

**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): August 22, 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 August 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: August 22, 2012

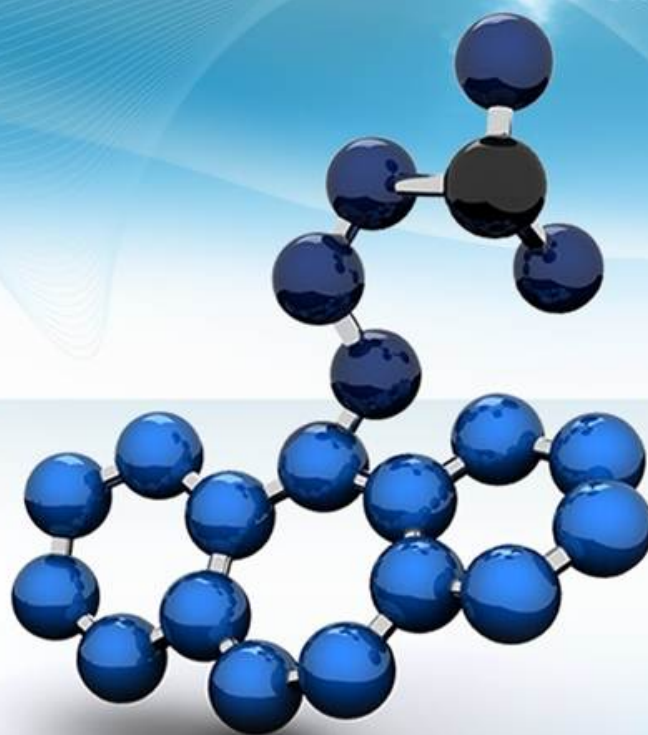
By: /s/ SETH LEDERMAN
Seth Lederman
President and Chief Executive Officer

TONIX

PHARMACEUTICALS

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TONIX



Corporate Presentation
August 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

- **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**
 - Targets sleep pathology
 - Central pain syndromes poorly addressed by opiate pain drugs or prescription 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 (Lehman, BofA) 	
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 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	FM	<ul style="list-style-type: none">• Cyclobenzaprine (CBP) in sublingual formulation and novel dose• Phase 2a successfully completed• First pivotal trial expected to begin Q1 2013
	PTSD	<ul style="list-style-type: none">• CBP in sublingual formulation and novel dose• Will leverage data from FM experience• Proof of concept trials anticipated in 2013• Seeking U.S. Department of Defense partnership
	Traumatic Brain Injury	<ul style="list-style-type: none">• CBP in novel formulation• Will leverage data from FM experience• Seeking U.S. Department of Defense partnership
TNX-201	Headache	<ul style="list-style-type: none">• NDA process based on existing grandfathered (DESI) product• Potentially shortened process for FDA approval
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 \$1.4 billion****
 - 2007-2010 CAGR of 18.4%***
- **First approved drug for FM in 2007**
 - Lyrica® (Pfizer) approved 2007: \$450 million in FM sales in 2011**
 - Cymbalta® (Eli Lilly) approved 2008: \$560 million in FM sales in 2011**
 - Savella® (Forest) approved 2009: \$137 million in FM sales in 2011**

* 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

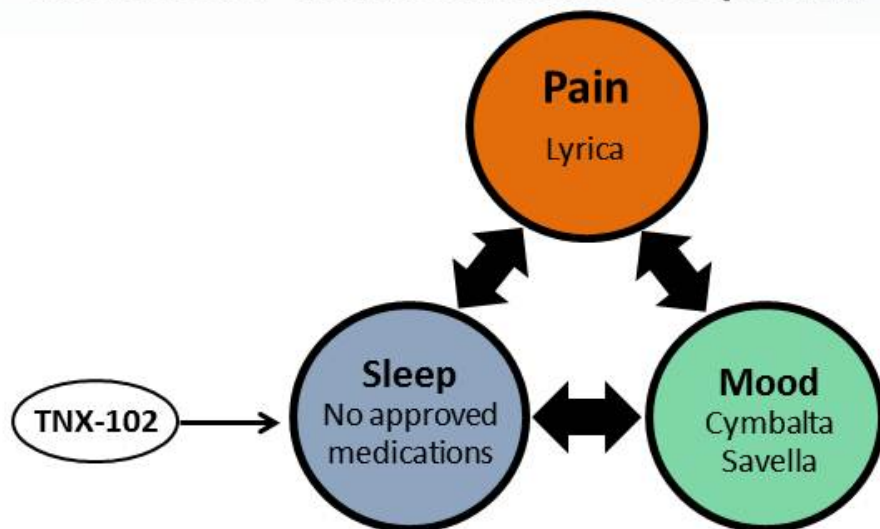
FM Market Dynamics

- **No FDA approved drugs until 2007**
- **Market growth driven by on-label drugs replacing off-label generics***
 - Lyrica replacing off-label generic analgesics
 - Cymbalta and Savella replacing off-label generic anti-depressants
- **Drugs for pain and mood approved, yet none for disturbed or non-restorative sleep**
 - TNX-102 to replace off-label generic muscle relaxants currently being used to address this problem

