# 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 9, 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))

#### 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 9, 2012, the Company issued a press release announcing that it has received positive results from an animal pharmacokinetic study of its new formulation of its lead drug, TNX-102, for the treatment of fibromyalgia syndrome, which is a tablet designed to be absorbed sublingually. Further, the Company stated that an oral solution of the new sublingual formulation will be used in the upcoming pharmacokinetic/bioavailability study, for which the Company recently received clearance from Health Canada.

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 9, 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.

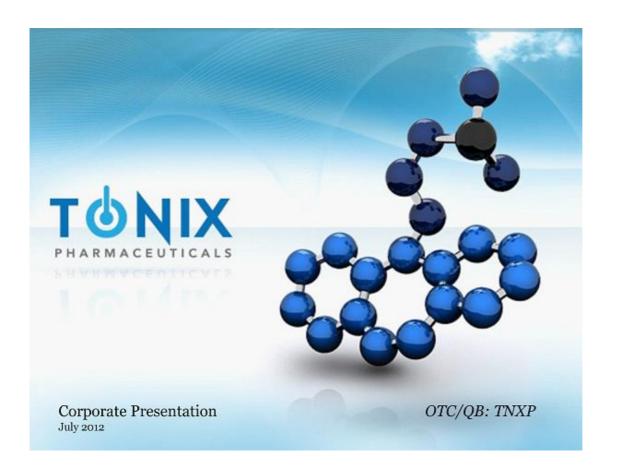
#### TONIX PHARMACEUTICALS HOLDING CORP.

By: /s/ SETH LEDERMAN

Seth Lederman

Date: July 9, 2012

President and Chief Executive Officer



### Disclosures

#### Forward-looking Statements

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

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

#### Information Regarding Disclosures

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

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

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

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

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

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### Company Overview

- Specialty pharmaceutical company developing innovative non-addictive products for chronic pain syndromes
  - Fibromyalgia syndrome (FM)
  - Post-traumatic stress disorder (PTSD)
- Unmet medical needs and large commercial opportunities
  - Targeting sleep pathology
  - Central pain syndromes poorly addressed by opiate pain drugs or benzodiazepine sleep drugs
- · Capital efficient, risk-mitigated development pathway
  - Near-term, value-creating milestones
- Experienced management and board

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## Experienced Leadership

	Selected Previous Corporate Affiliations	Selected Previous Product Affiliations
Seth Lederman, MD CEO & Chairman	<ul><li>Vela</li><li>Targent</li><li>Validus</li><li>Fontus</li></ul>	Fusilev*
Benjamin Selzer COO	<ul><li>Reliant</li><li>Aton</li><li>Investment Banking (Lehman, BofA)</li></ul>	LOVAZA unega-3-esid ethyl esters
Leland Gershell, MD, PhD CFO	<ul><li>Cowen</li><li>Apothecary</li><li>Favus</li><li>Madison Williams</li></ul>	Zolinza [vorinostat] capsules
Bruce Daugherty, PhD, MBA Senior Director of Drug Development	Merck     Roche Institute	Tredaptive

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# Accomplished Independent Board

	Selected Current & Previous Affiliations	Selected Previous Product Affiliations
Seth Lederman, MD Chairman	Vela Targent Validus/Fontus	Fusilev*
Stuart Davidson	Alkermes     Combion	
Patrick Grace	WR Grace     Chemed     Grace Institute	
Donald Landry, MD, PhD	Columbia University     Chair, Dept. of Medicine     Vela	
Ernest Mario, PhD	Glaxo Alza Reliant	LOVAZA CONCERTA
Charles Mather	Janney Montgomery Scott     Cowen     Smith Barney	
John Rhodes	Booz Allen Hamilton	
Samuel Saks, MD	Jazz     Alza     Cougar	Sodium oxybate) oral solution methylphenidate HCI

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# Product Pipeline

Product	Indication	Status
TNX-102	FM	Very low dose cyclobenzaprine (VLDC) in novel formulation Phase 2a successfully completed Pivotal trial expected to begin Q1 2013
TNX-105	PTSD	<ul> <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> <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> <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	US patent allowed     Potential for government funding

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### **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\*\*

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

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<sup>\*</sup> National Institutes of Health, U.S. Department of Health and Human Services

<sup>\*\*</sup> Decision Resources Pain Management Study: Fibromyalgia, January 2012

### **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

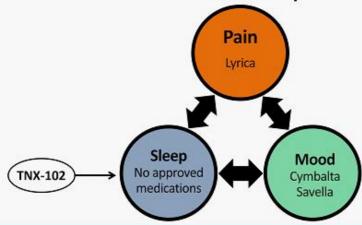
\* Frost & Sullivan Fibromyalgia Market Study, December 2010

