March 24, 2020

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Operational Highlights

Potential Vaccine, TNX-1800 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

Interim Analysis Results for Phase 3 RELIEF Study of TNX-102 SL for the Management of Fibromyalgia Expected Third Quarter 2020; Topline Data Expected First Half 2021

Expanded Pipeline in 2019 with Three In-licensed Programs

First Quarter 2020 Stock Offerings Raised $29.0 Million in Net Proceeds to Support Pipeline Advancement

NEW YORK, March 24, 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 and year ended December 31, 2019, and provided an overview of recent operational highlights.

"Our focus in 2020 will be on further advancement of our vaccine and pain programs: TNX-1800 as a potential vaccine to protect against COVID-19, TNX-801 as a potential vaccine against smallpox and monkeypox, and TNX-102 SL for the management of fibromyalgia. We expect results of the interim analysis for the Phase 3 RELIEF study for TNX-102 SL for the treatment of fibromyalgia in the third quarter of this year, however interruptions due to the COVID-19 pandemic may alter those timelines," said Seth Lederman, M.D., President and Chief Executive Officer. "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. Furthermore, we look forward to advancing our pipeline of other product candidates."

Recent Highlights

Research and Development

TNX-1800 (live recombinant horsepox virus (rHPXV/SARS-CoV2-S^3) vaccine from cell culture)

- In first quarter 2020, Tonix announced a strategic collaboration with the Southern Research Institute to support development of TNX-1800, a potential vaccine to protect against COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform, which the Company believes can be engineered to express relevant protein antigens from different infectious diseases to make a variety of vaccines. The collaboration with Southern Research will develop and test TNX-1800, which is designed to express the Spike protein from the SARS-CoV-2 virus that causes COVID-19. Tonix plans to test whether vaccination of animals with TNX-1800 will elicit an immune response to the SARS-CoV-2 Spike protein and if so, whether such an immune response will protect animals against COVID-19-like disease. TNX-1800 is in the pre-clinical, pre-Investigational New Drug (IND) application stage of development. The company expects preliminary data from animal experiments in the third 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)

- Tonix is developing TNX-801 as a preventative vaccine for active immunization against smallpox and monkeypox diseases for individuals at high risk for infection. In the first quarter of 2020, the Company presented data at the American Society of Microbiology Biothreats meeting that showed that TNX-801 protected macaques from challenge with monkeypox virus.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets)

- During the fourth quarter of 2019, the Company initiated the Phase 3 RELIEF study, a potential pivotal study of TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) 5.6 mg, a non-opioid, centrally acting analgesic, taken daily at bedtime for the management of fibromyalgia. RELIEF is a double-blind, randomized, placebo-controlled adaptive design trial designed to evaluate the efficacy and safety of TNX-102 SL in fibromyalgia. Interim analysis results are expected in the third quarter of 2020, with topline results expected in the first half of 2021 based on the currently-planned sample size. The COVID-19 pandemic may lead to a delay in recruitment for RELIEF which could delay the interim analysis and topline results, but to date the trial is on schedule.

- Supported by the previous safety and efficacy findings of TNX-102 SL in fibromyalgia at 2.8 mg and posttraumatic stress disorder (PTSD) at 5.6 mg, Tonix believes that using the 5.6 mg dose of TNX-102 SL in the Phase 3 RELIEF fibromyalgia study has the potential to provide clinical evidence to support the efficacy and safety of TNX-102 SL for the management of fibromyalgia. The registration of TNX-102 SL 5.6 mg for the fibromyalgia indication is expected to be supported by the long-term safety exposure data from the PTSD program for TNX-102 SL 5.6 mg.

- In February 2020, the Company announced it stopped enrollment in the Phase 3 RECOVERY study of TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) 5.6 mg for the treatment of PTSD following an unblinded, pre-specified interim analysis by the

Independent Data Monitoring Committee (IDMC). Based on interim analysis results of the first 50% of enrolled participants, the IDMC recommended stopping the trial for futility as TNX-102 SL is unlikely to demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms, as measured by the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) between those treated with TNX-102 SL and those receiving placebo. 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 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 to determine the next steps in this program, with the topline results expected to be reported in the second quarter of 2020.

- TNX-102 SL is in development for the treatment of agitation in Alzheimer's disease (AAD), which has been designated as a Fast Track development program by the Food and Drug Administration (FDA). The program is ready for a Phase 2 study which could potentially serve as a pivotal efficacy study to support a New Drug Application (NDA) approval.

- TNX-102 SL is in development as a treatment for alcohol use disorder (AUD), with an IND application to be submitted in the first half of 2020. The AUD program is expected to be ready for a Phase 2 proof-of-concept study upon FDA clearance of the IND application. AUD is a chronic relapsing brain disease characterized by compulsive alcohol use, loss of control over alcohol intake, and a negative emotional state when not using.

TNX-601 CR (tianeptine oxalate controlled-release)

- The Company announced in the fourth quarter of 2019 the successful completion of a Phase 1 study evaluating the safety, tolerability and pharmacokinetics (PK) of controlled release (CR) formulations of TNX-601 (tianeptine oxalate). TNX-601 CR is being developed as a once-daily treatment for major depressive disorder (depression) in addition to PTSD and corticosteroid-induced cognitive dysfunction. Tonix plans to start the first efficacy trial ex-U.S. in 2021 and request a pre-IND meeting with the FDA in 2020.

TNX-1300 (double mutant cocaine esterase)

- TNX-1300 is a recombinant protein under development as a treatment for a life-threatening degree of cocaine intoxication. TNX-1300 was granted Breakthrough Therapy designation by the FDA. Tonix in-licensed TNX-1300 in May 2019 from Columbia University, after a Phase 2 study on volunteers showed that TNX-1300 disintegrates cocaine in the blood stream after *i.v.* cocaine challenge. In 2019, the Company met with FDA to discuss and reach agreement on the design of toxicology studies for TNX-1300 to support a Phase 2 clinical study. The company has recertified TNX-1300 drug product for use in future clinical trials.