** 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 SL <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 CBP for FM

- **CBP 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 15 mg
- **Phase 2a trial of bedtime VLD cyclobenzaprine demonstrated improvement in core FM symptoms**
- **TNX-102 is designed specifically for FM management**
 - Rapid absorption
 - Minimize next day somnolence
 - Suitable for chronic use
 - Appropriate dose

CBP: Impressive Safety, Widely Used

- **Off-label CBP 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*

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**

Sodium Oxybate Data in FM & Sleep

- Jazz Pharmaceuticals was developing sodium oxybate for FM
- Phase 3 trials demonstrated highly significant improvements

Study	Treatment	n	Responders* n (%)	p-value (chi-square)
06-008	Placebo	183	50 (27)	-
	oxybate 4.5 g	182	84 (46)	<0.001
	oxybate 6.0 g	182	72 (40)	0.01
06-009	Placebo	188	38 (20)	-
	oxybate 4.5 g	194	69 (36)	<0.001
	oxybate 6.0 g	189	68 (36)	<0.001

Source: FDA briefing documents.

* Subjects that reported a 30% or more reduction in overall pain in week 14 as compared to baseline

- Sodium oxybate also caused decrease in A2+A3

CAP Rate	Placebo (n = 20)	Oxybate 4.5 g (n = 14)	p vs. placebo	Oxybate 6.0 g (n = 13)	p vs. placebo
A2+A3, %	-0.4	-2.1	0.18	-3.9	0.007
A1, %	-0.1	+5.8	0.172	+7.0	0.108

Source: Moldofsky et al., J. Rheum. October 2010:

<http://rheum.org/content/37/10/2156.full.pdf+html?sid=74107235-af7a-478a-8ed3-ebf7e2abe3aa>

Very Low Dose CBP (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 – Endpoints

- **Endpoints consistent with ACR* and OMERACT** guidelines**
- **Pain (Visual Analog Scale) and fatigue assessed ~24 hours following each dose**
- **Tenderness assessed via dolorimetry**
- **Mood assessed via Hospital Anxiety and Depression (HAD) scale and HAD depression subscale**
- **Fatigue also measured via clinical and patient global impression of change (CGIC/PGIC)**

