August 10, 2020

Tonix Pharmaceuticals Reports Second Quarter 2020 Financial Results and Operational Highlights

Preclinical data for TNX-1800, a Vaccine Candidate to Protect Against COVID-19, Expected in Fourth Quarter 2020

Interim Analysis Results for Phase 3 RELIEF Trial of TNX-102 SL for the Management of Fibromyalgia Expected in September 2020

Topline Data for RELIEF Trial Expected in Fourth Quarter 2020

NEW YORK, Aug. 10, 2020 (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, 2020, and provided an overview of recent operational highlights.

“The second quarter was highlighted by exciting progress for our lead immunology and central nervous system product candidates,” said Seth Lederman, M.D., President and Chief Executive Officer. “We expect to have the first data from animal studies of our lead COVID-19 vaccine candidate, TNX-1800, in the fourth quarter of this year. TNX-1800 is a live attenuated vaccine based on our proprietary horsepox vector system that carries a gene encoding the Spike protein from SARS-CoV-2, the virus that causes COVID-19. We have also continued to progress the Phase 3 RELIEF study of TNX-102 SL for fibromyalgia, having reached 50% enrollment in April and then completing enrollment in July, ahead of schedule. We look forward to interim data in September and topline results from the RELIEF study by the end of this year.”

Recent Highlights

Research and Development

COVID-19 vaccine candidate TNX-1800 (live attenuated vaccine based on horsepox virus vector) designed as a single-shot vaccine to elicit T cell immunity

- In June, Tonix announced an agreement with FUJIFILM Diosynth Biotechnologies to provide contract manufacturing and development services to support the manufacturing of TNX-1800 for clinical trial supply.
- Tonix expects small animal and non-human primate data from safety studies of TNX-1800 in COVID-19 models to measure safety and the immune response to the SARS-COV-2 Spike protein in the fourth quarter of 2020. In addition, we also expect data from non-human primate studies to measure efficacy in challenge studies using SARS-

COV-2 in the fourth quarter.

COVID-19 research collaboration with Southern Research

- In June, Tonix announced a new collaboration with Southern Research to study T cell immune responses to SARS-CoV-2 in volunteers who have recovered from COVID-19 or remain asymptomatic after exposure to SARS-CoV-2. The results are expected to support the Company's anticipated regulatory filings for TNX-1800, which is designed to express the SARS-CoV-2 Spike protein after vaccination.

COVID-19 research collaboration and option agreement with Columbia University

- In July, Tonix announced a partnership with Columbia University to apply precision medicine to the study of the T cell and antibody immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were exposed but remain asymptomatic. The research is designed to provide detailed immune responses to COVID-19 and to provide a foundation upon which to target vaccines and therapeutics to appropriate individuals by precision medicine.

COVID-19 vaccine candidates TNX-1800, TNX-1810, TNX-1820 and TNX-1830 (live attenuated vaccines based on horsepox virus vector) partnership with University of Alberta

- In May, Tonix announced a new collaboration with University of Alberta to develop three horsepox- based vaccines that are anticipated to elicit almost exclusively T cell immunity to proteins from SARS-COV-2 that are different from the Spike protein encoded by TNX-1800.

COVID-19 vaccine candidate TNX-2300 (live attenuated vaccine based on bovine parainfluenza virus) partnership with Kansas State University – new platform of a live attenuated vaccine designed to elicit T cell immunity by co-stimulation with CD40-ligand

- In July 2020, Tonix entered into a research and exclusive license option agreement with Kansas State University to develop a vaccine candidate for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform and the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity.

Plans to set up Advanced Development Center for process and analytical development

- In July, Tonix announced its intent to purchase an approximately 40,000 square foot facility in Massachusetts to use as laboratories to enable research and development functions associated with its expanding portfolio of immunological candidates, including vaccines for COVID-19 and biological products for other disorders.

Progress on TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for Fibromyalgia

- In July, Tonix completed enrollment of approximately 470 participants in the Phase 3 RELIEF trial, ahead of schedule. The RELIEF study is a potential pivotal study of TNX-102 SL 5.6 mg taken daily at bedtime for the management of fibromyalgia.
- Tonix expects results from an interim analysis of the RELIEF study from the first 50 percent of randomized participants that are evaluable for efficacy in September 2020. The interim analysis will be conducted by an Independent Data Monitoring Committee

which will review the unblinded data and make one of four recommendations: (1) stop the study for success; (2) continue the study as planned; (3) continue to enroll with a specified increase in the total number of participants in the full study; or (4) stop the study for futility.
- Tonix expects topline data for the RELIEF study in the fourth quarter of 2020 unless the interim Independent Data Monitoring Committee recommends an increase in the total number of participants.
- Tonix plans to initiate a second potentially pivotal Phase 3 trial, F306 or the RALLY study, to study TNX-102 SL for the management of fibromyalgia. Tonix expects enrollment to begin in the third quarter of this year. The trial design will be very similar to the ongoing Phase 3 RELIEF study. We expect the FDA to require two registration-quality clinical studies to support marketing approval.

Progress on TNX-102 SL (cyclobenzaprine HCl sublingual tablets) development for Alcohol Use Disorder

- In August, Tonix announced that it received FDA clearance of its IND for TNX-102 SL for the treatment of alcohol use disorder. This clearance supports the initiation of a Phase 2 proof-of-concept study.

