August 9, 2021

Tonix Pharmaceuticals Reports Second Quarter 2021 Financial Results and Operational Highlights

Central Nervous System Pipeline Progressing with Two Phase 2 Studies (TNX-1300 and TNX-1900) and One Phase 3 Study (TNX-102 SL) Expected to Start This Year

COVID-19 Pipeline Progressing with First-in-Human Trial of TNX-2100, a Novel in vivo Skin Test for COVID-19 T cell Immunity, Expected to Start This Year

New Advanced Development Center, Currently Under Construction, and Planned Acquisition of Infectious Disease R&D Facility Will Expand Internal R&D and Manufacturing Capabilities for Vaccines and Antiviral Therapeutics, With Initial Focus on COVID-19

At June 30, 2021, Cash and Cash Equivalents Totaled Approximately $166 Million

CHATHAM, N.J., Aug. 09, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the second quarter ended June 30, 2021 and provided an overview of recent operational highlights.

“Our clinical, manufacturing, and regulatory teams are advancing four programs into clinical trials by the end of 2021,” said Seth Lederman, M.D., President and Chief Executive Officer. “We look forward to initiating Phase 2 studies of TNX-1300 for cocaine intoxication and TNX-1900 for chronic migraine in the third and fourth quarters of 2021, respectively. We also expect to initiate a Phase 3 study of TNX-102 SL for PTSD outside of the U.S. and a first-in-human study of TNX-2100, a skin test diagnostic for COVID-19 T cell immunity, in the fourth quarter of 2021.”

Dr. Lederman continued, “We are expanding our R&D and manufacturing facilities. In July we announced an agreement to acquire an infectious disease research facility in Frederick, MD, and earlier this month we began construction on our Advanced Development Center (ADC) in New Bedford MA. We expect these facilities, coupled with our planned commercial scale manufacturing facility for vaccines in Hamilton, MT, will enable us to avoid future outsourcing bottlenecks and to work with greater efficiency in developing our programs for COVID-19, its variants, and other infectious diseases.”

Dr. Lederman added, “Recent reports of COVID-19 outbreaks in the U.S. and elsewhere, due primarily to the Delta variant, point to the urgent needs for more robust vaccines and more potent antiviral therapeutics. We believe the recent steps we have taken to strengthen our internal capabilities with company-controlled R&D and manufacturing facilities will accelerate our full pipeline of COVID-19 product candidates, which currently includes the

TNX-1800 vaccine, TNX-3500 antiviral, TNX-2100 diagnostic, and TNX-102 SL for treating Long COVID."

Recent Highlights—Key Product Candidates*

Central Nervous System (CNS) Pipeline

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

- In July 2021, Tonix announced that the RALLY study, the second Phase 3 trial of TNX-102 SL 5.6 mg for fibromyalgia, stopped enrolling new participants following recommendation from a pre-planned interim analysis by the Independent Data Monitoring Committee (IDMC). Based on interim analysis results of the first 50% of targeted participants (n=337), the IDMC recommended stopping the trial for futility as TNX-102 SL was unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in daily diary pain severity scores between those treated with TNX-102 SL 5.6 mg (2x 2.8 mg tablets) and those receiving placebo. Tonix remains blinded to the detailed interim analysis results and only received the recommendation made by the IDMC. Preliminary blinded safety data from these participants did not reveal any new safety signals, and the decision to discontinue enrolling new participants is not related to safety. The Company intends to continue studying those participants currently enrolled until completion and then proceed with a full analysis of the unblinded data, with the topline results expected to be reported in the fourth quarter of 2021, to determine the next steps in this program.

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

- Tonix intends to meet with the U.S. Food and Drug Administration (FDA) to discuss potential new endpoints for the indication of treatment of PTSD in the third quarter of 2021. The Company also expects to begin enrolling a Phase 3 study of TNX-102 SL in police in Kenya in the fourth quarter of 2021.

TNX-102 SL for the treatment of Long COVID Syndrome or Post-Acute Sequelae of COVID-19 (PASC)

- The Company met with the FDA in the third quarter of 2021 to seek agreement on the design of a potential Phase 2 pivotal study and the overall clinical development plan for TNX-102 SL as an indicated treatment for Long COVID. Tonix expects to receive official minutes from this meeting in the third quarter of 2021.

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 third quarter of 2021. Cocaine esterase is the most potent known catalyst for cocaine degradation. 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-1900 (intranasal potentiated oxytocin): small peptide for migraine, craniofacial pain,

insulin resistance and related disorders

- Tonix intends to submit an Investigational New Drug (IND) application to the FDA in the third quarter of 2021 and is targeting to start a Phase 2 study of TNX-1900 for the prophylactic treatment of chronic migraine in the U.S. in the fourth quarter of 2021. 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.

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, pending results of nonclinical toxicology studies and IND clearance.

COVID-19 Pipeline

TNX-1800 (live virus vaccine based on Tonix's horsepox virus vector, TNX-801): COVID-19 vaccine designed as a single-administration vaccine to elicit T cell immunity

- A Phase 1 safety study using TNX-1800 in humans is anticipated to start in the first half of 2022, pending IND clearance from the FDA and the production of cGMP material. 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 both upper and lower airways, which suggests an ability to inhibit forward transmission. The Company believes these findings also demonstrate the flexibility of the horsepox vaccine platform, and its capability to be engineered to construct new vaccines to protect against other diseases of interest in military and civilian populations.