TNX-1500 (monoclonal antibody anti-CD154)

- The Company entered into a research collaboration with Massachusetts General

Hospital to develop TNX-1500, Tonix's internally developed, proprietary anti-CD154 (or CD40-ligand) monoclonal antibody that targets CD154 for the prevention and treatment of organ transplant rejection. TNX-1500 is also a potential treatment for autoimmune conditions.

Other Pipeline Programs

- TNX-1600 (triple reuptake inhibitor): Obtained an exclusive license for a triple reuptake inhibitor, TNX-1600, to treat PTSD and potentially other central nervous system disorders. The transaction was a license agreement with Wayne State University and an asset acquisition from TRImaran Pharma, Inc.

- TNX-1700 (recombinant trefoil factor 2, or rTFF2): Obtained an exclusive license from Columbia University for the development of a biologic, TNX-1700 (recombinant trefoil factor 2, or rTFF2), for the treatment of gastric and pancreatic cancers. The in-licensed technology was invented and developed, in part, by Dr. Timothy C. Wang, Chief, Division of Digestive and Liver Diseases, and Director of the Gastrointestinal and Pancreas Cancer Program and Tumor Biology and Microenvironment program in the Herbert Irving Cancer Center at Columbia University.

Financial

Fourth Quarter 2019 Financial Results

Research and development expenses for the fourth quarter of 2019 totaled $5.7 million, compared to $5.1 million for the same period in 2018. This increase is primarily due to increased work related to TNX-601 CR, including the PK study, and an increase in non-clinical expenses related to pipeline development.

General and administrative expenses for the fourth quarter of 2019 totaled $3.0 million, compared to $2.6 million for the same period in 2018. The modest increase is primarily due to an increase in patent prosecution and maintenance costs.

Net loss available to common stockholders was $11.2 million, or $2.86 per share, for the fourth quarter of 2019, compared to net loss of $10.9 million, or $59.85 per share, for the fourth quarter of 2018. The weighted average common shares outstanding, basic and diluted, were 3,912,800 for the fourth quarter of 2019 and 181,344 for the fourth quarter of 2018, which amounts have been retroactively restated to reflect a 1-for-10 reverse stock split of our issued and outstanding shares that was effectuated on November 1, 2019.

Full Year 2019 Financial Results

Research and development expenses for full year 2019 totaled $18.2 million, compared to $17.6 million for the same period in 2018. This increase is primarily due to the ramp-up of work related to TNX-601 and an increase in expenses related to pipeline development.

General and administrative expenses for full year 2019 totaled $10.6 million, compared to $8.8 million for the same period in 2018. The increase is primarily due to higher insurance premiums and an increase in legal fees.

Net loss available to common stockholders was $31.1 million, or $19.33 per share, for full

year 2019, compared to net loss of $29.4 million, or $259.85 per share, for full year 2018. The weighted average common shares outstanding, basic and diluted, for 2019 was 1,608,568 shares. The weighted average common shares outstanding, basic and diluted, for 2018 was 112,968 shares.

At December 31, 2019, Tonix had $11.2 million of cash and cash equivalents, compared to $25.0 million as of December 31, 2018. In the first quarter of 2020, the Company raised net proceeds of approximately $29.0 million through equity financings and warrant exercises. Following the offerings, the Company had an aggregate of 49,353,134 shares of common stock outstanding. Cash used in operations was $26.7 million for the full year 2019, compared to $24.0 million for the full year 2018.

About TNX-801* and TNX-1800*

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. 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 and TNX-1800 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. In 2020, Tonix announced a program to develop a potential vaccine, TNX-1800* (live modified horsepox virus vaccine for percutaneous administration) to protect against the novel coronavirus disease emerging in 2019, or COVID-19. TNX-1800 is based on Tonix's proprietary horsepox vaccine platform and is molecularly designed to express the Spike protein of the SARS-CoV-2 virus that causes COVID-19. 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 the third quarter of 2020 and topline data in the first half 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 for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. 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 in depression will be performed outside the U.S. 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-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 Reports Fourth Quarter 2019 Financial Results

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Costs and expenses				
Research and development	$ 5,690	$ 5,057	$ 18,192	$ 17,558
General and administrative	3,044	2,593	10,636	8,764
Total costs and expenses	8,734	7,650	28,828	26,322
Operating loss	(8,734)	(7,650)	(28,828)	(26,322)

Interest income, net	27	62	210	233
Net loss	$ (8,707)	$ (7,588)	$ (28,618)	$ (26,089)
Preferred stock deemed dividend	2,474	3,266	2,474	3,266
Net loss available to common stockholders	$ (11,181)	$ (10,854)	$ (31,092)	$ (29,355)
Net loss per common share, basic and diluted	$ (2.86)	$ (59.85)	$ (19.33)	$ (259.85)
Weighted average common shares outstanding, basic and diluted*	3,912,800	181,344	1,608,568	112,968

* All per share amounts and number of shares in the condensed consolidated financial statements have been retroactively restated to reflect a 1-for-10 reverse stock split.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited) (1)

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 11,249	$ 25,034
Prepaid expenses and other	2,699	1,022
Total current assets	13,948	26,056
Other non-current assets	610	263
Total assets	$ 14,558	$ 26,319
Liabilities and stockholders' equity		
Total liabilities	$ 5,141	$ 2,655
Stockholders' equity	9,417	23,664
Total liabilities and stockholders' equity	$ 14,558	$ 26,319

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

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Source: Tonix Pharmaceuticals Holding Corp.