

**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): June 19, 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.

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 June 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: June 19, 2012

By: /s/SETH LEDERMAN

Seth Lederman

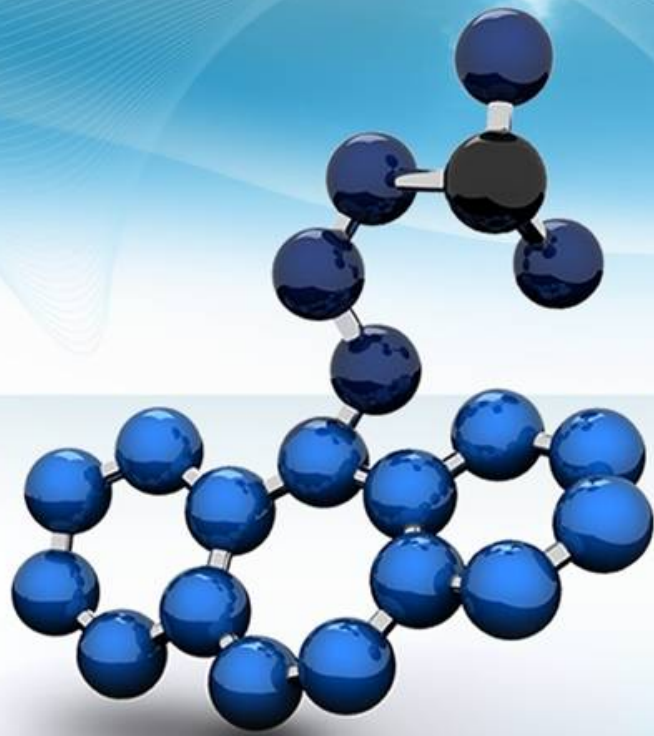
President and Chief Executive Officer

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Corporate Presentation
June 2012

OTC/QB: TNXP

Disclosures

Forward-looking Statements

The statements and discussions contained in this presentation that are not historical facts constitute forward-looking statements. These can be identified by the use of forward-looking words, such as “believes”, “expects”, “may”, “intends”, “anticipates”, “plans”, “estimates”, or any other analogous or similar expressions intended to identify forward-looking statements. These forward-looking statements and estimates as to future performance, estimates as to future valuations, and other statements contained herein regarding matters that are not historical facts, are only predictions and actual events or results may differ materially. We cannot assure or guarantee that any future results described in this presentation will be achieved, and actual results could vary materially from those reflected in such forward-looking statements.

Information contained in this presentation has been compiled from sources believed to be credible and reliable. However, we cannot guarantee such credibility and reliability. The forecasts and projections of events contained herein are based upon subjective valuations, analyses, and personal opinions.

Information Regarding Disclosures

The Common Stock and Warrants have not and will not be registered under the Securities Act of 1933, as amended (the “Act”), or under any state securities laws, nor has the Securities and Exchange Commission (the “Commission”) or any state regulatory authority endorsed the Offering. Any representation to the contrary is a criminal offense.

In making an investment decision, investors must rely upon their own examination of the company and the terms of the Offering, including the merits and risks involved. The acquisition of the Stock, if offered, should be considered only by persons who can bear the economic risk of their investment of an indefinite period of time and can afford a total loss of their investment. Each prospective investor in the Offering should, prior to purchasing any Stock, consult his own attorney and business advisor as to the legal, business, tax, and related matters concerning its investment and is urged to ask questions of, and receive answers from, the Company concerning the terms and conditions of the Offering and request any additional information they may consider Necessary in making an informed investment decision.

This presentation does not constitute an offer to sell or a solicitation of an offer to purchase any securities of any nature whatsoever, nor do the contents of the presentation constitute legal, tax, or business advice.





This presentation and the offering of the Company's Stock shall be kept confidential. The recipient agrees not to disclose to any third party any information contained herein, or any terms, conditions, or other facts with respect to the Offering, including, without limitation, that the Company is or may be contemplating the Offering.

Information included herewith has been obtained from the Company and other sources believed to be reliable, but the accuracy or completeness of such information is not guaranteed by, and should not be construed as a representation by the Company. Any representations and warranties will be contained only in a definitive agreement signed by the investor and the Company.

