April 17, 2017

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Programs Update

First Participant Enrolled in Phase 3 HONOR Study of TNX-102 SL in Military-Related PTSD in 1Q2017

TNX-102 SL Designated a Breakthrough Therapy for PTSD by the U.S. FDA in 4Q2016

NEW YORK, April 17, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (NASDAQ:TNXP) (Tonix), a company that is developing innovative pharmaceutical products to address public health challenges, announced financial results for the fourth quarter and full year ended December 31, 2016.

Seth Lederman, M.D., president and chief executive officer of Tonix, stated, “Tonix achieved significant momentum in the last quarter of 2016, which has carried over into 2017. Tonix is focused on pioneering a differentiated approach for the treatment of posttraumatic stress disorder (PTSD), through improving sleep quality. TNX-102 SL*, having shown potential advantages over existing treatments for this disorder, received Breakthrough Therapy designation from the United States Food and Drug Administration (FDA) in December 2016.”

“In the first quarter of 2017, the FDA accepted the protocol design for our Phase 3 HONOR study to support the registration of TNX-102 SL for PTSD.” Dr. Lederman continued, “As we planned, the study was initiated in March and is on track to have an unblinded interim analysis (IA) by an independent data monitoring committee in the first half of 2018. If the IA results require continued enrollment, topline results from the full 550-participant trial are expected to be available in the second half of 2018. With successful capital raising activities completed in 2017, Tonix is fully funded through the completion of, and announcement of the topline results, from the HONOR study.”

At December 31, 2016, Tonix had cash, cash equivalents, and marketable securities of $26.1 million. Since January 1, 2017, Tonix has raised approximately $9.1 million in net proceeds through an at-the-market offering and approximately $8.3 million of net proceeds from the sale of common stock in an underwritten public offering. Approximately 7.5 million shares were outstanding as of April 13, 2017.

Recent Events:

- Enrolled the first participant in the 12-week, double-blinded, placebo-controlled Phase 3 HONOR study of TNX-102 SL 5.6 mg, in military-related PTSD.
- Held the Initial Cross-Disciplinary Breakthrough meeting with the FDA. Minutes from the meeting indicated that registration of TNX-102 SL could be solely supported by the

Phase 3 HONOR study if topline data are statistically persuasive.
- Received Notice of Allowance for U.S. Patent Application 14/214,333, titled, “Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride,” covering the proprietary sublingual formulation of TNX-102 SL. Patent expected to be issued in 2Q2017 with protection through 2034.
- Synthesized a potential smallpox-preventing vaccine candidate, TNX-801, a live form of horsepox virus, which has demonstrated protective vaccine activity in mice. TNX-801 is the first-ever synthesized chimeric horsepox virus.
- Developed a novel formulation of tianeptine oxalate, TNX-601, as a potential daytime treatment for PTSD.
- Regained compliance with NASDAQ listing requirements by completing a 1-for-10 reverse stock split.

2016 Highlights:

- Successfully transitioned Tonix’s core development program of TNX-102 SL from fibromyalgia to PTSD, leveraging promising Phase 2 AtEase results, regulatory approval clarity, and the urgent public health issue in military-related PTSD.
- Cash used in operating activities for the fourth quarter of 2016 totaled $5.4 million, representing a 35% decrease as compared to the third quarter of 2016, and a 54% decrease as compared to the fourth quarter of 2015.

Programs Update

TNX-102 SL 5.6 mg, for PTSD

- Completed a highly informative End-of-Phase 2 Chemistry, Manufacturing and Controls (CMC) meeting with the FDA and received FDA agreement on the proposed CMC data package to support the TNX-102 SL New Drug Application (NDA) submission.
- Completed a successful Pre-Phase 3/End-of-Phase 2 meeting with the FDA to thoroughly vet the Phase 3 clinical program to support the registration of TNX-102 SL for PTSD. Received FDA agreement on the proposed NDA clinical/nonclinical data package, and encouragement to submit a Breakthrough Therapy designation request.
- Awarded Breakthrough Therapy designation by the FDA for TNX-102 SL for the treatment of PTSD, providing eligibility for priority review of an NDA and increased guidance and organizational commitment from FDA senior managers.
- Presented encouraging topline data from the Phase 2 AtEase study.
- Presented clinical results from a retrospective analysis of the Phase 2 AtEase study demonstrating potential efficacy of TNX-102 SL 5.6 mg, in the reduction of reckless, self-destructive behavior and suicidal behaviors, with especially strong evidence of clinical improvement in combat-related PTSD patients.
- Hosted a PTSD Awareness Day with key opinion leaders in PTSD research, highlighting the challenges in treating this growing mental health concern, particularly among veterans.

TNX-801 (Live Virus Vaccine) for Smallpox Prevention

- Successfully synthesized first-ever chimeric horsepox virus (HPXV), TNX-801, a live form of HPXV that has demonstrated protective vaccine activity in mice and is being developed as a smallpox preventing vaccine.

- If licensed by the FDA, TNX-801 is eligible for a highly-attractive priority review voucher. This voucher is fully transferrable and may be sold to other companies for priority review of any NDA or Biologics License Application (BLA).