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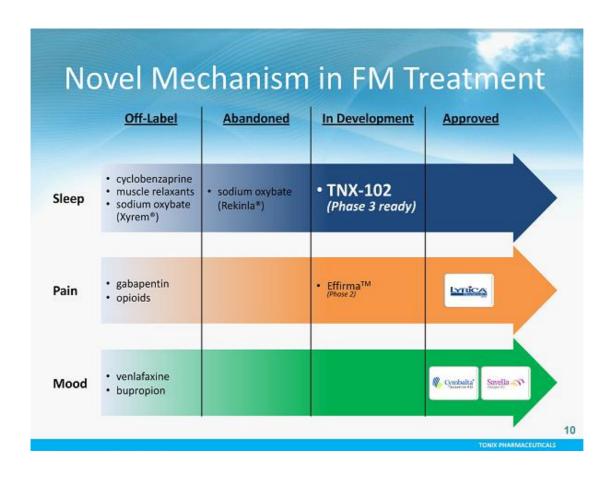
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- Medications that target pain or depressed mood are approved for the management of FM
- TNX-102 will be a first-in-class medication targeting disturbed or "non-restorative" sleep in FM



NOW AND A REAL PROPERTY.



# 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

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### Sodium Oxybate Data in FM & Sleep

 Phase 3 trials of sodium oxybate demonstrated highly significant improvements in fibromyalgia symptoms

Study	Treatment	n	Responders* n (%)	p-value (chi-square)
	Placebo	183	50 (27)	196
06-008	oxybate 4.5 g	182	84 (46)	<0.001
	oxybate 6.0 g	182	72 (40)	0.01
	Placebo	188	38 (20)	
06-009	oxybate 4.5 g	194	69 (36)	<0.001
	oxybate 6.0 g	189	68 (36)	< 0.001

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.

Source: FDA briefing documents.
\* Subjects that reported a 30% or more reduction in overall pain in week 14 as compared to baseline

### 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

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### 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

\*\*Outcame Measures in Rheumatology Clinical Trials

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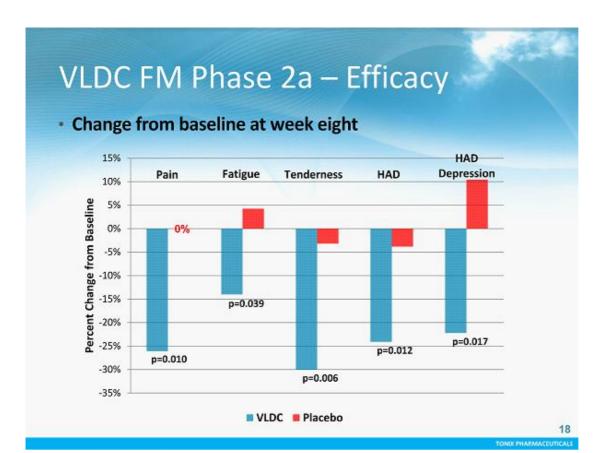
### VLDC FM Phase 2a – Demographics

- 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

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### 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	Р
CAP <sub>A2+A3(Norm)</sub> ≤33%	72%	33%	0.019

Variable	r	) Correlation
Variable	Г	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: Novel Formulations

#### Sublingual (SL) TNX-102 cyclobenzaprine 2.4 mg tablet

- PK studies in animals showed unexpected properties for novel formulation
  - · Rapid, efficient sublingual absorption
  - · Efficient systemic clearance
- Solution form of SL tablet human PK study to dose in July
  - Data expected Q3 2012
- SL tablet (commercial formulation, GMP) human PK study to dose in Q3
  - · Data expected early Q4 2012

#### Pro-micellar TNX-102 cyclobenzaprine 2.4 mg gelcap

- Human PK study completed, 10 subject 3-way crossover design
  - · No food effect on proprietary formulation

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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

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### 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

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### TNX-105: VLDC for PTSD

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

\* National Institutes of Mental Health & National Institutes of Health

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### 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

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### **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

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# **Upcoming Milestones**

Timing	Milestones Related to TNX-102 in Fibromyalgia
Q3 2012	Completion of human PK study on proprietary formulation
Q4 2012	Completion of human PK/PD on commercial formulation, dose
Q1 2013	Commencement of first pivotal trial
H1 2014	<ul> <li>Final study results of first pivotal trial</li> <li>Potential partnering</li> </ul>
Timing	Milestones Related to TNX-105 in PTSD
H1 2013	Commencement of proof of concept study in PTSD patients

