August 8, 2022

Tonix Pharmaceuticals Reports Second Quarter 2022 Financial Results and Operational Highlights

Phase 1 Study of TNX-801, a Vaccine in Development for the Prevention of Monkeypox and Smallpox, Expected to Initiate in First Half 2023 in Kenya; the U.S. has Declared Monkeypox a Public Health Emergency

U.S. National Institute of Drug Abuse (NIDA) Grant Awarded for the Development of TNX-1300 for Cocaine Intoxication; Phase 2 Study of TNX-1300 Expected to Initiate in Fourth Quarter 2022

Advanced Development Center in Dartmouth, Mass. is Open and Expected to Imminently Conduct Process Development and Clinical Trial Manufacturing of Live-Virus Vaccines

Cash and Cash Equivalents Totaled Approximately $145 Million at June 30, 2022

CHATHAM, N.J., Aug. 08, 2022 (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, 2022, and provided an overview of recent operational highlights.

“The rapidly expanding outbreaks of monkeypox in the U.S. and approximately 80 other countries outside of Africa have brought attention to our work on a novel monkeypox vaccine, TNX-801, which has already been shown to protect non-human primates against a challenge with lethal doses of monkeypox. The U.S. has declared monkeypox a public health emergency. In addition, we are excited by the many opportunities ahead for our pipeline of CNS, rare disease, immunology and infectious disease product candidates,” said Seth Lederman, M.D., Chief Executive Officer of Tonix. “We are on track to have four CNS programs in the clinic by the end of 2022, including our most advanced program, TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for fibromyalgia, which is in mid-Phase 3 development, Phase 2 studies of TNX-102 SL for Long COVID and PTSD and a Phase 2 study of TNX-1300 for cocaine intoxication.”

Recent Highlights—Key Product Candidates*

Infectious Disease Pipeline

TNX-801 (live horsepox virus vaccine for percutaneous administration): vaccine against smallpox and monkeypox designed as a single-administration vaccine to elicit T cell immunity

- In July 2022, Tonix announced a collaboration with the Kenya Medical Research Institute (KEMRI) to plan, seek regulatory approval for and conduct a Phase 1 clinical study in Kenya to develop TNX-801 as a vaccine to protect against monkeypox and smallpox. The study is expected to start in the first half of 2023.
- Tonix presented data from a research collaboration with The University of Alberta in a poster presentation at the 4th Symposium of the Canadian Society for Virology. The poster titled, "Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox," describes data from animals vaccinated with TNX-801 to protect against monkeypox. The poster presentation reports that all animals (n=8) vaccinated with TNX-801 were fully protected with sterilizing immunity from a challenge with intra-tracheal monkeypox. The vaccinations with TNX-801 were well tolerated. Synthetic horsepox virus is the basis for the Company's TNX-801 vaccine in development to protect against monkeypox and smallpox and for the Company's Recombinant Pox Virus (RPV) platform to protect against other pathogens, including SARS-CoV-2.
- Tonix announced the issuance of U.S. Patent for TNX-801 smallpox and monkeypox vaccine and Recombinant Pox Virus (RPV) platform technology. This patent is expected to provide Tonix with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments.

TNX-1850 (live virus vaccine based on Tonix's recombinant pox virus vector): COVID-19 vaccine designed as single-administration vaccine to elicit T cell immunity

- Tonix announced the issuance of U.S. Patent for TNX-801 smallpox and monkeypox vaccine and Recombinant Pox Virus (RPV) platform technology (TNX-1850). This patent is expected to provide Tonix with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments.

TNX-2300: Live virus vaccine based on a bovine parainfluenza virus vector to protect against COVID-19

- In April 2022, Tonix extended a sponsored research agreement with Kansas State University to develop a vaccine candidate, TNX-2300, for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform based on bovine parainfluenza virus. The efficacy of co-expression of the CD40-ligand, also known as CD154, to stimulate T cell immunity will also be tested.
- Attenuated bovine parainfluenza virus has previously been shown to be an effective antigen delivery vector in humans. Notably and most importantly, following extensive testing in non-human primates, the attenuated BPI3V was shown to be well tolerated, infectious, immunogenic, and stable in infants and children. The vector is well suited for mucosal immunization using a nasal atomizer, but it can also be delivered parenterally.

Central Nervous System (CNS) Pipeline

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

- Enrollment continues in the RESILIENT study, a double-blind, randomized, placebo-controlled, potentially pivotal Phase 3 study of TNX-102 SL for the management of

fibromyalgia. The two-arm trial is expected to enroll approximately 470 participants in the U.S. Results from a planned interim analysis are expected in the first quarter of 2023.

