

**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): September 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

Copy of correspondence to:

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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 September 19, 2012, the Company issued a press release announcing that the Company would present at the 2012 American College of Rheumatology/Association of Rheumatology Health Professionals Annual Scientific Meeting and that the abstract of preclinical and human pharmacokinetic data related to the Company's fibromyalgia and post-traumatic stress disorder programs being presented was published online.

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 September 2012 *

99.02 Press Release, dated September 19, 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: September 19, 2012

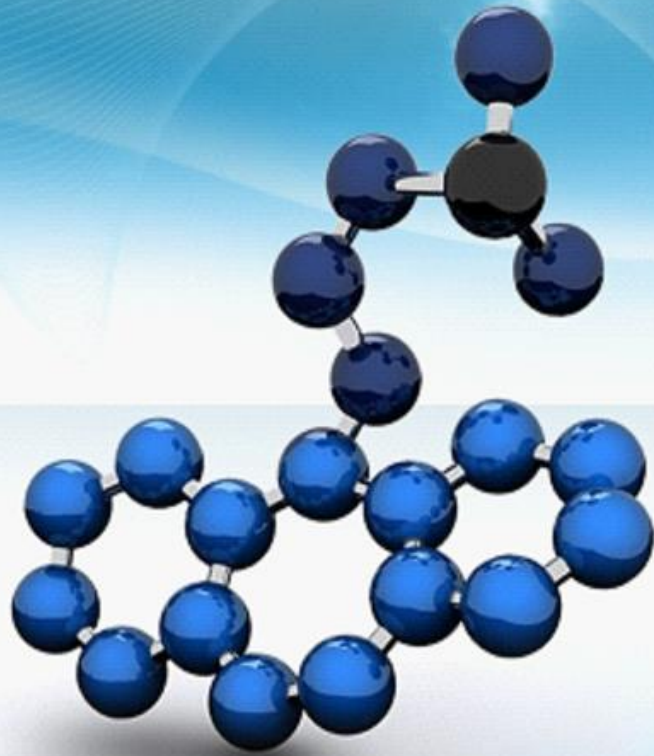
By: /s/LELAND GERSHELL
Leland Gershell
Chief Financial Officer

TONIX

PHARMACEUTICALS

PHARMACEUTICALS

PHARMACEUTICALS



Corporate Presentation
September 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 drugs for chronic pain syndromes**
 - Large and underserved indications
 - Unique, non-addictive treatment approach – targets sleep quality
- **Pivotal trial in fibromyalgia (FM) to report in 2013**
 - Phase 2 data demonstrated efficacy
- **Capital-efficient strategy mitigates risk and cost**
 - 505(b)(2) leverages established safety database
- **Strong market exclusivity**
 - Protection expected to 2033
- **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 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	<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 brain
 - 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****
 - 2007-2010 CAGR of 18.4%***
- **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

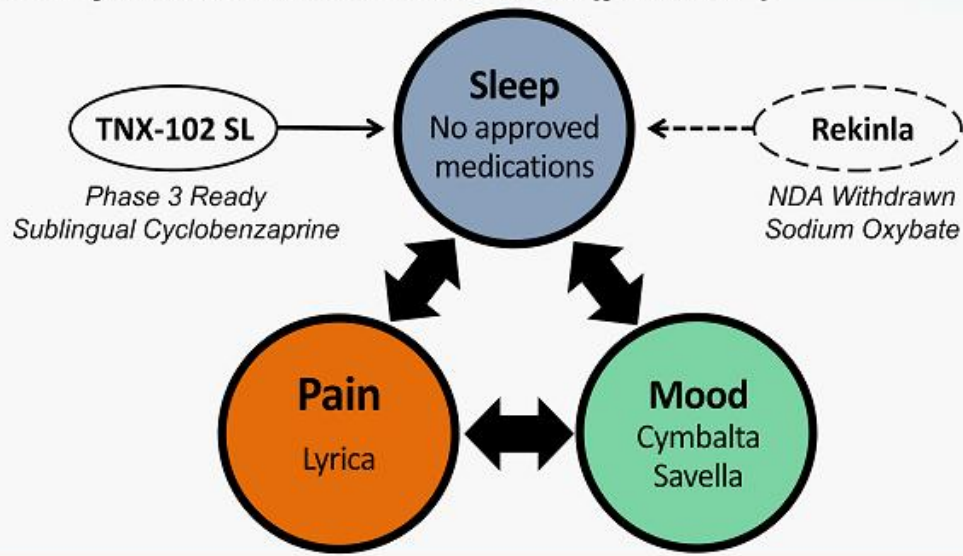
	<u>Legacy Off-Label</u>	<u>Abandoned</u>	<u>In Development</u>	<u>FDA Approved</u>
Sleep	<ul style="list-style-type: none"> cyclobenzaprine muscle relaxants sodium oxybate (Xyrem®)* 	<ul style="list-style-type: none"> sodium oxybate (Rekinla®)** 	<ul style="list-style-type: none"> TNX-102 SL (Phase 3 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 ($p < 0.001$)**