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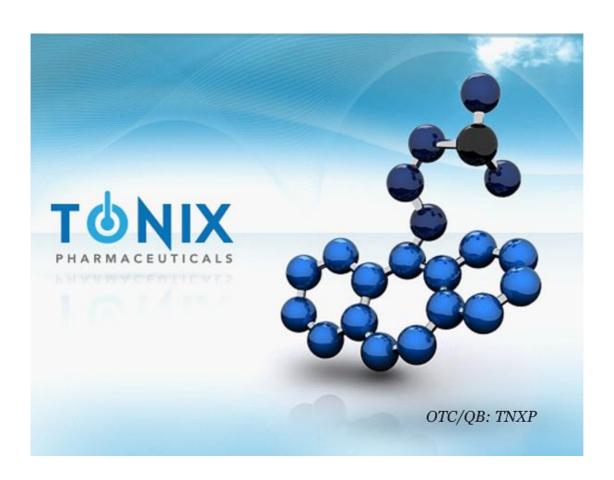
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### **Investment Summary**

- 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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July 9, 2012

#### TONIX PHARMACEUTICALS REPORTS POSITIVE PRECLINICAL DATA ON SUBLINGUAL TNX-102

New Formulation of Very Low Dose Cyclobenzaprine for Bedtime Use Designed to Treat Fibromyalgia by Facilitating Restorative Sleep

**NEW YORK July 9, 2012** – Tonix Pharmaceuticals Holding Corp. (OTCBB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing non-addictive treatments for chronic pain syndromes, including fibromyalgia ("FM"), today reported positive data from an animal pharmacokinetic ("PK") study of its novel sublingual ("SL") formulation of TNX-102, the Company's very low dose cyclobenzaprine.

"TONIX is developing TNX-102 as a therapy to help people afflicted with FM get the relief they need, by improving sleep quality," said Seth Lederman, M.D., Chief Executive Officer of TONIX. "With better sleep quality, patients report a reduction in their chronic pain. Sleep quantity and sleep quality are different. The clinical data support the idea that improving sleep quality leads to significant alleviation of FM symptoms. We believe that improving sleep quality allows the natural restorative properties of sleep to work on reducing pain. TONIX is pursuing this goal through our novel formulations of cyclobenzaprine."

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*.

The new research reported by TONIX today demonstrates that the Company's SL TNX-102 (2.4 mg) tablet provides faster delivery and more efficient absorption of cyclobenzaprine as compared to the currently available pills that deliver cyclobenzaprine to the stomach. In fact, TONIX discovered that cyclobenzaprine given in a novel SL formulation is absorbed as well as 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.

The Company recently announced that it received clearance from Health Canada to initiate a pharmacokinetic/bioavailability study of an oral solution formulation of its SL TNX-102 tablet in comparison to a marketed oral cyclobenzaprine tablet (5 mg) and to intravenous cyclobenzaprine (2.4 mg) in healthy adults in Canada. For more information about this trial, please visit <a href="http://www.clinicaltrials.gov/ct2/show?term=tonix&rank=1">http://www.clinicaltrials.gov/ct2/show?term=tonix&rank=1</a>.

"We are pleased to announce the discovery that our SL TNX-102 formulation can deliver cyclobenzaprine rapidly and efficiently into the bloodstream and that it is also rapidly cleared. The existing literature taught away from this discovery and led scientists to believe that the cyclobenzaprine molecule itself had an inherently long plasma half-life that could not be shortened. We believe the improved pharmacokinetic profile of SL TNX-102 will enable it to provide several significant advantages over commercial oral formulations of cyclobenzaprine, including targeting the sleeping brain with greater dose intensity when taken at bedtime and lower rates of side-effects such as next-day grogginess or hangover. The PK profile of SL TNX-102 appears well suited to allow the natural restorative processes of sleep to relieve FM pain." said Dr. Lederman. "We have filed with the U.S. Patent and Trademark Office for patents on SL TNX-102, which we believe is an important advance for FM patients that should ultimately reduce the use of addictive pain killers and sedatives," continued Dr. Lederman. "We look forward to executing on our clinical study plan toward the commercialization of what we anticipate will be an effective, well-tolerated, and differentiated treatment option for FM. We remain on track to enroll patients into the first of two pivotal efficacy studies of TNX-102 in FM in the first quarter of 2013."

TONIX also plans to explore the utility of proprietary, low dose formulations of cyclobenzaprine in a new treatment paradigm for post-traumatic stress disorder ("PTSD").

#### **About TNX-102**

TNX-102 is a bedtime medicine containing very low dose cyclobenzaprine (2.4 mg). TONIX is designing TNX-102 for faster and more efficient absorption relative to currently marketed cyclobenzaprine products. TONIX believes its SL formulation of TNX-102 administered at bedtime 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 (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 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 fibromyalgia 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 central nervous system conditions, 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.