

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 28, 2012

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**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

**Copy of correspondence to:**

Marc J. Ross, Esq.  
Harvey Kesner, 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))
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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 28, 2012

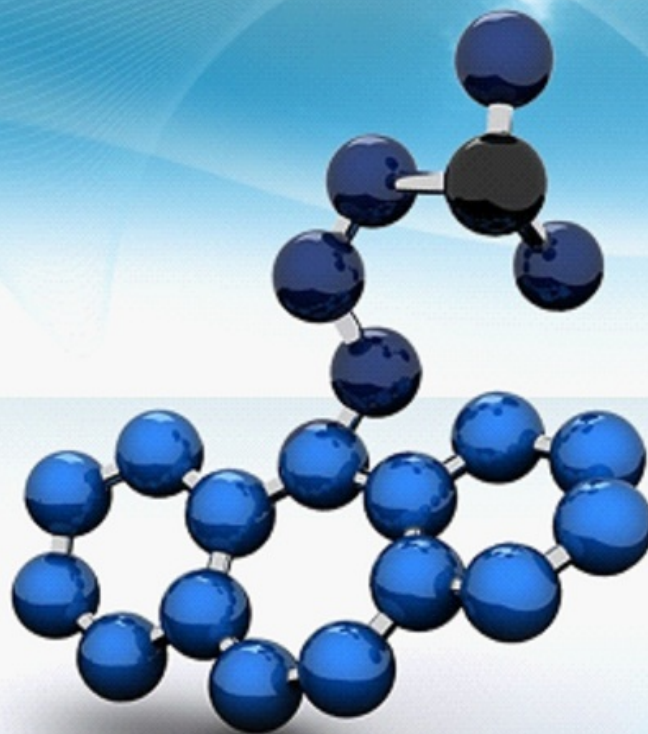
By: /s/ SETH LEDERMAN  
Seth Lederman  
Chief Executive Officer

# TONIX

PHARMACEUTICALS

PHARMACEUTICALS

PHARMACEUTICALS



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.*

# TONIX Profile




Full Name:	Tonix Pharmaceuticals Holding Corp.
Ticker:	TNXP
Exchange:	OTC/QB
Common Shares Outstanding:	34.3 million (as of November 27, 2012)
52-week Trading Range*:	\$0.25 - \$2.06
Auditor:	EisnerAmper LLP
Corporate Counsel:	Sichenzia Ross Friedman FERENCE LLP
Patent Counsel:	Ropes & Gray LLP

\* Stock first traded in February 2012

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



# Accomplished Independent Board

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

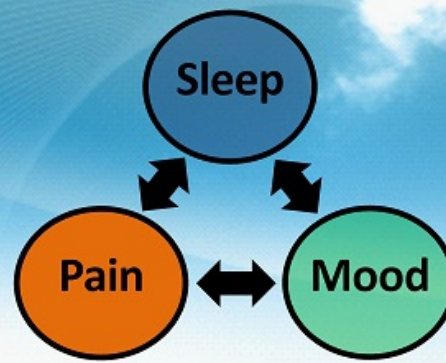
# Product Pipeline

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

TNX-102 SL Program:

***Fibromyalgia***

# Fibromyalgia



- **Complex syndrome**

- Despite three FDA-approved medications, patients are dissatisfied
- FDA primary endpoint is pain

- **Complaint: “Hurt all over, can’t sleep”**

- Central pain – originates in the CNS
- Restorative sleep can improve pain and other symptoms
- No benefit from opiates or prescription sleep drugs

- **~90% of diagnosed patients are female**

- Management believes affected men may self-medicate

# 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	Prior Indication	Approval Year	2011 U.S. Sales in FM**
Lyrica®	Pfizer	Pain (neuropathic)	2007	\$450 million
Cymbalta®	Eli Lilly	Depression	2008	\$560 million
Savella®	Forest	Depression****	2009	\$101 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

