

**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): July 30, 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 8.01 Other Events.

On July 30, 2012, the Company issued a press release announcing that it has completed the human pharmacokinetic and bioavailability study of its new formulation of its lead drug, TNX-102 SL, for the treatment of fibromyalgia syndrome, which is a tablet designed to be absorbed sublingually. Further, the Company stated that the initial results from the study were positive, with no serious adverse events reported and that the Company is on target for a pivotal trial of the TNX-102 SL formulation for the first quarter of 2013.

A copy of the press release that discusses this matter is filed as Exhibit 99.02 to, and incorporated by reference in, this report. The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Corporate Presentation by the Company for July 2012 *

99.02 Press Release, dated July 30, 2012, issued by Tonix Pharmaceuticals Holding Corp.

* Furnished herewith.

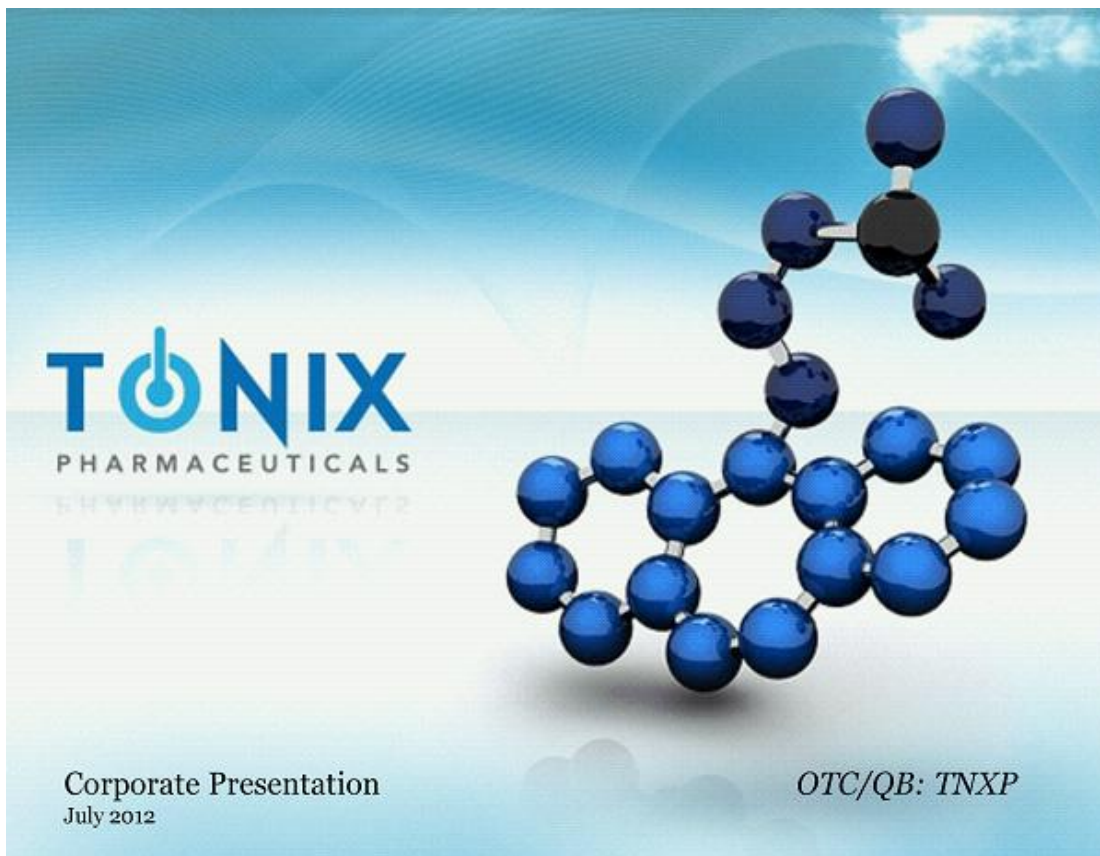
SIGNATURE

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: July 30, 2012

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







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," "estimated" 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 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 (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	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 \$1.4 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

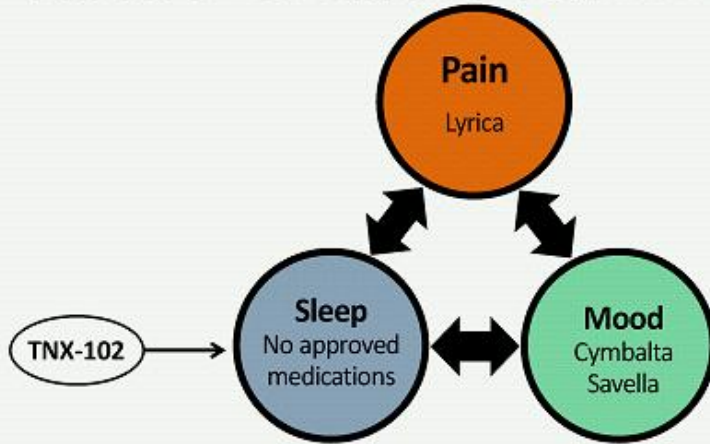
* Frost & Sullivan Fibromyalgia Market Study, December 2010

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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 (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 			

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

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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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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.