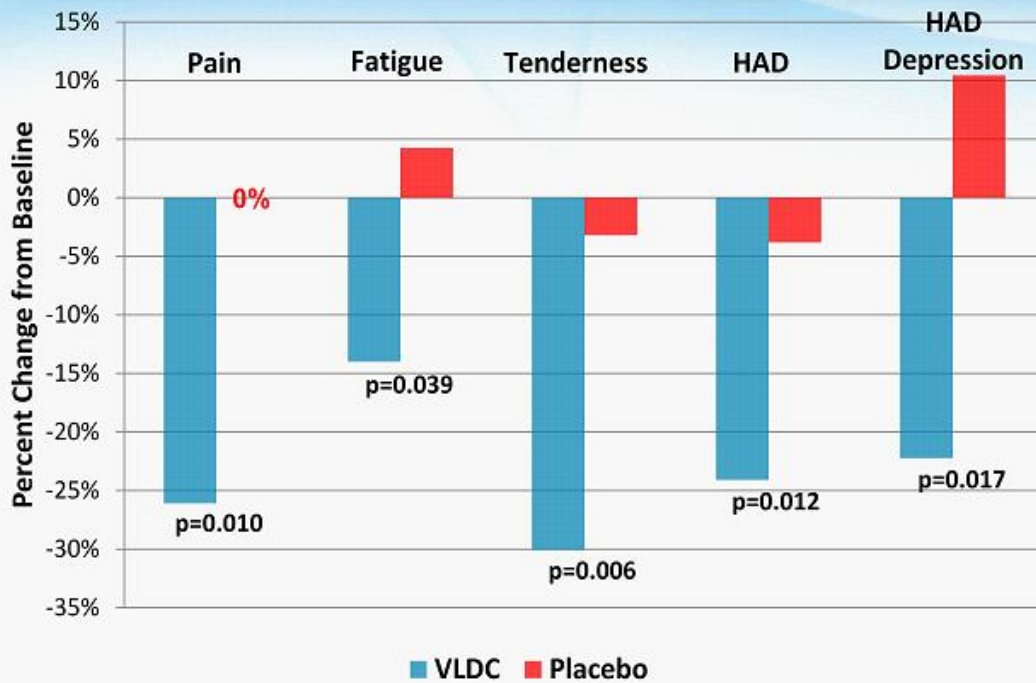
Bedtime Cyclobenzaprine: FM Phase 2a – Overview

- **Double blind, randomized, placebo controlled**
- **36 fibromyalgia patients; 18 per arm**
 - Cyclobenzaprine or placebo taken between dinner and bedtime daily
- **Eight-week, dose escalating study, from 1mg to 4mg**
 - Average bedtime cyclobenzaprine dose at week eight was 3.1mg
 - Lowest available dose of cyclobenzaprine is 5mg
- **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 2a – 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	• Randomized, double-blind placebo-controlled clinical trial showed short-term benefit in fibromyalgia*
2007	• High-dose, controlled-release formulations approved
2010	• >1 billion tablets prescribed annually

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

Current Cyclobenzaprine Products Not Optimal for Fibromyalgia

- **Loss of efficacy in fibromyalgia with chronic use**
 - Benefit at month 1 lost by month 6*
- **Current formulations poorly-suited for bedtime dosing**
 - Slow uptake via oral route
 - ~2 hours before cyclobenzaprine is detectable in blood
 - Persistence in blood stream contributes to next-morning grogginess
- **Despite shortcomings, legacy off-label cyclobenzaprine is widely used in the management of fibromyalgia**