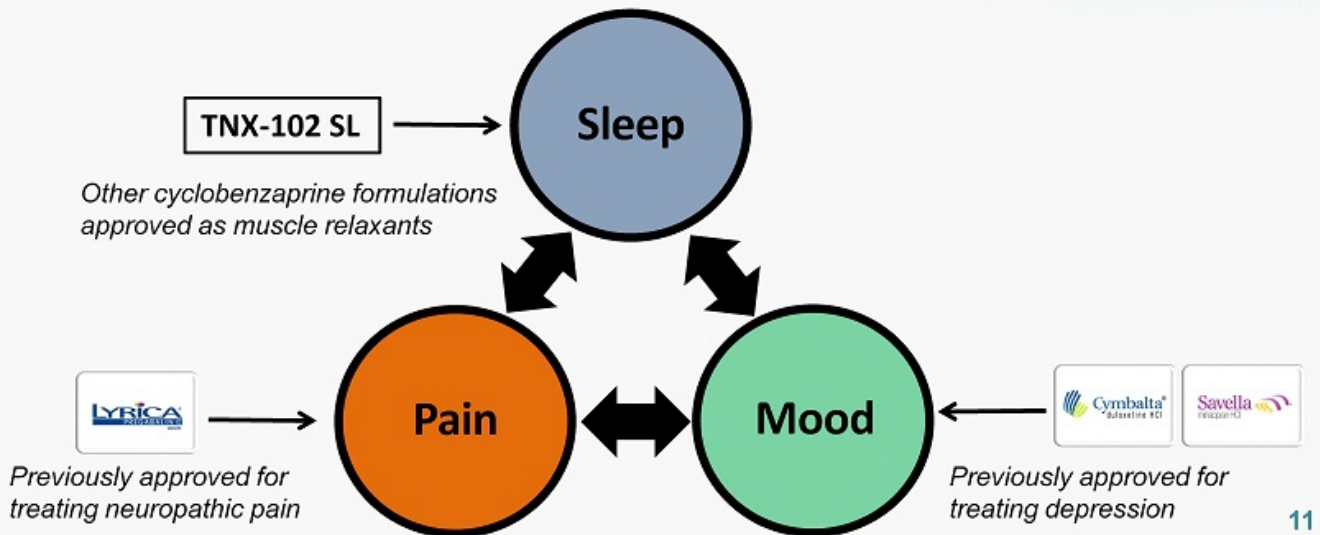
\*\* Decision Resources Pain Management Study: Fibromyalgia, January 2012

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

\*\*\*\* EU only

# Sleep Quality: Validated Target in FM

- **TNX-102 SL** expected to be first-in-class FDA-approved product targeting sleep quality for the “management of FM”
- Cyclobenzaprine is FDA approved as a muscle relaxant but has off-label use as a slow-acting sleep aid in fibromyalgia



# Cyclobenzaprine: Impressive Safety, Widely Used

- **Not a controlled substance**
- **No recognized addictive potential**
- **FDA approved as Flexeril® since 1977 for muscle spasm**
- **Used off-label as slow-acting sleep aid in fibromyalgia**
- **Not approved for treating sleep**
- **Alza bought Flexeril from Merck in 2001**
- **High-dose controlled-release product for muscle spasm (Amrix®) approved by FDA in 2007**

