

November 8, 2021



# Tonix Pharmaceuticals Reports Third Quarter 2021 Financial Results and Operational Highlights

*Expansion of Internal Research and Development Capabilities Underway to Accelerate Infectious Disease Programs and Prepare for Future Pandemic Responses*

*COVID-19 Pipeline Progressing with First-in-Human Trial of TNX-2100 Novel Skin Test for SARS-CoV-2 Functional T cell Immunity Expected to Start this Quarter*

*Phase 2 Trial of TNX-1300 in Cocaine Intoxication Expected to Start this Quarter*

*At September 30, 2021, Cash and Cash Equivalents Totaled Approximately \$183 Million*

CHATHAM, N.J., Nov. 08, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2021 and provided an overview of recent operational highlights.

“Our new infectious disease Research and Development Center (RDC) in Frederick, Md. is operational, and we have begun the build-out of our Advanced Development Center (ADC) in the New Bedford, Mass. Business Park -- two important milestones in our goal to becoming a leading innovator and manufacturer of vaccines, therapeutics and diagnostics for infectious diseases,” said Seth Lederman, MD, President and CEO of Tonix.

“The facilities are designed to accelerate our current COVID-19 programs and provide us with the internal resources and capabilities to develop a broad-based infectious disease portfolio, including live virus vaccines and skin test diagnostics that specifically target new pathogens within the rapid response timeframe set forth in the American Pandemic Preparedness Plan, or AP3,” he added.

AP3, which was recently released by the White House’s U.S. Office of Science and Technology Policy calls for strengthening the nation’s pandemic and biowarfare defenses, including the capability to develop vaccines against new pathogens within 100 days of the pathogen’s sequence becoming available. This 100-day goal is a key component of preparedness for future pandemics. Tonix believes its new RDC and ADC will provide the capabilities to help address this need. The Company is also planning a Commercial Manufacturing Center (CMC) in Hamilton, Mont. to produce clinical-scale live virus vaccines and potentially other products for pandemic responses.

Dr. Lederman said, “Our portfolio of COVID-19 programs continues to advance. The COVID-19 portfolio currently includes a live virus vaccine candidate based on our recombinant pox

virus (RPV) platform, a diagnostic skin test to measure functional T cell immunity, and therapeutic candidates for acute COVID-19 and Long COVID. We expect first-in-human testing of our SARS-CoV-2 diagnostic to measure T cell immunity to begin before year end, followed by the anticipated start of a Phase 2 trial in Long COVID and a Phase 1 trial for our T cell inducing vaccine in 2022.”

As part of its infectious disease research and development programs, in the third quarter of 2021 Tonix expanded its research collaboration with Columbia University to better understand immune responses to SARS-CoV-2 in healthy individuals who have recovered from COVID-19. This work is expected to provide a foundation for tailoring vaccines and therapeutics to appropriate individuals with precision medicine.

Dr. Lederman added, “The Company’s clinical calendar for our pipeline of central nervous system candidates includes the anticipated start this quarter of a Phase 2 trial of TNX-1300, an emergency antidote for cocaine intoxication, and the anticipated start of three additional Phase 2 studies in 2022, including TNX-601 CR in major depressive disorder, TNX-102 SL in posttraumatic stress disorder, and TNX-1900 in the prophylactic treatment of chronic migraine.”