Company Overview

- **Specialty pharmaceutical company developing innovative non-addictive products for chronic pain syndromes**
 - Fibromyalgia syndrome (FM)
 - Post-traumatic stress disorder (PTSD)
- **Unmet medical needs and large commercial opportunities**
 - Targeting sleep pathology
 - Central pain syndromes poorly addressed by opiate pain drugs or benzodiazepine sleep drugs
- **Capital efficient, risk-mitigated development pathway**
 - Near-term, value-creating milestones
- **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 	
Benjamin Selzer COO	<ul style="list-style-type: none"> • Reliant • Aton • Investment Banking 	
Leland Gershell, MD, PhD CFO	<ul style="list-style-type: none"> • Cowen • Apothecary • Favus • 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: Chairman, 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	FM	<ul style="list-style-type: none">• Very low dose cyclobenzaprine (VLDC) in novel formulation• Phase 2a successfully completed• Pivotal trial expected to begin Q1 2013
TNX-105	PTSD	<ul style="list-style-type: none">• VLDC in novel formulation• Will leverage data from TNX-102 experience• Proof of concept trials anticipated in 2013• Seeking U.S. Department of Defense funding
TNX-107	Traumatic Brain Injury	<ul style="list-style-type: none">• VLDC in novel formulation• Will leverage data from TNX-102 experience• Seeking U.S. Department of Defense funding
TNX-201	Headache	<ul style="list-style-type: none">• NDA process for existing grandfathered (DESI) product• Potentially shortened process for FDA approval• DESI to New Drug Application (NDA) switch products enjoy mandated exclusivity
TNX-301	Alcoholism	<ul style="list-style-type: none">• US patent allowed• Potential for government funding

FM Market Opportunity

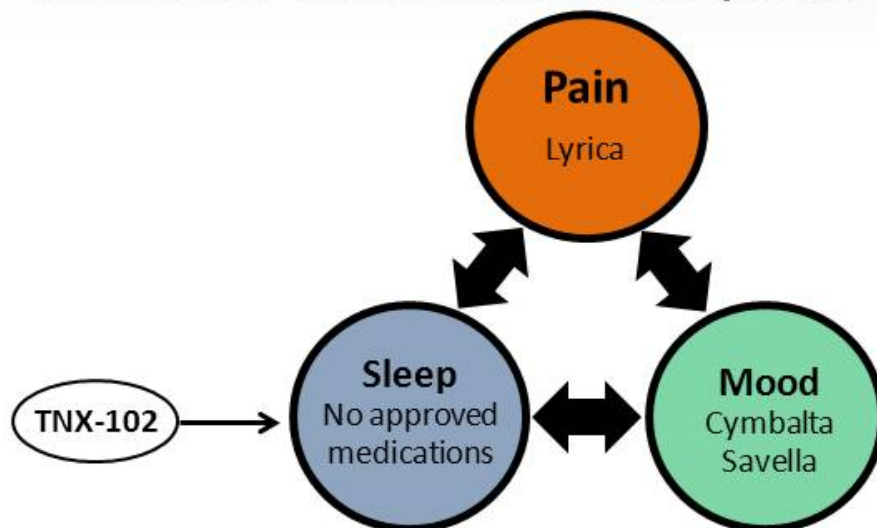
- **~5 million U.S. patients***
- **U.S. prescription drug market estimated at \$1.2 billion****
 - 2007-2010 CAGR of 18.4%**
- **No FDA approved drugs until 2007**
 - Lyrica® (Pfizer) approved 2007: replacing off-label generic analgesics
 - Cymbalta® (Eli Lilly) approved 2008, Savella® (Forest) approved 2009: replacing off-label generic anti-depressants
 - Drugs for pain and mood, yet nothing for disturbed or non-restorative sleep
- **TNX-102 to replace off-label generic muscle relaxants**

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




** Frost & Sullivan Fibromyalgia Market Study, December 2010

Fibromyalgia: A Vicious Cycle

- Medications that target pain or depressed mood are approved for the management of FM
- TNX-102 will be a first-in-class medication targeting disturbed or “non-restorative” sleep in FM



Novel Mechanism in FM Treatment

	<u>Off-Label</u>	<u>Abandoned</u>	<u>In Development</u>	<u>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 <i>(Phase 3 ready)</i> 	
Pain	<ul style="list-style-type: none"> gabapentin opioids 		<ul style="list-style-type: none"> Effirma™ <i>(Phase 2)</i> 	
Mood	<ul style="list-style-type: none"> venlafaxine bupropion 			 

TNX-102: Optimizing Cyclobenzaprine for Fibromyalgia

- **Cyclobenzaprine widely used off-label in FM**
- **Current doses and formulations poorly suited for FM**
 - Long half life contributes to somnolence and accumulation
 - Lowest approved daily dose is 15mg
- **VLDC demonstrated improvement in core FM symptoms in Phase 2a trial**
- **TNX-102 is designed specifically for FM management**
 - Rapid absorption
 - Minimize next day somnolence

