May 12, 2020

Tonix Pharmaceuticals Reports First Quarter 2020 Financial Results and Operational Highlights

Four Potential Vaccines in Development to Protect Against New Coronavirus Disease 2019 (COVID-19) Based on the Company's Horsepox Virus Vaccine Platform

Potential Vaccine, TNX-801, in Development to Protect Against Smallpox and Monkeypox Based on Horsepox Virus

Achieves 50 Percent Enrollment in Phase 3 RELIEF Study of TNX-102 SL (Cyclobenzaprine HCl Sublingual Tablets) for the Management of Fibromyalgia; Topline Results Expected First Quarter 2021

NEW YORK, May 12, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended March 31, 2020, and provided an overview of recent operational highlights.

"We have continued to expand our portfolio, recently adding three new potential vaccines to protect against COVID-19, bringing the total COVID-19 vaccines candidates to four," said Seth Lederman, M.D., President and Chief Executive Officer. "TNX-1800 is designed to elicit a predominant T cell response and TNX-1810, -1820 and -1830 are designed to elicit almost pure T cell responses. We believe that T cell responses are important in protecting against COVID-19, in contrast to many other vaccine programs that are designed to elicit predominantly antibody responses. The horsepox vector is related to vaccines that prevented and eradicated smallpox, therefore we expect horsepox-based vaccines can be manufactured at a scale consistent with a global pandemic. We also remain focused on advancing TNX-801 as a potential vaccine against smallpox and monkeypox, and TNX-102 SL for the management of fibromyalgia. We expect topline results from the Phase 3 RELIEF study for TNX-102 SL for the management of fibromyalgia in the first quarter of 2021, barring any interruptions due to the COVID-19 pandemic. In addition to these programs, we maintain a strong and growing pipeline of product candidates including TNX-102 SL as a treatment for agitation in Alzheimer's disease and alcohol use disorder, TNX-601 CR as a treatment for major depressive disorder, treatment for PTSD and treatment for corticosteroid-induced cognitive dysfunction, TNX-1300 for the treatment of cocaine intoxication, TNX-1500 for the prevention and treatment of organ transplant rejection, and TNX-1200 as a vaccine against smallpox and monkeypox disease."

Recent Highlights

Research and Development

TNX-1800, TNX-1810, TNX-1820 and TNX-1830 (live recombinant modified horsepox virus vaccines from cell culture)

- Tonix is developing four potential vaccines, based on the horsepox viral vector platform, to protect against COVID-19: TNX-1800, TNX-1810, TNX-1820 and TNX-1830*. The Company believes its proprietary horsepox vaccine platform can be engineered to express relevant protein antigens from different infectious diseases to make a variety of vaccines. In the first quarter of 2020, Tonix announced a strategic collaboration with the Southern Research Institute to develop and test TNX-1800, which is designed to express the Spike protein from the SARS-CoV-2 virus that causes COVID-19. In addition, Tonix recently disclosed a new collaboration, with the University of Alberta, to develop three new potential vaccines, TNX-1810, TNX-1820 and TNX-1830, to protect against COVID-19 based on the horsepox vector platform, but designed to express different SARS-CoV-2 antigens than TNX-1800. TNX-1800, TNX-1810, TNX-1820 and TNX-1830 are in the pre-clinical, pre-Investigational New Drug (IND) application stage of development. The company expects preliminary data from animal experiments with TNX-1800 in the fourth quarter of 2020, but the COVID-19 pandemic may lead to a delay in this timeline.

TNX-801 (live synthesized horsepox virus (sHPXV) vaccine from cell culture)

- The Company is developing TNX-801 as a preventative vaccine for the U.S. strategic national stockpile and as an active immunization against smallpox and monkeypox diseases for individuals at high risk for infection. Tonix presented data at the American Society of Microbiology Biothreats meeting in late January showing that TNX-801 was well tolerated and fully protected macaques from challenge with monkeypox virus.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets)

- In April 2020, Tonix announced that 50 percent enrollment had been achieved in the Phase 3 RELIEF trial, a potential pivotal study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg taken daily at bedtime for the management of fibromyalgia. An optional interim analysis of the first 50 percent of randomized participants that are evaluable for efficacy is expected to be conducted, with results expected in September 2020. The COVID-19 pandemic may also lead to a delay in recruitment of the second 50% of participants and topline results, but to date trial enrollment remains on schedule. The long-term safety exposure data of TNX-102 SL 5.6 mg collected in PTSD studies are expected to support the fibromyalgia New Drug Application (NDA).

- The Company continues to expect to report topline results from the Phase 3 RECOVERY study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the treatment of PTSD in the second quarter of 2020. During the first quarter of 2020, the Company announced it stopped enrollment in RECOVERY following an unblinded, pre-specified interim analysis by the Independent Data Monitoring Committee (IDMC) which recommending stopping the trial for futility. Preliminary blinded safety data from these participants did not reveal any serious and/or unexpected adverse events and the decision to discontinue enrollment in the study was not related to safety. A full analysis of the unblinded data will be conducted to determine the next steps in this program.

Financial

First Quarter 2020 Financial Results

Research and development expenses for the first quarter of 2020 totaled $4.7 million, compared to $3.9 million for the same period in 2019. This increase is primarily due to increased clinical expenses related to the ongoing Phase 3 trials of TNX-102 SL in both fibromyalgia and PTSD and the beginning of the COVID-19 vaccine work.

General and administrative expenses for the first quarter of 2020 totaled $2.6 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.

