

**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): November 5, 2012

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

333-150419
(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

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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 November 2012 *

* 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: November 5, 2012

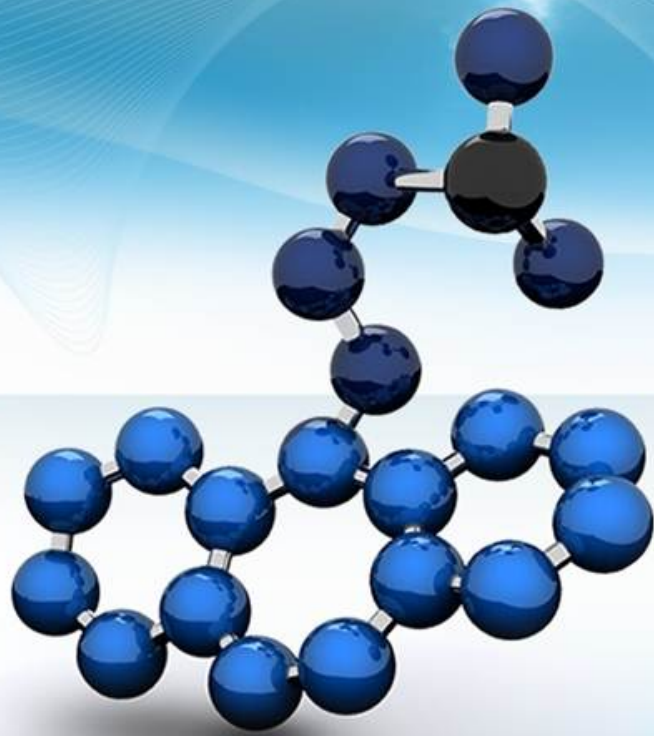
By: /s/SETH LEDERMAN
Seth Lederman
Chief Executive Officer

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Corporate Presentation
November 2012

OTC/QB: TNXP




Disclosures

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 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. 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. Investors should read the risk factors set forth in the Annual Report on Form 10-K filed with the SEC on March 30, 2012 and future periodic reports filed with the Securities and Exchange Commission. All of the Company's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.



Company Overview

- **Developing novel medications for challenging disorders of the central nervous system (CNS)**
 - Large and underserved indications
- **Pivotal trial in fibromyalgia (FM) to report in 2013**
 - Phase 2 data demonstrated efficacy
 - Unique, non-addictive treatment approach – targeting sleep quality
- **Capital-efficient strategy mitigates risk and cost**
 - 505(b)(2) leverages established safety database
- **Strong market exclusivity on lead product candidates**
 - Protection expected to 2033 on proprietary sublingual tablet
- **Experienced management and board**

Experienced Leadership

	Selected Previous Corporate Affiliations	Selected Previous Product Affiliations
Seth Lederman, MD CEO & Chairman	<ul style="list-style-type: none"> • Vela • Targent • Validus • Fontus 	
Leland Gershell, MD, PhD CFO	<ul style="list-style-type: none"> • Cowen • Apothecary Capital • Favus Research • Madison Williams 	
Bruce Daugherty, PhD, MBA Senior Director of Drug Development	<ul style="list-style-type: none"> • Merck • Roche Institute 	

Accomplished Independent Board

	Selected Current & Previous Affiliations	Selected Previous Product Affiliations
Seth Lederman, MD Chairman	<ul style="list-style-type: none"> Vela Targent Validus/Fontus 	
Stuart Davidson	<ul style="list-style-type: none"> Alkermes Combion 	
Patrick Grace	<ul style="list-style-type: none"> WR Grace Chemed Grace Institute 	
Donald Landry, MD, PhD	<ul style="list-style-type: none"> Columbia University Chair, Dept. of Medicine Vela 	
Ernest Mario, PhD	<ul style="list-style-type: none"> Glaxo Alza Reliant 	
Charles Mather	<ul style="list-style-type: none"> Janney Montgomery Scott Cowen Smith Barney 	
John Rhodes	<ul style="list-style-type: none"> Booz Allen Hamilton 	
Samuel Saks, MD	<ul style="list-style-type: none"> Jazz Alza Cougar 	