Cyclobenzaprine: Impressive Safety, Widely Used

- **Off-label cyclobenzaprine is the third most widely prescribed medication for FM***
- **1977: FDA approved Flexeril® (Merck)**
- **1990s: Extensive safety and efficacy studies (Merck)**
- **2007: FDA approved controlled-release formulation (15/30 mg)**
- **2010: >1 billion tablets prescribed annually**
- **Not a controlled substance, no recognized addictive potential**

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

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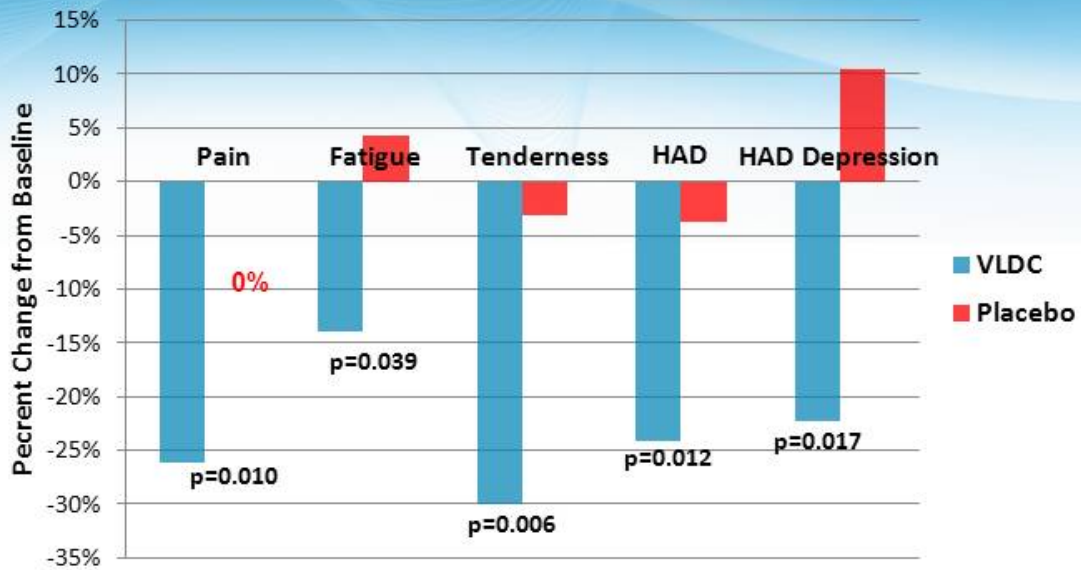
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VLDC FM Phase 2a – Overview

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

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

VLDC FM Phase 2a – Efficacy



Change from Baseline (week 8): tenderness measured by dolorimetry;
HAD = Hospital Anxiety and Depression Scale; HAD Depression = HAD depression subscale

VLDC FM Phase 2a – Safety

- **No serious adverse events in either arm**
- **No discontinuations due to adverse events in treatment arm**
- **Adverse event types consistent with Flexeril label**

Adverse Event (>10%)	VLDC (n = 18), n (%)	Placebo (n = 18), n (%)
Any adverse event	15 (83)	15 (83)
Headache	7 (39)	3 (17)
Dry mouth	6 (33)	1 (6)
Somnolence	4 (22)	2 (11)
Constipation	3 (17)	1 (6)
Dizziness	3 (17)	1 (6)
Nausea	2 (11)	5 (28)
Flu syndrome	2 (11)	1 (6)
Rhinitis	2 (11)	1 (6)
Pruritis	2 (11)	0 (0)

Relationship between Sleep and FM

- **FM patients complain of poor sleep**
 - Non-restorative sleep exacerbates FM symptoms
- **Cyclic alternating pattern (CAP) is an objective physiological measure of the quality of sleep**
 - A2, A3 patterns = indices of sleep instability (poor sleep quality)
 - A1 pattern = index of sleep stability
- **FM patients demonstrate increased A2/A3**

VLDC Phase 2a FM – Sleep Data

- **Data link restorative sleep mechanism of cyclobenzaprine and improvement in FM symptoms**
- **No plan to conduct sleep studies with TNX-102**
 - Not needed for approval

Sleep EEG	VLDC	Placebo	p
CAP _{A2+A3(Norm)} ≤33%	72%	33%	0.019

Variable	VLDC CAP _{A2+A3(Norm)} Correlation	
	r	p
Fatigue	0.617	0.006
HAD score	0.505	0.033
HAD depression subscore	0.556	0.017
Patient-rated change in fatigue	0.614	0.007
Clinician-rated change in fatigue	0.582	0.011

TNX-102: Unique Market Position

- **Specifically designed for the treatment of FM**
- **Differentiated from / not competitive with other FM therapies**
 - First-in-class sleep quality treatment indicated for bedtime dosing
 - Restorative sleep shown to improve pain and fatigue
 - High patient dissatisfaction, physicians frequently switch drugs
- **With a unique formulation and new indication, reimbursement coverage is expected**

