

**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): August 14, 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

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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 August 14, 2012, the Company issued a press release announcing that its new sublingual formulation of its fibromyalgia drug TNX-102 reduces the production of a problematic metabolite, according to data from a recently-completed clinical trial.

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 August 2012 \*

99.02 Press Release, dated August 14, 2012, issued by Tonix Pharmaceuticals Holding Corp.

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\* Furnished herewith.

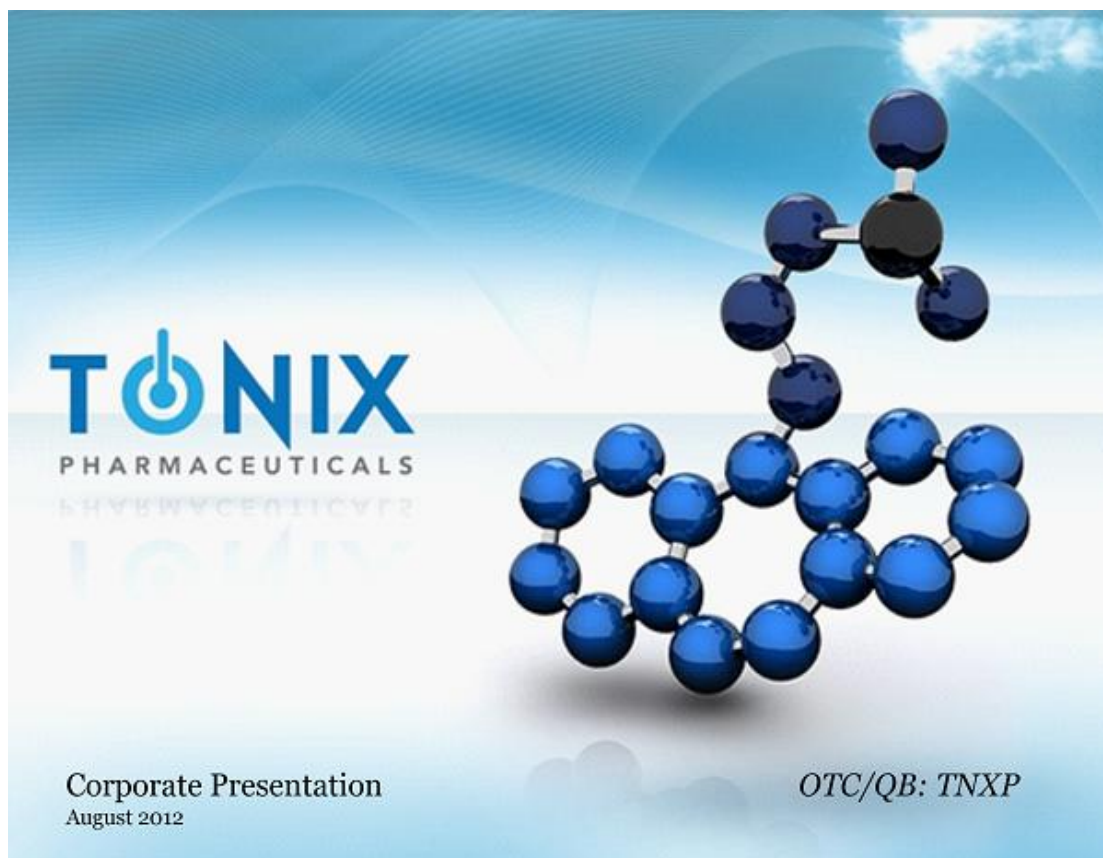
**SIGNATURE**

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 14, 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
<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>Benjamin Selzer</b> COO	<ul style="list-style-type: none"> <li>• Reliant</li> <li>• Aton</li> <li>• Investment Banking (Lehman, BofA)</li> </ul>	
<b>Leland Gershell, MD, PhD</b> CFO	<ul style="list-style-type: none"> <li>• Cowen</li> <li>• Apothecary</li> <li>• Favus</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

