

May 9, 2016



# **Tonix Pharmaceuticals Reports First Quarter 2016 Financial Results and Provides Programs Update**

## **Key Clinical Results in Fibromyalgia and Post-Traumatic Stress Disorder (PTSD) to be Reported in 2016**

NEW YORK, May 09, 2016 (GLOBE NEWSWIRE) -- [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) (Tonix), which is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder (PTSD), announced financial results for the first quarter ended March 31, 2016.

“Our focus remains on the advancement of TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) in our flagship, Phase 3 trial in fibromyalgia and in our landmark, registration-quality Phase 2 trial in PTSD to completion,” said Seth Lederman, M.D., president and chief executive officer of Tonix. “We look forward to the weeks and months ahead and remain on track to announce top-line data from our Phase 3 AFFIRM study of TNX-102 SL in fibromyalgia in the third quarter of this year and our Phase 2 AtEase clinical trial of TNX-102 SL in PTSD later this month.”

At March 31, 2016, Tonix held cash, cash equivalents, and marketable securities totaling approximately \$27.5 million.

## **Recent Clinical Highlights and Upcoming Milestones**

### **TNX-102 SL – Fibromyalgia Program**

- Tonix is developing TNX-102 SL for daily use at bedtime for the management of fibromyalgia, a chronic pain condition.
- In May 2016, Tonix announced that it completed enrollment in the randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial of TNX-102 SL 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 TNX-102 SL in fibromyalgia in the second quarter of 2016.
- Results from the completed Phase 2b BESTFIT clinical trial of TNX-102 SL in fibromyalgia were the subject of three posters presented at the American College of Rheumatology Annual Meeting on November 10, 2015.
- Tonmya<sup>®</sup> has been conditionally accepted by the U.S. Food and Drug Administration

(FDA) as the proposed tradename of TNX-102 SL for fibromyalgia.

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, nonrestorative 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.

### **TNX-102 SL – PTSD Program**

- Tonix is also developing TNX-102 SL, the same proprietary product candidate as for fibromyalgia, for daily use at bedtime for the management of PTSD, a serious mental health problem.
- Tonix expects to report top-line data from the randomized, double-blind, placebo-controlled, 12-week Phase 2 AtEase clinical trial in the last half of May 2016.
- AtEase is a study of military-related PTSD and recruited more than 240 patients.
- 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 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-102 SL is an Investigational New Drug and has not been approved for any indication.

### **First Quarter Financial Results**

Tonix reported a net loss of \$14.0 million, or \$0.74 per share, for the first quarter of 2016 compared to a net loss of \$9.7 million, or \$0.71 per share, for the first quarter of 2015. Net loss for the three months ended March 31, 2016, excluding non-cash expenditures of \$0.9 million, was \$13.1 million, as compared to a net loss of \$8.4 million, excluding non-cash expenditures of \$1.3 million, for the three months ended March 31, 2015. 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, 2016, Tonix's cash, cash equivalents and marketable securities totaled \$27.5 million compared to \$43.0 million at December 31, 2015. Management believes that Tonix's existing funds are sufficient to fund

its operating expenses and ongoing clinical trials for at least the next 12 months.

### **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](http://www.tonixpharma.com).

### **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)**

	<b>Three Months ended March 31,</b>	
	<b><u>2016</u></b>	<b><u>2015</u></b>
	<b>(unaudited)</b>	
Costs and expenses		
Research and development	\$ 10,671	6,829
General and administrative	<u>3,343</u>	<u>2,867</u>
Total costs and expenses	14,014	9,696
Operating loss	(14,014 )	(9,696 )
Interest income, net	38	15
Net loss	\$ (13,976 )	(9,681 )
Net loss per common share, basic and diluted	\$ (0.74 )	(0.71 )
Weighted average common share outstanding, basic and diluted	18,860	13,696

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

	<b>March 31,</b>	<b>December 31,</b>
	<b><u>2016 (unaudited)</u></b>	<b><u>2015 (1)</u></b>
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 27,486	\$ 43,016
Prepaid expenses and other current assets	<u>3,168</u>	<u>3,343</u>
Total current assets	30,654	46,359
Non-current assets	<u>692</u>	<u>659</u>
Total assets	\$ 31,346	\$ 47,018
<b>Liabilities and stockholders' equity</b>		
Total liabilities	\$ 4,008	\$ 6,756
Stockholders' equity	<u>27,338</u>	<u>40,262</u>
Total liabilities and stockholders' equity	\$ 31,346	\$ 47,018

(1) The condensed consolidated balance sheets for the years ended December 31, 2015 has 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.

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