Acquisition of potential migraine and craniofacial drug TNX-1900 (intranasal oxytocin)

- In June 2020, Tonix announced the acquisition of non-addictive migraine and pain treatment technologies from Trigemina, Inc., and the assumption of license for some of the technologies from Stanford University. The lead asset, TNX-1900, oxytocin solution for intranasal delivery, is a proprietary, patented enhanced formulation of nasal oxytocin, currently being studied as a candidate for prophylaxis of chronic migraine.
- Results from a preclinical study of TNX-1900 were posted at the American Academy of Neurology's first-ever Sports Concussion Conference in June 2020. The presentation, titled "Intranasal (IN) Oxytocin Relieves Pain and Depressive Behavior in a Rodent Model of Mild Traumatic Brain Injury (TB)," included data from preclinical studies which investigated the efficacy of intranasal oxytocin in relieving pain and associated depressive behavior following mild traumatic brain injury.

Progress on oncology partnership with Columbia University on TNX-1700 (stabilized recombinant version of Trefoil Factor 2 (TFF2))

- Results from a preclinical study of TNX-1700, Tonix's in-licensed asset from Columbia University, were presented in a poster at the American Association of Cancer Research Virtual Annual Meeting II held online June 22-24, 2020. The poster, titled "Stabilized recombinant trefoil factor 2 (TFF2-CTP) enhances anti-tumor activity of PD-1 blockage in mouse models of colorectal cancer," included preclinical data investigating the role of PD-L1 in colorectal tumorigenesis and evaluating the utility of targeting myeloid-derived suppressor cells (MDSCs) with TNX-1700 in combination with PD-1 blockade in mouse models of colorectal cancer. The data show that anti-PD-1 monotherapy was unable to evoke anti-tumor immunity in this model of colorectal cancer, but TNX-1700 augmented the efficacy of anti-PD-1 therapy, showing greater anti-tumor activity in PD-L1-overexpressing mice. TNX-1700 is being developed for the treatment of gastric, colon and pancreatic cancers under a license from Columbia University.

Financial

Second Quarter 2020 Financial Results

At June 30, 2020, Tonix had $55.0 million of cash and cash equivalents, compared to $11.2 million as of December 31, 2019. Cash used in operations was approximately $10.0 million for the three months ended June 30, 2020, compared to $4.7 million for the three months ended June 30, 2019. In July 2020, the Company raised net proceeds of approximately $9.6 million through a registered direct offering of common stock.

Research and development expenses for the second quarter of 2020 totaled $10.6 million, compared to $3.6 million for the same period in 2019. This increase is predominantly due to the acquisition of technologies of Trigemina, Inc., timing of development milestones related to the ongoing Phase 3 trial of TNX-102 SL in fibromyalgia and increased activities relating to COVID-19 vaccine work.

General and administrative expenses for the second quarter of 2020 totaled $3.6 million, compared to $2.4 million for the same period in 2019. The increase is primarily due to an increase in legal fees, patent prosecution and maintenance costs, and non-cash compensation expense.

Net loss was $14.2 million, or $0.23 per share, for the second quarter of 2020, compared to net loss of $5.8 million, or $9.42 per share, for the second quarter of 2019. The weighted average common shares outstanding, basic and diluted, for the second quarter of 2020 was 62,391,006, compared to 620,204 shares for the second quarter of 2019.

Tonix entered into a sales agreement with AGP on April 8, 2020, pursuant to which Tonix may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to $50.0 million in at-the-market offerings (“ATM”) sales. As of June 30, 2020, Tonix sold approximately 53.0 million shares of common stock under the sales agreement, for gross proceeds of approximately $35.3 million.

As of August 7, 2020, the Company has an aggregate of 130,273,710 shares of common stock outstanding.

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 immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead vaccine candidate, TNX-1800*, 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 expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix is also developing TNX-2300*, a second live replicating vaccine candidate for the prevention of

COVID-19 which employs bovine parainfluenza virus as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an interim analysis in September 2020 and topline data in the fourth quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is also Phase 2 ready. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD; TNX-1500* (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions; and TNX-1700* (rTFF2), a biologic being developed to treat gastric and pancreatic cancers.

*TNX-1800, TNX-801, TNX-2300, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs 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 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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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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,	
	2020	**2019**	**2020**	**2019**
Costs and expenses				
Research and development	$ 10,571	$ 3,554	$ 15,247	$ 7,450
General and administrative	3,621	2,352	6,242	4,753
Total costs and expenses	14,192	5,906	21,489	12,203
Operating loss	(14,192)	(5,906)	(21,489)	(12,203)
Interest income, net	13	66	37	130
Net loss	$ (14,179)	$ (5,840)	$ (21,452)	$ (12,073)
Warrant deemed dividend	-	-	451	-
Preferred stock deemed dividend	-	-	1,260	-
Net loss available to common stockholders	$ (14,179)	$ (5,840)	$ (23,163)	$ (12,073)
Net loss per common share, basic and diluted	$ (0.23)	$ (9.42)	$ (0.54)	$ (21.77)
Weighted average common shares outstanding, basic and diluted	62,391,006	620,204	43,209,988	554,624

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

	June 30, 2020	December 31, 2019(1)
Assets		

Cash and cash equivalents	$	55,022	$	11,249
Prepaid expenses and other		2,605		2,699
Total current assets		57,627		13,948
Other non-current assets		718		610
Total assets	$	58,345	$	14,558
Liabilities and stockholders' equity				
Total liabilities	$	4,773	$	5,141
Stockholders' equity		53,572		9,417
Total liabilities and stockholders' equity	$	58,345	$	14,558

(1) The condensed consolidated balance sheet for the year ended December 31, 2018 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.

Source: Tonix Pharmaceuticals Holding Corp.