory problems

Poor quality of life

Typical patient has onset at 30-40 years of age with persistence for rest of life

Patients remain unsatisfied despite approved products

Patients typically take multiple medications

'Off-label' use of opioids and sedative-hypnotics despite no sustained benefit

Expensive, burdensome condition

Health utilization and medication costs are substantial

Managed care / payers recognize need for new medicines

Fibromyalgia has a highly negative economic impact

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Resource utilization over preceding 12 months

Outpatient visits	82.9%
Any emergency room visit	40.2%
Mean number of emergency room visits [†]	2.4

Productivity measures over preceding 12 months

Missed any work due to fibromyalgia	47.4%
Mean days of work missed [†]	58.4
Received disability income benefits	29.9%
Mean months on disability [†]	10.6

[†] Means include only subjects who experienced the event

Source: Robinson et al. Pain Med 2012;13:1366-76.

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PHARMACEUTICALS

Sleep quality is a new target for fibromyalgia therapy

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Restorative sleep improves pain and other fibromyalgia symptoms

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

Clinical validation from proof-of-concept study

Phase 2a trial showed pain and sleep benefit with very low dose oral cyclobenzaprine (CBP)**

TNX-102 SL: sublingual tablet formulation of CBP

Designed for chronic use at bedtime

Phase 2b results demonstrate broad-spectrum activity in patients enrolled in the BESTFIT trial***

Significant improvements across core fibromyalgia symptom domains

Well-tolerated

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

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

*** *Phase 2b BESTFIT preliminary top line results*

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 improved pain in fibromyalgia in the BESTFIT study

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Outcome Measure at Week 12	Intent-to-Treat Population [†]	p value	Method
Daily Pain Diary, NRS	Mean Change**	0.086	MMRM
		0.172	JTC-MI
Daily Pain Diary, NRS	Proportion Achieving 30% Improvement*	0.030	LR
Clinic NRS 7-day pain recall	Mean Change	0.029	MMRM
FIQ-R Pain Item	Mean Change	0.004	MMRM

NRS = Numeric Pain Scale; **FIQ-R** = Fibromyalgia Impact Questionnaire-Revised

MMRM = Mixed-Effect Model, 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; was primary endpoint for FDA approval of Savella

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

p < 0.05 → achieved statistical significance

Source: Phase 2b BESTFIT preliminary top line results



TNX-102 SL improved sleep quality in fibromyalgia in the BESTFIT study

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Outcome Measure at Week 12	Intert -to- Treat Population	p value	Method
Daily Sleep Quality Diary, NRS	Mean Change*	<0.001	MMRM
PROMIS Sleep Disturbance	T-score Change*	0.003 0.004	MMRM JTC-MI
FIQ-R Sleep Quality Item	Mean Change	<0.001	MMRM

PROMIS = Patient-Reported Outcome Measures in Sleep

* Declared secondary endpoint

$p < 0.05 \rightarrow$ achieved statistical significance

Source: Phase 2b BESTFIT preliminary top line results

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TNX-102 SL broadly improved fibromyalgia symptoms in the BESTFIT study

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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
		0.015	JTC-MI
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 preliminary top line results



No serious adverse events (SAE) reported

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 (41.7% TNX-102 SL vs. 1.0% placebo)

Abnormal taste (7.8% TNX-102 SL vs. 0.0% placebo)

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

Source: Phase 2b BESTFIT preliminary top line results



End-of-Phase 2 clinical/non-clinical meeting held with FDA in February 2013

Acceptable to submit 505(b)(2) New Drug Application (NDA)

Two adequate and well-controlled efficacy and safety trials in fibromyalgia patients

Requesting FDA meeting to review BESTFIT results and discuss efficacy requirements for NDA

One-year exposure data to support chronic use label

Open-label extension study to BESTFIT ongoing, to complete in August 2015

Definitive repeat dose pharmacokinetic “bridging” study



PTSD: a significant and growing public health problem ¹⁶

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	2019E
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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

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"