Product	Indication	Status
TNX-102	FM	<ul style="list-style-type: none"><li>• Very low dose cyclobenzaprine (VLDC) in novel formulation</li><li>• Phase 2a successfully completed</li><li>• Pivotal trial expected to begin Q1 2013</li></ul>
TNX-105	PTSD	<ul style="list-style-type: none"><li>• VLDC in novel formulation</li><li>• Will leverage data from TNX-102 experience</li><li>• Proof of concept trials anticipated in 2013</li><li>• Seeking U.S. Department of Defense funding</li></ul>
TNX-107	Traumatic Brain Injury	<ul style="list-style-type: none"><li>• VLDC in novel formulation</li><li>• Will leverage data from TNX-102 experience</li><li>• Seeking U.S. Department of Defense funding</li></ul>
TNX-201	Headache	<ul style="list-style-type: none"><li>• NDA process for existing grandfathered (DESI) product</li><li>• Potentially shortened process for FDA approval</li><li>• DESI to New Drug Application (NDA) switch products enjoy mandated exclusivity</li></ul>
TNX-301	Alcoholism	<ul style="list-style-type: none"><li>• US patent allowed</li><li>• Potential for government funding</li></ul>

# 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

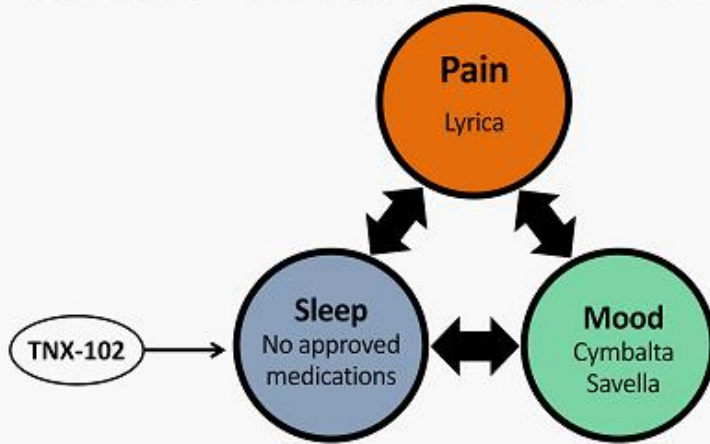
# FM Market Dynamics

- **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>
<b>Sleep</b>	<ul style="list-style-type: none"> <li>cyclobenzaprine</li> <li>muscle relaxants</li> <li>sodium oxybate (Xyrem®)</li> </ul>	<ul style="list-style-type: none"> <li>sodium oxybate (Rekinla®)</li> </ul>	<ul style="list-style-type: none"> <li><b>TNX-102</b> (Phase 3 ready)</li> </ul>	
<b>Pain</b>	<ul style="list-style-type: none"> <li>gabapentin</li> <li>opioids</li> </ul>		<ul style="list-style-type: none"> <li>Effirma™ (Phase 2)</li> </ul>	
<b>Mood</b>	<ul style="list-style-type: none"> <li>venlafaxine</li> <li>bupropion</li> </ul>			

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# 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

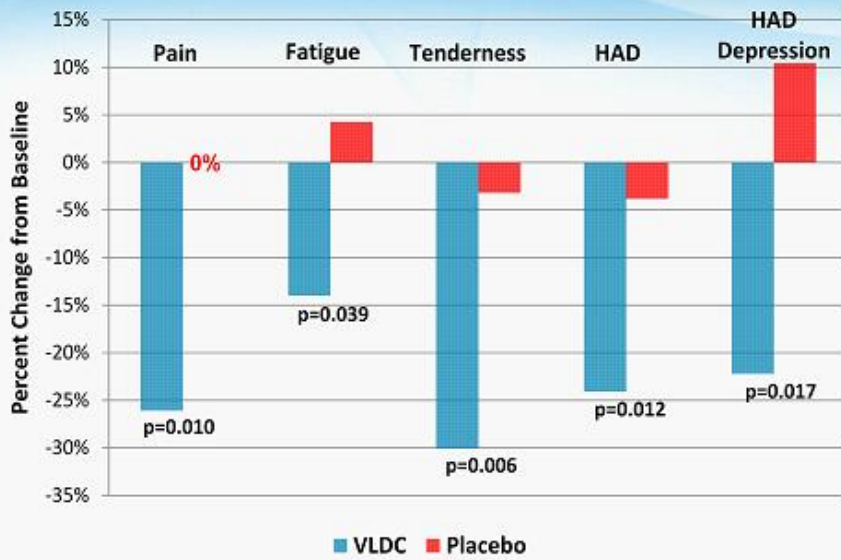
# VLDC FM Phase 2a – Demographics

- 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 <sub>A2+A3(Norm)</sub> ≤33%	72%	33%	0.019

