March 12, 2018

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial Results and Provides Programs Update

Interim Analysis for Phase 3 HONOR study of Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) in Military-Related PTSD Expected in Third Quarter of 2018; Topline Results Expected in Fourth Quarter of 2018

NEW YORK, March 12, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and to improve biodefense through developing potential medical counter-measures, today announced financial results for the fourth quarter and full year ended December 31, 2017.

“We remain on track to report results from the interim analysis in the third quarter of this year for the Phase 3 HONOR study of Tonmya*, an FDA-designated Breakthrough Therapy for the treatment of posttraumatic stress disorder (PTSD),” commented Seth Lederman, M.D., President and Chief Executive Officer of Tonix. “The interim readout will be based on approximately 50 percent of the total number of efficacy evaluable participants in the study and we anticipate reaching this 50 percent randomization level in the first quarter of this year. Topline results of all efficacy evaluable participants, if needed, are anticipated in the fourth quarter of 2018.”

“In addition,” Dr. Lederman continued, “we are excited about developing a potential second indication for TNX-102 SL for the treatment of agitation in Alzheimer’s disease. We are on schedule to submit an Investigational New Drug (IND) application to the FDA for a Phase 2 study in this indication before the end of this month.”

At December 31, 2017, Tonix had cash and cash equivalents of $25.5 million. Net cash used in operating activities for the full year was $19.1 million.

Recent Highlights:

- Completed a successful pre-IND meeting with the FDA to discuss TNX-102 SL as a clinical candidate for the treatment of agitation in Alzheimer’s disease.

- Appointed General David L. Grange (retired) to the Board of Directors. General Grange is the current CEO of Pharm-Olam International, Ltd. and the former CEO of

Pharmaceutical Product Development, Inc., both global clinical research organizations. General Grange is also a retired U.S. Army Brigadier General, who brings military experience, expertise in business and government partnerships, as well as experience in clinical development services.

- Received a Notice of Allowance from the U.S. Patent and Trademark Office related to the use of Tonmya's active ingredient (cyclobenzaprine HCl) for the treatment of PTSD. Also received Notice of Allowance from the Japanese Patent Office related to the eutectic formulation of TNX-102 SL.

- Announced publication of a peer-reviewed article in PLOS ONE, describing the successful synthesis and characterization of a potential smallpox-preventing vaccine based on horsepox virus (TNX-801).

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

Fourth Quarter Financial Results

Tonix reported a net loss of $5.5 million, or $0.71 per share, for the fourth quarter of 2017, compared to a net loss of $7.5 million, or $2.08 per share, for the fourth quarter of 2016. The net loss for the three months ended December 31, 2017, excluding non-cash expenditures of $0.3 million, was $5.2 million, as compared to a net loss of $6.4 million, excluding non-cash expenditures of $1.1 million, for the three months ended December 31, 2016. 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 $21.1 million, or $3.17 per share, for the year ended December 31, 2017, compared to a net loss of $38.8 million, or $15.41 per share, for the year ended December 31, 2016. The net loss for the year ended December 31, 2017, excluding non-cash expenditures of $1.8 million, was $19.3 million, as compared to a net loss of $35.2 million, excluding non-cash expenditures of $3.6 million, for the year ended December 31, 2016. 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 $19.1 million for the year ended December 31, 2017, as compared to $37.3 million for the year ended December 31, 2016. At December 31, 2017, Tonix's cash, cash equivalents and marketable securities totaled $25.5 million, compared to $26.1 million at December 31, 2016.

About Tonmya and the Phase 3 HONOR Study

Tonmya is a patented sublingual transmucosal formulation of cyclobenzaprine that is in

Phase 3 development. 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. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets), was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the U.S., the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants in approximately 40 U.S. sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that (i) a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive, and (ii) an additional abuse assessment study is not required for the NDA filing. Additional details of the HONOR study are available at www.thehonorstudy.com or https://clinicaltrials.gov/ct2/show/NCT03062540.

In 2017, the U.S. Patent and Trademark Office issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034. Tonix was also awarded European patent (Patent No. 2,501,234, "Methods and Compositions for Treating Symptoms Associated with Posttraumatic Stress Disorders Using Cyclobenzaprine"). This patent is expected to provide Tonmya, upon European marketing authorization, with European market exclusivity until November 2030 and the exclusivity may be extended based on the timing of the European marketing authorization of Tonmya for PTSD. Also, in December 2017, the Japanese Patent Office issued Japanese Patent No. 6259452, "Compositions and Methods for Transmucosal Absorption," related to the pharmacokinetic profile of Tonmya, or TNX-102 SL.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and to improve biodefense through developing potential medical counter-measures. Tonix's lead product candidate, Tonmya, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease and has completed a pre-IND (Investigational New Drug) meeting with the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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, risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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 substantial competition. 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, 2017, as filed with the Securities and Exchange Commission (the "SEC") on March 9, 2018, and periodic reports filed with the SEC on or after the date thereof. 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 thereof.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(1)

	Three Months ended December 31,		Twelve Months ended December 31,	
	2017	2016	2017	2016
	(unaudited)			
Costs and expenses				
Research and development	$3,634	4,879	$13,342	28,533
General and administrative	1,909	2,631	7,949	10,436
Total costs and expenses	5,543	7,510	21,291	38,969
Operating loss	(5,543)	(7,510)	(21,291)	(38,969)
Interest income, net	50	28	168	127
Net loss	$(5,493)	(7,482)	$(21,123)	(38,842)
Net loss per common share, basic and diluted	$(0.71)	(2.08)	$(3.17)	(15.41)
Weighted average common shares outstanding, basic and diluted	7,786,850	3,595,748	6,665,091	2,521,016

(1) The condensed consolidated statements of operations for the years ended December 31, 2017 and 2016 have been derived from the audited financial statements, but do not include all 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, 2017	December 31, 2016
Assets		
Cash, cash equivalents and marketable securities	$25,496	$26,121
Prepaid expenses and other current assets	947	1,019
Total current assets	26,443	27,140
Non-current assets	311	370
Total assets	$26,754	$27,510
Liabilities and stockholders' equity		
Total liabilities	$2,138	$2,149
Stockholders' equity	24,616	25,361
Total liabilities and stockholders' equity	$26,754	$27,510

(1) The condensed consolidated balance sheets for the years ended December 31, 2017 and 2016 have been derived from the audited financial statements, but do not include all the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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