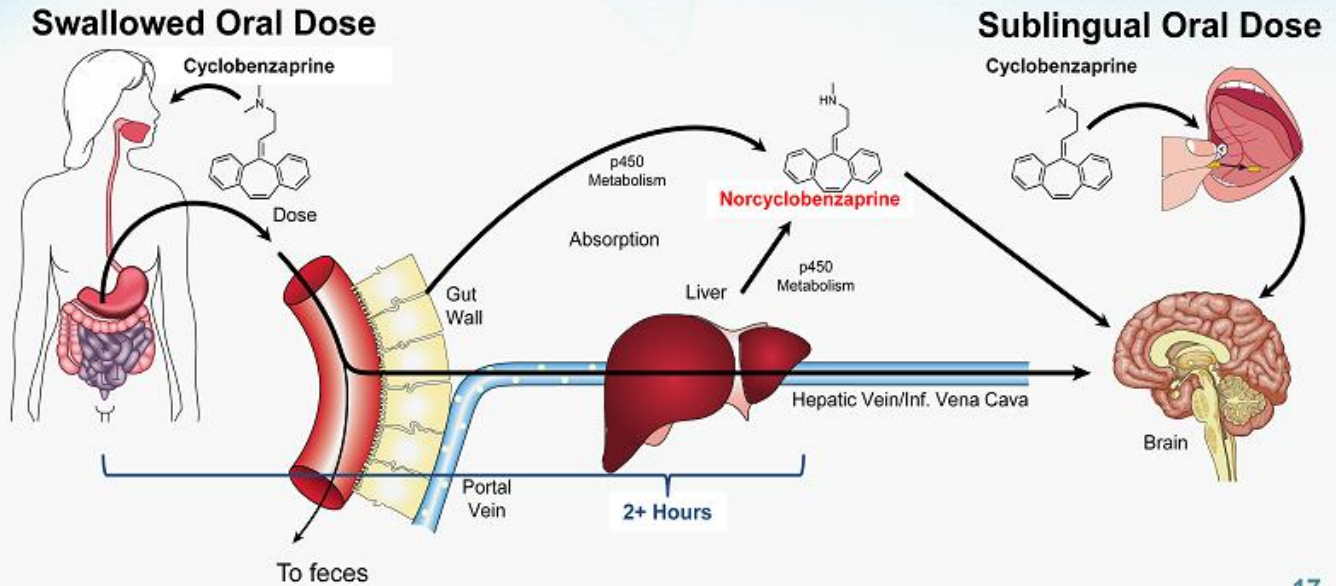
* Carette et al., *Arthritis & Rheumatism* January 1994

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

- **Optimized for chronic bedtime dosing**
 - Sublingual transmucosal delivery
 - Designed for rapid onset and decreased next-morning hangover
 - Drug exposure better matched to sleeping period
- **Avoids 'first-pass' liver production of persistent metabolite**
 - Accumulation of psychoactive metabolite believed to impair long-term efficacy
- **Proprietary formulation**
 - Unique properties cannot be achieved by crushing Flexeril tablets

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 expected to be conducted in 2013**
 - 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
Q4 2012	<ul style="list-style-type: none">• Manufacture commercial tablets
Q1 2013	<ul style="list-style-type: none">• Commence first pivotal trial
Q4 2013	<ul style="list-style-type: none">• Topline results from first pivotal trial• Evaluate partnership opportunities
Timing	Milestones Related to PTSD
H1 2013	<ul style="list-style-type: none">• Commence proof of concept study in PTSD patients

Intellectual Property

- **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

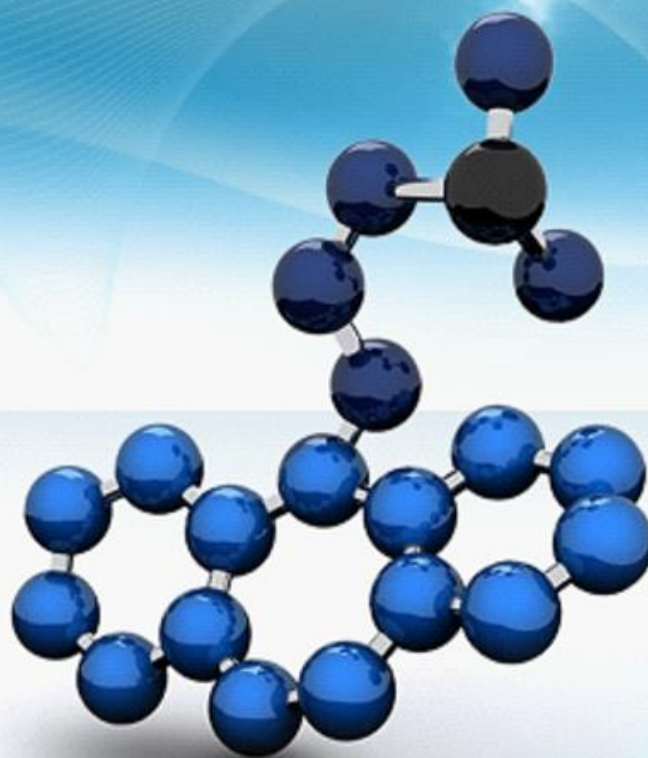
- **Active patenting strategy**

Investment Highlights

- **Developing novel drugs for chronic pain syndromes**
 - Large and underserved indications
 - Unique, non-addictive treatment approach – targets sleep quality
- **Pivotal trial in fibromyalgia to report in 2013**
 - Phase 2 data demonstrated efficacy
- **Capital-efficient strategy mitigates risk and cost**
 - 505(b)(2) leverages established safety database
- **Strong market exclusivity**
 - Protection expected to 2033
- **Experienced management and board**

