November 10, 2016

# Tonix Pharmaceuticals Reports Third Quarter 2016 Financial Results

## First Phase 3 Trial for Treatment of Military-Related Posttraumatic Stress Disorder (PTSD) Planned to Begin in First Quarter 2017

NEW YORK, Nov. 10, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing a next-generation treatment for PTSD, announced financial results for the third quarter ended September 30, 2016.

“Tonix undertook significant changes in the third quarter,” said Seth Lederman, M.D., president and chief executive officer of Tonix. “We shifted our clinical development strategy to focus resources on our promising PTSD program following a successful End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). Positive data from AtEase – a 12-week randomized, double-blind, placebo-controlled Phase 2 clinical study evaluating TNX-102 SL*, 5.6 mg, in military-related PTSD – bolstered our enthusiasm for moving forward with this therapy. We plan to initiate the HONOR study, a 12-week Phase 3 trial evaluating TNX-102 SL, 5.6 mg, in military-related PTSD, in the first quarter of the coming year.”

At September 30, 2016, Tonix had $26.7 million in cash and cash equivalents and marketable securities, as compared to $31.2 million as of June 30, 2016. During the quarter ended September 30, 2016, Tonix raised approximately $1.4 million in net proceeds from the fully exercised over-allotment from a June 2016 underwritten offering, and $2.5 million in net proceeds through an at-the-market offering. Subsequent to the quarter end, Tonix raised approximately $4.6 million in net proceeds from an underwritten offering.

**Upcoming Milestones and Recent Program Highlights: TNX-102 SL, 5.6 mg, for PTSD**

- FDA acceptance of the Phase 3 HONOR study design and interim analysis plan expected in the fourth quarter of 2016.
- Phase 3 HONOR study, a 12-week randomized, double-blind, placebo-controlled trial, is planned to begin in the first quarter of 2017. The primary efficacy endpoint is mean change from baseline in total CAPS-5 at week 12 compared between TNX-102 SL, 5.6 mg, and placebo. This is the same primary endpoint used in the Phase 2 AtEase study.
- Topline data from the first interim analysis of the Phase 3 HONOR study in approximately 180 military-related PTSD patients expected to be released in the second half of 2017.
- New results will be presented today at the International Society for Traumatic Stress Studies 32nd Annual Meeting, from a retrospective analysis of AtEase study data regarding the effects of TNX-102 SL on reckless and self-destructive behaviors in

patients with military-related PTSD.
- Tonix hosted a PTSD Awareness Day with key opinion leaders in PTSD research, highlighting the challenges in combating this growing mental health concern, especially in veterans. The webcast of the event can be accessed here: http://edge.media-server.com/m/p/4x5b6c44.

PTSD affects approximately 8.6 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 result 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 (cyclobenzaprine HCl sublingual tablets) is an Investigational New Drug and has not been approved for any indication.*

**Third Quarter Financial Results**

Tonix reported a net loss of $7.6 million, or $0.29 per share, for the third quarter of 2016 compared to a net loss of $13.3 million, or $0.72 per share, for the third quarter of 2015. Net loss for the three months ended September 30, 2016, excluding non-cash expenditures of $0.8 million, was $6.8 million, as compared to a net loss of $12.4 million, excluding non-cash expenditures of $0.9 million, for the three months ended September 30, 2015. 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 needed to support these and other corporate development activities.

Tonix reported a net loss of $31.4 million, or $1.45 per share, for the nine months ended September 30, 2016 compared to a net loss of $34.7 million, or $2.15 per share, for the nine months ended September 30, 2015. Net loss for the nine months ended September 30, 2016, excluding non-cash expenditures of $2.5 million, was $28.9 million, as compared to a net loss of $31.3 million, excluding non-cash expenditures of $3.4 million, for the nine months ended September 30, 2015. 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 needed to support these and other corporate development activities.

Cash used in operations was $8.4 million and $31.9 million for the three and nine months ended September 30, 2016, respectively, as compared to $12.3 million and $30.6 million for the three and nine months ended September 30, 2015, respectively. At September 30, 2016, Tonix's cash, cash equivalents and marketable securities totaled $26.7 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 clinical activity 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, with its lead program focusing on posttraumatic stress disorder. This disorder is a serious condition 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.

**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, 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 share and per share amounts)**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| Costs and expenses | | | | |
| Research and development | $ 5,466 | $ 10,314 | $ 23,653 | $ 26,014 |
| General and administrative | 2,143 | 2,966 | 7,806 | 8,746 |
| Total costs and expenses | 7,609 | 13,280 | 31,459 | 34,760 |
| Operating loss | (7,609 ) | (13,280 ) | (31,459 ) | (34,760 ) |
| Interest income, net | 31 | 30 | 99 | 66 |
| Net loss | $ (7,578 ) | $ (13,250 ) | $ (31,360 ) | $ (34,694 ) |
| Net loss per common share, basic and diluted | $ (0.29 ) | $ (0.72 ) | $ (1.45 ) | $ (2.15 ) |
| Weighted average common shares outstanding, basic and diluted | 26,131,085 | 18,423,816 | 21,601,574 | 16,103,382 |

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

| | September 30, 2016 | December 31, 2015(1) |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and marketable securities | $ 26,738 | $ 43,016 |
| Prepaid expenses and other current assets | 2,483 | 3,343 |
| Total current assets | 29,221 | 46,359 |
| Other non-current assets | 580 | 659 |
| Total assets | $ 29,801 | $ 47,018 |
| **Liabilities and stockholders' equity** | | |
| Total liabilities | $ 2,696 | $ 6,756 |
| Stockholders' equity | 27,105 | 40,262 |
| Total liabilities and stockholders' equity | $ 29,801 | $ 47,018 |

(1) The condensed consolidated balance sheet for the year ended December 31, 2015 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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