TNX-102 SL for the treatment of Long COVID, also known as Post-Acute Sequelae of COVID-19 (PASC)

- The Company continues to expect to start a Phase 2 clinical study with TNX-102 SL as a potential treatment for a subset of patients with Long COVID with multi-site pain in the third quarter of 2022.
- As previously announced, the results of a retrospective observational database study of over 50,000 adult U.S. patients with Long COVID showed that over 40% of patients had fibromyalgia-like multi-site pain. These findings support the feasibility of the planned Phase 2 study which will enroll Long COVID patients with multi-site pain.

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

- Tonix expects to begin enrolling a Phase 2 study of TNX-102 SL in police in Kenya in the third quarter of 2022.

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

- In August 2022, Tonix announced that it received a Cooperative Agreement grant from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), to support development of TNX-1300.
- The Company expects to initiate a new Phase 2 clinical study of TNX-1300 for the treatment of cocaine intoxication in the fourth quarter of 2022, pending agreement with the U.S. Food and Drug Administration (FDA). The Phase 2 trial, which has the potential to be a pivotal study, is a single-blind, open-label, placebo-controlled, randomized study comparing the safety of a single 200 mg dose of TNX-1300 to standard of care alone in approximately 60 emergency department patients presenting with cocaine intoxication.
- A positive Phase 2a study of volunteer cocaine users in a controlled laboratory setting has been previously completed. TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

TNX-1900 (intranasal potentiated oxytocin): small peptide for migraine, craniofacial pain, insulin resistance and related disorders, and obesity associated binge eating disorder

- Tonix announced that U.S. Patent 11,389,473 issued in July 2022. The patent, entitled "Magnesium-Containing Oxytocin Formulations and Methods of Use" claims methods and compositions for treating pain, including migraine headaches, using intranasal magnesium-containing oxytocin formulations. This patent, excluding possible patent term extensions, is expected to provide Tonix with U.S. market exclusivity until January 2036.
- Tonix announced the publication of a paper, entitled "Impact of Magnesium on Oxytocin Receptor Function," in the journal *Pharmaceutics*, that described results from a research team led by Professor David Yeomans. The paper includes data showing the enhancing effects of magnesium (Mg^{2+}) on the activity of intranasal oxytocin in an

animal model of craniofacial pain. The Mg^{2+} potentiated formulation of intranasal oxytocin is the basis for the Company's TNX-1900 drug candidate in development to prevent migraine headaches in chronic migraineurs. Professor Yeomans was the scientific founder of Trigemina, Inc. from which Tonix acquired rights to the Mg^{2+}potentiated oxytocin technology. The potential clinical significance of these observations is that the formulation of oxytocin plus Mg^{2+} in Tonix's TNX-1900 has the potential to enhance oxytocin efficacy for pain as well as for other uses.
- The Company expects to begin enrollment in a Phase 2 study of TNX-1900 for the prevention of migraine headache in chronic migraineurs the first half of 2023.

TNX-601 ER (tianeptine hemioxalate extended-release tablets): small molecule for the treatment of major depressive disorder (MDD), PTSD, and neurocognitive dysfunction associated with corticosteroid use.

- In July 2022, Tonix announced development of a new extended release formulation of TNX-601, for the treatment of MDD. Tonix expects to initiate a Phase 2 study of TNX-601 ER for the treatment of MDD in the first quarter of 2023, pending FDA clearance of its Investigational New Drug (IND) application.

Rare Disease Pipeline

TNX-2900 (intranasal potentiated oxytocin): small peptide for the treatment of Prader-Willi syndrome (PWS)

- Tonix delivered a presentation titled, "TNX-2900 (Intranasal Oxytocin + Magnesium) in Development for the Treatment of Hyperphagia in Adolescents and Young Adults with Prader-Willi Syndrome" at the World Orphan Drug Congress USA in July 2022.
- TNX-2900 has received Orphan Drug designation from the FDA for the treatment of PWS.

Immunology Pipeline

TNX-1500 (anti-CD40L monoclonal antibody): third generation monoclonal antibody for prophylaxis of organ transplant rejection and treatment of autoimmune disorders.

- Tonix announced data from three oral presentations at the 2022 American Transplant Congress by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital for TNX-1500 targeting CD40-ligand (CD40L), which is also known as CD154.
- The presentations titled, "Long-Term Rejection Free Renal Allograft Survival with Fc-Modified Anti-CD154 Antibody Monotherapy in Nonhuman Primates," "*TNX-1500, an Fc-modified Anti-CD154 Antibody, Prolongs Nonhuman Primate Cardiac Allograft Survival*," and "*Novel Targetable Pathways in Costimulation Pathway Blockade*" include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. Blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in a non-human primate cardiac allograft model without clinical thrombosis.
- A Phase 1 study of TNX-1500 is expected to start in the first half of 2023.