Product Pipeline

Product	Indication	Status
TNX-102 SL	Fibromyalgia	<ul style="list-style-type: none">• Cyclobenzaprine (CBP) in sublingual formulation• First pivotal trial to begin 1Q 2013• Topline results in 4Q 2013
	PTSD (Post-Traumatic Stress Disorder)	<ul style="list-style-type: none">• Cyclobenzaprine in sublingual formulation• Proof of concept data in 2013• Seeking U.S. Department of Defense partnership
TNX-201	Headache	<ul style="list-style-type: none">• Proprietary product based on grandfathered compound• Potentially shortened process for approval by the US Food and Drug Administration (FDA)
TNX-301	Alcoholism	<ul style="list-style-type: none">• Patents issued (US, EU)• Potential for government funding

Fibromyalgia

- **Chronic pain syndrome**
 - Central pain – originates in the CNS
 - Despite three FDA-approved medications, patients are dissatisfied
- **Complaint: “Hurt all over, can’t sleep”**
 - No benefit from opiates or prescription sleep drugs
- **FDA primary endpoint is pain**
- **Problem with sleep quality**
 - Restorative sleep can improve pain and other symptoms
- **~90% of diagnosed patients are female**

Fibromyalgia Market Opportunity

- **~5 million U.S. patients***
- **U.S. prescription drug market in 2011 ~\$1.4 billion****
 - 2007–2011 CAGR of 17%**
- **First approved drug for fibromyalgia in 2007**

Product	Company	Approval Year	Estimated 2011 US Sales for FM**
Lyrica®	Pfizer	2007	\$450 million
Cymbalta®	Eli Lilly	2008	\$560 million
Savella®	Forest	2009	\$137 million

- **Market growth driven by on-label drugs replacing legacy off-label generics*****

* National Institutes of Health, U.S. Department of Health and Human Services




** Decision Resources Pain Management Study: Fibromyalgia, January 2012

*** Frost & Sullivan Fibromyalgia Market Study, December 2010

Managed Care Perspective on FM

- **Fibromyalgia presents a significant economic burden**
 - Studies show high cost in overall care, lost productivity, and disability
- **Physicians and payors are aware of high unmet need in pharmacological treatment of fibromyalgia**
 - Patients take many products without evidence of efficacy
- **All FDA-approved fibromyalgia products are branded and on-patent**
 - Reimbursed at Tier 2 and enjoy growing sales in fibromyalgia
 - Growth continues despite presence of legacy off-label generics in Tier 1

Evolution of Fibromyalgia Market

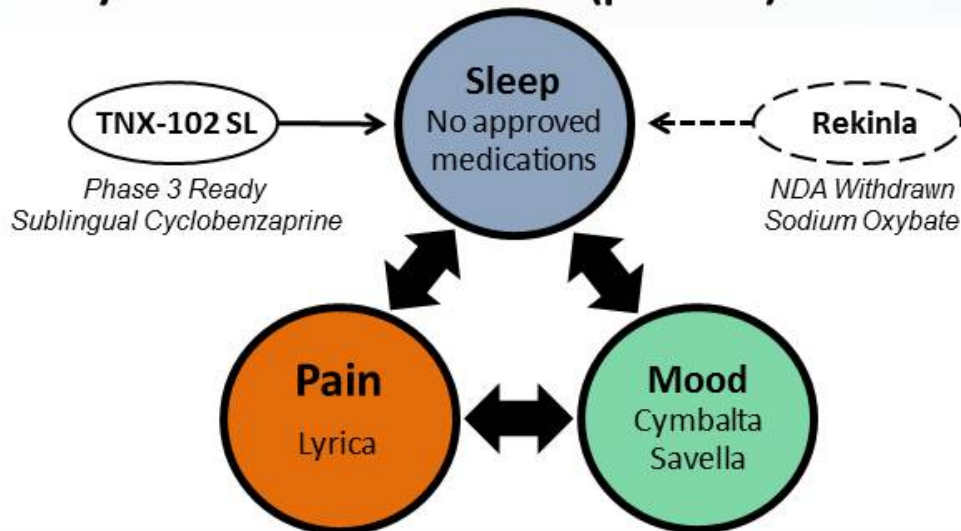
	<u>Legacy Off-Label</u>	<u>Abandoned</u>	<u>In Development</u>	<u>FDA Approved</u>
Sleep	<ul style="list-style-type: none"> cyclobenzaprine muscle relaxants sodium oxybate (Xyrem®)* 	<ul style="list-style-type: none"> sodium oxybate (Rekinla®)** 	<ul style="list-style-type: none"> TNX-102 SL (Phase 3 ready) 	
Pain	<ul style="list-style-type: none"> gabapentin opioids 		<ul style="list-style-type: none"> Effirma™ (Phase 2) 	
Mood	<ul style="list-style-type: none"> venlafaxine bupropion 			 