### **Recent Highlights—Facilities and Corporate**

- In October 2021, Tonix held a ribbon-cutting ceremony at the Company’s 48,000 square foot research and development center (RDC) in Frederick, Md., which is expected to provide internal capacity to discover and develop vaccines and antiviral drugs against COVID-19, its variants, and other infectious diseases. The ceremony was attended by federal, state and local officials, including U.S. Senator for Maryland Ben Cardin, U. S. Congressman David Trone representing Maryland’s 6<sup>th</sup> Congressional District, Nan Mann representing U.S. Senator Chris Van Hollen, Maryland Department of Commerce Representatives Heather Gramm and Tamar Osterman, Maryland State Delegates Karen Lewis-Young and Kenneth Kerr, Frederick County Executive Jan Gardner, Frederick County Office of Economic Director Helen Propheter, the City of Frederick Mayor Michael O’Connor and the City of Frederick Director of Economic Development Richard Griffin. The center is operational with a dedicated staff of scientists and technicians. The main building was constructed as a biosafety level (BSL) -3 facility but has been operating at BSL-2. Tonix plans to make appropriate upgrades and seek certification for BSL-3 so that research may be conducted on live SARS-CoV-2 and other pathogens.
- In August 2021, Tonix announced that it commenced construction on its Advanced Development Center (ADC) for the development and manufacturing of Good Manufacturing Practice or GMP live-virus vaccines to support Phase 1 and 2 clinical trials. The facility, located in New Bedford, Mass., is planned to be BSL-2 and expected to be operational in the first half of 2022. A groundbreaking ceremony held August 3, 2021 was attended by federal, state and local officials, including U.S. Representative Bill Keating, Massachusetts Housing and Economic Development Secretary Mike Kennealy and New Bedford Mayor Jon Mitchell.
- Tonix also intends to build a Commercial Manufacturing Center (CMC) in Hamilton, Mont. where it purchased approximately 44 acres of land. The CMC will focus on developing and manufacturing commercial scale live-virus vaccines and is also

intended to be BSL-2. Construction is expected to be initiated for the CMC in 2022. Together, the Company expects these three facilities may qualify the RPV platform for programs that are designed to carry out the goals of AP3.

### **Highlights—Key Product Candidates\***

#### *COVID-19 Pipeline*

*TNX-1800 (live virus vaccine based on Tonix's recombinant pox virus vector): COVID-19 vaccine designed as a single-administration vaccine to elicit T cell immunity*

- In March 2021, positive efficacy results from a study of TNX-1800 in which non-human primates were vaccinated with TNX-1800 and challenged with live SARS-CoV-2 were reported. TNX-1800 was found to induce protection against infection in the upper airway, which suggests an ability to inhibit forward transmission. Tonix has completed a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) and expects to begin a Phase 1 study using TNX-1800 in humans in the second half of 2022.

*TNX-2100 (diagnostic skin test): SARS-CoV-2 epitope peptide mixtures for intradermal administration to measure the delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2*

- Tonix expects to initiate a first-in-human clinical study in the fourth quarter of 2021. TNX-2100, designed to measure functional *in vivo* T cell immunity to SARS-CoV-2, is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130). Tonix's proposed skin test has the potential to serve as: 1) a biomarker for cellular (T-cell mediated) immunity and protective immunity; 2) a method to stratify participants in COVID-19 vaccine trials by immune status; 3) an endpoint in COVID-19 vaccine trials, and 4) a biomarker of durability of vaccine protection.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets): small molecule for the treatment of Long COVID Syndrome or Post-Acute Sequelae of COVID-19 (PASC)*

- Tonix has completed a pre-IND meeting with the FDA and intends to initiate a Phase 2 study in patients with Long Covid in the first half of 2022 following IND clearance.

*TNX-3500 (sangivamycin): antiviral inhibitor of SARS-CoV-2 for the treatment of COVID-19 and potential other viral disorders*

- Tonix intends to conduct further nonclinical animal studies prior to submitting an IND and initiating a Phase 1 study.

#### *Immunology Pipeline*

*TNX-1500 (anti-CD154 monoclonal antibody): third generation monoclonal antibody as first line monotherapy for preventing or treating organ transplant rejection and treating autoimmune disorders.*

- Tonix expects to start a Phase 1 study in the second half of 2022. Preliminary results from an ongoing experiment in heart transplants indicated that TNX-1500 appeared to have comparable efficacy to historical experiments using the chimeric mouse-primate

anti-CD40L monoclonal antibody based on mu5c8 and no evidence of thrombosis has been observed.

#### *Central Nervous System (CNS) Pipeline*

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets): small molecule for the management of fibromyalgia*

- The positive Phase 3 study, called RELIEF, achieved statistical significance on the primary endpoint in December, 2020. Tonix initiated a second Phase 3 study, RALLY in September 2020. Based on disappointing efficacy results at the interim analysis of RALLY in July 2021, the Company stopped enrolling new participants. Topline results from RALLY are expected before the end of 2021. The Company will determine the next steps in this program based on analysis of the RALLY data, which will include pharmacogenomic analyses of RALLY and RELIEF.