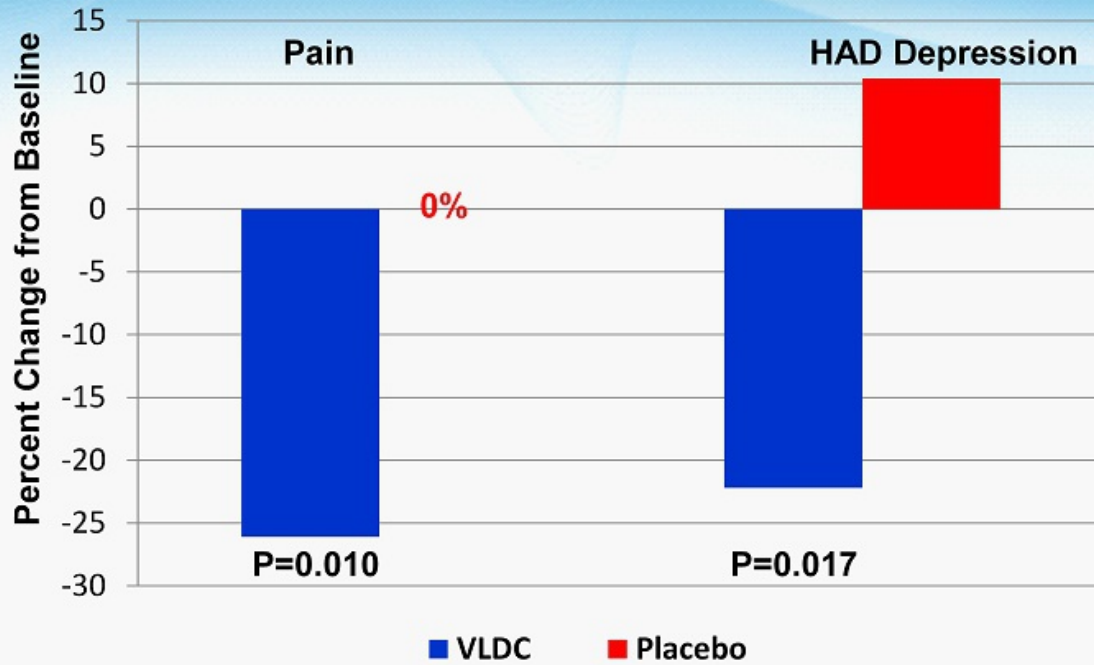
# Bedtime Cyclobenzaprine: FM Phase 2 – Overview

- **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>

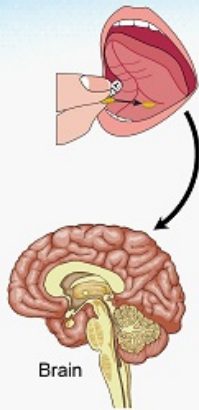


# Bedtime Cyclobenzaprine: FM Phase 2 – Efficacy



HAD = Hospital Anxiety and Depression Score

# 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: 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, nightly bedtime dosing
  - Pre-defined efficacy endpoint = pain (Numeric Rating Scale)
  - Topline results expected by YE 2013

## *Partnership – ready Program*

- **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 ( $\geq 100$  patients x one year)

TNX-102 SL Program:

***Post-traumatic Stress Disorder***

# 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 Prozac®, 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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TONIX PHARMACEUTICALS

# Upcoming Milestones

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

# 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**
  - Phase 2 data demonstrated efficacy
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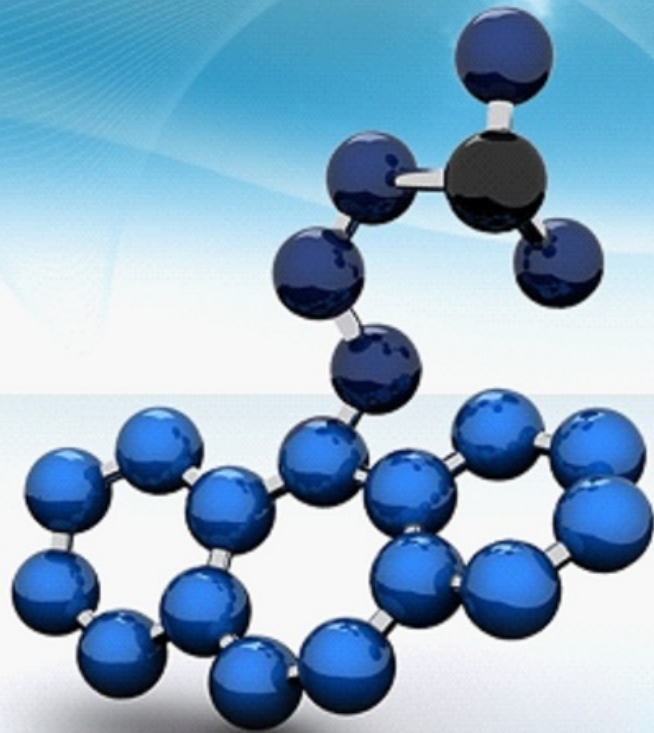


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