

# Tonix Pharmaceuticals Highlights Therapeutic Programs on CEONEWS.Tv

## CEO Discusses Company's Unique Approach to Treating Fibromyalgia by Improving Sleep Quality

NEW YORK, NY -- (MARKETWIRE) -- 09/20/12 -- Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing non-addictive treatments for chronic pain syndromes, including fibromyalgia ("FM") and post-traumatic stress disorder ("PTSD"), today announced that Seth Lederman, M.D., Chief Executive Officer of TONIX, discussed the Company's progress and potential with CEONEWS.Tv. The interview is available at <a href="http://www.ceonews.tv/tnxp">http://www.ceonews.tv/tnxp</a>.

In the interview, Dr. Lederman discussed the Company's unique approach to the treatment of FM by improving sleep quality. TONIX's lead product candidate is TNX-102 sublingual ("TNX-102-SL"), a novel, proprietary rapid-dissolve tablet formulation of cyclobenzaprine ("CBP"), which is on track to enter pivotal testing in FM patients early next year. Cyclobenzaprine has an established safety record, as two oral medications containing this active ingredient have been approved by the FDA for muscle spasm and one has been on the market since the late 1970's.

TONIX is pioneering the development of a novel formulation of CBP for FM, and in a randomized, double-blind, placebo-controlled, eight-week Phase 2 trial in FM patients, TONIX demonstrated that low-dose CBP given at bedtime resulted in a significant decrease in next-day pain and other core symptoms, as well as a significant improvement in sleep quality. Although FM patients use legacy CBP products off-label to obtain relief, none of the legacy CBP drugs are approved for this condition. In one study, the legacy CBP product Flexeril® provided a beneficial effect in the short term, but this benefit was lost with sustained use.

TONIX is developing TNX-102 SL to optimize the delivery and metabolism of CBP for bedtime use in FM, and the Company expects it to be the first drug approved for FM that works by improving sleep quality. Dr. Lederman said he believes that TNX-102-SL will transform the treatment of FM.

TONIX expects to conduct the first of two pivotal clinical trials for TNX-102 SL next year, and with continued positive results, believes the Company will be in a position to entertain partnerships with larger companies for further development and eventual commercialization. Dr. Lederman pointed out that a significant trend within the pharmaceutical industry is the increasing reliance on drug innovation by small, nimble companies such as TONIX, which are able to efficiently leverage advances in science and medicine to generate important new therapeutic products. Large pharmaceutical companies have expertise in designing and

conducting the final studies to enable product approval as well as in managed care interactions prior to launch. Also, large pharmaceutical companies have extensive sales organizations and commercial expertise, so they are most effective at selling new medicines, Dr. Lederman added.

Dr. Lederman practiced rheumatology as a faculty member at Columbia University's College of Physicians and Surgeons and at Presbyterian Hospital in New York City. Dr. Lederman served as a research scientist and clinician in the early days of the AIDS epidemic. Dr. Lederman's past accomplishments include the elucidation of the molecular basis of T cell helper function, which led to the development of therapeutic candidates for autoimmune diseases and organ transplant rejection in collaboration with Biogen-IDEC and CellTech/UCB. Dr. Lederman founded Targent Pharmaceuticals, which sold the rights to levo-leucovorin to Spectrum Pharmaceuticals, who now markets it as Fusilev® for the treatment of colorectal cancer.

### About Fibromyalgia

Fibromyalgia 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 CBP for bedtime use. TONIX designed TNX-102 SL to provide faster and more efficient absorption of CBP, 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 CBP preparations. TONIX has shown that CBP is active at blocking certain central nervous system receptors known to have effects on sleep and sleep maintenance, including the serotonin 5-HT2A receptor and the histamine H1 receptor.

#### **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 <a href="https://www.tonixpharma.com">www.tonixpharma.com</a>.

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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