May 10, 2021

Tonix Pharmaceuticals Reports First Quarter 2021 Financial Results and Operational Highlights

Announced Positive Efficacy Data from Animal Studies of COVID-19 Vaccine Candidate, TNX-1800

Interim Analysis of Second Confirmatory Phase 3 Study in FibromyalgiaExpected in Third Quarter 2021

Deep Pipeline Progressing with Three Central Nervous System (CNS) Programs Expected to Enter Phase 2 Trials This Year

At March 31, 2021, Cash and Cash Equivalents Totaled Approximately $164 Million

CHATHAM, N.J., May 10, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the first quarter ended March 31, 2021 and provided an overview of recent operational highlights.

“Tonix possesses a deep pipeline of high-value programs ranging from preclinical to mid-Phase 3 development, with three CNS programs poised to enter Phase 2 trials this year,” said Seth Lederman, M.D., President and Chief Executive Officer. “Our strategy is to in-license, acquire or internally invent high impact therapeutic programs which we can validate, de-risk and advance in clinical development through potentially value-creating milestones. We believe successful Phase 2 and Phase 3 trials can be inflection points for program value.”

Dr. Lederman continued, “Our clinical, manufacturing, and regulatory teams are progressing programs across multiple modalities including small molecule drugs, synthetic peptides, biologics, monoclonal antibodies and live virus vaccines. The three CNS drug candidates we expect to enter Phase 2 trials this year include: TNX-1300, an *E. coli* produced biologic in development as an *i.v.* administered antidote for cocaine intoxication; TNX-1900, a synthetic peptide in development as an intranasally delivered therapeutic for the treatment of chronic migraine; and TNX-601 CR, a controlled release oral formulation in development for the treatment of major depressive disorder.”

“Our most advanced program is a confirmatory Phase 3 trial of TNX-102 SL for the management of fibromyalgia. We expect to report an interim analysis in the third quarter of this year and topline data in the first quarter of next year,” continued Dr. Lederman. “We believe that if the topline results are positive, this study will support a New Drug Application, which we would expect to submit in 2022.”

Recent Highlights

*Research and Development**

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

- In March 2021, 50 percent of the planned total number of participants had been randomized in the RALLY study, the second potentially pivotal Phase 3 trial of TNX-102 SL for fibromyalgia. The Company expects the results of an interim analysis[1] in the third quarter of 2021, followed by topline results in the first quarter of 2022. Tonix expects to submit a New Drug Application (NDA) for TNX-102 SL for fibromyalgia to the U.S. Food and Drug Administration (FDA) in 2022, pending positive results from the second Phase 3 study.

- In December 2020, TNX-102 SL met its pre-specified primary endpoint in the first Phase 3 study, RELIEF (p=0.01), significantly reducing daily pain compared to placebo in participants with fibromyalgia. Activity was also shown in key secondary endpoints of improving sleep, reducing fatigue, and improving overall fibromyalgia symptoms and function.

TNX-102 SL for the management of PTSD

- Tonix completed the Phase 3 RECOVERY trial and reported topline results in the fourth quarter of 2020 in which TNX-102 SL did not meet the primary efficacy endpoint. As a next step, we intend to meet with the FDA to discuss potential new endpoints for the indication of treatment of PTSD. We also expect to begin enrolling a Phase 3 PTSD study of TNX-102 SL in police in Kenya, in the third quarter of 2021.

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

- 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 block forward transmission and stimulate long-term T cell immunity. The Company believes these findings also demonstrate the flexibility of the horsepox vaccine platform, TNX-801, and its capability to be tailored to other diseases of interest in military and civilian populations.

- A Phase 1 safety study using TNX-1800 in humans is anticipated to start in the first half of 2022, pending Investigational New Drug (IND) clearance from the FDA and the production of GMP material.

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

- TNX-2100, designed to measure functional, or meaningful, *in vivo* T cell immunity to SARS-CoV-2, is a test comprising three different mixtures of synthetic peptides (TNX-

2110, -2120 and -2130). T cell immunity to SARS-CoV-2 persists longer than antibody immunity, is sometimes present in the absence of a measurable antibody response and is believed to provide an important element of protection against serious COVID-19 illness after infection with SARS-CoV-2.[2-6] Tonix expects to initiate a first-in-human clinical study in the fourth quarter of 2021.

- 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-601 CR (tianeptine oxalate and naloxone controlled-release tablets): small molecule product candidate for treatment of major depressive disorder, PTSD and neurocognitive dysfunction associated with corticosteroid use.

- Tonix received the official minutes from a Type B pre-IND meeting with the FDA on its development plan for TNX-601 CR for the treatment of major depressive disorder (MDD). Based on the official minutes, Tonix expects to submit the IND to conduct a human abuse potential study and meet with the FDA's controlled substances staff (CSS) to reach agreement on the details of the abuse potential study. Pending the results of ongoing nonclinical toxicology studies, Tonix expects to be in a position to initiate a Phase 2 study for the treatment of MDD in the fourth quarter of 2021.

TNX-1900 (intranasal potentiated oxytocin): small peptide product candidate for migraine, craniofacial pain, insulin resistance and related disorders

- Tonix intends to submit an 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. also in the third quarter of 2021. A Phase 2 trial under an investigator-initiated IND was completed in the U.S. using TNX-1900 prior to Tonix's acquisition of the program.