Poor sleep quality after trauma is linked to onset of PTSD

Correlated with depression, substance abuse and suicide

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

Antagonist at serotonin 2A, adrenergic α -1, histamine-1 receptors



Phase 2 efficacy study of TNX-102 SL to begin in 4Q 2014

Leverage fibromyalgia formulation, clinical experience, manufacturing know-how

Overlap between PTSD and fibromyalgia

~50% of fibromyalgia or PTSD patients meet criteria for the other disorder

Patients experience disturbed sleep

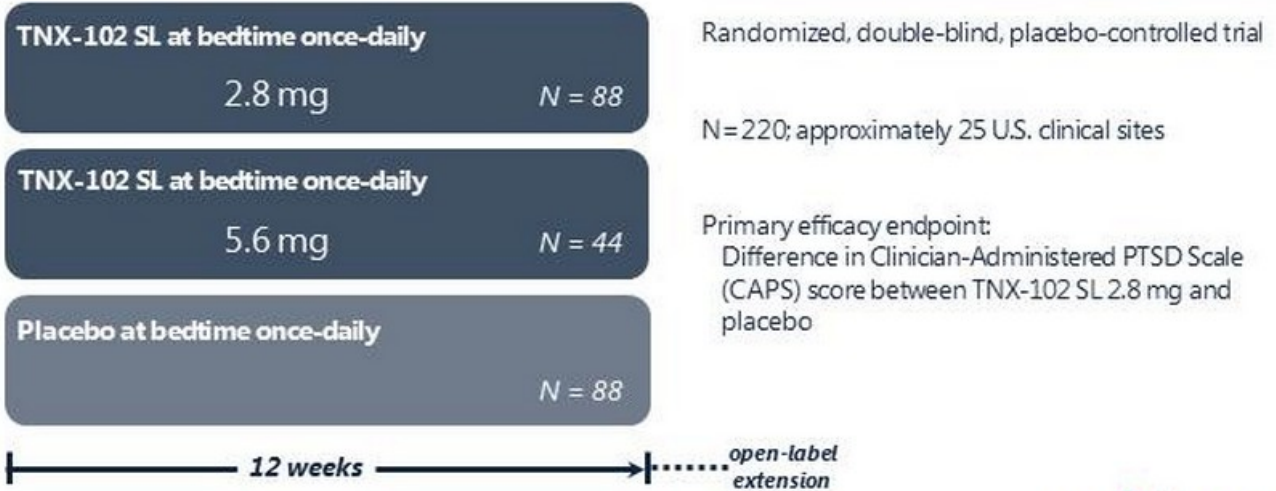
Widespread pain is considered "co-morbid" with PTSD

Opioid and sedative-hypnotic drug misuse common

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

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To begin enrollment in 4Q14



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70 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
Approximately 60% receive treatment**

All of the FDA approved prescription medications contain barbiturates

Over-the-counter medications are inadequate for many

Class	Product	Company	Regulatory Status	Approval Year in ETTH
Barbiturate	Fiorinal [®]	Actavis	Approved NDA	1990
	Fioricet [®]	Actavis	Approved NDA	1992
Barbiturate + Opiate	Fioricet with Codeine [®]	Actavis	Approved NDA	1992
New molecular target	TNX-201	Tonix	Pre-IND	2019E

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

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

Novel molecular mechanism

Based on proprietary discoveries by Tonix

Non-barbiturate, non-opioid

Mechanism of action distinct from acetaminophen and barbiturates

Comparative pharmacokinetic and safety study to be conducted in 1Q 2015

Pre-IND meeting with FDA held in January 2014



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

Corporate

- ✓ July 2014 – \$7.2 million in net proceeds from common stock offering

TNX-102 SL – Fibromyalgia

- ✓ September 2014 – Reported top line results from Phase 2b BESTFIT study
- Meet with FDA to determine remaining requirements for NDA
- Begin Phase 3 registration program

TNX-102 SL – Post-traumatic Stress Disorder

- ✓ June 2014 – Received IND clearance
- 4Q 2014 – Start Phase 2 AtEase efficacy study

TNX-201 – Episodic Tension-type Headache

- ✓ January 2014 – Held Pre-IND meeting
- 1Q 2015 – Conduct clinical pharmacology study



Management team

Seth Lederman, MD
Chief Executive Officer



Leland Gershell, MD, PhD
Chief Financial Officer



Bruce Daugherty, PhD
Chief Scientific Officer



Don Kellerman, PharmD
SVP, Clinical Development
& Regulatory Affairs



Seth Ledeman, MD (Chair)

Targent Pharmaceuticals
Vela Pharmaceuticals

Stuart Davidson

Alkermes
Combion

Patrick Grace

WR Grace
Chemed

Donald Landry, MD, PhD

Chair, Department of Medicine
Columbia University

Ernest Mario, PhD

Glaxo, ALZA
Reliant Pharmaceuticals

Charles Mather

Janney Montgomery Scott
Cowen, Smith Barney

John Rhodes

NYSERDA, NRDC
Booz Allen Hamilton

Samuel Saks, MD

ALZA
Jazz Pharmaceuticals

NASDAQ: TNXP

Cash reported at June 30, 2014*	\$ 43.9 million
Net cash used in operations in 2Q14	\$ 5.7 million
<hr/>	
Shares outstanding†	10.8 million
<hr/>	

* Does not include \$7.2 million in net proceeds from stock offering in July 2014

† As of October 8, 2014



TNX-102 SL: late-stage clinical program for large market opportunity

- Strong clinical evidence of broad activity in lead indication
- Well-known safety profile with excellent tolerability in patients studied
- Current fibromyalgia treatment options leave many patients unsatisfied

Multiple opportunities (fibromyalgia, PTSD, headache)

Team distinguished by track record of successful drug development

Well-capitalized to execute on key near-term milestones





NASDAQ: TNXP

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