** American College of Rheumatology*

*** Outcome Measures in Rheumatology Clinical Trials*

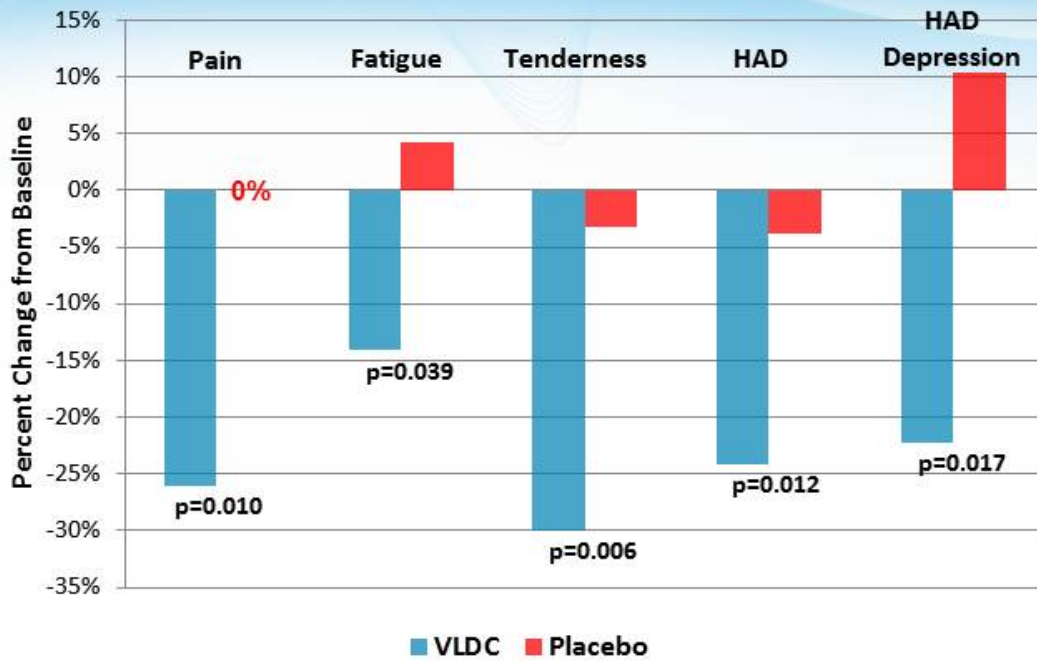
VLDC FM Phase 2a – Demographics

- **Duration of FM diagnosis history similar between arms**
- **50% of patients in each group had FM for >five years**

Characteristic	VLDC (n = 18)	Placebo (n = 18)
Sex, n (%)		
Male	0 (0)	1 (6)
Female	18 (100)	17 (94)
Age, yrs, mean (SD) range	45.9 (11.4) 26-62	39.3 (9.3) 23-56
Race (white, non-Hispanic) (%)	18 (100)	18 (100)
Weight, kg, mean (SD) range	68.1 (10.1) 53-86	73.8 (16.3) 53-108
Height, cm, mean (SD) Range	162.3 (8.8) 148-178	165.9 (5.6) 160-178

VLDC FM Phase 2a – Efficacy

- Change from baseline at week eight



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 FDA 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

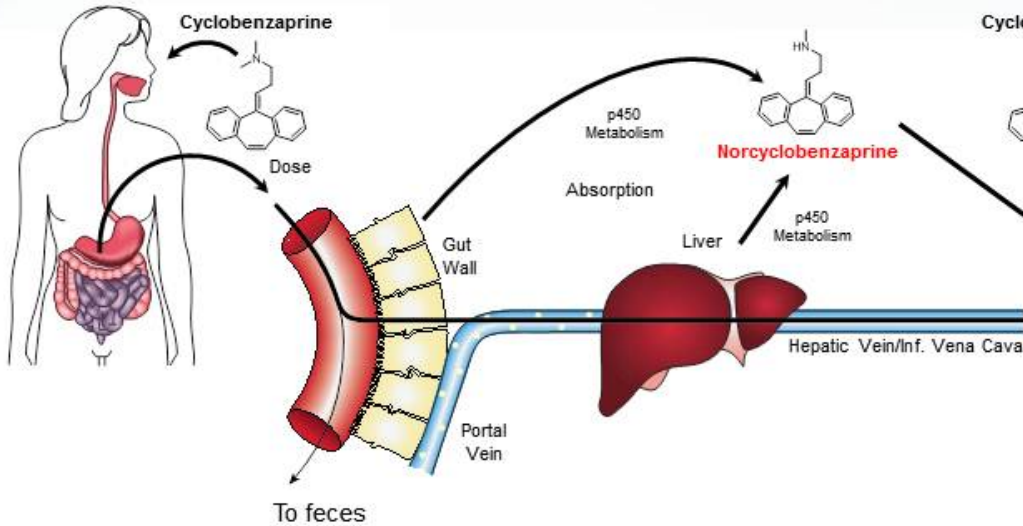
TNX-102 SL: Sublingual CBP

- **Faster and more efficient transmucosal absorption**
 - First-in-class sleep quality treatment indicated for chronic, bedtime dosing
 - Targeting rapid onset and decreased next-morning hang-over
- **Avoids “first pass” liver production of persistent metabolite**
 - Norcyclobenzaprine is a psychoactive metabolite that interacts with similar brain receptors and accumulates over time decreasing CBP effects
- **Proprietary formulation**
 - Human PK study of sublingual solutions compared TONIX’s proprietary formulation technology with cyclobenzaprine alone: PK characteristics are not replicated by crushing Flexeril® tablets

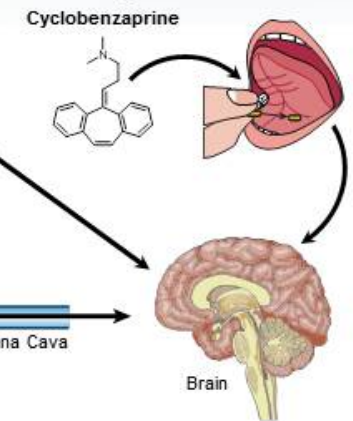
TNX-102 SL: Sublingual CBP

- **Faster absorption**
- **Bypasses liver “first pass” metabolism**
 - Decreases norcyclobenzaprine: persistent psychoactive metabolite

