

February 20, 2024



## **Tonix Pharmaceuticals to Participate in the 2024 BIO CEO & Investor Conference**

CHATHAM, N.J., Feb. 20, 2024 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals, will present at the BIO CEO & Investor Conference on February 26, 2024 at 1:30 p.m. ET in New York City.

Investors interested in arranging a meeting with the Company's management during the conference can register on the BIO CEO & Investor Conference website [here](#).

### **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's development portfolio is focused on central nervous system disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA for Tonmya, which has completed two positive Phase 3 studies for the management of fibromyalgia. Tonix intends to meet with the FDA in the first half of 2024 and submit an NDA for the approval of Tonmya for the management of fibromyalgia in the second half of 2024. TNX-102 SL is being developed to reduce the severity of acute stress reaction and the frequency of acute stress disorder and posttraumatic stress disorder. This trial is being sponsored by the University of North Carolina and received funding support from the U.S. Department of Defense. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition, and topline results from a proof-of-concept study were reported in the third quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA and received funding from the National Institute on Drug Abuse (NIDA). 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 (PWS). TNX-2900 has been granted Orphan Drug designation by the FDA and an investigational new drug (IND) application has been cleared to support a Phase 2 study in PWS patients. 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 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 product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

## **Forward Looking Statements**

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," "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, 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.

## **Investor Contact**

Jessica Morris  
Tonix Pharmaceuticals  
[investor.relations@tonixpharma.com](mailto:investor.relations@tonixpharma.com)  
(862) 904-8182

Peter Vozzo  
ICR Westwicke  
[peter.vozzo@westwicke.com](mailto:peter.vozzo@westwicke.com)  
(443) 213-0505

**Media Contact**

Ben Shannon  
ICR Westwicke  
[ben.shannon@westwicke.com](mailto:ben.shannon@westwicke.com)  
443-213-0495



Source: Tonix Pharmaceuticals Holding Corp.