August 21, 2012

Tonix Pharmaceuticals Issues Letter to Shareholders

Tonix Makes Substantial Progress in the Development of Sublingual TNX-102 for the Treatment of Fibromyalgia

NEW YORK, NY -- (MARKETWIRE) -- 08/21/12 -- Tonix Pharmaceuticals Holding Corp. ("TONIX" or the "Company") (OTCQB: TNXP) (PINKSHEETS: TNXP) today announced that the following Letter to Shareholders will be posted today to the investor relations section of the Company's website at www.tonixpharma.com.

Shareholder Letter

To My Fellow Shareholders:

Tonix Pharmaceuticals Holding Corp. (TONIX) has made significant progress in nearly every aspect of its business since becoming a publicly-traded company in October 2011, and I am pleased to report on some of these corporate achievements in this letter.

TONIX's lead development candidate is TNX-102, a proprietary medication designed to be taken at bedtime for the chronic treatment of fibromyalgia. More specifically, TNX-102 targets sleep quality to reduce pain and other debilitating symptoms of fibromyalgia.

Fibromyalgia is a chronic pain disorder that affects approximately five million people in the United States (U.S.), most of whom (~90%) are women. We believe that TNX-102 will be a significant advancement in patient care and in the science and practice of medicine. Because many fibromyalgia patients remain unsatisfied with currently available medications, we also believe TNX-102 represents a significant commercial opportunity. The U.S. market for prescription drugs used to treat fibromyalgia is already approximately $1.4 billion annually, and has been growing at 18% per year since 2007.

We are developing TNX-102 as a sublingual (under-the-tongue, or SL) tablet, which we have named TNX-102 SL. The TNX-102 SL tablet is based on novel technology that rapidly delivers cyclobenzaprine into the body. The tablet quickly dissolves under the tongue and releases cyclobenzaprine, which is absorbed across the mucous membrane into the patient's bloodstream. The rapid absorption of TNX-102 SL is due to our tablet's proprietary design and formula. Patients cannot get the same rapid absorption simply by crushing existing cyclobenzaprine products and placing the powder under their tongues. Although we have evaluated other routes of delivering TNX-102, the SL formulation has become our lead and flagship program.

TONIX is also developing TNX-102 SL for the treatment of post-traumatic stress disorder

(PTSD). Like fibromyalgia patients, PTSD patients suffer from poor quality sleep and many have widespread pain. PTSD reportedly affects a significant number of U.S. soldiers who have been deployed in Afghanistan and Iraq. We hope to work with the U.S. Department of Defense on future clinical trials.

TNX-102 SL for FM and PTSD is designed for chronic bedtime use and targets sleep quality. By targeting sleep quality, we believe chronic treatment with sublingual bedtime cyclobenzaprine, a non-addictive medicine, can reduce pain in fibromyalgia and PTSD patients. In this way, TONIX will help reduce the use and abuse of prescription sleep medicines and pain killers. Currently available prescription sleep medicines increase the quantity, but not the quality of sleep.

Similar to the pain in fibromyalgia, PTSD pain originates in the brain, so prescription pain killers, including addictive opiates, are not effective in reducing it. Unfortunately, many patients wind up taking prescription opiates out of desperation and some become addicted. We believe that an effective, non-addictive alternative to opiates for these patients will improve their health and well-being.

I would like to highlight some of our recent corporate achievements below:

- ***Clinical progress with TNX-102 SL***

  TNX-102 SL is a small, rapidly dissolving tablet containing 2.4 mg of cyclobenzaprine for sublingual administration. Our clinical and preclinical studies provide support for TNX-102 SL to be an effective and well-tolerated therapy for fibromyalgia and also demonstrate a number of potentially beneficial characteristics compared with current cyclobenzaprine-containing products that are frequently used off-label to treat fibromyalgia. Much of the progress we have made has been reflected in a steady stream of recent TONIX news announcements.

  We have reported that the exposure to cyclobenzaprine over time provided by TNX-102 SL's formulation appears well matched to improving sleep quality following bedtime use. Compared with oral cyclobenzaprine, our proprietary sublingual formulation technology allows cyclobenzaprine to be taken up into the bloodstream more rapidly, particularly in the critical first hour of sleep.