Swallowed Oral Dose



Sublingual Oral Dose



TNX-102 SL: Pivotal Development in FM

- **First Phase 3 efficacy trial in FM to begin in Q1 2013**
 - Randomized, double-blind, placebo controlled
 - 12-week treatment period
 - Pre-defined efficacy endpoint of pain
- **Streamlined first pivotal focused on pain**
 - 76 patients; 8-10 U.S. centers
 - Topline results expected by YE 2013
 - Cost and time efficient
 - Other FM endpoints will be studied to inform second Phase 3 trial design
- **Subsequent requirements for FDA approval**
 - 24 week double-blind, randomized, pivotal in 300 patients
 - Open-label safety exposure study per ICH guidelines (≥ 100 patients x one year)

TNX-102 SL: Unique Market Position in FM

- **Specifically designed for the treatment of FM**
- **Differentiated from / not competitive with other therapies**
 - First-in-class sleep quality treatment indicated for bedtime dosing
 - Restorative sleep shown to improve key symptoms
 - High patient dissatisfaction, physicians frequently switch drugs
- **With a unique formulation and new indication, reimbursement coverage of TNX-102 is expected**
 - Initial payor market research indicates strong likelihood of reimbursement

TNX-102 SL: Sublingual CBP 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 in FM for PTSD**
- **Phase 2 proof of concept study to be conducted in 2013**

* 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
- Department of Defense has a strong interest in promoting research on therapeutics

Intellectual Property

- **Active patenting strategy to extend TNX-102 SL exclusivity**
- **Pharmacokinetics (PK)**
 - Patent filed around unique PK profile with sublingual (June 2012)
 - 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

Upcoming Milestones

Timing	Milestones Related to TNX-102 SL in Fibromyalgia
Q4 2012	<ul style="list-style-type: none">• Completion of human PK on commercial formulation, dose
Q1 2013	<ul style="list-style-type: none">• Commencement of first pivotal trial
Q4 2013	<ul style="list-style-type: none">• Topline results from first pivotal trial• Evaluate partnership opportunities
Timing	Milestones Related to TNX-102 SL in PTSD
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**

TONIX Public Profile

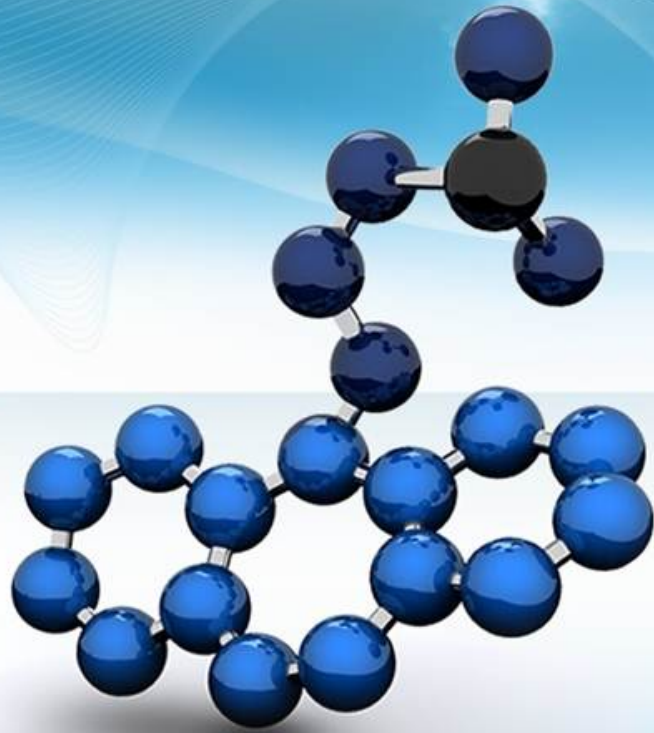
Full Name:	Tonix Pharmaceuticals Holding Corp.
Ticker:	TNXP
Exchange:	OTC/QB
Common Shares Outstanding:	34.3 million
52-week Trading Range*:	\$0.83 - \$2.06
Auditor:	EisnerAmper LLP
Corporate Counsel:	Sichenzia Ross Friedman FERENCE LLP
Transfer Agent:	Vstock Transfer, LLC

* Stock first traded in February 2012

TONIX
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БНУБМУСЕНТИСВТЗ

TONIX



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