March 4, 2016

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2015 Financial Results and Provides Programs Update

NEW YORK, March 04, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced financial results for the fourth quarter and full year ended December 31, 2015.

“Tonix made tremendous progress over the course of 2015 on the clinical, regulatory and operational fronts. We remain very focused on progressing our flagship clinical development program, a Phase 3 trial in fibromyalgia of Tonmya® (TNX-102 SL, cyclobenzaprine HCl sublingual tablets, 2.8 mg) and our registration-quality Phase 2 study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in PTSD,” said Seth Lederman, M.D., president and chief executive officer of Tonix. “We look forward to the year ahead as we will announce top-line data from our Phase 2 AtEase clinical trial of TNX-102 SL in PTSD in the second quarter, followed by top-line data from our Phase 3 AFFIRM study in fibromyalgia in the third quarter of this year.”

At December 31, 2015, Tonix held cash, cash equivalents, and marketable securities totaling approximately $43.0 million.

Recent Clinical Highlights and Upcoming Milestones

Tonmya – Fibromyalgia Program

- Tonix is developing TNX-102 SL for daily use at bedtime for the management of fibromyalgia, a chronic condition.
- In May 2015, Tonix commenced the randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial of Tonmya in fibromyalgia.
- Tonix expects to report top-line data from the AFFIRM trial in the third quarter of 2016.
- The primary efficacy endpoint in AFFIRM is a 30% pain responder analysis at week 12.
- Tonix expects to commence a second, 12-week Phase 3 trial of Tonmya in fibromyalgia in the second quarter of 2016.
- Results from the completed Phase 2b BESTFIT clinical trial of Tonmya in fibromyalgia was the subject of three posters presented at the American College of Rheumatology Annual Meeting on November 10, 2015.

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, non-restorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life and frequently are disabled. To learn more, please visit www.affirmstudy.com.

TNX-102 SL – PTSD Program

- Tonix is also developing TNX-102 SL, the same proprietary product candidate as Tonmya, for daily use at bedtime for the management of PTSD, a chronic condition.
- In December 2015, Tonix exceeded full enrollment of approximately 240 patients with military-related PTSD in the randomized, double-blind, placebo-controlled, 12-week Phase 2 AtEase clinical trial of TNX-102 SL.
- Tonix expects to report top-line data from the AtEase study in the second quarter of 2016.
- The primary efficacy endpoint of AtEase will evaluate the performance of TNX-102 SL 2.8 mg as measured by the mean change from baseline on the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5).
- In December 2015, Tonix signed a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Materiel Development Activity (USAMMDA) to explore expansion and potential development of TNX-102 SL for the treatment of military-related PTSD.

PTSD affects approximately 8.4 million Americans and is a chronic and severely debilitating condition, in which patients experience nightmares and disturbed sleep, and which is associated with depression and suicide. Individuals who suffer from PTSD experience impaired social functioning, occupational disability, intense anxiety and avoidance, emotional numbness, intense guilt or worry, agitation and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable or violent behaviors, additional reasons that make it a critical public health concern. PTSD can develop from witnessing or experiencing a traumatic event or ordeal in which there was the threat or actual occurrence of grave physical harm.

TNX-201 – Episodic Tension Headache Program

In June 2015, Tonix initiated a single-dose Phase 2 proof-of-concept clinical trial to evaluate the ability of TNX-201 (dexisometheptene mucate capsules 140 mg) to treat episodic tension-type headache. Tonix completed the randomized, double-blind, placebo controlled study in the first quarter of 2016. In February 2016, Tonix reported that the drug failed to show efficacy and development was terminated.

Fourth Quarter and Full Year Financial Results

Tonix reported a net loss of $13.4 million, or $0.71 per share, for the fourth quarter of

2015, compared to a net loss of $9.0 million, or $0.83 per share, for the fourth quarter of 2014. For the year ended December 31, 2015, Tonix reported a net loss of $48.1 million, or $2.86 per share, compared to a net loss of $27.6 million, or $2.77 per share, for the comparable period in 2014. At December 31, 2015, Tonix's cash, cash equivalents and marketable securities totaled $43.0 million compared to $38.2 million at December 31, 2014.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

The United States Food and Drug Administration (FDA) has conditionally accepted "Tonmya" as the proposed trade name of TNX-102 SL for fibromyalgia. Tonmya, TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved by the FDA for any indication.

Safe Harbor / 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 possible 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, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, 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 per share amounts) (1)
(unaudited)

	Three Months ended	Twelve Months ended

	December 31,			December 31,
	2015	2014	2015	2014
Costs and expenses				
Research and development	$ 9,490	5,775	$ 35,504	18,617
General and administrative	3,912	3,229	12,658	9,039
Total costs and expenses	13,402	9,004	48,162	27,656
Operating loss	(13,402)	(9,004)	(48,162)	(27,656)
Interest income, net	42	15	108	40
Net loss	$ (13,360)	(8,989)	$ (48,054)	(27,616)
Net loss per common share, basic and diluted	$ (0.71)	(0.83)	$ (2.86)	(2.77)
Weighted average common shares outstanding, basic and diluted	18,832	10,776	16,791	9,986

1. The condensed consolidated statements of operations for the years ended December 31, 2015 and 2014 have been derived from the audited financial statements, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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

	December 31, 2015	December 31, 2014 (1)
Assets		
Cash, cash equivalents and marketable securities	$ 43,016	$ 38,184
Prepaid expenses and other current assets	3,343	852
Total current assets	46,359	39,036
Non-current assets	659	506
Total assets	$ 47,018	$ 39,542
Liabilities and stockholders' equity		
Total liabilities	$ 6,756	$ 3,450
Stockholders' equity	40,262	36,092
Total liabilities and stockholders' equity	$ 47,018	$ 39,542

1. The condensed consolidated balance sheets for the years ended December 31, 2015 and 2014 have been derived from the audited financial statements, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

Contact:

Bradley J. Saenger
Chief Financial Officer
(212) 980-9155 x107
bradley.saenger@tonixpharma.com

Jenene Thomas Communications (investors)
Jenene Thomas
(908) 938-1475
jenene@jenenethomascommunications.com

Dian Griesel Int'l. (media)
Susan Forman / Laura Radocaj
(212) 825-3210
sforman@dgicomm.com
lradocaj@dgicomm.com

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