* Prescribed off-label for treatment-refractory patients, dispensing controlled by central mail-order pharmacy

** Jazz Pharmaceuticals had sought indication for refractory patients who failed other treatments; NDA withdrawn

Sleep Quality: Validated Target in FM

- **TNX-102 SL will be a first-in-class FDA-approved medication targeting sleep quality for the “management of FM”**
- **By targeting sleep quality, Rekinla demonstrated powerful efficacy in both Phase 3 studies ($p < 0.001$)**



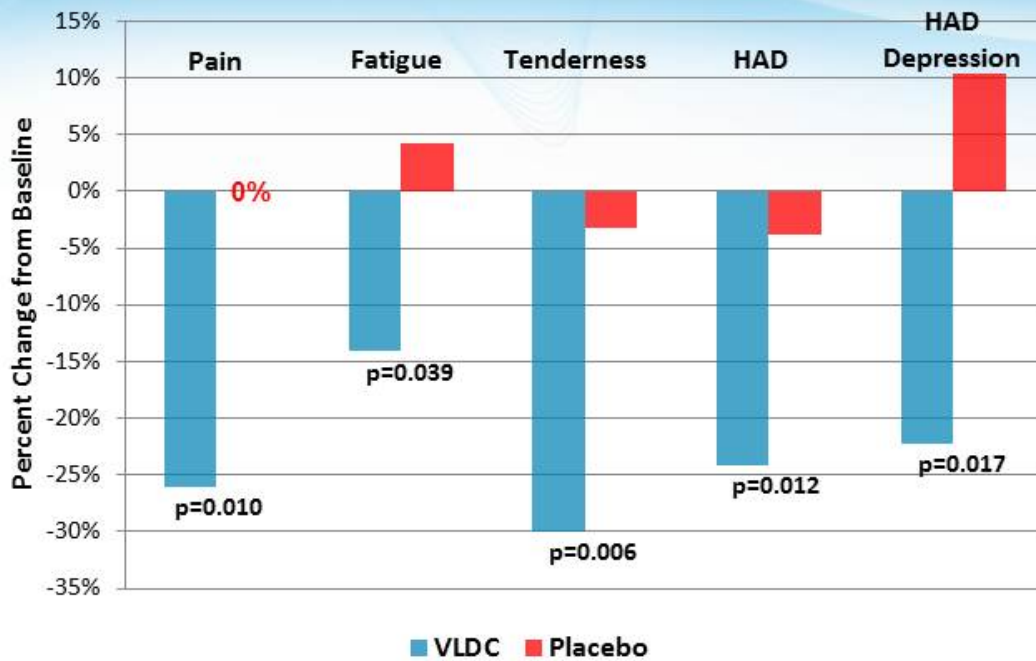
Bedtime Cyclobenzaprine: FM Phase 2 – Overview

- **Double blind, randomized, placebo controlled**
- **36 fibromyalgia patients; 18 per arm**
 - Very low dose cyclobenzaprine (VLDC) or placebo taken between dinner and bedtime daily
- **Eight-week, dose escalating study, from 1 mg to 4 mg**
 - Average bedtime cyclobenzaprine dose at week eight was 3.1 mg
 - Lowest available dose of cyclobenzaprine is 5 mg
- **Conducted at two academic centers in Canada**
- **Published in Journal of Rheumatology* December 2011**
 - Harvey Moldofsky, MD – lead investigator (University of Toronto)

* Moldofsky et al., *J. Rheum.* December 2011: <http://jrheum.org/content/early/2011/08/30/jrheum.110194.full.pdf+html>

