May 14, 2018

Tonix Pharmaceuticals Reports First Quarter 2018 Financial Results and Provides Programs Update

Interim Analysis for Phase 3 HONOR study of Tonmya® in Military-Related PTSD Expected in Third Quarter of 2018

NEW YORK, May 14, 2018 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense, today announced financial results for the first quarter ended March 31, 2018.

"In April 2018, we announced enrollment of 50% of the planned total number of participants for the Phase 3 HONOR study, and we continue to expect an interim analysis on this first 50% of participants in the third quarter of 2018," said Seth Lederman, M.D., President and Chief Executive Officer. "We also recently announced receiving Investigational New Drug (IND) clearance by the U.S. Food and Drug Administration (FDA) for TNX-102 SL for the treatment of agitation in Alzheimer's disease (AAD). Leveraging the existing safety and tolerance data for TNX-102 SL and our understanding of its mechanism of action, this IND allows us to start a Phase 2, potentially pivotal efficacy study in AAD. It further supports the potential use of TNX-102 SL in multiple therapeutic areas."

Upcoming Milestones and Recent Program Highlights

- A pre-planned interim analysis based on the first 50% of randomized participants in the Phase 3 HONOR study of Tonmya* (cyclobenzaprine HCl sublingual tablets) is anticipated in the third quarter of 2018 after the first 50% of patients have completed 12 weeks of treatment. Randomization of 50% of participants in the Phase 3 HONOR study was completed in April.
- Topline results from the full Phase 3 HONOR study of 550 participants (unless stopped for success at the interim analysis) anticipated in the first quarter of 2019.
- Received IND clearance by the FDA in May, supporting the initiation of a Phase 2 potential pivotal efficacy study of TNX-102 SL 5.6 mg for agitation in Alzheimer's disease.
- Continued expansion of patent portfolio. U.S. Patent No. 9,918,948 issued, protecting the use of Tonmya for the treatment of PTSD. Upon approval, patent protection is expected until at least 2030. Japanese Patent No. 6,310,542 issued, protecting the eutectics and methods of manufacturing eutectic formulations. Upon

approval, patent protection is expected until at least 2034.

**Tonmya has been conditionally accepted by the 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.*

First Quarter 2018 Financial Results

At March 31, 2018, Tonix had $19.3 million of cash and cash equivalents, compared to $25.5 million as of December 31, 2017. Cash used in operations was $6.8 million for the three months ended March 31, 2018, compared to $4.8 million for the three months ended March 31, 2017.

Research and development expenses for the first quarter of 2018 totaled $5.2 million, compared to $3.0 million for the same period in 2017. The increase was largely due to a multiple-dose, randomized, open-label, pharmacokinetic bridging study that was conducted primarily in the first quarter of 2018.

General and administrative expenses for the first quarter of 2018 were $1.8 million, compared to $2.1 million for the same period in 2017. This decrease is due primarily to a reduction in compensation-related expenses including decreases in cash and stock-based compensation.

Net loss was $6.9 million, or $0.88 per share, for the first quarter of 2018, compared to net loss of $5.1 million, or $1.27 per share, for the first quarter of 2017. The net loss for the three months ended March 31, 2018, excluding non-cash expenditures of $0.4 million, was $6.5 million, as compared to a net loss, excluding non-cash expenditures of $0.6 million, of $4.5 million for the first quarter of 2017. The higher net loss was primarily due to increased research and development expenses.

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 biological products to improve biodefense through 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 received Investigational New Drug (IND) clearance from the U.S. FDA to support the initiation of a Phase 2 efficacy study. 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.

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

	Three Months Ended March 31,	
	2018	**2017**
Costs and expenses		
Research and development	$ 5,170	$ 2,994
General and administrative	1,818	2,097
Total costs and expenses	6,988	5,091
Operating loss	(6,988)	(5,091)
Interest income, net	53	27
Net loss	$ (6,935)	$ (5,064)
Net loss per common share, basic and diluted	$ (0.88)	$ (1.27)
Weighted average common shares outstanding, basic and diluted	7,850,298	3,985,529

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)
(Unaudited)

	March 31, 2018	December 31, 2017[1]
Assets		
Cash and cash equivalents	$ 19,253	$ 25,496
Prepaid expenses and other current assets	1,429	947
Total current assets	20,682	26,443
Other non-current assets	298	311
Total assets	$ 20,980	$ 26,754
Liabilities and stockholders' equity		
Total liabilities	$ 2,369	$ 2,138
Stockholders' equity	18,611	24,616
Total liabilities and stockholders' equity	$ 20,980	$ 26,754

(1) The condensed consolidated balance sheet for the year ended December 31, 2017 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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Source: Tonix Pharmaceuticals Holding Corp.