*TNX-102 SL for the treatment of Posttraumatic Stress Disorder (PTSD)*

- Tonix completed a meeting with the FDA to discuss potential new endpoints for the indication of treatment of PTSD, and expects to begin enrolling a Phase 2 study of TNX-102 SL in police in Kenya in the first quarter of 2022.

*TNX-1300 (recombinant double mutant cocaine esterase): biologic for life-threatening cocaine intoxication*

- Tonix expects to initiate a Phase 2 open-label safety study in an emergency department setting to study TNX-1300 in the fourth quarter of 2021. Results of a positive Phase 2 study of volunteer cocaine users in a controlled laboratory setting were reported prior to Tonix licensing the technology. TNX-1300 has been granted Breakthrough Therapy designation (BTD) by the FDA.

*TNX-601 CR (tianeptine oxalate and naloxone controlled-release tablets): small molecule for the treatment of major depressive disorder, PTSD and neurocognitive dysfunction associated with corticosteroid use.*

- Tonix previously completed a Phase 1 trial for formulation development outside of the U.S. Based on official minutes from a pre-IND meeting with the FDA, the Company expects to initiate a Phase 2 study for the treatment of depression in the first half of 2022.

*TNX-1900 (intranasal potentiated oxytocin): small peptide for migraine, craniofacial pain, insulin resistance and related disorders*

- Tonix intends to initiate a Phase 2 study of TNX-1900 for the prophylactic treatment of chronic migraine in the U.S. in the second half of 2022. A Phase 2 trial under an investigator-initiated IND was completed in the U.S. using the TNX-1900 formulation prior to Tonix's acquisition of the program.

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

## Recent Highlights--Financial

As of September 30, 2021, Tonix had \$183.0 million of cash and cash equivalents, compared to \$77.1 million as of December 31, 2020. Cash used in operations was approximately \$12.9 million for the three months ended September 30, 2021, compared to \$15.3 million for the three months ended September 30, 2020.

### Third Quarter 2021 Financial Results

R&D expenses for the third quarter of 2021 were \$13.1 million, compared to \$8.8 million for the same period in 2020. This increase is predominately due to increased manufacturing expenses of \$1.8 million, non-clinical expenses of \$1.6 million, employee-related expenses of \$1.0 million and regulatory/legal expenses of \$0.6 million offset by a decrease in clinical expenses of \$0.7 million.

G&A expenses for the third quarter of 2021 were \$5.5 million, compared to \$3.2 million for the same period in 2020. The increase is primarily due to an increase in employee-related expenses of \$1.3 million.

Net loss available to common stockholders was \$18.5 million, or \$0.05 per share, basic and diluted, for the third quarter of 2021, compared to net loss of \$12.0 million, or \$0.09 per share, basic and diluted, for the third quarter of 2020. The basic and diluted weighted average common shares outstanding for the third quarter of 2021 was 366,425,157, compared to 127,199,834 shares for the third quarter of 2020.

### About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. The Company'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<sup>1</sup> (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300<sup>2</sup> is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800<sup>3</sup>, is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is developing TNX-2100<sup>4</sup>, an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study in the fourth quarter of 2021, pending IND clearance. TNX-3500<sup>5</sup> (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

<sup>1</sup>*TNX-102 SL is an investigational new drug and has not been approved for any indication.*

<sup>2</sup>*TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

<sup>3</sup>*TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.*

<sup>4</sup>*TNX-2100 is an investigational new biologic and has not been approved for any indication*

<sup>5</sup>*TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.*

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, the risks related to the operation of research and manufacturing facilities, risks related to 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, 2020, as filed with the Securities and Exchange Commission (the “SEC”) on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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.

**TONIX PHARMACEUTICALS HOLDING CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In Thousands, Except Share and Per Share Amounts)**  
**(unaudited)**



Stockholders' equity

Total liabilities and stockholders' equity

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\$

<sup>1</sup>The condensed consolidated balance sheets for the year ended December 31, 2020 has been derived from the audited financial statements but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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