TNX-601 (tianeptine oxalate) for PTSD

- Developed a novel formulation of tianeptine that may provide improved stability, consistency, and manufacturability as compared to known forms of tianeptine. Currently there is no tianeptine-containing product approved in the U.S., although tianeptine sodium (amorphous) has been available in Europe, Asia, and Latin America for the treatment of depression since 1987. Clinical studies in Europe have shown activity of tianeptine sodium in treating PTSD.

Fourth Quarter and Full Year Financial Results

Tonix reported a net loss of $7.5 million, or $2.08 per share, for the fourth quarter of 2016, compared to a net loss of $13.4 million, or $7.96 per share, for the fourth quarter of 2015. The net loss for the three months ended December 31, 2016, excluding non-cash expenditures of $1.1 million, was $6.4 million, as compared to a net loss of $12.3 million, excluding non-cash expenditures of $1.1 million, for the three months ended December 31, 2015. The reduced net loss was primarily due to decreased research and development expenses for clinical studies and related research, as well as lower general and administrative expenses needed to support these and other corporate development activities.

Tonix reported a net loss of $38.8 million, or $15.41 per share, for the year ended December 31, 2016, compared to a net loss of $48.1 million, or $28.62 per share, for the year ended December 31, 2015. The net loss for the year ended December 31, 2016, excluding non-cash expenditures of $3.6 million, was $35.2 million, as compared to a net loss of $43.5 million, excluding non-cash expenditures of $4.6 million, for the year ended December 31, 2015. The reduced net loss was primarily due to decreased research and development expenses for clinical studies and related research, as well as lower general and administrative expenses needed to support these and other corporate development activities.

Cash used in operations was $37.3 million for the year ended December 31, 2016, as compared to $42.5 million for the year ended December 31, 2015. At December 31, 2016, Tonix's cash, cash equivalents and marketable securities totaled $26.1 million, compared to $43.0 million at December 31, 2015. Management believes that existing cash and marketable securities are sufficient to fund Tonix's operating expenses and planned clinical trial through at least the next 12 months.

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.*

About Posttraumatic Stress Disorder

PTSD can develop from witnessing or experiencing a traumatic event in which there was the severe threat of, or actual occurrence of, grave physical harm or death. PTSD affects approximately 8.6 million Americans and is a chronic and severely debilitating condition in which patients re-experience the horrific traumas that resulted in the condition in the forms of

intrusive memories, flashbacks, and nightmares. PTSD typically is characterized by disrupted sleep, anxiety, agitation, avoidance, emotional numbness and estrangement from family and friends, guilt or negative beliefs about self, and sometimes is associated with clinical depression and suicidal thinking. Individuals who suffer from PTSD usually have significant impairment in social functioning, occupational disability, and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable violent or suicidal behaviors. It is estimated that more than 19 percent of the 1.9 million U.S. veterans who were deployed to the recent conflicts in Iraq and Afghanistan suffer from PTSD.

About Tonix Pharmaceuticals Holding Corp.
Tonix is developing innovative pharmaceutical products to address public health challenges. TNX-102 SL is in Phase 3 development and has been granted Breakthrough Therapy designation by the FDA for the treatment of PTSD. PTSD is a serious condition characterized by chronic disability, inadequate treatment options especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. The Protectic™ protective eutectic and Angstro-Technology™ formulation are essential elements of the proprietary TNX-102 SL composition for which a Notice of Allowance has been issued by the U.S. Patent and Trademark Office. Other development efforts include TNX-801, a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus and TNX-601 (tianeptine oxalate), a clinical candidate at Pre-IND (Investigational New Drug) application stage, designed for daytime use for the treatment of PTSD.

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, 2016, as filed with the Securities and Exchange Commission (the "SEC") on April 13, 2017, 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.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts) (1)

	Three Months ended December 31,		Twelve Months ended December 31,	
	2016	2015	2016	2015
	(unaudited)			
Costs and expenses				
Research and development	$ 4,879	9,490	$ 28,533	35,504
General and administrative	2,631	3,912	10,436	12,658
Total costs and expenses	7,510	13,402	38,969	48,162
Operating loss	(7,510)	(13,402)	(38,969)	(48,162)
Interest income, net	28	43	127	108
Net loss	$ (7,482)	(13,359)	$ (38,842)	(48,054)
Net loss per common share, basic and diluted	$ (2.08)	(7.96)	$ (15.41)	(28.62)
Weighted average common shares outstanding, basic and diluted	3,596	1,883	2,521	1,679

(1) The condensed consolidated statements of operations for the years ended December 31, 2016 and 2015 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) (1)

	December 31, 2016	December 31, 2015
Assets		
Cash, cash equivalents and marketable securities	$ 26,121	$ 43,016
Prepaid expenses and other current assets	1,019	3,343
Total current assets	27,140	46,359
Non-current assets	370	659
Total assets	$ 27,510	$ 47,018
Liabilities and stockholders' equity		
Total liabilities	$ 2,149	$ 6,756
Stockholders' equity	25,361	40,262
Total liabilities and stockholders' equity	$ 27,510	$ 47,018

(1) The condensed consolidated balance sheets for the years ended December 31, 2016 and 2015 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.

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