Net loss available to common stockholders was $9.0 million, or $0.37 per share, for the first quarter of 2020, compared to net loss of $6.2 million, or $12.76 per share, for the first quarter of 2019. The weighted average common shares outstanding, basic and diluted, for the first quarter of 2020 was 24,028,970, compared to 488,315 shares for the first quarter of 2019.

At March 31, 2020, Tonix had $30.7 million of cash and cash equivalents, compared to $11.2 million as of December 31, 2019. In the first quarter of 2020, the Company raised net proceeds of approximately $28.8 million through equity financings and warrant exercises. Cash used in operations was $9.3 million for the three months ended March 31, 2020, compared to $8.6 million for the three months ended March 31, 2019.

On April 8, 2020, Tonix entered into a sales agreement with AGP, 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 May 11, 2020, the Company has an aggregate of 52,302,475 shares of common stock outstanding.

About TNX-1800, TNX-1810, TNX-1820, TNX-1830 and TNX-801*

TNX-1800 is a modified horsepox virus that is designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19 and to elicit a predominant T cell response. TNX-1810, TNX-1820 and TNX-1830 are modified horsepox viruses that are designed to express different SARS-CoV-2 proteins than Spike and to elicit almost pure T cell responses. TNX-801 is a live virus vaccine based on synthesized horsepox[1]. Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been explored as platforms for vaccine development because they possess: (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) readily manufacturable at scale, and (7) ability to provide direct antigen presentation. Relative to vaccinia, horsepox has substantially decreased virulence in mice[1]. TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge[2].

[1]*Noyce RS, et al. (2018) PLoS One. 13(1):e0188453*
[2]*Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)*

*TNX-801, TNX-1800, TNX-1810, TNX-1820 and TNX-1830 are in the pre-IND stage and have not been approved for any indication

About the Phase 3 RELIEF Study

The RELIEF study is a double-blind, randomized, placebo-controlled adaptive design trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in fibromyalgia. The trial is expected to enroll approximately 470 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there will be a run-in period in which patients will start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all patients will have the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint is daily diary pain severity score change from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

The RELIEF study is expected to have one unblinded interim analysis when the study has results from approximately the first 50% of efficacy-evaluable patients, pending agreement with the FDA. Additional details about the RELIEF study are available at www.theRELIEFstudy.com or clinicaltrials.gov (NCT04172831).

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing drugs and biologics to treat and prevent human disease and alleviate suffering. Tonix's current portfolio includes biologics to prevent infectious diseases, and small molecules and biologics to treat pain, psychiatric and addiction conditions. Tonix is developing four potential vaccines, based on the horsepox viral vector platform to protect against the novel coronavirus disease emerging in 2019, or COVID-19: TNX-1800, TNX-1810, TNX-1820 and TNX-1830*. TNX-1800 is designed to express the Spike protein of the SARS-CoV-2 and to a predominant T cell response. TNX-1810, TNX-1820 and TNX-1830 are designed to express different proteins from SARS-CoV-2 and to elicit almost pure T cell responses. TNX-801* (live horsepox virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Tonix's most advanced drug development programs are focused on delivering safe and effective long-term treatments for fibromyalgia, or FM, and posttraumatic stress disorder, or PTSD. Tonix's most advanced product candidate, TNX-102 SL**, is in Phase 3 development as a bedtime treatment for fibromyalgia and PTSD. The Company is enrolling participants in the Phase 3 RELIEF trial in fibromyalgia and expects results from an unblinded interim analysis in September of 2020 and topline data in the first quarter of 2021. The Phase 3 RECOVERY trial (P302) for TNX-102 SL (trade name Tonmya***) in PTSD has stopped enrollment based on the Independent Data Monitoring Committee's recommendation to stop the study for futility following an interim analysis of the first 50% of enrolled participants. Topline data for RECOVERY are expected in the second 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 in the pre-Investigational New Drug (IND) application stage. 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 cocaine intoxication and has FDA Breakthrough Therapy Designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for depression as well as PTSD and corticosteroid-induced cognitive dysfunction. The first efficacy study will be in the treatment of major depressive disorder. TNX-1600 (a triple reuptake inhibitor) is a pre-clinical new molecular entity (NCE) being developed as a treatment for PTSD. Tonix's preclinical pipeline includes 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-1200* (live vaccinia virus vaccine for percutaneous administration) is in development to protect against smallpox and monkeypox. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-1800, TNX-1810, TNX-1820, TNX-1830, TNX-801, TNX-1200 and TNX-1300 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

***Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

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.

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

	Three Months Ended March 31,	
	2020	**2019**
COSTS AND EXPENSES:		
Research and development	$ 4,676	$ 3,896
General and administrative	2,621	2,401
	7,297	6,297
Operating Loss	(7,297)	(6,297)
Interest income, net	24	64
Net loss	(7,273)	(6,233)
Warrant deemed dividend	451	-
Preferred stock deemed dividend	1,260	-
Net loss available to common stockholders	$ (8,984)	$ (6,233)
Net loss per common share, basic and diluted	$ (0.37)	$ (12.76)
Weighted average common shares outstanding, basic and diluted	24,028,970	488,315

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

	March 31, 2020	**December 31, 2019 (1)**
Assets		
Cash and cash equivalents	$ 30,665	$ 11,249
Prepaid expenses and other current assets	2,731	2,699
Total current assets	33,396	13,948
Other non-current assets	536	610
Total assets	$ 33,932	$ 14,558

Liabilities and stockholders' equity				
Total liabilities	$	2,685	$	5,141
Stockholders' equity		31,247		9,417
Total liabilities and stockholders' equity	$	33,932	$	14,558

(1) The condensed consolidated balance sheet for the year ended December 31, 2019 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.