Variable	VLDC CAP <sub>A2+A3(Norm)</sub> 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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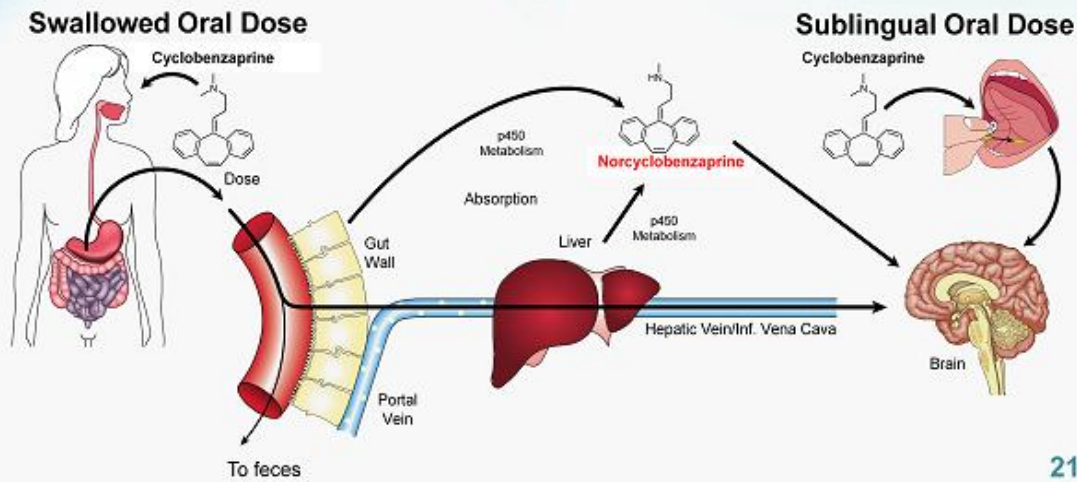


# TNX-102: Sublingual CBP

- **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: Sublingual CBP

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



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

# Investment Summary

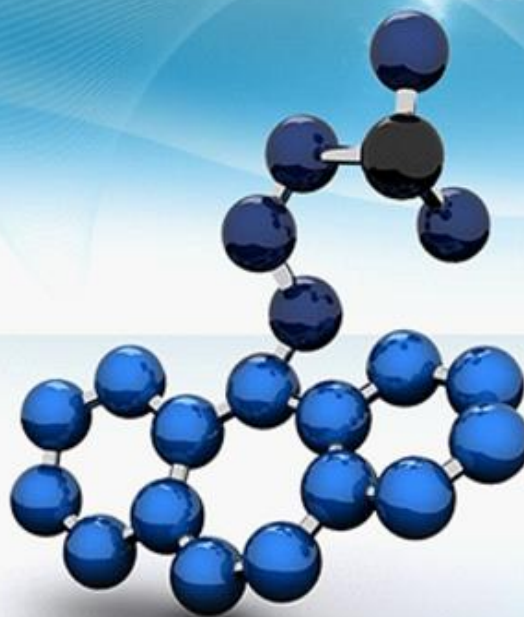
- **Significant unmet needs and large market opportunities**
- **First-in-class products; not competitive with existing therapies**
- **Capital efficient, low risk drug development strategy**
- **Near-term value inflection points**
- **Experienced management and board**



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*OTC/QB: TNXP*



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**TONIX PHARMACEUTICALS REPORTS THAT SUBLINGUAL FORMULATION OF FIBROMYALGIA DRUG REDUCES PRODUCTION OF A PSYCHOACTIVE METABOLITE, IMPROVING SUITABILITY FOR LONG-TERM, CHRONIC TREATMENT**

*Results Further Support the Development of Sublingual TNX-102 to Treat Fibromyalgia by Improving Sleep*

**NEW YORK (August 14, 2012)** – Tonix Pharmaceuticals Holding Corp. (OTCBB: TNXP) (“TONIX” or the “Company”), a specialty pharmaceutical company developing non-addictive treatments for chronic pain syndromes, today reports that its new sublingual (under-the-tongue) formulation of its fibromyalgia (FM) drug TNX-102 reduces the production of a problematic metabolite, according to data from a recently-completed clinical trial.