**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 July 2022, Tonix announced the appointment of Sina Bavari, Ph.D. as Executive Vice President, Infectious Disease Research and Development. In this role, Dr. Bavari will be responsible for leading Tonix's development of its growing infectious disease pipeline and will serve as a key member of the Company's executive leadership team.
- In June 2022, Tonix held a ribbon-cutting ceremony for its Advanced Development Center (ADC) located in the New Bedford Business Park in North Dartmouth, Massachusetts. The new facility is designed for accelerated research, development and analytical capabilities, as well as the production of clinical trial quality vaccines for infectious diseases, including monkeypox, smallpox and COVID-19 as well as other infectious diseases for pandemic preparedness. The ADC is open and expected to soon perform process development and clinical trial manufacturing of live-virus vaccines.

Recent Highlights--Financial

As of June 30, 2022, Tonix had $145.5 million of cash and cash equivalents, compared to $178.7 million as of December 31, 2021. In June 2022, Tonix issued 2,500,000 shares of Series A convertible redeemable preferred stock and 500,000 shares of Series B convertible redeemable preferred stock to certain institutional investors in a private placement for gross proceeds of $28.5 million. The Company expects to use the proceeds to redeem the preferred stock.

Cash used in operations was approximately $21.2 million for the three months ended June 30, 2022, compared to $19.1 million for the same period in 2021. Capital expenditures were approximately $14.4 million for the three months ending June 30, 2022 compared to $1.4 million for the same period in 2021. The increase was primarily due to the continued buildout of the ADC in North Dartmouth, Mass.

Second Quarter 2022 Financial Results

Research and development (R&D) expenses for the three months ended June 30, 2022 were $16.6 million, compared to $18.1 million for the same period in 2021. The decrease is predominately due to decreased non-clinical expenses, offset by an increase in employee-related expenses. We continue to expect R&D expenses to increase during 2022 as we move our clinical development programs forward and invest in our development pipeline.

General and administrative (G&A) expenses for the three months ended June 30, 2022 were $6.8 million, compared to $5.4 million for the same period in 2021. The increase is primarily due to employee-related expenses.

Net loss available to common stockholders was $27.4 million, or $1.22 per share, basic and diluted, for the three months ended June 30, 2022, compared to net loss of $23.6 million, or $2.25 per share, basic and diluted, for the same period in 2021. The basic and diluted weighted average common shares outstanding for the three months ended June 30, 2022 was 22,404,371, compared to 10,483,112 shares for the same period in 2021.

About 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 first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate 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 that is Phase 2 ready and has been granted Breakthrough Therapy designation by the FDA. 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 half 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 first half of 2023. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. 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 first half of 2023. Tonix's lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform. A Phase 1 study of the COVID-19 vaccine is expected to be initiated 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.

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,	
	2022	2021	2022	2021
COSTS AND EXPENSES:				
Research and development	$ 16,579	$ 18,133	$ 35,001	$ 33,460
General and administrative	6,757	5,429	14,771	10,838
	23,336	23,562	49,772	44,298
Operating Loss	(23,336)	(23.562)	(49,772)	(44,298)
Interest and other income, net	196	9	215	92
Net loss	(23,140)	(23,553)	(49,557)	(44,206)
Preferred stock deemed dividend	4,255	—	4,255	—
Net loss available to common stockholders	$ (27,395)	$ (23,553)	$ (53,812)	$ (44,206)
Net loss per common share, basic and diluted	$ (1.22)	$ (2.25)	$ (2.76)	$ (4.49)

Weighted average common shares outstanding, basic and diluted	22,404,371	10,483,112	19,462,280	9,843,309

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands)
(Unaudited)

	June 30, 2022	December 31, 2021[1]
Assets		
Cash and cash equivalents	$ 145,478	$ 178,660
Restricted cash	31,500	-----
Prepaid expenses and other	14,769	10,389
Total current assets	191,747	189,049
Other non-current assets	84,418	51 ,851
Total assets	$ 276,165	$ 240,900
Liabilities and stockholders' equity		
Total liabilities	$ 16,383	$ 22,183
Temporary equity	31,500	-
Stockholders' equity	228,282	218,717
Total liabilities and stockholders' equity	$ 276,165	$ 240,900

[1]The condensed consolidated balance sheet for the year ended December 31, 2021 has been derived from the audited financial statements but do 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.