March 15, 2021

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

Announced Positive Phase 3 RELIEF Study Results for TNX-102 SL 5.6 mg in Fibromyalgia

Interim Analysis Results from Second Confirmatory Phase 3 Study, RALLY, Expected in Third Quarter 2021: Interim Cohort Enrolled

Efficacy Data from Animal Studies of COVID-19 Vaccine Candidate, TNX-1800, Expected in First Quarter 2021

Phase 1 Safety Study in Humans of TNX-1800 Expected to Start in Second Half 2021

At December 31, 2020, Cash and Cash Equivalents Totaled $77.1 Million;Approximately $110 Million in Gross Proceeds Raised Subsequent to Year-End

CHATHAM, N.J., March 15, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2020, and provided an overview of recent operational highlights.

“We continue to make progress across our development programs and are steadily advancing our diverse pipeline of CNS and immunology product candidates,” said Seth Lederman, M.D., President and Chief Executive Officer. “In 2021, we expect to deliver on several important milestones. Following on the success of our first pivotal Phase 3 fibromyalgia study, RELIEF, we look forward to reporting interim and topline data from a second potentially pivotal Phase 3 fibromyalgia study, RALLY, this year. We recently reported that we achieved enrollment of the first 50 percent of participants in RALLY, which we expect will be the interim analysis cohort. We also expect to report preclinical efficacy data from our COVID-19 vaccine candidate this quarter and start a Phase 1 study in humans in the second half of this year. Finally, we expect to initiate new clinical trials this year for several other programs including a Phase 2 cocaine intoxication trial, Phase 2 migraine trial, and a proof-of-concept study for the skin test for COVID-19 exposure to measure T cell immunity.”

Recent Highlights

*Research and Development**

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

- TNX-102 SL is a non-opioid, centrally-acting analgesic, taken once daily at bedtime, being developed for the management of fibromyalgia. In December 2020, Tonix announced TNX-102 SL met its pre-specified primary endpoint in the Phase 3 RELIEF study (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. The drug was generally well tolerated with no new safety signals observed. RELIEF was a 14-week randomized, double-blind, placebo-controlled trial of TNX-102 SL 5.6 mg that included 503 participants with fibromyalgia.

- Tonix recently announced that 50 percent of the planned total number of participants have been randomized in the second potentially pivotal Phase 3 trial of TNX-102 SL for fibromyalgia, the RALLY study. Approximately 670 participants are targeted for enrollment for the full study. The Company expects the results of an interim analysis in the third quarter of 2021, followed by topline results in the fourth quarter of 2021. Following a second positive Phase 3 study, Tonix expects to submit a New Drug Application for TNX-102 SL for fibromyalgia to the U.S. Food and Drug Administration (FDA) in 2022.

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 November 2020, the Company announced results following vaccination of non-human primates with TNX-1800 in COVID-19 models to measure safety and the immune response to the SARS-CoV-2 Spike protein. Data demonstrated that TNX-1800 at a low dose induces a strong immune response to SARS-CoV-2 in non-human primates, with all eight animals manifesting "takes", a skin reaction which is a validated biomarker of functional T cell immunity.

- 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 are expected in the first quarter of 2021.

- A Phase 1 safety study using TNX-1800 in humans is anticipated to start in the second half of 2021, pending Investigational New Drug (IND) clearance from the FDA.

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

- Based on guidance from the FDA the Company plans to file an IND in the second quarter of 2021 and initiate clinical trials in the second half of 2021. The Company has already manufactured peptides under cGMP. TNX-2100 is designed to measure functional, or meaningful, *in vivo* T cell immunity to SARS-CoV-2. 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. TNX-2100 is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130), which are designed to represent different protein components of the SARS-CoV-2 virus.

- Tonix's proposed skin test has the potential to serve as: 1) a biomarker for cellular 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-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 second 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. 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.

- In June 2020, Tonix acquired the assets of Trigemina, Inc., including the rights to develop TNX-1900 for migraine and craniofacial pain. In December 2020, Tonix acquired an exclusive license to the University of Geneva's technology for using oxytocin to treat insulin resistance and related syndromes, including obesity. This license allows Tonix to expand its intranasal potentiated oxytocin development program into cardiometabolic syndromes, which include insulin resistance, impaired glucose tolerance, and obesity.

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

- In February 2021, Tonix announced an agreement whereby the Company has 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.

- Prader-Willi syndrome is an orphan disease that occurs in approximately one in 15,000 births, and is recognized as the most common genetic cause of life-threatening childhood obesity, affecting males and females with equal frequency and all races and ethnicities. There is currently no approved treatment for either the suckling (breastfeeding) deficit in infants or the obesity and hyperphagia in older children associated with Prader-Willi syndrome. Tonix plans to submit applications to the FDA for Orphan Drug and Fast Track designations for TNX-2900.

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

- Tonix expects to initiate a Phase 2 open-label safety study in an emergency room setting to study TNX-1300 in the second quarter of 2021. Results of a positive Phase 2 study of volunteer cocaine users in a controlled laboratory setting were reported prior to Tonix licensing the technology. Cocaine esterase is the most potent known catalyst for cocaine degradation.