TNX-102: Development Plan

- **Formulation and PK trials**

- 30-subject, 3-week human PK study on first formulation completed
- PK study of second formulation in beagle dogs completed
- Human PK study of commercial formulation to be conducted Q3 2012

- **Pivotal efficacy trial**

- 12-week study, 150 patients per arm
- Study design and endpoints to mirror those used by Lyrica and Cymbalta
 - Pain and a composite endpoint of other FM symptoms
- Final study results expected 1H 2014

- **Partnership for second pivotal trial and commercialization**

TNX-105: VLDC for PTSD

- **3.5% of U.S. adult population has suffered from PTSD in past 12 months***
 - Any trauma can lead to PTSD
- **Unsatisfied market**
 - Only Zoloft® and Paxil® have FDA approval
- **Widespread painkiller abuse and addiction**
- **Leverage formulation and clinical work of TNX-102 to advance TNX-105**

* National Institutes of Mental Health & National Institutes of Health

FM & PTSD are Related Conditions

- **Symptom overlap**

- PTSD is thought to be exacerbated by non-restorative sleep
- Some are believed to suffer from both conditions simultaneously
- Some patients with FM meet PTSD criteria, and *vice versa*

- **PTSD has both combat and civilian forms**

- Zoloft and Paxil are approved for PTSD
- Brand prescriptions filled by generic sertraline and paroxetine
- DOD has a strong interest in promoting research on therapeutics

Intellectual Property

- **Active patenting strategy to extend exclusivity**
 - Patent filed around unique PK profile (June 2012)
 - Difficult patent class to circumvent
- **TNX-102**
 - Methods of Use patents for use of VLDC in treatment of FM issued, expiration mid-2020
 - Two formulation patents issued, expiration in mid-2021
- **TNX-105**
 - Methods of Use patent filed for use of VLDC in treatment of PTSD
 - Two formulation patents issued, expiration in mid-2021

Upcoming Milestones

Timing	Milestones Related to TNX-102
Q3 2012	<ul style="list-style-type: none">• Completion of human PK study on proprietary formulation
Q3 2012	<ul style="list-style-type: none">• Completion of human PK/PD on commercial formulation and dose
Q1 2013	<ul style="list-style-type: none">• Commencement of initial pivotal trial
Q3 2013	<ul style="list-style-type: none">• Interim look at initial pivotal trial data
H1 2014	<ul style="list-style-type: none">• Final study results of initial pivotal trial• Potential partnering
Timing	Milestones Related to TNX-105
H1 2013	<ul style="list-style-type: none">• Commencement of proof of concept study in PTSD patients

Investment Summary

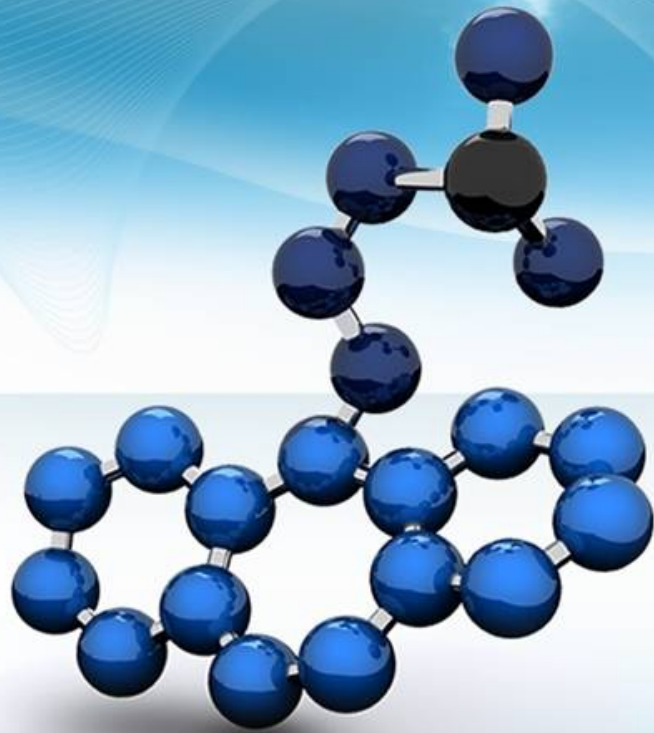
- **Significant unmet needs and large market opportunities**
- **First-in-class products; not competitive with existing therapies**
- **Capital efficient, low risk drug development strategy**
- **Near-term value inflection points**
- **Experienced management and board**

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OTC/QB: TNXP