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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://rheum.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*

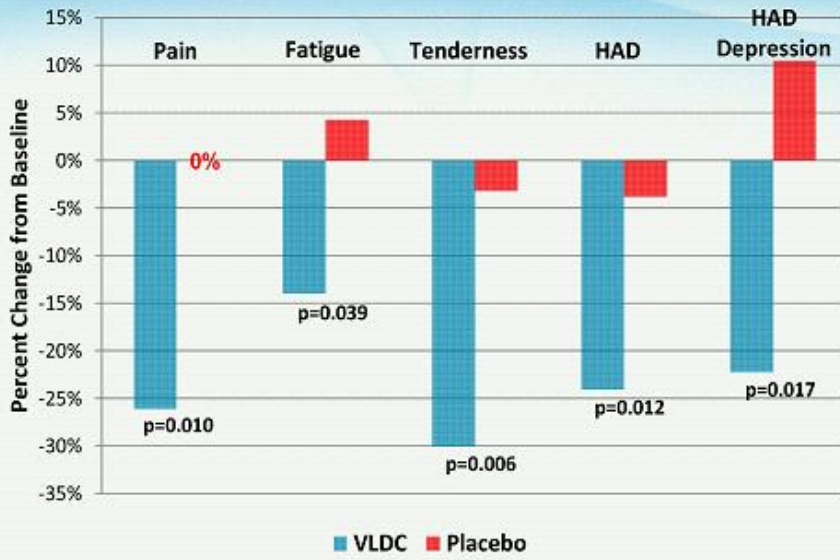
VLDC FM Phase 2a – Demographics

- 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

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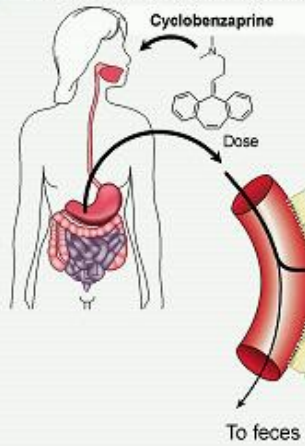
TNX-102: Sublingual Cyclobenzaprine

- **Specifically designed for the treatment of FM**
 - Human PK study of sublingual solution version of proprietary tablet showed rapid transmucosal absorption
- **Faster and more efficient absorption**
 - First-in-class sleep quality treatment indicated for bedtime dosing
 - Targeting rapid onset and decreased next-morning hang-over
- **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
- **Study in SL tablet commercial formulation expected to dose September 2012**

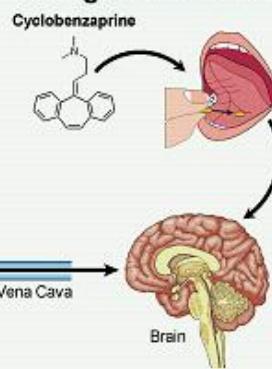
TNX-102: Sublingual Cyclobenzaprine

- **Faster absorption**
- **Bypasses GI tract “first pass” metabolism**

Swallowed Oral Dose



Sublingual Oral Dose



To feces

TNX-102: Pivotal Development

- **First pivotal efficacy trial in fibromyalgia to begin in Q1 2013**
 - 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 in H1 2014
- **Partnership for second pivotal trial and commercialization**

TNX-102: Unique Market Position

- **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**

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**

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 VLDC exclusivity**
- **Pharmacokinetics**
 - Patent filed around unique PK profile with sublingual (June 2012)
 - Surprising and unexpected observations
 - Difficult patent class to circumvent
- **Method of Use**
 - FM: issued patent, expiration mid-2020
 - PTSD: patent filed in 2010
- **Formulation**
 - Two issued patents, expirations in mid-2021

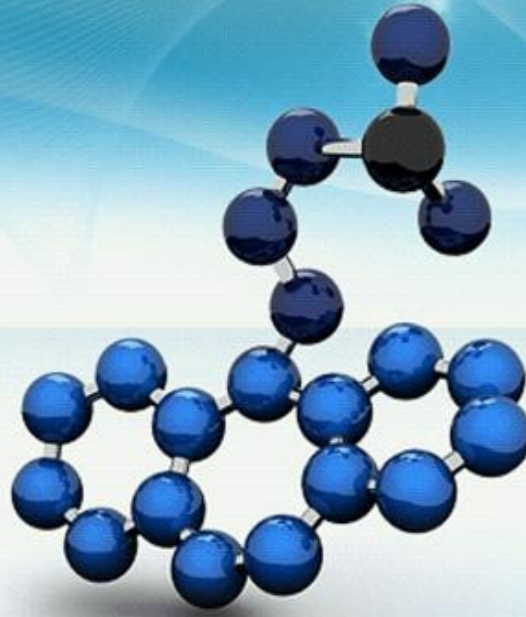
Upcoming Milestones

Timing	Milestones Related to TNX-102 in Fibromyalgia
Q3 2012	<ul style="list-style-type: none">• Completion of human PK study on proprietary formulation
Q4 2012	<ul style="list-style-type: none">• Completion of human PK/PD on commercial formulation, dose
Q1 2013	<ul style="list-style-type: none">• Commencement of first pivotal trial
H1 2014	<ul style="list-style-type: none">• Final study results of first pivotal trial• Potential partnering
Timing	Milestones Related to TNX-105 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**

