May 11, 2015

Tonix Pharmaceuticals Reports First Quarter 2015 Financial Results and Clinical Update

On Track to Commence Two Clinical Studies This Quarter;

Phase 2 Proof-of-Concept Headache Study Results Due by Year-End

NEW YORK, May 11, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) ("Tonix") announced financial results for the first quarter ended March 31, 2015.

"Our experienced development team has made significant progress over the past several months, which included obtaining U.S. Food and Drug Administration (FDA) agreement on the acceptable primary endpoint for our Phase 3 fibromyalgia study as well as input on our Phase 2 proof-of-concept tension headache study design. Our successful preparation paves the way for several prominent milestones in our portfolio of drug candidates for central nervous system disorders," said Seth Lederman, M.D., chairman and CEO of Tonix. "We are very excited about the upcoming initiation of our Phase 3 fibromyalgia study of TNX-102 SL. In addition, our Phase 2 study of TNX-102 SL in military-related post-traumatic stress disorder (PTSD) is progressing as expected. Our Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is on track to start this quarter, and from which we expect to report top-line data in the fourth quarter of 2015."

"Having three large, adequate, and well-controlled clinical studies in high-value therapeutic indications simultaneously ongoing validates our business model of developing next generation medicines for significant unmet needs in a capital-efficient manner," added Dr. Lederman.

Tonix ended the March 31, 2015 quarter with $58.2 million in cash.

Recent Clinical Highlights and Upcoming Milestones

- TNX-102 SL (cyclobenzaprine HCl sublingual tablet, 2.8 mg) is in clinical development for two indications, fibromyalgia and post-traumatic stress disorder:

  - A 500-subject Phase 3 study in fibromyalgia will be conducted at 30-35 U.S. centers, and top-line results from this study are expected in the second half of 2016. Fibromyalgia afflicts five to 15 million Americans, and clinicians and patients report widespread dissatisfaction with currently marketed products. To learn more, please visit www.clinicaltrials.gov (NCT02436096); and,

- A 220-patient Phase 2 study in military-related PTSD is currently enrolling at up to 25 U.S. sites, and top-line results from this study are expected in the first half of 2016. PTSD afflicts roughly eight million Americans, with an especially high incidence among military personnel returning from the Persian Gulf wars. Both of the FDA-approved drugs for PTSD have been shown to be ineffective in military populations, and are associated with an increased risk of suicidality. To learn more, please visit www.ateasestudy.com.

- TNX-201 (dexisometheptene mucate) is in clinical development for episodic tension-type headache. A 200-patient Phase 2 proof-of-concept study will begin this quarter, from which top-line results are expected in the fourth quarter of this year. Approximately 75 million people in the U.S. suffer from frequent episodic tension-type headache, a condition that is estimated to be three times as prevalent as migraine. All of the drugs approved for tension headache contain barbiturates. If approved by the FDA, TNX-201 may become the only non-narcotic prescription medicine for episodic tension-type headache and the first new prescription pharmaceutical approved for this indication in more than 40 years. To learn more, please visit www.clinicaltrials.gov (NCT02423408).

First Quarter Financial Results

For the three months ended March 31, 2015, Tonix reported a net loss of $9.7 million, or $0.71 per share, as compared to a net loss of $5.2 million, or $0.59 per share, for the first quarter of 2014. The higher net loss was primarily due to increased research and development expense for clinical studies and related research as well as increased general and administrative expense to support these and other corporate development activities. At March 31, 2015, Tonix's cash totaled $58.2 million as compared to $38.2 million at December 31, 2014.

About Tonix Pharmaceuticals

Tonix Pharmaceuticals is dedicated to the development of next-generation medicines for common yet challenging disorders of the central nervous system, characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. Tonix's clinical-stage candidates are being developed for fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache. To learn more, please visit www.tonixpharma.com.

Cautionary Note on 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" 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 filed with the SEC on February 27, 2015 and future periodic reports filed with the Securities and Exchange Commission. 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,	
	2015	**2014**
Costs and expenses		
Research and development	$6,829	$3,550
General and administrative	2,867	1,619
Total costs and expenses	9,696	5,169
Operating loss	(9,696)	(5,169)
Interest income, net	15	5
Net loss	$(9,681)	$(5,164)
Net loss per common share, basic and diluted	$(0.71)	$(0.59)
Weighted average common shares outstanding, basic and diluted	13,696,482	8,718,199

TONIX PHARMACEUTICALS HOLDING CORP.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

(Unaudited)

	March 31, 2015	**December 31, 2014(1)**
Assets		
Cash	$58,181	$38,184
Prepaid expense and other current assets	1,805	852
Total current assets	59,986	39,036
Other non-current assets	484	506
Total assets	$60,470	$39,542
Liabilities and stockholders' equity		
Total liabilities	$3,584	$3,450
Stockholders' equity	56,886	36,092

Total liabilities and stockholders' equity	$60,470	$39,542

(1) The condensed consolidated balance sheet for the year ended December 31, 2014 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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