November 8, 2019

Tonix Pharmaceuticals Reports Third Quarter 2019 Financial Results and Operational Highlights

50% of Enrollment Complete for Phase 3 RECOVERY Trial of Tonmya® for the Treatment of PTSD

Results from RECOVERY Interim Analysis Expected First Quarter 2020

Topline Data Expected Second Quarter 2020 Based on Currently-Planned Sample Size

NEW YORK, Nov. 08, 2019 (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 September 30, 2019, and provided an overview of recent operational highlights. Tonix's lead product candidate, TNX-102 SL*, is in Phase 3 development for the treatment of both posttraumatic stress disorder (PTSD) and fibromyalgia.

"We recently reported that we have enrolled over 50 percent of the current target number of participants for our Phase 3 RECOVERY study of TNX-102-SL or Tonmya®** for the treatment of PTSD," said Seth Lederman, M.D., President and Chief Executive Officer. "The first 50% of participants (n = 125) are the cohort for the interim analysis of the RECOVERY study for which we expect results in the first quarter of 2020. We also expect to report topline data from RECOVERY in the second quarter of 2020 unless the Independent Data Monitoring Committee (IDMC) recommends increasing the number of participants. In addition, we are planning to start a new Phase 3 study of TNX-102 SL in fibromyalgia, the F304 or RELIEF study."

Recent Highlights

Research and Development

TNX-102 SL (cyclobenzaprine HCl sublingual tablets)

- Based on guidance from its recent Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA), the Company plans to conduct an interim analysis for the currently-enrolling Phase 3 RECOVERY study. Pending final approval by FDA, the planned interim analysis will have three possible recommendations: 1) keep the current sample size and continue as planned; 2) provide the opportunity to increase the sample size to include up to a maximum of 120 additional participants, based on certain criteria; and 3) stop the study early for futility.
- Changed the timing of primary endpoint analysis for the currently-enrolling Phase 3

RECOVERY study from Week 4 to Week 12, to correspond to the two previous studies of TNX-102 SL in PTSD, based on guidance from the FDA.

- Initiated a single-dose, randomized, open-label, 3-way crossover study to evaluate the dose-proportionality and food-effect of TNX-102 SL in healthy subjects (TNX-CY-F110). This study is one of the requirements to support a New Drug Application (NDA) for TNX-102 SL.
- Completed long-term studies in participants with PTSD to evaluate the tolerability of TNX-102 SL 5.6 mg to support an NDA for the treatment of PTSD. The data provide Tonix with exposure data of daily dosing of TNX-102 SL 5.6 mg for at least 12 months in more than 50 individuals, and daily dosing of TNX-102 SL 5.6 mg for at least 6 months in more than 100 individuals. The data was collected in open label extension (OLE) studies of the PTSD program. Based on FDA guidance, the long-term studies in PTSD are also expected to support an NDA for the treatment fibromyalgia.
- Met with the FDA in October to discuss the development plan for TNX-102 SL as a treatment for alcohol use disorder (AUD). This new indication is expected to be developed under a separate IND. 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.
- Met with FDA to discuss the continuation of the Breakthrough Therapy Designation (BTD) for TNX-102 for PTSD in August 2019 after receiving the “Intent to Rescind” letter in December 2018. FDA is considering the data we submitted to support the continuation of the BTD. The FDA has advised that there is no timetable for their decision on whether to withdraw the “Intent to Rescind” letter or rescind BTD or for any other action. The BTD for TNX-102 SL for PTSD and the “Intent to Rescind” letter both continue to remain in effect.
- Awarded U.S. Patent No. 10,357,465 for the composition and formulation of TNX-102 SL. This patent, “Eutectic Formulations of Cyclobenzaprine Hydrochloride,” includes 14 claims directed to eutectics of cyclobenzaprine hydrochloride and mannitol and methods of making those eutectics. U.S. market exclusivity, excluding possible patent term extensions, is expected through 2035.
- Announced the upholding of the Company’s European method of use patent, 2501234B1, for TNX-102 SL for use of the active ingredient in TNX-102 SL, cyclobenzaprine, for the treatment of PTSD, by the European Patent Office.

TNX-601 CR (tianeptine oxalate)

- Dosed healthy subjects in a Phase 1 study evaluating the safety, tolerability and pharmacokinetics (PK) of controlled release (CR) formulations of TNX-601 (tianeptine oxalate). TNX-601 is being developed as a potential daytime treatment for PTSD. Data from this study are expected by the end of 2019. Expected to be Phase 2 ready for ex-US study and IND-ready in the US in 2020.
- Awarded U.S. patent No. 10,449,203 for crystalline tianeptine oxalate salt, the active ingredient of TNX-601.This patent “Tianeptine Oxalate Salts and Polymorphs,” includes claims directed to crystalline tianeptine oxalate salts, and disclosures directed to methods of using those crystalline forms and their compositions. U.S. market exclusivity, excluding possible patent term extensions, is expected through December 28, 2037.

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 licensed assets were 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 (TBM) program in the Herbert Irving Cancer Center at Columbia University.

TNX-1500 (monoclonal antibody anti-CD154)

- 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.

*TNX-1300*** (double-mutant cocaine esterase)*

- Met with FDA to discuss and reach agreement on the design of toxicology studies for TNX-1300 to support a Phase 2 clinical study.

