November 9, 2018

Tonix Pharmaceuticals Reports Third Quarter 2018 Financial Results and Operational Highlights

New Phase 3 Trial of Tonmya® for the Treatment of PTSD to Commence First Quarter 2019

NEW YORK, Nov. 09, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense, today announced financial results for the third quarter ended September 30, 2018, and an overview of recent operational highlights.

“We are pleased to be initiating a new Phase 3 study of Tonmya* for the treatment of PTSD in the first quarter of 2019,” said Seth Lederman, M.D., President and Chief Executive Officer. “This new Phase 3 study has several innovative design features that are based on retrospective analyses of data from the Phase 3 HONOR and Phase 2 AtEase studies, in addition to feedback received from the FDA during a Breakthrough Therapy Clinical Guidance meeting in October. It has been preliminarily accepted by the FDA as a potential pivotal efficacy study to support the registration of Tonmya for the treatment of PTSD.”

Recent Program Highlights

- Received the U.S. Food and Drug Administration’s (FDA) preliminary agreement on the new PTSD Phase 3 study design in October. The new Phase 3 study of Tonmya will begin in the first quarter of 2019 and will have several innovative design features including: restricting enrollment to individuals with PTSD who experienced an index trauma within nine years of screening; enrolling participants who have experienced civilian traumas, in addition to participants whose traumas are military-related; and a CAPS-5 primary endpoint assessed at Week 4 instead of at Week 12, the end of the treatment period. This new 12-week study will require a baseline CAPS-5 score of ≥ 33 for enrollment, as was the case with the Phase 3 HONOR study.

- Presented results and retrospective analyses of the Phase 3 HONOR study in a poster presentation at CNS Summit 2018 in November.

- New composition of matter patent was issued in November which expands the Company’s intellectual property protection for Tonmya, or TNX-102 SL, in the U.S.

The patent is part of an expanding portfolio of patents and patent applications and other intellectual property addressing the formulation, manufacturing, and uses of Tonmya, or TNX-102 SL, for a variety of indications including posttraumatic stress disorder, agitation in Alzheimer's disease and fibromyalgia.

- Presented results and retrospective analyses of the Phase 3 HONOR study and Phase 2 AtEase Study at the 2018 Military Health System Research Symposium in August.

- Phase 3 HONOR study stopped early in July based on interim analysis of Week 12 data in 274 PTSD participants.

- Received Fast Track designation for TNX-102 SL for agitation in Alzheimer's disease, from the FDA in July. The Company received FDA comments on a Phase 2 / potential pivotal efficacy study protocol for this indication in October.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

Third Quarter 2018 Financial Results

Research and development expenses for the third quarter of 2018 totaled $3.3 million, compared to $3.9 million for the same period in 2017. This decrease is predominately due to the termination of the Phase 3 HONOR study at the end of July 2018.

General and administrative expenses for the third quarter of 2018 were $2.3 million, compared to $1.9 million for the same period in 2017. This increase is primarily due to an increase in legal fees related to patent prosecution, as well as investor and public relations.

Net loss was $5.5 million, or $0.57 per share, for the third quarter of 2018, compared to net loss of $5.8 million, or $0.77 per share, for the third quarter of 2017.

At September 30, 2018, Tonix had $14.7 million of cash and cash equivalents, compared to $25.5 million as of December 31, 2017. Cash used in operations was $4.9 million for the three months ended September 30, 2018, compared to $5.0 million for the three months ended September 30, 2017.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix is developing Tonmya, which is in Phase 3 development and has been granted Breakthrough Therapy designation, as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under a separate IND to support a Phase 2, potential pivotal, efficacy study and has been

designated a Fast Track development program by the FDA for this indication. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a unique mechanism and designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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; 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, 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 2018 Financial Results

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Costs and expenses				
Research and development	$ 3,264	$ 3,908	$ 12,501	$ 9,708
General and administrative	2,277	1,927	6,171	6,040
Total costs and expenses	5,541	5,835	18,672	15,748
Operating loss	(5,541)	)	(18,672)	)

Interest income, net	62	(5,835 49		(15,748 118
Net loss	$ (5,479)	$ (5,786)	$ (18,501)	$ (15,630)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.77)	$ (2.15)	$ (2.49)
Weighted average common shares outstanding, basic and diluted	9,587,025	7,508,036	8,616,039	6,287,062

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

	September 30, 2018	December 31, 2017(1)
Assets		
Cash and cash equivalents	$ 14,674	$ 25,496
Prepaid expenses and other current assets	1,206	947
Total current assets	15,880	26,443
Other non-current assets	175	311
Total assets	$ 16,055	$ 26,754
Liabilities and stockholders' equity		
Total liabilities	$ 2,346	$ 2,138
Stockholders' equity	13,709	24,616
Total liabilities and stockholders' equity	$ 16,055	$ 26,754

(1) The condensed consolidated balance sheet for the year ended December 31, 2017 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.