August 13, 2018

Tonix Pharmaceuticals Reports Second Quarter 2018 Financial Results and Operational Highlights

HONOR Study Results to be Included in Poster Presentation at a Scientific Conference in August 2018

FDA Meeting in October 2018 Confirmed to Discuss New Phase 3 Study for Tonmya® in PTSD

New Phase 3 Study for Tonmya May Initiate as Early as 2019

NEW YORK, Aug. 13, 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 second quarter ended June 30, 2018, and an overview of recent operational highlights.

“In developing Tonmya for PTSD we have learned a tremendous amount about the condition and how to design and conduct trials for PTSD patients, especially those with military-related PTSD. PTSD is serious psychiatric disorder and we remain committed to developing a treatment option that may help alleviate symptoms of the condition,” said Seth Lederman, M.D., President and Chief Executive Officer. “We look forward to presenting results from the HONOR study at a scientific conference in August and meeting with the FDA in October to discuss the new Phase 3 study of Tonmya for the treatment of PTSD.”

Recent Program Highlights

- In July, Tonix completed a planned, unblinded interim analysis of 274 randomized participants (50% of planned) for the Phase 3 HONOR study of Tonmya* in military-related posttraumatic stress disorder (PTSD). Based on a pre-specified study continuation threshold at Week 12, the study was discontinued due to inadequate separation from placebo at this time point as measured by the primary endpoint, the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5). Meaningful improvement in overall PTSD symptoms was observed at Week 4. At Week 4, the Tonmya treated group separated from placebo in CAPS-5 ($p = 0.019$) and in the Clinical Global Impression – Improvement (CGI-I) scale ($p = 0.015$), a key secondary endpoint. Also, at Week 4, sleep quality improved as measured by both the PROMIS sleep disturbance scale and the CAPS-5 sleep disturbance item, supporting the proposed mechanism of action of Tonmya.

- TNX-102 SL, as a bedtime treatment for agitation in Alzheimer’s disease, received

Investigational New Drug (IND) clearance in May 2018. Fast Track designation was granted by the FDA in July. Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. It reflects the recognition by the FDA that TNX-102 SL has the potential to address a large unmet medical need for a serious condition. A Phase 2, potential pivotal, efficacy study protocol submitted in July 2018 is pending FDA review and acceptance.

- New data related to suicidal ideation and behaviors in military-related PTSD from the Phase 2 AtEase study was presented at the American Society of Clinical Psychopharmacology in May 2018.

- Preliminary results from the successfully completed pivotal Phase 1 multiple-dose bridging pharmacokinetic study of Tonmya, or TNX-102 SL were reported. These results support the applicability of the abbreviated 505(b)(2) regulatory pathway for a New Drug Application approval for TNX-102 SL using AMRIX®# as the reference product.

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD which has been designated as a Breakthrough Therapy in December 2016. TNX-102 SL is an investigational new drug and has not been approved for any indication.*
 # AMRIX (cyclobenzaprine HCl extended-release capsules) is indicated for 2-3 weeks use as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. The recommended adult dose for most patients is one AMRIX 15 mg capsule taken once daily. Some patients may require up to 30 mg/day, given as one AMRIX 30 mg capsule taken once daily or as two (2) AMRIX 15 mg capsules taken once daily.

Second Quarter 2018 Financial Results

Research and development expenses for the second quarter of 2018 totaled $4.1 million, compared to $2.8 million for the same period in 2017. The increase is primarily due to clinical development work associated with the PTSD program.

General and administrative expenses for the second quarter of 2018 were $2.1 million, compared to $2.0 million for the same period in 2017. The increase is primarily due to an increase in professional services fees, partially offset by a decrease in compensation-related expenses as a result of fewer personnel.

Net loss was $6.1 million, or $0.73 per share, for the second quarter of 2018, compared to net loss of $4.8 million, or $0.65 per share, for the second quarter of 2017. The greater net loss was primarily due to higher research and development expenses.

At June 30, 2018, Tonix had $16.7 million of cash and cash equivalents, compared to $25.5 million as of December 31, 2017. Cash used in operations was $5.5 million for the three months ended June 30, 2018, compared to $4.4 million for the three months ended June 30, 2017. Research and development expenses are expected to decrease following the orderly closing of the HONOR study, in the near term.

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 is developing Tonmya, which has been granted Breakthrough Therapy designation, as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease under a separate IND to support a Phase 2, potential pivotal, efficacy study and has been granted Fast Track designation by the FDA for this indication. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a unique mechanism and 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)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	**2017**	**2018**	**2017**

Costs and expenses				
Research and development	$ 4,067	$ 2,806	$ 9,237	$ 5,800
General and administrative	2,076	2,016	3,894	4,113
Total costs and expenses	6,143	4,822	13,131	9,913
Operating loss	(6,143)	(4,822)	(13,131)	(9,913)
Interest income, net	56	42	109	69
Net loss	$ (6,087)	$ (4,780)	$ (13,022)	$ (9,844)
Net loss per common share, basic and diluted	$ (0.73)	$ (0.65)	$ (1.60)	$ (1.74)
Weighted average common shares outstanding, basic and diluted	8,391,709	7,327,890	8,122,499	5,666,457

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

	June 30, 2018	December 31, 2017(1)
Assets		
Cash, cash equivalents and marketable securities	$ 16,679	$ 25,496
Prepaid expenses and other current assets	1,480	947
Total current assets	18,159	26,443
Other non-current assets	196	311
Total assets	$ 18,355	$ 26,754
Liabilities and stockholders' equity		
Total liabilities	$ 2,513	$ 2,138
Stockholders' equity	15,842	24,616
Total liabilities and stockholders' equity	$ 18,355	$ 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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