  Just as important, we have shown that TNX-102 SL is metabolized differently in the body than oral cyclobenzaprine. Oral cyclobenzaprine is absorbed into the small intestine and transported directly to the liver where it is metabolized into norcyclobenzaprine in a process called "first-pass hepatic metabolism." Norcyclobenzaprine is a long-lived, psychoactive metabolite that we believe interferes with cyclobenzaprine's efficacy over time, potentially contributing to the reported decrease of benefit of oral cyclobenzaprine in fibromyalgia when taken chronically. In contrast, TNX-102 SL avoids first-pass hepatic metabolism to norcyclobenzaprine, so that its efficacy is expected to be durable.

  We believe these unique properties will translate into significant efficacy and tolerability advantages of TNX-102 SL in fibromyalgia patients, which we expect to demonstrate in our upcoming pivotal clinical trial program.

- ***Update on Phase 3 Plan for TNX-102 SL in Fibromyalgia***

  The favorable characteristics of TNX-102 SL support our selection of this candidate for advancement into a pivotal program to obtain U.S. Food and Drug Administration (FDA) approval in fibromyalgia. Based on data we have generated in past months, we performed a comprehensive review which refined the design of our planned pivotal Phase 3 program. In this review, we engaged thought leaders in fibromyalgia and clinical trial design. We have concluded this review, and I am pleased to describe our updated plans, which we believe will enable TONIX to accomplish the regulatory and commercial goals we have set with less time and expense than previously estimated.

  The TNX-102 SL pivotal program will feature two randomized, double-blind, placebo-controlled efficacy trials with treatment durations of 12 weeks and 24 weeks, conducted sequentially. The 24-week trial will contain the pre-defined primary endpoint of "pain" as well as pre-defined secondary endpoints that will assess the impact of TNX-102 SL on other established fibromyalgia measures. We believe that information learned from these secondary endpoints will be important for product labeling. The second pivotal trial is expected to commence in 2014, following the conclusion of the initial pivotal in late 2013.

  Although our prior plan was to conduct the 12-week pivotal trial with this full complement of efficacy analyses, following our recent review of the program, we have elected to focus that trial on "pain" as the sole pre-defined efficacy endpoint. Fibromyalgia is a pain syndrome, and pain is the critical symptom for a novel product to address. Based on the published results of our Phase 2a study, we plan to enroll 76 patients in our first pivotal study. We remain on track to initiate this 12-week trial in the first quarter of 2013 and expect to have results in late 2013.

- ***Intellectual Property Expansion***

  We continue to build our intellectual property portfolio on TNX-102 in fibromyalgia. TONIX already holds a "method of use" patent for bedtime dosing of cyclobenzaprine to treat fibromyalgia that provides protection into 2021. We have filed additional patent applications to protect TNX-102 SL and methods of using compositions containing it. We believe that the unique attributes of TNX-102 SL support a multi-tiered patent strategy that will provide TONIX market exclusivity for TNX-102 SL to the year 2033. TONIX is the sole owner of this intellectual property.

  The foundation of our patent strategy for TNX-102 SL is based on the surprising and unexpected findings observed in our preclinical and clinical studies with sublingual cyclobenzaprine. We believe that these results support claims to the pharmacokinetics and metabolic disposition of sublingual cyclobenzaprine and its use to treat fibromyalgia. Pharmacokinetics (PK)-based patent claims have proven difficult for generic companies to avoid or successfully challenge. For a generic drug to be approved by the FDA, the generic copy must demonstrate that it is a bioequivalent of the innovator drug. As a consequence, if the innovator's patent claims the PK profile of its drug, the generic bioequivalent copy would likely infringe the PK-based patent claim. For a generic company to challenge the validity of our patents, they would have

to prove by clear and convincing evidence that the subject matter of our patent claims, should they issue, which we believe they will, were either already known (prior art) or not disclosed or useful. We have no reason to believe that our intellectual property in the context of TNX-102 SL is vulnerable to a prior art, utility, or disclosure challenge. For these reasons, we believe that TONIX will enjoy substantial patent exclusivity for TNX-102 SL.