TNX-102 is the Company’s low dose form of cyclobenzaprine. Cyclobenzaprine is a drug originally approved by the Food and Drug Administration for short term treatment of acute muscle spasm several decades ago and it is currently one of the most widely prescribed off-label medications for FM. TONIX has shown that low dose cyclobenzaprine given before bedtime is effective to reduce the pain suffered by FM patients and to improve the quality of sleep. Yet when given as an oral pill on a chronic daily regimen, cyclobenzaprine can lose its effectiveness over time.

Tonix’s research sheds light on a potential cause of this problem. Tonix has discovered that a significant amount of cyclobenzaprine from oral tablets is converted into a metabolite called norcyclobenzaprine, which builds up in the body with daily dosing. Although norcyclobenzaprine had been described previously in cases of overdose, Tonix has found that the levels of norcyclobenzaprine are significant even at low doses and that norcyclobenzaprine is a psychoactive substance. Norcyclobenzaprine has a similar effect on the brain as cyclobenzaprine, so the accumulation of the metabolite over time is expected to interfere with the beneficial effects of bedtime cyclobenzaprine. Norcyclobenzaprine makes it impossible to use currently available cyclobenzaprine tablets in a chronic bedtime dosing regimen to achieve beneficial effects on the sleeping brain and still have the drug largely cleared by the next morning.

TONIX’s new sublingual formulation of cyclobenzaprine (TNX-102 SL) can significantly reduce this problem, according to the Company’s pharmacokinetic study. The study showed that levels of the norcyclobenzaprine metabolite can be reduced by using a sublingual formulation compared to oral cyclobenzaprine tablets. As a result, TNX-102 SL is a significant advance over oral tablets and is suitable for long-term treatment.

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“The study shows that bedtime TNX-102 SL should offer a substantial improvement over off-label oral tablets in the treatment of fibromyalgia,” said Seth Lederman, M.D., Chief Executive Officer of TONIX. “That’s why we believe our drug has the potential to be a game-changing medication in relieving pain and other symptoms of fibromyalgia, even though the oral tablet version of cyclobenzaprine is already available.”

“Delivering the drug under the tongue gets it into the bloodstream faster, and changes the way the drug is metabolized,” Lederman explained. “As a result, the production of the psychoactive, persistent metabolite, norcyclobenzaprine, is decreased. We look forward to commencing a pivotal trial of TNX-102 SL in fibromyalgia in the first quarter of 2013. We believe the drug will help people afflicted with fibromyalgia get the relief they need, by improving sleep quality.”

The new results reported by TONIX today come from a study designed to confirm in humans the results obtained in animals which demonstrate that the Company’s TNX-102 SL (2.4 mg) tablet provides faster delivery and more efficient absorption of cyclobenzaprine as compared to the currently available oral (5 mg or 10 mg) pills that deliver cyclobenzaprine to the stomach. In those studies, TONIX discovered that cyclobenzaprine given in a novel sublingual formulation is absorbed with a profile comparable to intravenous cyclobenzaprine. Cyclobenzaprine is the active ingredient in two prescription muscle relaxants that have been approved by the U.S. Food and Drug Administration and are marketed by other companies.

### **About 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. 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**

TNX-102 is a bedtime medicine containing very low dose cyclobenzaprine (2.4 mg). In a randomized, double-blind, placebo-controlled eight-week Phase 2 study in FM patients, TONIX demonstrated that treatment with TNX-102 led to significant improvements in pain and other core symptoms. TONIX is optimizing TNX-102 for faster and more efficient absorption relative to currently marketed cyclobenzaprine products. TONIX believes its TNX-102 SL formulation will provide more targeted sleep quality effects with less likelihood of side effects than commercially available cyclobenzaprine preparations. Previous studies of the mechanism by which cyclobenzaprine works have discovered that it acts selectively on serotonin receptor type 2a (5HT<sub>2a</sub>) 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 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 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 post-traumatic stress disorder, 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 central nervous system conditions, please visit [www.tonixpharma.com](http://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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