November 9, 2015

# Tonix Pharmaceuticals Reports Third Quarter 2015 Financial Results and Provides Programs Update

## 2016 to Feature Key Clinical Results in Fibromyalgia, Post-Traumatic Stress Disorder, and Tension Headache

NEW YORK, Nov. 9, 2015 (GLOBE NEWSWIRE) --Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) ("Tonix"), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, announced financial results for the third quarter ended September 30, 2015.

"We expect that 2016 will be a breakthrough year for Tonix, as we anticipate reporting results from each of three ongoing key clinical trials," said Seth Lederman, M.D., president and CEO of Tonix. "We will announce top-line data from our Phase 3 AFFIRM study of Tonmya™ (cyclobenzaprine HCl sublingual tablets, 2.8 mg) in fibromyalgia in the third quarter. In the second quarter, we will announce top-line data from our Phase 2 AtEase clinical trial of TNX-102 SL, the same proprietary product candidate as Tonmya, in PTSD. In the first quarter, we will announce top-line data from our Phase 2 proof-of-concept clinical trial of TNX-201 (dexisometheptene mucate) in episodic tension-type headache."

At September 30, 2015, Tonix held cash, cash equivalents, and marketable securities totaling $55.0 million.

**Recent Clinical Highlights and Upcoming Milestones**

***Tonmya – Fibromyalgia Program***

- Tonix is developing Tonmya for daily use at bedtime for the management of fibromyalgia, a chronic condition.
- In May 2015, Tonix launched the randomized, double-blind, placebo-controlled, 12-week Phase 3 AFFIRM clinical trial of Tonmya in fibromyalgia.
- Tonix now expects to report top-line data from the AFFIRM trial in the third quarter of 2016, as narrowed from prior guidance of second half 2016.
- The primary efficacy endpoint in AFFIRM is a 30% pain responder analysis at week 12.
- Tonix expects to commence a second Phase 3 clinical trial of Tonmya in fibromyalgia in the second quarter of 2016.
- Results from the completed Phase 2b BESTFIT clinical trial of Tonmya in fibromyalgia will be the subject of three posters to be 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.
- As supported by patient enrollment trends, Tonix now expects to enroll 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, an increase from the prior 220-patient goal.
- Tonix now expects to report top-line data from the AtEase study in the second quarter of 2016, as narrowed from prior guidance of first half 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).
- Tonix presented an overview of its development of TNX-102 SL for PTSD at the 2015 Military Health System Research Symposium held recently in Fort Lauderdale, Florida (see http://www.tonixpharma.com/research-development/scientific-publications).

PTSD affects approximately 8.5 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. To learn more, please visit www.ateasestudy.com.

***TNX-201 – Episodic Tension-Type Headache Program***

- TNX-201 (dexisometheptene mucate) is in early clinical development for the treatment of episodic tension-type headache.
- Tonix is conducting a randomized, double-blind, placebo-controlled Phase 2 proof-of-concept study to evaluate the potential activity of TNX-201 in episodic tension-type headache according to a variety of efficacy measures, as well as safety and tolerability.
- Tonix expects to report top-line results of this Phase 2 study in the first quarter of 2016.

It is estimated that more than 21 million Americans suffer from frequent episodic tension-type headache, many of whom turn to prescription medications for relief. However, current prescription options indicated for these headaches all contain barbiturates. To learn more, please visit www.clinicaltrials.gov (NCT02423408).

**Third Quarter Financial Results**

For the three months ended September 30, 2015, Tonix reported a net loss of $13.3 million, or $0.72 per share, as compared to a net loss of $7.4 million, or $0.71 per share, for the three months ended September 30, 2014. Net loss for the three months ended September 30, 2015, excluding non-cash expenditures of $0.9 million, was $12.4 million, as compared to a net loss of $6.5 million, excluding non-cash expenditures of $0.9 million, for the three months ended September 30, 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. Cash used in operations was $30.6 million for the nine months ended September 30, 2015, as compared to $14.6 million for the nine months ended September 30, 2014. At September 30, 2015 Tonix's cash, cash equivalents, and marketable securities totaled $55.0 million, as compared to $38.2 million at December 31, 2014.

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is dedicated to the invention and development of novel pharmaceutical products that it believes will have broad societal impact, since they address medical conditions that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's lead product candidate Tonmya is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at www.tonixpharma.com.

*Tonmya, TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved for any indications.*

**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" 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, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and November 6,*

*2015, respectively, 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2015** | **2014** | **2015** | **2014** |
| Costs and expenses | | | | |
| Research and development | $10,314 | $5,217 | $26,014 | $12,842 |
| General and administrative | 2,966 | 2,217 | 8,746 | 5,810 |
| Total costs and expenses | 13,280 | 7,434 | 34,760 | 18,652 |
| Operating loss | (13,280) | (7,434) | (34,760) | (18,652) |
| Interest, net | 30 | 15 | 66 | 25 |
| Net loss | $(13,250) | $(7,419) | $(34,694) | $(18,627) |
| Net loss per common share, basic and diluted | $(0.72) | $(0.71) | $(2.15) | $(1.92) |
| Weighted average common shares outstanding, basic and diluted | 18,423,816 | 10,496,504 | 16,103,382 | 9,719,142 |

**TONIX PHARMACEUTICALS HOLDING CORP.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

**(in thousands; unaudited)**

| | **September 30, 2015** | **December 31, 2014(1)** |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents, and marketable securities | $55,047 | $38,184 |
| Prepaid expenses and other current assets | 2,142 | 852 |
| Other non-current assets | 636 | 506 |
| Total assets | $57,825 | $39,542 |
| **Liabilities and stockholders' equity** | | |
| Total liabilities | $5,174 | $3,450 |
| Stockholders' equity | 52,651 | 36,092 |
| Total liabilities and stockholders' equity | $57,825 | $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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