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OTC/QB: TNXP

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**TONIX PHARMACEUTICALS ANNOUNCES COMPLETION OF CLINICAL TRIAL OF
SUBLINGUAL TNX-102****RESULTS SUPPORT DEVELOPMENT AS A BEDTIME THERAPY FOR FIBROMYALGIA**

NEW YORK (July 30, 2012) – Tonix Pharmaceuticals Holding Corp. (OTCBB: TNXP) (“TONIX” or the “Company”), a specialty pharmaceutical company developing therapies for challenging disorders of the central nervous system (“CNS”), including fibromyalgia syndrome (“FM”) and post-traumatic stress disorder (“PTSD”), announces that the clinical portion of a human study of a solution version of TNX-102 2.4 mg sublingual tablets (“TNX-102 SL”) has completed. TNX-102 is TONIX’s very low dose form of cyclobenzaprine, which the Company is developing as a first-in-class medication for the management of FM.

This comparative pharmacokinetic (“PK”) and bioavailability study was conducted in Canada by a leading global clinical research organization. The trial evaluated a solution formulation of the Company’s TNX-102 SL tablet containing 2.4 mg of cyclobenzaprine, a control sublingual solution that was designed to simulate crushed immediate-release cyclobenzaprine tablets (2.4 mg), oral ingestion of an immediate-release cyclobenzaprine tablet (5 mg), and intravenous cyclobenzaprine (2.4 mg). The study enrolled 23 healthy adult volunteers and periodically measured circulating blood levels of cyclobenzaprine over six days after receiving study medication.

Seth Lederman, M.D., Chairman and President of TONIX said, “We designed TNX-102 SL to work overnight following bedtime administration, with the goal of improving the pain and other symptoms of FM by improving sleep quality. We view these results as highly encouraging. This was a stringent test of sublingual absorption of cyclobenzaprine, as patients receiving sublingual formulations were instructed to spit and rinse 90 seconds following administration. TNX-102 SL was well-tolerated, and no serious adverse events were reported. The PK results demonstrated that the solution formulation of TNX-102 SL delivered cyclobenzaprine to the systemic circulation more efficiently than the sublingual solution of a simulated crushed tablet and faster than the ingested tablet. We believe the kinetics of plasma cyclobenzaprine demonstrated by TNX-102 SL will translate to more rapid effects compared with current cyclobenzaprine products. We believe these improvements favor its advancement in the FM indication. The data also indicate that, in contrast to our proprietary formulation, sublingual absorption cannot be achieved by crushing currently-available cyclobenzaprine products. We are on track to commence a pivotal clinical trial of TNX-102 SL tablets for FM in the first quarter of 2013.”

FM is a common and complex central nervous system condition characterized by chronic diffuse musculoskeletal pain, increased pain sensitivity at multiple tender points, fatigue, abnormal pain processing, and disturbed sleep, and often features psychological stress. In a Phase 2a trial, TONIX demonstrated that bedtime administration of very low dose cyclobenzaprine improves core FM symptoms including pain, tenderness, fatigue, and depression, and also demonstrated that improvements in key symptoms correlate with increased nights of restorative sleep. These results were published in the December 2011 issue of the *Journal of Rheumatology*. Previous studies of the mechanism by which cyclobenzaprine works have discovered that it acts selectively on serotonin receptor type 2a (5HT2a) and alpha-2 adrenergic receptors. Serotonin is thought to play a major role in the central inhibition of pain.

About TONIX

TONIX is developing innovative prescription medications for challenging disorders of the CNS. The Company targets conditions characterized by significant unmet medical need, inadequate existing treatment options, and high dissatisfaction among both patients and physicians. TONIX's core technology improves the quality of sleep in patients with chronic pain syndromes. TONIX's lead products are designed to be fundamental advances in sleep hygiene and pain management and to be safer and more effective than currently available treatments. TONIX's products are the result of a program to harvest advances in science and medicine to search for potential therapeutic solutions among known pharmaceutical agents. TONIX is developing new formulations that have been optimized for new therapeutic uses. Its most advanced product candidates, TNX-102 for FM and TNX-105 for PTSD, are novel dosage formulations of cyclobenzaprine, the active ingredient in two U.S. FDA-approved muscle relaxants. To learn more about the Company and its pipeline of treatments for CNS conditions, please visit www.tonixpharma.com.

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