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# TONIX Pharmaceuticals Completes Pre-IND Meeting With FDA for Potential New Treatment for Post-Traumatic Stress Disorder

NEW YORK, NY -- (MARKETWIRE) -- 10/24/12 -- Tonix Pharmaceuticals Holding Corp. (OTCQB: TNXP) ("TONIX" or the "Company"), a specialty pharmaceutical company developing novel treatments for challenging disorders of the central nervous system, including fibromyalgia ("FM") and post-traumatic stress disorder ("PTSD"), today reported that it recently held a pre-Investigational New Drug ("IND") meeting with the US Food and Drug Administration ("FDA") to discuss its proposed development of the Company's novel sublingual tablet formulation of cyclobenzaprine ("CBP") for bedtime use, TNX-102 SL, for the treatment of PTSD.

"We found the meeting to be productive and informative and are encouraged to continue our development of bedtime TNX-102 SL to treat PTSD. The FDA has provided clear clinical guidance for the further development of TNX-102 SL for PTSD. TONIX plans to file an IND for PTSD by the end of the year," said Seth Lederman, M.D., Chief Executive Officer of TONIX.

Dr. Lederman continued, "PTSD is an enormous and underreported unmet medical need, particularly among troops in combat deployments and veterans. Chronic pain and sleep disturbances are common and co-morbid features of PTSD, and abuse and addiction to prescription pain and insomnia medications are widespread among patients despite the lack of evidence for their effectiveness in this syndrome. We believe TNX-102 SL holds promise to benefit PTSD symptoms by improving sleep quality."

## ***About PTSD***

PTSD is an anxiety disorder that can develop from seeing or experiencing a terrifying event or ordeal in which there was the threat or actual occurrence of grave physical harm. PTSD was once associated primarily with war veterans, but civilian PTSD can be triggered by serious accidents, natural or human-caused disasters, exposure to terrorist attacks, violent personal assaults or sexual abuse, or even sudden and major emotional losses. People with PTSD experience persistent symptoms that include strong and unwanted memories of the event, bad dreams, emotional numbness, intense guilt or worry, angry outbursts, feelings of anxiety, and avoiding thoughts and situations that are reminders of the trauma. The National Institute of Mental Health estimates that PTSD affects about 7.7 million American adults at some point during their lifetime.

## ***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, which is believed to translate into reductions in daytime pain. The Company's lead product candidate, TNX-102 SL, is a novel under-the-tongue tablet formulation of CBP, the active ingredient in two U.S. FDA-approved muscle relaxants, and is expected to enter a Phase 3 program in FM in early 2013. In a randomized, double-blind, placebo-controlled, eight-week Phase 2 trial, TONIX demonstrated that low-dose CBP given at bedtime resulted in a significant decrease in next-day pain and other core FM symptoms, as well as in a significant improvement in sleep quality. Legacy CBP products are widely used by FM patients, but are neither designed nor approved for this indication. TONIX is also exploring the utility of TNX-102 SL in a new treatment paradigm for PTSD.

To learn more about the Company, please visit [www.tonixpharma.com](http://www.tonixpharma.com).

*TNX-102 SL is an IND. A US IND relating to FM has been filed with the FDA. 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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