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OTC/QB: TNXP



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**TONIX PHARMACEUTICALS ANNOUNCES POSTER PRESENTATION
AT THE 2012 AMERICAN COLLEGE OF RHEUMATOLOGY ANNUAL SCIENTIFIC MEETING**

Published Abstract Describes Metabolism and Receptor Interactions of Bedtime Cyclobenzaprine Treatment for Fibromyalgia

NEW YORK (September 19, 2012) – Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) (“TONIX” or the “Company”), a specialty pharmaceutical company developing non-addictive treatments for chronic pain syndromes, today announced the on-line publication of the abstract of preclinical and human pharmacokinetic data related to the Company’s fibromyalgia and post-traumatic stress disorder programs that it will present at the 2012 American College of Rheumatology (ACR) / Association of Rheumatology Health Professionals Annual Scientific Meeting to be held from November 10-14, 2012 at the Walter E. Washington Convention Center in Washington, D.C. The abstract can be accessed at <http://www.acrannualmeeting.org/> by members of the ACR or by individuals registered to attend the meeting.

The presentation details are as follows:

Abstract Title: Cyclobenzaprine (CBP) and Its Major Metabolite Norcyclobenzaprine (nCBP) are Potent Antagonists of Human Serotonin Receptor 2a (5-HT_{2a}), Histamine Receptor H₁ and Alpha-Adrenergic Receptors: Mechanistic and Safety Implications for Treating Fibromyalgia Syndrome by Improving Sleep Quality
Date: Monday, November 12, 2012 from 9:00 a.m. to 6:00 p.m.
Location: Poster Hall (Hall B)
Session: Fibromyalgia and Soft Tissue Disorders
Presented by: Bruce Daugherty, Ph.D., Senior Director of Drug Development, TONIX
Abstract: #960

The abstract presents data showing blood levels of a metabolite, norcyclobenzaprine (nCBP), were unexpectedly high and persistent in healthy volunteers who ingested a 5 mg tablet of cyclobenzaprine (CBP). A single oral dose of 5 mg CBP exhibits a maximum blood level, or C_{max} of 4.12 ng/ml, and a blood half-life, or T_{1/2} of 31 hours, similar to previously reported results. However, nCBP was produced by the liver and appeared in the blood with a C_{max} of 1.27 ng/ml and a T_{1/2} of 73 hours. Previously, plasma nCBP had only been detected in cases of overdose.

The abstract also showed that that CBP and nCBP are both active at blocking certain central nervous system receptors, which include the serotonin 5-HT_{2A} receptor, the histamine H₁ receptor and the adrenergic alpha 1A receptor.

Dr. Daugherty, the lead author of the study commented, "CBP is metabolized to nCBP, which persists in plasma at biologically relevant concentrations after oral CBP in healthy subjects. Antagonists of 5HT2a and H-1 are known to have effects on sleep and sleep maintenance. Adrenergic antagonists may have effects on autonomic dysfunction. The accumulation of biologically active nCBP without N⁺-glucuronidation may affect responses to CBP therapy in a chronic bedtime dosing regimen."

About Fibromyalgia

Fibromyalgia ("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. Despite the fact that most FM patients suffer from poor sleep, there are no medications indicated for FM that work by improving sleep quality. Research has shown that the restorative sleep of FM patients is disrupted by alarm signals called CAP A2 and A3. 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*.

About TNX-102 SL

TNX-102 SL is a novel sublingual formulation of cyclobenzaprine for bedtime use. TONIX designed TNX-102 SL to provide faster and more efficient absorption of cyclobenzaprine, relative to currently marketed products approved for other indications. TONIX believes TNX-102 SL administered at bedtime will provide more targeted sleep quality effects with less likelihood of side effects than commercially-available cyclobenzaprine preparations.

About TONIX

TONIX is developing innovative prescription medications for challenging disorders of the central nervous system. 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 product is designed to be a fundamental advance in sleep hygiene and pain management and to be safer and more effective than currently available treatments. Its most advanced product candidate, TNX-102 SL for FM and post-traumatic stress disorder, is a novel dosage formulation of cyclobenzaprine, the active ingredient in two U.S. FDA-approved muscle relaxants. To learn more about the Company, please visit www.tonixpharma.com.

Certain statements in this press release are forward-looking within the meaning of 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. 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. The information set forth herein speaks only as of the date hereof.

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