TNX-1600 (triple reuptake inhibitor)

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

TNX-801 (live virus vaccine for percutaneous [scarification] administration)

- Joined the Alliance for Biosecurity, a coalition of biopharmaceutical companies and laboratory/academic partners that promotes a strong public-private partnership to ensure medical countermeasures are available to protect public health and enhance national health security.

Financial

Raised $5.4 million in gross proceeds in an underwritten public offering in July 2019.

Third Quarter 2019 Financial Results

Research and development expenses for the third quarter of 2019 totaled $5.1 million, compared to $3.3 million for the same period in 2018. This increase is primarily due to timing of activities related to the PTSD RECOVERY study, ramp-up of work related to TNX-601, and an increase in non-clinical expenses related to development of the pipeline.

General and administrative expenses for the third quarter of 2019 totaled $2.8 million, compared to $2.3 million for the same period in 2018. The modest increase is primarily due to an increase in patent prosecution costs and higher insurance premiums.

Net loss was $7.8 million, or $5.69 per share, for the third quarter of 2019, compared to net loss of $5.5 million, or $54.99 per share, for the third quarter of 2018. The weighted average common shares outstanding were 1,377,857 for the third quarter of 2019 and 99,640 for the

third 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.

At September 30, 2019, Tonix had $10.0 million of cash and cash equivalents, compared to $25.0 million as of December 31, 2018. Cash used in operations was $6.6 million for the third quarter of 2019, compared to $4.9 million for the same period last year.

About the Phase 3 RECOVERY Study

The RECOVERY Phase 3 study is a double-blind, randomized, placebo-controlled study of Tonmya 5.6 mg (2 x 2.8 mg sublingual tablets) over 12 weeks of treatment for civilian and military-related PTSD. The RECOVERY Phase 3 study restricts enrollment of study participants to individuals with PTSD who experienced an index trauma within nine years of screening. Two previous PTSD studies of Tonmya by the Company (P201 and P301) restricted enrollment to participants who experienced traumas during military service since 2001. The primary efficacy endpoint is the Week 12 mean change from baseline in the severity of PTSD symptoms as measured by CAPS-5 between those treated with Tonmya and those receiving placebo. The CAPS-5 is a standardized structured clinical interview and serves as the standard in research for measuring the symptom severity of PTSD. A formal unblinded interim analysis will be completed when approximately 50 percent (n=125) of participants have been randomized and have completed or discontinued the 12-week course of treatment with bedtime Tonmya 5.6 mg or placebo sublingual tablets. The Company expects to report the results of the interim analysis and the recommendation of the IDMC in the first quarter of 2020. If the current projected population of 250 study participants remains unchanged, the Company expects to report topline data in the second quarter of 2020.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Tonix's lead product candidate, TNX-102 SL, is in development for posttraumatic stress disorder (PTSD), fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder (AUD). TNX-102 SL is in Phase 3 development as a bedtime treatment for PTSD (trade name Tonmya) and fibromyalgia. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling and results from an interim analysis are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. The Company is planning the Phase 3 RELIEF trial (F304) in fibromyalgia. The agitation in Alzheimer's disease program is Phase 2 ready and the development for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix is advancing two other PTSD therapeutic programs in the pre-IND stage, with different mechanisms than TNX-102 SL and designed for daytime dosing: TNX-601 (tianeptine oxalate-CR tablets) and TNX-1600 (a triple reuptake inhibitor). TNX-601 is in clinical formulation testing outside of the U.S and is expected to be IND-ready in 2020. Tonix's programs for treating addiction conditions also include TNX-1300 (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication. 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. Finally, TNX-801 (live virus vaccine for percutaneous [scarification] administration) to potentially prevent smallpox and TNX-701 (undisclosed small molecule) to

prevent radiation effects are being advanced as medical countermeasures to improve biodefense.

**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 U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL for the treatment of PTSD.*

****TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has 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; 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, 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 Third 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		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018

Costs and expenses				
Research and development	$ 5,052	$ 3,264	$ 12,502	$ 12,501
General and administrative	2,839	2,277	7,592	6,171
Total costs and expenses	7,891	5,541	20,094	18,672
Operating loss	(7,891)	(5,541)	(20,094)	(18,672)
Interest income, net	53	62	183	171
Net loss	$ (7,838)	$ (5,479)	$ (19,911)	$ (18,501)
Net loss per common share, basic and diluted	$ (5.69)	$ (54.99)	$ (23.93)	$ (195.51)
Weighted average common shares outstanding, basic and diluted*	1,377,857	99,640	832,050	94,628

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

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

	September 30, 2019	December 31, 2018(1)
Assets		
Cash and cash equivalents	$ 10,024	$ 25,034
Prepaid expenses and other	1,529	1,022
Total current assets	11,553	26,056
Other non-current assets	719	263
Total assets	$ 12,272	$ 26,319
Liabilities and stockholders' equity		
Total liabilities	$ 2,417	$ 2,655
Stockholders' equity	9,855	23,664
Total liabilities and stockholders' equity	$ 12,272	$ 26,319

(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.

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Source: Tonix Pharmaceuticals Holding Corp.