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

- In April 2021, Tonix entered into an exclusive worldwide licensing agreement with OyaGen, Inc. to develop TNX-3500 (sangivamycin, formerly OYA1) for the treatment of COVID-19 and potentially other viral disorders. It has demonstrated broad-spectrum activity in laboratory-based assays against the coronaviruses SARS-CoV-2 and

MERS-CoV. 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. In experiments at the Massachusetts General Hospital, a teaching hospital of Harvard Medical School, TNX-1500 product candidate is being studied as monotherapy or in combination with mycophenolate mofetil in heart and kidney organ transplants in non-human primates. 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-human anti-CD40L monoclonal antibody (mAb) hu5c8 and no evidence of thrombosis has been observed.

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

Recent Highlights—Facilities and Corporate

- In August 2021, Tonix announced that it has 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 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 local, state, and federal officials, including U.S. Representative Bill Keating, Massachusetts Housing and Economic Development Secretary Mike Kennealy and New Bedford Mayor Jon Mitchell.

- In July 2021, Tonix entered into a contingent non-binding Purchase and Sales Agreement in connection with an infectious disease R&D facility in Maryland, 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 BSL-2 facility, currently owned and operated by Tonix partner Southern Research, has housed research relating to Tonix's COVID-19 vaccine candidate, TNX-1800, and to Tonix's smallpox and monkeypox candidate, TNX-801. Tonix expects the transaction to close in the fourth quarter of 2021.

- In June 2021, Tonix announced that plans were advancing to construct a commercial-scale manufacturing facility to develop and manufacture vaccines in Hamilton, Montana. Construction on the greenfield site is expected to start in 2022.

- Tonix announced its addition to both the broad-market Russell 3000® index and the small-cap Russell 2000® Index as part of the annual reconstitution of the Russell stock indexes, which was effective after the market opened on June 28, 2021. Russell indexes are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies.

- In July 2021, Tonix announced the appointment to its Board of Directors of Carolyn E. Taylor, who brings over 35 years of experience in corporate law, including 15 years as a partner at Covington & Burling LLP and six years as general counsel of two start-up companies.

Recent Highlights--Financial

As of June 30, 2021, Tonix had $165.7 million of cash and cash equivalents, compared to $77.1 million as of December 31, 2020.

Cash used in operations was approximately $19.1 million for the three months ended June 30, 2021, compared to $10.1 million for the three months ended June 30, 2020. The increase in cash used in operations resulted primarily from an increase in research and development programs and general and administrative activities as defined below.

Second Quarter 2021 Financial Results

Research and development expenses for the second quarter of 2021 were $18.1 million, compared to $10.6 million for the same period in 2020. This increase is predominately due to increased non-clinical expenses of $7.1 million, manufacturing expenses of $2.7 million, employee-related expenses of $1.2 million and regulatory/legal expenses of $0.4 million offset by a decrease in clinical expenses of $4.1 million. We expect research and development expenses to increase during 2021 as we move our clinical development programs forward and continue to invest in our development pipeline.

General and administrative expenses for the second quarter of 2021 were $5.4 million, compared to $3.6 million for the same period in 2020. The increase is primarily due to an increase in employee-related expenses of $1.1 million, an increase in investor relations/public relations expenses of $0.2 million, an increase in financial reporting expenses of $0.2 million and an increase in insurance premiums of $0.2 million.

Net loss available to common stockholders was $23.6 million, or $0.07 per share, basic and diluted, for the second quarter of 2021, compared to net loss of $14.2 million, or $0.23 per share, basic and diluted, for the second quarter of 2020. The basic and diluted weighted average common shares outstanding for the second quarter of 2021 was 331,281,242, compared to 62,391,006 shares for the second quarter of 2020.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. 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[1], is in mid-Phase 3 development for the management of fibromyalgia. Tonix's immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800[2], is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix reported positive efficacy data from animal studies of TNX-1800 in the first

quarter of 2021. TNX-801[2], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox. TNX-3500[3] (sangivamycin) is a small molecule antiviral drug in the pre-IND stage of development.

[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.
[2]TNX-1800 and TNX-801 are investigational new biologicsat the pre-IND stage of development and have not been approved for any indication.
[3]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.

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 development of R&D 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**

COSTS AND EXPENSES:				
Research and development	$ 18,133	$ 10,571	$ 33,460	$ 15,247
General and administrative	5,429	3,621	10,838	6,242
	23,562	14,192	44,298	21,489
Operating Loss	(23,562)	(14,192)	(44,298)	(21,489)
Interest and other income, net	9	13	92	37
Net loss	(23,553)	(14,179)	(44,206)	(21,452)
Warrant deemed dividend	—	—	—	451
Preferred stock deemed dividend	—	—	—	1,260
Net loss available to common stockholders	$ (23,553)	$ (14,179)	$ (44,206)	$ (23,163)
Net loss per common share, basic and diluted	$ (0.07)	$ (0.23)	$ (0.14)	$ (0.54)
Weighted average common shares outstanding, basic and diluted	331,281,242	62,391,006	310,807,619	43,209,988

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	June 30, 2021	December 31, 2020[1]
Assets		
Cash and cash equivalents	$165,719	$77,068
Prepaid expenses and other	11,550	10,921
Total current assets	177,269	87,989
Other non-current assets	11,896	10,194
Total assets	$189,165	$98,183
Liabilities and stockholders' equity		
Total liabilities	$8,672	$10,535
Stockholders' equity	180,493	87,648

Total liabilities and stockholders' equity	$189,165	$98,183

[1]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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Source: Tonix Pharmaceuticals Holding Corp.