Bedtime Cyclobenzaprine: FM Phase 2 – Efficacy

- Change from baseline at week eight



Cyclobenzaprine: Impressive Safety, Widely Used

- **Not a controlled substance**
- **No recognized addictive potential**

Timeframe	Cyclobenzaprine History
1977	• Flexeril® (Merck) FDA approved for muscle spasm
1990's	• Extensive safety and efficacy studies
1994	• Publication of a randomized, double-blind, placebo-controlled, six-month clinical trial of daily cyclobenzaprine in FM*
2007	• High-dose, controlled-release formulations approved
Today	• >1 billion tablets prescribed annually

* Carette et al., *Arthritis & Rheumatism* January 1994

Current CBP Products Not Optimal for Chronic Fibromyalgia Treatment

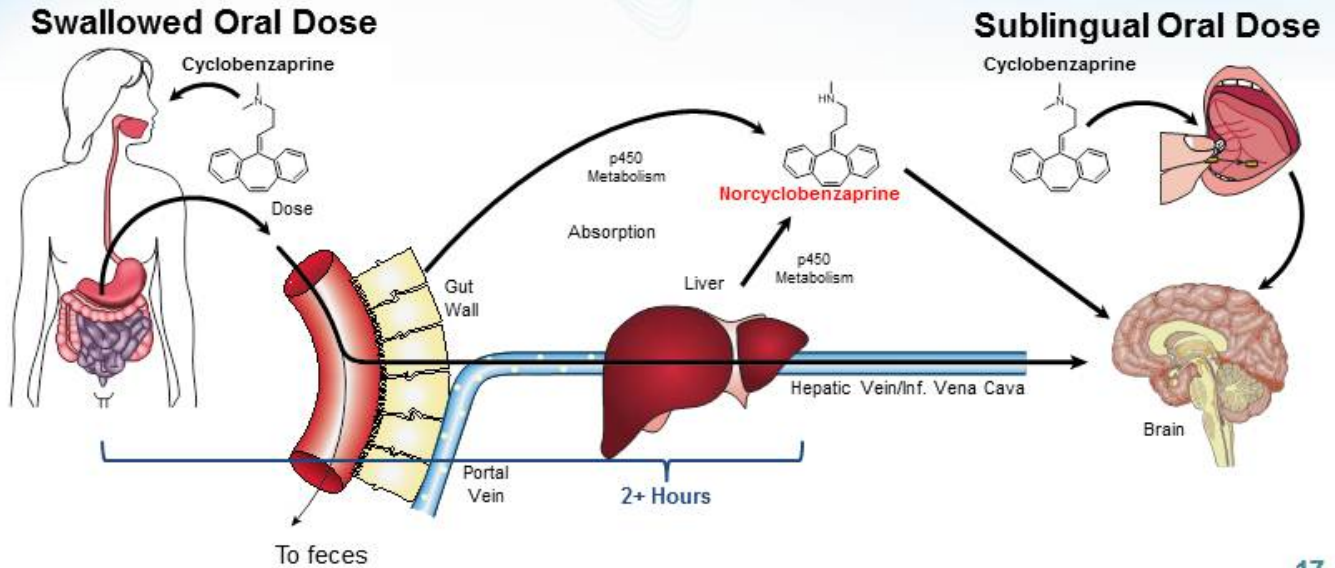
- **Current daytime regimens poorly suited for FM**
 - Chronic daytime cyclobenzaprine may confound long-term efficacy
- **Current doses poorly suited for bedtime use**
 - Off-label use of available doses of cyclobenzaprine at bedtime associated with next-morning grogginess
- **Current formulations poorly suited for bedtime use**
 - Slow systemic absorption via oral route
- **Despite shortcomings, legacy off-label cyclobenzaprine is widely used in the management of fibromyalgia**

TNX-102 SL: First-in-Class Fibromyalgia Medicine

- **Chronic bedtime dosing**
 - Drug exposure during the night to target non-restorative sleep
- **Lower dose than available CBP tablets**
 - Tailored to reduce next-morning grogginess
- **Proprietary sublingual formulation**
 - Transmucosal delivery
 - Rapid systemic absorption demonstrated in humans
 - Avoids “first-pass” metabolism which produces psychoactive metabolite

