December 20, 2023

Tonix Pharmaceuticals Announces Registered Direct Offering of up to $144 Million

Led by healthcare-focused institutional investors.

$30 million financing upfront with up to an additional $114 million tied to the exercise of warrants.

CHATHAM, N.J., Dec. 20, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that the Company has signed securities purchase agreements with certain healthcare-focused institutional investors that have agreed to provide up to $144 million in gross proceeds to Tonix through a registered direct offering that includes initial upfront funding of $30 million.

About the Registered Direct Offering

Pursuant to the securities purchase agreements, the Company has agreed to issue an aggregate of 54,054,054 shares of common stock (or prepaid warrants) and two series of registered warrants to purchase an aggregate of 162,162,162 shares of common stock for a purchase price of $0.555 per share and associated warrants (less $0.0001 in the case of prepaid warrants). The Series C warrants are exercisable at $0.555 per share and the Series D warrants are exercisable at $0.85 per share as follows:

- Series C warrants for an aggregate cash exercise price of approximately $45 million, exercisable until the earlier of two years from the initial exercisable date and 10 trading days following notice by the Company to the warrant holder of the Company's public announcement of the U.S. Food and Drug Administration's acknowledgement and acceptance of the Company's new drug application relating to TNX-102 SL in patients with Fibromyalgia;
- Series D warrants for an aggregate cash exercise price of approximately $69 million exercisable for five years from the initial exercisable date.

Neither the Series C nor the Series D warrants shall be exercisable until the Company receives shareholder approval authorizing the exercise of such warrants.

A.G.P./Alliance Global Partners is acting as the sole placement agent for the offering.

The closing of the offering is expected to occur on December 22, 2023, subject to customary closing conditions.

Tonix currently intends to use the net proceeds from the offering for the preparation of their new drug application relating to TNX-102 SL in patients with fibromyalgia, as well as working capital and general corporate purposes. For further information, please see the Company's current report on Form 8-K to be filed with the SEC.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix's development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), has completed two positive Phase 3 studies for the management of fibromyalgia. Tonix intends to meet with the FDA and submit an NDA for the approval of TNX-102 SL for the management of fibromyalgia in the second half of 2024. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition, and topline results were reported in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin) is being studied in binge eating disorder, pediatric obesity, bone health in autism and social anxiety disorder by academic collaborators under investigator-initiated INDs. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2024 Tonix's rare disease development portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology development portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases, including TNX-1800, in development as a vaccine to protect against COVID-19. During the fourth quarter of 2023, TNX-1800 was selected by the U.S. National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) Project NextGen for inclusion in Phase 1 clinical trials. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

** Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.*

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 including those relating to the completion of the offering, the satisfaction of customary closing conditions, the intended use of proceeds from the offering and other statement that are predictive in nature. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” 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, statements about the expected closing of the offering; anticipated gross proceeds from the offering; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. 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 for the year ended December 31, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2023, and periodic reports filed with the SEC on or after the date thereof. All of Tonix'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 thereof.

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