August 14, 2017

Tonix Pharmaceuticals Reports Second Quarter 2017 Financial Results and Provides Programs Update

Interim Analysis of Phase 3 HONOR study of Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) in Military-Related PTSD Expected 1H18 and Topline Results Expected 2H18

NEW YORK, Aug. 14, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company in Phase 3 development of Tonmya*, a U.S. Food and Drug Administration-designated Breakthrough Therapy for the treatment of posttraumatic stress disorder (PTSD), and in various development stages for other innovative pharmaceutical and biological products to address public health challenges, recently announced financial results for the second quarter ended June 30, 2017.

“The past quarter was a busy and exciting time for us as we continued enrollment in the Phase 3 HONOR study of Tonmya for the treatment of military-related PTSD,” said Seth Lederman, M.D., president and chief executive officer of Tonix. “HONOR remains on track for an unblinded interim analysis of 50% of efficacy evaluable participants in the first half of 2018 and to report topline results from the full study in the second half of 2018. As discussed with the U.S. Food and Drug Administration (FDA) at the Initial Cross-Disciplinary Breakthrough Therapy meeting, statistically persuasive topline data from this interim analysis could support early filing of a New Drug Application (NDA).”

The sublingual formulation of Tonmya is designed for transmucosal absorption of the active ingredient, cyclobenzaprine, which acts on PTSD symptoms by improving sleep quality. It is administered once daily at bedtime. The FDA has indicated that no additional drug dependence and addiction study is needed for the Tonmya NDA.

At June 30, 2017, Tonix had cash and cash equivalents of $34.4 million. Net cash used in operating activities for the three months ended June 30, 2017 was $4.4 million.

Recent Program Highlights:

- Continued enrollment of the HONOR study, a 12-week, multi-center, double-blind, placebo-controlled Phase 3 study of Tonmya 5.6 mg (2 x 2.8 mg tablets) for the treatment of military-related PTSD. Interim results of approximately 275 efficacy evaluable participants are due 1H18. Topline results from the full study (550 participants), if needed, are scheduled for 2H18.
- Received notice that the U.S. Patent and Trademark Office has issued a patent

(U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034.

- Participated in the "Pathophysiology of Posttraumatic Stress Disorder: Rethinking Drug Targets" summit sponsored by the Department of Defense. The invitation-only meeting assembled experts from government, industry and academia and was the first of its kind. Motivated by the need for more effective and safe pharmacological therapies for PTSD among the military population, the summit was co-hosted by the U.S. Army Medical Materiel Development Activity's Neurotrauma and Psychological Health Project Management Office and the Joint Program Committee/Military Operational Medicine Research Program.
- Presented additional retrospective analyses of treatment response and safety parameters from the Phase 2 AtEase study at the Annual Scientific Convention of the Society of Biological Psychiatry, available at http://bit.ly/2uulTLP.
- Presented additional retrospective analyses of treatment response from the Phase 2 AtEase study the Annual Meeting of the American Society of Clinical Psychopharmacology, available at http://bit.ly/2utvAhN.
- Continued development of TNX-801 (synthesized horsepox) to meet Good Manufacturing Practice quality for a study to be supported by an Investigational New Drug (IND) application.
- Received FDA conditional acceptance of the proposed trade name Tonmya*(ton-MY-ah)* for TNX-102 SL for the treatment of PTSD.

For a video overview of the current Tonix development pipeline, please see http://ir.tonixpharma.com/video.

**Tonmya® has been conditionally accepted by the 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.*

Second Quarter Financial Results

Tonix reported a net loss of $4.8 million, or $0.65 per share, for the second quarter of 2017, compared to a net loss of $9.8 million, or $4.97 per share, for the second quarter of 2016. The net loss for the three months ended June 30, 2017, excluding non-cash expenditures of $0.5 million, was $4.3 million, as compared to a net loss, excluding non-cash expenditures of $0.7 million, of $9.1 million for the second quarter of 2016. The lower net loss was primarily due to decreased research and development expense for clinical studies and related research, as well as lower general and administrative expense related to these and other corporate development activities.

Tonix reported a net loss of $9.8 million, or $1.74 per share, for the six months ended June 30, 2017, compared to a net loss of $23.8 million, or $12.31 per share, for the six months ended June 30, 2016. The net loss for the six months ended June 30, 2017, excluding non-cash expenditures of $1.1 million, was $8.7 million, as compared to a net loss of $22.1 million, excluding non-cash expenditures of $1.7 million, for the six months

ended June 30, 2016. The lower net loss was primarily due to decreased research and development expense during the first six months of 2017 for clinical studies and research, as well as lower general and administrative expense needed to support these and other corporate development activities.

Cash used in operations was $4.4 million and $9.2 for the three and six months ended June 30, 2017, respectively, as compared to $8.0 million and $23.5 million for the three and six months ended June 30, 2016, respectively. At June 30, 2017, cash, cash equivalents, and marketable securities totaled $34.4 million, compared to $26.1 million at December 31, 2016. Management believes that cash, cash equivalents and marketable securities as of June 30, 2017 are sufficient to fund operating expenses and the Phase 3 HONOR study to completion with up to 550 participants.

About Tonmya and the Phase 3 HONOR Study

Tonmya is a patented sublingual transmucosal formulation of cyclobenzaprine that is in Phase 3 development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets), was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the United States, the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants across approximately 35 clinical sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In the Initial Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges. In addition to Tonmya for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND application stage, designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, to be developed as a potential smallpox-preventing vaccine.

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, substantial competition; 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2016, as filed with the Securities and Exchange Commission (the “SEC”) on April 13, 2017, and future periodic reports filed with the SEC on or after the date hereof. 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 hereof.

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,	
	2017	**2016**	**2017**	**2016**
Costs and expenses				
Research and development	$2,806	$7,516	$5,800	$18,187
General and administrative	2,016	2,320	4,113	5,663
Total costs and expenses	4,822	9,836	9,913	23,850
Operating loss	(4,822)	(9,836)	(9,913)	(23,850)
Interest income, net	42	30	69	68
Net loss	$(4,780)	$(9,806)	$(9,844)	$(23,782)
Net loss per common share, basic and diluted	$(0.65)	$(4.97)	$(1.74)	$(12.31)
Weighted average common shares outstanding, basic and diluted	7,327,890	1,973,643	5,666,457	1,931,193

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

	June 30, 2017	**December 31, 2016(1)**
Assets		
Cash, cash equivalents and marketable securities	$34,355	$26,121
Prepaid expenses and other current assets	1,130	1,019

Total current assets	35,485	27,140
Other non-current assets	338	370
Total assets	$35,823	$27,510
Liabilities and stockholders' equity		
Total liabilities	$1,854	$2,149
Stockholders' equity	33,969	25,361
Total liabilities and stockholders' equity	$35,823	$27,510

(1) The condensed consolidated balance sheet for the year ended December 31, 2016 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.

For more information:

Jessica Smiley
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 980-9155 x18

Media Contact
Rich Allan
Russo Partners
rich.allan@russopartnersllc.com
(646) 942-5588

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