TNX-102 SL: Sublingual CBP Tablet

- **Faster absorption**
- **Bypasses liver “first-pass” metabolism**



TNX-102 SL: Pivotal Development in FM

- **First Phase 3 efficacy trial to begin in 1Q 2013**
 - Randomized, double blind, placebo controlled, 76 patients; 8-10 U.S. centers
 - 12-week treatment period, daily bedtime dosing
 - Pre-defined efficacy endpoint = pain (Visual Analog Scale)
 - Topline results expected by YE 2013
- **Subsequent requirements for FDA approval**
 - 24-week placebo-controlled efficacy trial in ~300 patients
 - Open-label safety exposure study per International Committee on Harmonization (ICH) guidelines (≥ 100 patients x one year)
- **“Managed Care” study**
 - Demonstrate clinical superiority of TNX-102 SL over generic CBP

TNX-102 SL: Sublingual CBP for PTSD

- **Patients experience disturbed sleep and widespread pain**
 - Painkiller abuse and addiction is common
- **3.5% of U.S. adult population has suffered from PTSD in past 12 months***
 - Experiencing any trauma can lead to PTSD
- **Unsatisfied market**
 - Only Zoloft® and Paxil® have FDA approval
- **Phase 2 proof-of-concept study to be conducted in 2013**
 - Pre-IND meeting held October 2012 encourages further development
 - Leverage fibromyalgia formulation and clinical work

** National Institutes of Mental Health & National Institutes of Health 2010*

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Upcoming Milestones

Timing	Milestones Related to Fibromyalgia
4Q 2012	<ul style="list-style-type: none">• Manufacture commercial tablets
1Q 2013	<ul style="list-style-type: none">• Commence first pivotal trial
4Q 2013	<ul style="list-style-type: none">• Topline results from first pivotal trial• Evaluate partnership opportunities
Timing	Milestones Related to PTSD
1H 2013	<ul style="list-style-type: none">• Commence proof of concept study in PTSD patients

TNX-102 SL: Intellectual Property

- **Pharmacokinetics (PK)**
 - Patent filed around unique PK profile
 - Surprising and unexpected observations
 - Protection expected through 2033
 - Difficult patent class to circumvent
- **Method of Use**
 - FM: issued patent, expiration mid-2021
 - PTSD: patent filed in 2010
- **Composition of Matter**
 - Patent in preparation

Investment Highlights

- **Developing novel medications for challenging disorders of the central nervous system**
 - Large and underserved indications
- **Pivotal trial in fibromyalgia to report in 2013**
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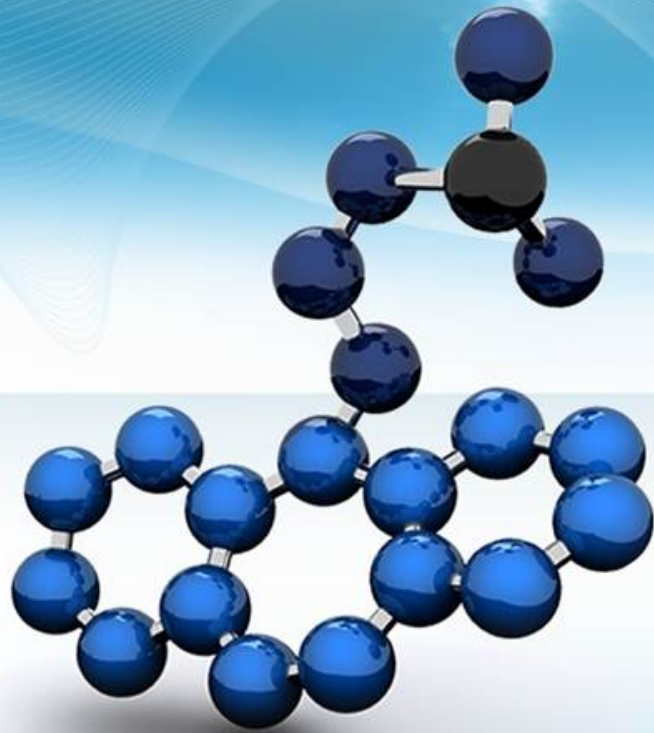
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