February 2, 2023

# Tonix Pharmaceuticals Announces Acquisition of Preclinical Infectious Disease Portfolio from Healion Bio, Inc.

*The Acquired Portfolio of Infectious Disease Assets Includes a Class of Potential Broad Spectrum Oral Antiviral Agents, TNX-3900 with a Host-Directed Mechanism*

*Tonix Plans to Develop the TNX-3900 Series of Molecules as Oral Antivirals Either as Monotherapy or in Combination with Other Antivirals*

*The TNX-3900 Class of Antivirals Has a Novel Mechanism of Action Based on Inhibition of Certain Cathepsin Proteases which are Required for Cell Infection by Many Viruses like SARS-CoV-2*

*Sina Bavari, Ph.D., Tonix EVP of Infectious Disease R&D and Director of the Frederick, MD Research and Development Center (RDC) was a Scientific Founder of Healion Bio, Inc.*

CHATHAM, N.J., Feb. 02, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby Tonix has acquired all of the assets of Healion Bio, Inc. (Healion) including its entire portfolio of next-generation antiviral technology assets. Healion's drug portfolio includes a class of broad-spectrum small molecule oral antiviral drug candidates with a novel host-directed mechanism of action. Host-directed antivirals modulate human cells and tissues and are different from direct-acting antivirals which inhibit virus proteins and processes. Tonix's TNX-3900, formerly known as HB-121, are cathepsin protease inhibitors, some of which have strong activity *in vitro* against SARS-CoV-2.

"We are excited to develop Healion's drug programs that include TNX-3900, which is a class of drugs with potential broad spectrum anti-viral activity, either as monotherapies or in combination with other antivirals", said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Broad-spectrum antiviral agents have the potential to reduce viral load and allow the adaptive immune system to alert the other arms of the immune system to mount a protective response. Examples of other classes of host-directed antivirals that have been approved by the U.S. Food and Drug Administration (FDA) include alpha interferon like Pegasys® (peginterferon alfa-2a) for viral hepatitis, the CCR5 antagonist Selzentry® (maraviroc) for HIV, and the anti-IL-6 receptor antagonist monoclonal antibody Actemra® (tocilizumab) for COVID-19."

Sina Bavari, Ph.D., Executive Vice President for Infectious Disease Research at Tonix said, "I am pleased to be reunited with the infectious disease assets of Healion, since I was the scientific founder of Healion after I retired from my position as Chief of R&D at the United States Army Medical Research Institute of Infectious Disease (USAMRIID). While Healion

made some progress developing these advanced technologies, Tonix's state-of-the art facilities and depth of drug development expertise have the potential to advance the TNX-3900 class of drugs into clinical trials. On behalf of the talented scientific team that I direct at our 48,000 square-foot cutting-edge infectious disease research facility in Frederick, Md., I am pleased to add this technology to the therapeutic development programs underway."

**About TNX-3900**

TNX-3900 is the term for a series of molecules that inhibit essential cathepsins which are required by viruses such as coronaviruses and filoviruses to infect cells. Because of the unique antiviral mechanism of these compounds, the Company believes they can potentiate the activity of other antivirals with differing mechanisms. The Company believes this makes cathepsin inhibitors suitable for combination therapy.

**Tonix Pharmaceuticals Holding Corp.***

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022. 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 second quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the first quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023. Tonix's rare disease 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 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 and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second quarter of 2023. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801, a next-generation vaccine to prevent COVID-19, TNX-1850, a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600, and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800, recently licensed from Curia. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the second half of 2023.

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

This press release and further information about Tonix can be found at 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; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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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