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

Phase 3 HONOR Study of U.S. FDA-Designated Breakthrough Therapy for PTSD, TNX-102 SL, Fully Funded and Currently Enrolling

NEW YORK, May 15, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, recently announced financial results for the first quarter ended March 31, 2017.

“Beginning enrollment in the first quarter of 2017 of the Phase 3 HONOR study of TNX-102 SL* for the treatment of posttraumatic stress disorder (PTSD) was an important milestone for Tonix,” said Seth Lederman, M.D., president and chief executive officer of Tonix. “We remain on track with our previously-disclosed guidance for reporting results next year, and are pleased to note that this pivotal study is fully funded through completion. If the topline data from the HONOR study are statistically persuasive, we can file a new drug application with the U.S. Food and Drug Administration (FDA) seeking approval for TNX-102 SL for PTSD.

PTSD affects approximately 8.6 million Americans, nearly 1 million of whom are military veterans. Patients with military-related PTSD experience severe symptoms, and currently-approved drugs have not shown efficacy in these patients, creating an urgent need for a new therapeutic approach.”

At March 31, 2017, Tonix had cash, cash equivalents, and marketable securities of \$22.4 million. Subsequent to quarter end, Tonix raised net proceeds totaling approximately \$16.3 million. Tonix announced an underwritten public offering of common stock in the first quarter that closed in April 2017 and resulted in net proceeds of approximately \$8.3 million. Additionally, Tonix raised approximately \$8.0 million in net proceeds through an at-the-market offering in April 2017. Net cash used in operating activities for the first quarter was \$4.8 million.

Upcoming Milestones and Recent Program Highlights

- Interim analysis from approximately 275 randomized participants in the Phase 3 HONOR study is anticipated in the first half of 2018.
- Topline results from the Phase 3 HONOR study of 550 participants (if needed) are anticipated in the second half of 2018.
- Enrolled the first participant in the 12-week, double-blinded, placebo-controlled Phase 3 HONOR study of TNX-102 SL 5.6 mg for the treatment of military-related PTSD in March 2017.

- Held the Initial Cross-Disciplinary Breakthrough meeting with the FDA in March 2017. Minutes from the meeting indicated that registration of TNX-102 SL could be solely supported by the Phase 3 HONOR study if topline data are statistically persuasive.
- Eutectic proprietary Protectic™ formulation patent (U.S. Patent No. 9,636,408), issued in May 2017, provides for TNX-102 SL market exclusivity until 2034.
- In the first quarter of 2017, announced synthesis of a potential smallpox-preventing vaccine candidate, TNX-801, a live form of horsepox virus, which has demonstrated protective vaccine activity in mice. TNX-801 is the first-ever synthesized chimeric horsepox virus.
- In the first quarter of 2017, announced addition to pipeline of tianeptine oxalate, TNX-601, a novel oral formulation for development as a potential daytime treatment for PTSD.

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

First Quarter Financial Results

Tonix reported a net loss of \$5.1 million, or \$1.27 per share, for the first quarter of 2017, compared to a net loss of \$14.0 million, or \$7.41 per share, for the first quarter of 2016. The net loss for the three months ended March 31, 2017, excluding non-cash expenditures of \$0.6 million, was \$4.5 million, as compared to a net loss, excluding non-cash expenditures of \$1.0 million, of \$13.0 million for the first 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.

Cash used in operations was \$4.8 million for the three months ended March 31, 2017, compared to \$15.5 million for the three months ended March 31, 2016. At March 31, 2017, cash, cash equivalents, and marketable securities totaled \$22.4 million, compared to \$26.1 million at December 31, 2016. Management believes that cash, cash equivalents and marketable securities as of March 31, 2017, in addition to the approximately \$16.3 million net proceeds raised from the recent public offerings, are sufficient to fund operating expenses and the Phase 3 HONOR study to completion with up to 550 participants.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address public health challenges. TNX-102 SL is in Phase 3 development and has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. 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. Tonix was issued U.S. patent 9,636,408 “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride”, which includes compositions of cyclobenzaprine HCl and methods of manufacturing the eutectic. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix’s proprietary TNX-102 SL composition. The patent provides Tonix with U.S. market exclusivity until 2034. Other development efforts include TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, and TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND

(Investigational New Drug) application stage, designed for daytime use for the treatment of PTSD.

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 March 31,	
	2017	2016
Costs and expenses		
Research and development	\$ 2,994	\$ 10,671
General and administrative	2,097	3,343
Total costs and expenses	5,091	14,014
Operating loss	(5,091)	(14,014)
Interest income, net	27	38
Net loss	\$(5,064)	\$(13,976)
Net loss per common share, basic and diluted	\$ (1.27)	\$ (7.41)
Weighted average common shares outstanding, basic and diluted	3,985,529	1,886,043

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

(Unaudited)

	<u>March 31, 2017</u>	<u>December 31, 2016 (1)</u>
Assets		
Cash, cash equivalents and marketable securities	\$22,423	\$26,121
Prepaid expenses and other current assets	1,009	1,019
Total current assets	23,432	27,140
Other non-current assets	352	370
Total assets	<u>\$23,784</u>	<u>\$27,510</u>
Liabilities and stockholders' equity		
Total liabilities	\$ 1,809	\$ 2,149
Stockholders' equity	21,975	25,361
Total liabilities and stockholders' equity	<u>\$23,784</u>	<u>\$27,510</u>

(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.

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Source: Tonix Pharmaceuticals Holding Corp.