

September 6, 2012



# **TONIX Pharmaceuticals' CEO Discusses the Company's New Treatment for Fibromyalgia on News-Medical.net**

## **New Drug Aims to Reduce Pain by Improving Sleep Quality**

NEW YORK, NY -- (MARKETWIRE) -- 09/06/12 -- Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing a non-addictive treatment for fibromyalgia ("FM") and post-traumatic stress disorder ("PTSD"), announces the airing of an interview with TONIX's Chief Executive Officer Seth Lederman, M.D. on News-Medical.net, the A to Z of Medical News in the United Kingdom. In the interview, Dr. Lederman highlights TONIX's lead drug candidate TNX-102 SL, which targets sleep quality in patients with FM and PTSD. The interview can be accessed at <http://www.news-medical.net/news/20120829/Sleep-disorder-treatment-an-interview-with-Dr-Seth-Lederman-President-and-CEO-of-Tonix-Pharmaceuticals.aspx>.

In the interview, Dr. Lederman reviews the underlying pathology associated with pain and restorative sleep, stating, "A very important aspect of restorative sleep is that it refreshes the body's system for perceiving and processing pain. Healthy people who experience an athletic injury or some other sort of painful event can wake up from a night of restorative sleep with the pain significantly diminished. Even before the injury is repaired, their bodies have a mechanism to adapt to pain and to work around it. However, people who are unable to get restorative sleep, are also unable to benefit from restorative sleep's ability to reset their body's processes that perceive and process pain. Therefore pain can accumulate from day to day. Over time, this swamps the system with pain. They become unable to adapt to pain and to work around it."

Dr. Lederman continues, "The mechanism by which the body can turn off or extinguish pain is called central inhibition, a process that allows the brain to turn off perception of pain. In extreme cases, central inhibition kicks in when there is no hope for the body to avoid further pain and when continuing to perceive pain is counter-productive. Central inhibition can extinguish pain perception attached to these severe, but localized injuries. In FM, central inhibition fails at a higher level, and the pain is widespread."

Fibromyalgia affects an estimated five million Americans, and FM patients have an associated sleep disorder that prevents them from getting restorative sleep. 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 oftentimes 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. Currently available prescription drugs for insomnia

increase the quantity of sleep, but not the quality.

"Patients with FM hurt all over their bodies," explained Dr. Lederman. "They also cannot get restorative sleep. There is a vicious cycle of chronic pain and non-restorative sleep. Pain disturbs sleep and people with non-restorative sleep have a greater sensitivity to pain and more trouble extinguishing pain."

TONIX is developing TNX-102 SL, a sublingual tablet formulation of cyclobenzaprine, to help FM sufferers obtain the restorative sleep they need. In patients with FM, increased restorative sleep leads to a reduction in their chronic pain. In a randomized, double-blind, placebo-controlled, eight-week Phase 2 clinical study, TONIX showed that low-dose, bedtime cyclobenzaprine significantly improved core FM symptoms, with reductions in pain, fatigue, and depressive scores, and also decreased non-restorative sleep. These data were published in the December 2011 issue of the *Journal of Rheumatology*. 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.

In discussing the Company's strategy for advancing TNX 102-SL toward commercialization, Dr. Lederman described the Company's pivotal clinical trial plans. "The first of two double-blind, randomized, placebo-controlled Phase 3 studies in FM will enroll 76 subjects divided into two groups and is expected to begin in the first quarter of 2013. Thirty-eight patients will receive TNX-102 SL and 38 patients will receive placebo. The primary efficacy analysis will be a comparison of pain scores at 12 weeks. We expect to report data from this study by the end of 2013."

#### **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 PTSD, 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](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.*

**Contacts:**

***Tonix Pharmaceuticals Holding Corp.***

Benjamin Selzer  
Chief Operating Officer  
(212) 980-9155 x106

[Email Contact](#)

***LHA***

Anne Marie Fields  
(212) 838-3777

[Email Contact](#)

or

Bruce Voss  
(310) 691-7100

[Email Contact](#)