TNX-2900 (novel formulation of intranasal potentiated oxytocin): small peptide product candidate for the treatment of Prader-Willi syndrome

- Tonix entered into an agreement in February 2021 whereby the Company licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome from Inserm, the French National Institute of Health and Medical Research. The co-exclusive license allows Tonix to expand its intranasal potentiated oxytocin development program to a new indication. Tonix plans to submit applications to the FDA for Orphan Drug and Fast Track designations for TNX-2900.

TNX-3500 (sangivamycin): antiviral inhibitor of SARS-CoV-2 for 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. The active ingredient of TNX-3500 has been studied for safety in humans

in prior studies on cancer patients at the U.S. National Cancer Institute but has not been approved for marketing in any jurisdiction. Tonix intends to conduct further preclinical studies this year.

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

- 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. Tonix expects to initiate a Phase 2 open-label safety study in an emergency room setting to study TNX-1300 in the third quarter of 2021.

TNX-1500 (anti-CD154 monoclonal antibody): third generation monoclonal antibody as a potential first line monotherapy for preventing or treating organ transplant rejection and treating autoimmune disorders.

- In January 2021, Tonix entered into a second research collaboration with Harvard Medical School Teaching Hospital/Massachusetts General Hospital (MGH) in Boston for TNX-1500, a humanized monoclonal antibody (mAb) that targets the CD40-ligand for the prevention of organ transplant rejection. The new collaboration will focus on kidney transplantation, while an earlier collaboration with MGH is focused on heart transplantation. The Company expects to have TNX-1500 GMP material available in the third quarter of 2021.

[1]Pending agreement from FDA on statistical analysis plan.
[2]Dan, JM et al., Science. 2021. Jan 6 : eabf4063. Published online 2021 Jan 6. doi: 10.1126/science.abf4063
[3]Le Bert, N. et al., J Exp Med. 2021 May 3; 218(5): e20202617. Published online 2021 Mar 1. doi: 10.1084/jem.20202617
[4]Gaebler, C., et al. 2021. Nature. 10.1038/s41586-021-03207-w
[5]Wang, Y., et al. 2020. J. Clin. Invest. 130:5235–5244. 10.1172/JCI138759
[6]Rydyznski Moderbacher, et al., Cell. 2020 Nov 12; 183(4): 996–1012.e19. doi: 10.1016/j.cell.2020.09.038

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

Financial

As of March 31, 2021, Tonix had $164.2 million of cash and cash equivalents, compared to $77.1 million as of December 31, 2020. During the first quarter of 2021, the Company raised gross proceeds of approximately $110 million from two previously announced securities purchase agreements. Cash used in operations was approximately $21.1 million for the first quarter ended March 31, 2021, compared to $9.3 million for the first quarter ended March 31, 2020. The increase in cash used in operations resulted primarily from an increase in research and development and general and administrative activities as defined below.

First Quarter 2021 Financial Results

Research and development expenses for the first quarter of 2021 were $15.3 million, compared to $4.7 million for the same period in 2020. This increase is predominately due to timing of milestones related to the Phase 3 RELIEF study and the initiation of a second Phase 3 study of TNX-102 SL for FM, RALLY, in the third quarter of 2020, as well as activities to prepare for initiation of Phase 2 clinical studies of TNX-1300, TNX-1900 and TNX-601 CR by the end of 2021. New activities related to the development of TNX-1800 as a potential COVID-19 vaccine, and increased spending related to our development pipeline also contributed to the increase.

General and administrative expenses for the first quarter of 2021 were $5.4 million, compared to $2.6 million for the same period in 2020. The increase is primarily due to an increase in financial reporting expenses, patent prosecution and maintenance costs and an increase in salaries and headcount.

Net loss available to common stockholders was $20.7 million, or $0.07 per share, basic and diluted, for the first quarter of 2021, compared to net loss of $9.0 million, or $0.37 per share, basic and diluted, for the first quarter of 2020. The basic and diluted weighted average common shares outstanding for the first quarter of 2021 was 290,106,510, compared to 24,028,970 shares for the first 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, with positive data from the Phase 3 RELIEF study reported in December 2020. The Company expects interim data from the second Phase 3 study, RALLY, in the third quarter of 2021[2] and topline data in the first quarter of 2022. 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[3], 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[3], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

[1]TNX-102 SL is an investigational new drug and has not been approved for any indication.
[2]Pending agreement from FDA on statistical analysis plan.
[3]TNX-1800 and TNX-801 are investigational new 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 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 March 31,	
	2021	**2020**
COSTS AND EXPENSES:		
Research and development	$ 15,327	$ 4,676
General and administrative	5,409	2,621
	20,736	7,297
Operating loss	(20,736)	(7,297)
Interest and other income, net	83	24
Net loss	(20,653)	(7,273)
Warrant deemed dividend	-	451
Preferred stock deemed dividend	-	1,260

Net loss available to common stockholders	$ (20,653)	$ (8,984)
Net loss per common share, basic and diluted	$ (0.07)	$ (0.37)
Weighted average common shares outstanding, basic and diluted	290,106,510	24,028,970

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

	March 31, 2021[1]	December 31, 2020[1]
Assets		
Cash and cash equivalents	$ 164,214	$ 77,068
Prepaid expenses and other	8,951	10,921
Total current assets	173,165	87,989
Other non-current assets	10,356	10,194
Total assets	$ 183,521	$ 98,183
Liabilities and stockholders' equity		
Total liabilities	$ 6,605	$ 10,535
Stockholders' equity	176,916	87,648
Total liabilities and stockholders' equity	$ 183,521	$ 98,183

[1] The condensed consolidated balance sheets for the periods ended March 31, 2021 and December 31, 2020 have 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.