TNX-1500 (monoclonal antibody anti-CD154): 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 announced a second research collaboration with the Massachusetts General Hospital (MGH) in Boston to develop 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.

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

Financial

As of December 31, 2020, Tonix had $77.1 million of cash and cash equivalents, compared to $11.2 million as of December 31, 2019. Cash used in operations was approximately $48.6 million for the full year ended December 31, 2020, compared to $26.7 million for full year ended December 31, 2019. The increase in cash used in operations resulted principally from an increase in research and development and general and administrative activities as defined below.

For the year ended December 31, 2020, net proceeds from financing activities were $123.1 million, predominantly from the sale of common stock and exercise of warrants. In January 2021, the Company sold 50,000,000 shares of common stock at $0.80 per share, priced at-the-market, for gross proceeds of approximately $40 million, and net proceeds of approximately $36.9 million, after deducting the underwriting discount and other offering expenses. In February 2021, the Company sold 58,333,334 shares of common stock at $1.20 per share in a registered direct public offering, priced at-the-market, for gross proceeds of approximately $70 million, and net proceeds of approximately $65.0 million, after deducting the underwriting discount and other offering expenses.

Fourth Quarter 2020 Financial Results

Research and development expenses for the fourth quarter of 2020 were $12.1 million, compared to $5.7 million for the same period in 2019. This increase is predominantly due to two Phase 3 studies ongoing during this time for TNX-102 SL for fibromyalgia as well as the development of potential COVID-19 vaccine candidate, TNX-1800, which was not in development in 2019.

General and administrative expenses for the fourth quarter of 2020 were $4.9 million, compared to $3.0 million for the same period in 2019. The increase is primarily due to an increase in financial reporting expenses, patent prosecution and maintenance costs and an increase in headcount.

Net loss available to common stockholders was $17.0 million, or $0.10 per share, basic and diluted, for the fourth quarter of 2020, compared to net loss of $11.2 million, or $2.86 per share, basic and diluted, for the fourth quarter of 2019. The basic and diluted weighted average common shares outstanding for the fourth quarter of 2020 was 163,873,489, compared to 3,912,800 shares for the fourth of 2019.

Full Year 2020 Financial Results

Research and development expenses for full year 2020 were $36.2 million, compared to $18.2 million for the same period in 2019. This increase is predominantly due to the timing of development milestones related to the Phase 3 RELIEF and RALLY studies in fibromyalgia in 2020, increased activities for the development of potential vaccine candidates, TNX-1800 and TNX-801 as well as the Trigemina asset acquisition.

General and administrative expenses for full year 2020 were $14.4 million, compared to $10.6 million for the same period in 2019. The increase is primarily due to an increase in legal fees, patent prosecution and maintenance costs, financial reporting expenses and increased employee headcount.

Net loss available to common stockholders was $52.2 million, or $0.55 per share, basic and diluted, for full year 2020, compared to net loss available to common stockholders of $31.1 million, or $19.33 per share, basic and diluted, for full year 2019. The basic and diluted weighted average common shares outstanding for full year 2020 was 94,591,715, compared to 1,608,568 shares for full year 2019.

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 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, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY, in the third quarter of 2021[2] and topline data in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. 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 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 submission and 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 Reports Fourth Quarter 2020 Financial Results

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

	Full Year Ended December 31,		Three Months Ended December 31,	
	2020	2019	2020	2019
Costs and expenses				
Research and development	$ 36,157	$ 18,192	$ 12,097	$ 5,690
General and administrative	14,354	10,636	4,926	3,044
Total costs and expenses	50,511	28,828	17,023	8,734
Operating loss	(50,511)	(28,828)	(17,023)	(8,734)
Interest income, net	48	210	2	27
Net loss	$ (50,463)	$ (28,618)	$ (17,021)	$ (8,707)
Warrant deemed dividend	(451)	-	-	-
Preferred stock deemed dividend	(1,260)	(2,474)	-	(2,474)
Net loss available to common stockholders	$ (52,174)	$ (31,092)	$ (17,021)	$ (11,181)
Net loss per common share, basic and diluted	$ (0.55)	$ (19.33)	$ (0.10)	$ (2.86)
Weighted average common shares outstanding, basic and diluted	94,591,715	1,608,568	163,873,489	3,912,800

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

	December 31, 2020[1]	December 31, 2019[1]
Assets		
Cash and cash equivalents	$ 77,068	$ 11,249
Prepaid expenses and other	10,921	2,699
Total current assets	87,989	13,948
Other non-current assets	10,194	610
Total assets	$ 98,183	$ 14,558
Liabilities and stockholders' equity		
Total liabilities	$ 10,535	$ 5,141
Stockholders' equity	87,648	9,417
Total liabilities and stockholders' equity	$ 98,183	$ 14,558

[1]The condensed consolidated balance sheets for the years ended December 31, 2020 and December 31, 2019 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.