August 12, 2019

Tonix Pharmaceuticals Reports Second Quarter 2019 Financial Results and Operational Highlights

Enrollment Continues for Phase 3 RECOVERY Trial of Tonmya® for the Treatment of PTSD; Topline Data Expected First Half of 2020

Pipeline Expanded in Addiction Medicine with Cocaine Antidote TNX-1300 and Potential New Alcohol Use Disorder Indication for TNX-102 SL

Balance Sheet Strengthened with July Equity Offering

NEW YORK, Aug. 12, 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 June 30, 2019, and an overview of recent operational highlights. Tonix's lead program is the development of TNX-102 SL, or Tonmya* (cyclobenzaprine HCl sublingual tablets), for the treatment of posttraumatic stress disorder (PTSD), which is currently being studied in a Phase 3 efficacy trial.

"Enrollment continues in our Phase 3 RECOVERY study of Tonmya for the treatment of PTSD, and we anticipate topline results in the first half of 2020, as previously guided," said Seth Lederman, M.D., President and Chief Executive Officer. "Since the end of the first quarter, we have re-started Phase 3 development of TNX-102 SL for fibromyalgia. We are also expanding TNX-102 SL development to include alcohol use disorder (AUD), which is in the pre-investigational new drug (IND) application stage. We also added to our pipeline with the in-licensing of TNX-1300**, a Phase 2 biologic for the treatment of cocaine intoxication, and with the internal development of TNX-1500 for the prevention and treatment of organ transplant rejection. Finally, we successfully raised equity proceeds to reinforce our balance sheet and further fund our programs. The first half of 2019 has been an exciting time for Tonix and provides great momentum for the rest of the year."

Recent Highlights

- In July 2019, raised gross proceeds of approximately $5.4 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company. The Company expects to use the net proceeds to help fund Phase 3 development of TNX-102 SL, to advance the development of TNX-1300 and for working capital and other general corporate purposes.

- Presented results from pharmacokinetic (PK) analyses of TNX-102 SL in a poster presentation at the American Society of Clinical Psychopharmacology. The Company's poster titled, 'Steady-State Pharmacokinetic Properties of a Sublingual Formulation of Cyclobenzaprine (CBP) HCl (TNX-102 SL): Comparison to Simulations of Oral Immediate Release CBP' reports PK results of TNX-102 SL, a sublingual form of cyclobenzaprine studied in a comparative PK, open-label, randomized, parallel, two-arm, multiple-dose pivotal bridging study, with the reference listed drug AMRIX® (cyclobenzaprine HCl extended release capsules). The study provided the necessary PK data to support TNX-102 SL as a 505(b)(2) regulatory approval pathway which can streamline the U.S. Food and Drug Administration (FDA) approval of TNX-102 SL by relying on the safety findings and relevant labeling information of AMRIX.

- Added a new program to study TNX-102 SL as a treatment for alcohol use disorder (AUD). Tonix plans to meet with the FDA in October 2019 to discuss this new indication which will 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. An estimated 16 million people in the United States have AUD. Sleep disturbance is extremely common in alcohol recovery; it can significantly impact daytime cognition, mood, and ability to participate in alcohol treatment, and is associated with increased risk of relapse. Tonix believes that by improving sleep quality, the rate of successful recovery for people with AUD can be substantially improved.

- Expanded pipeline with a Phase 2 biologic, TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) for cocaine intoxication. Currently there is no specific pharmacotherapy indicated for cocaine

intoxication, a state characterized by acute agitation, hyperthermia, tachycardia, arrhythmias, and hypertension, with the potential life-threatening sequelae of myocardial infarction, cerebrovascular accident, rhabdomyolysis, respiratory failure, and seizures. Patients are currently managed only by supportive care for the adverse effects of cocaine overdose on the cardiovascular and central nervous systems.

- Expanded pipeline with TNX-1500, Tonix's internally developed, proprietary anti-CD154 monoclonal antibody (mAb) that targets CD154 for the prevention and treatment of organ transplant rejection. TNX-1500 is also a potential treatment for autoimmune conditions. TNX-1500 is in the pre-IND application stage.

- Expanded intellectual property for the composition and formulation of TNX-102 SL in China and the United States, providing intellectual property protection until 2034 and 2035, respectively.

Second Quarter 2019 Financial Results

At June 30, 2019, Tonix had $12.2 million of cash and cash equivalents, compared to $25.0 million as of December 31, 2018. Cash used in operations was $4.7 million for the second quarter of 2019, compared to $5.5 million for the same period last year and $8.6 million for the first quarter of 2019.

Research and development expenses for the second quarter of 2019 totaled $3.6 million, compared to $4.1 million for the same period in 2018. This decrease is primarily due to timing of development milestones related to the PTSD HONOR study which was completed in 2018.

General and administrative expenses for the second quarter of 2019 totaled $2.4 million, compared to $2.1 million for the same period in 2018. The modest increase is primarily due to an increase in patent prosecution costs and higher insurance premiums in 2019.

Net loss was $5.8 million, or $0.95 per share, for the second quarter of 2019, compared to net loss of $6.1 million, or $7.23 per share, for the second quarter of 2018. The weighted average common shares outstanding for the second quarter of 2019 was 6,167,012 shares. The weighted average common shares outstanding for the second quarter of 2018, which gives effect to the 1-for-10 reverse stock split in November 2018, was 842,041 shares.

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, to improve biodefense through potential medical counter-measures, and to prevent and treat organ transplant rejection. Tonix's lead program is for the development of Tonmya* (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia, agitation in Alzheimer's disease and alcohol use disorder, to be developed under separate Investigational New Drug applications (INDs) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development, the agitation in Alzheimer's program is Phase 2 ready and the alcohol use disorder program is in the pre-IND application stage. TNX-1300** (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Data is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted outside of the U.S. TNX-801 (live virus vaccine for percutaneous (scarification) administration) is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage. Finally, TNX-1500 is being developed to prevent and treat organ transplant rejection, as well as to treat autoimmune conditions, and is in the pre-IND application stage.

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

***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 atwww.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; 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 on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Costs and expenses				
Research and development	$ 3,554	$ 4,067	$ 7,450	$ 9,237
General and administrative	2,352	2,076	4,753	3,894
Total costs and expenses	5,906	6,143	12,203	13,131
Operating loss	(5,906)	(6,143)	(12,203)	(13,131)
Interest income, net	66	56	130	109
Net loss	$ (5,840)	$ (6,087)	$ (12,073)	$ (13,022)
Net loss per common share, basic and diluted	$ (0.95)	$ (7.23)	$ (2.19)	$ (15.98)
Weighted average common shares outstanding, basic and diluted	6,167,012	842,041	5,511,249	815,120

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

	June 30, 2019	**December 31, 2018(1)**
Assets		
Cash and cash equivalents	$ 12,150	$ 25,034
Prepaid expenses and other current assets	2,009	1,022
Total current assets	14,159	26,056
Other non-current assets	849	263
Total assets	$ 15,008	$ 26,319
Liabilities and stockholders' equity		
Total liabilities	$ 2,186	$2,655
Stockholders' equity	12,822	23,664
Total liabilities and stockholders' equity	$ 15,008	$ 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9159

Scott Stachowiak (media)
Russo Partners
scott.stachowiak@russopartnersllc.com
(646) 942-5630

Peter Vozzo (investors)
Westwicke Partners
peter.vozzo@westwicke.com
(443) 213-0505

Source: Tonix Pharmaceuticals Holding Corp.