- ***Perspective on TNX-102 SL Commercial Opportunity in Fibromyalgia***

  With the continued evolution of both the payor environment and the fibromyalgia marketplace, we are currently updating our expectations on reimbursement potential and our market sales forecasts. To accomplish this we have engaged an experienced market consulting firm to investigate TNX-102 SL with the payor community and to forecast the sales potential of TNX-102 SL.

  Managed care views fibromyalgia as a high cost environment and is keenly interested in new solutions that would provide better therapeutic value, improve patients' lives, and reduce the total cost of care for these patients. Given the profile of TNX-102 SL, we believe that reimbursement will not pose a significant barrier to patient access to TNX-102 SL.

  Our work on positioning TNX-102 SL to managed care for favorable reimbursement is an ongoing process that will involve clinical trials specifically designed to demonstrate the value of TNX-102 SL relative to generic cyclobenzaprine. We believe comparator studies will show a superior tolerability profile that will support favorable reimbursement of TNX-102 SL.

  Ultimately, it may be possible to compare the benefit in long-term, chronic use since off-label generic cyclobenzaprine is known to lose effectiveness and tolerability over time. We expect to provide further detail on these plans in the coming months.

- ***Management and Board Additions***

  With the recruitments this past April of Leland Gershell, M.D., Ph.D. as Chief Financial Officer and Bruce Daugherty, Ph.D. as Senior Director of Drug Development, TONIX made two significant additions to its management team. A well-regarded Wall Street equity research analyst who has closely followed the biopharmaceutical industry for more than seven years, Dr. Gershell brings an extensive network of institutional investor relationships and public markets savvy to TONIX. He has already successfully managed SEC disclosure filings including two 10-Q's and one S-1 and has raised the visibility of TONIX within the investment community. Dr. Daugherty brings drug development expertise earned from his career in big pharmaceutical companies, with more than 20 years at Merck & Co. spanning multiple drug development and management roles. In his role at TONIX, Dr. Daugherty has already contributed to the advancement of our understanding of the therapeutic action of cyclobenzaprine in the brain.

  We also highlight the addition of Samuel Saks, M.D. to our Board of Directors in May. Among his numerous and significant accomplishments in the pharmaceutical industry,

Dr. Saks co-founded and served as CEO of Jazz Pharmaceuticals. At Jazz, Dr. Saks gained approval of sodium oxybate under the trade name of Xyrem® for narcolepsy-related conditions. Importantly, and of particular relevance to TONIX, Dr. Saks designed and led the effort to develop bedtime sodium oxybate under the trade name of Rekinla® for the management of fibromyalgia. Those studies included a Phase 3 program that revealed nightly sodium oxybate to improve sleep quality and demonstrated very significant clinical efficacy in fibromyalgia. After Dr. Saks left Jazz, the company announced it would stop seeking FDA approval for Rekinla in fibromyalgia for reasons unrelated to efficacy or commercial opportunity. Dr. Saks' pharmaceutical career has also included management positions at ALZA Corporation and service on the Board of Directors of Cougar Biotechnology. Both of these companies were acquired by Johnson & Johnson.

- ***News Coverage***

  TONIX has been active in disseminating the value proposition of our company via various media outlets. Please visit our website for links to interviews of our executives and coverage of TONIX by news outlets.

- ***Upcoming Milestones***

  We look forward to multiple upcoming events. In early October, we are meeting with officials at the FDA to discuss our PTSD program. In mid-October, we expect to receive more data from a human PK study of TNX-102 SL. Furthermore, in early November, we will be presenting data from our preclinical and clinical program of TNX-102 for fibromyalgia at the American College of Rheumatology's national meeting in Washington, D.C.

  Following the anticipated filing of our 2012 10-K, which is expected to be filed in March 2013, we plan to apply for listing on a national securities exchange, likely either NASDAQ or NYSE MKT.

  TONIX's continued success depends on your ongoing support, and we are grateful for your confidence in our mission. We are committed to delivering scientific and drug development progress that is intended to enhance the value of our company and reward you for your investment.

Sincerely,

Seth Lederman, M.D.

President and Chief Executive Officer

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. 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 candidate, sublingual TNX-102 for fibromyalgia 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 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.

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