March 18, 2019

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results and Operational Highlights

Phase 3 RECOVERY Trial of Tonmya® for the Treatment of PTSD Initiated and Enrolling

Topline Data Expected First Half 2020

NEW YORK, March 18, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix, or the Company), 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 fourth quarter and full year ended December 31, 2018, and an overview of recent operational highlights.

“Looking forward into 2019, we are excited about the recent initiation of our new Phase 3 study of Tonmya for PTSD. The RECOVERY study incorporates learnings and analyses from our Phase 2 and Phase 3 studies in over 500 military-related PTSD participants, and is intended to support the registration of Tonmya for PTSD. We look forward to topline data in the first half of 2020,” said Seth Lederman, M.D., President and Chief Executive Officer. “In addition to Tonmya for PTSD, we maintain a strong and growing pipeline of product candidates, including TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer’s disease, and TNX-601 as a daytime treatment for PTSD and neurocognitive dysfunction associated with corticosteroid use, a potential indication.”

Recent Clinical and Regulatory Highlights

- Enrolled first participant in the Phase 3 RECOVERY study of Tonmya for the treatment of PTSD in March. This pivotal efficacy study incorporates several innovative design features, based on analyses of data from our prior PTSD trials. In November 2018, we received Food and Drug Administration (FDA) acceptance of the study design, which includes participants who have experienced civilian traumas in addition to those with military-related traumas, and restricts enrollment to participants who experienced an index trauma within nine years of screening.

- Completed a Clinical Guidance meeting with the FDA in March to discuss the fibromyalgia registration plan for TNX-102 SL and a new Phase 3 study to support this indication.

- Received European use patent issuance for TNX-601 (tianeptine oxalate) for the treatment of neurocognitive dysfunction associated with corticosteroids use, a potential indication. TNX-601 is also being developed as a daytime treatment for PTSD. A

Phase 1 pharmacokinetic study of proprietary tianeptine oxalate formulations will be conducted outside of the U.S. and the result is expected in the second half of 2019.

- Successfully completed a Phase 1 pivotal bridging pharmacokinetic study of TNX-102 SL in 2018, the data for which was deemed sufficient by the FDA to support the 505(b)(2) NDA submission for Tonmya and TNX-102 SL.

Recent Corporate Highlights

- Strengthened our balance sheet in December 2018 by completing a public equity offering. The transaction resulted in gross proceeds of $15.9 million, including the over-allotment proceeds, which will be used, in part, to fund the new Phase 3 RECOVERY trial of Tonmya for PTSD.

- Announced a Share Repurchase Program to buy up to $2 million in value of the Company's outstanding stock from time to time.

Fourth Quarter 2018 Financial Results

Research and development expenses for the fourth quarter of 2018 totaled $5.1 million, compared to $3.6 million for the same period in 2017. This increase is due primarily to costs related to the close-out of the Phase 3 HONOR study as well as other activities related to the PTSD program.

General and administrative expenses for the fourth quarter of 2018 were $2.6 million, compared to $1.9 million for the same period in 2017. This increase is due primarily to an increase in legal fees related to patent prosecution, as well as an increase in investor and public relations expenses due to increased investor meetings.

Net loss available to common stockholders was $10.9 million, or $6.10 per share, for the fourth quarter of 2018, compared to net loss of $5.5 million, or $7.07 per share, for the fourth quarter of 2017. In addition to the factors above, fourth quarter 2018 net loss available to common stockholders was impacted by a one-time, non-cash preferred stock deemed dividend in the fourth quarter of 2018. The weighted average common shares outstanding, basic and diluted for the fourth quarter of 2018 was 1,778,524 shares. The weighted average common shares outstanding, basic and diluted for the fourth quarter of 2017 was 750,804 shares.

As of March 13, 2019, all Series A convertible preferred stock had been converted into common stock. Total common stock outstanding as of March 13, 2019 was 6,089,728.

Full Year 2018 Financial Results

Research and development expenses for full year 2018 totaled $17.6 million, compared to $13.3 million for full year 2017. This increase is due primarily to the continued development work related to the PTSD program, including the completion of the NDA-required pivotal bridging pharmacokinetic study of TNX-102 SL in 2018.

General and administrative expenses for full year 2018 were $8.8 million, compared to $8.0 million for full year 2017. This increase is due primarily to increased patent prosecution costs

and an increase in investor and public relations expenses due to increased investor meetings.

Net loss available to common stockholders was $29.4 million, or $26.81 per share, for full year 2018, compared to net loss of $21.1 million, or $31.69 per share, for full year 2017. The weighted average common shares outstanding, basic and diluted for 2018 was 1,094,867 shares. The weighted average common shares outstanding, basic and diluted for 2017 was 666,509 shares.

At December 31, 2018, Tonix had $25.0 million of cash and cash equivalents, compared to $25.5 million as of December 31, 2017. Cash and cash equivalents at December 31, 2018 includes net proceeds of $14.4 million from the Company's public offering of common stock in December 2018. Cash used in operations was $24.0 million for full year 2018, compared to $19.1 million for full year 2017.

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 program is for the development of Tonmya, which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate INDs to support potential pivotal efficacy studies. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but using a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication -neurocognitive dysfunction associated with corticosteroid use. A Phase 1 pharmacokinetic study of proprietary tianeptine oxalate formulations will be conducted outside of the U.S. in 2019. 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.

**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 the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

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, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, 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 Reports Fourth Quarter 2018 Financial Results

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

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
	(Unaudited)			
Costs and expenses				
Research and development	$ 5,057	$ 3,634	$ 17,558	$ 13,342
General and administrative	2,593	1,909	8,764	7,949
Total costs and expenses	7,650	5,543	26,322	21,291
Operating loss	(7,650)	(5,543)	(26,322)	(21,291)
Interest income, net	62	50	233	168
Net loss	$ (7,588)	$ (5,493)	$ (26,089)	$ (21,123)
Preferred stock deemed dividend	3,266	-	3,266	-
Net loss available to common shareholders	$ (10,854)	$ (5,493)	$ (29,355)	$ (21,123)
Net loss per common share, basic and diluted	$ (6.10)	$ (7.07)	$ (26.81)	$ (31.69)
Weighted average common shares outstanding, basic and diluted	1,778,524	750,804	1,094,867	666,509

(1) *The condensed consolidated statements of operations for the years ended December 31, 2018 and 2017 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, 2018	December 31, 2017
Assets		
Cash and cash equivalents	$ 25,034	$ 25,496
Prepaid expenses and other current assets	1,022	947
Total current assets	26,056	26,443
Other non-current assets	263	311
Total assets	$ 26,319	$ 26,754
Liabilities and stockholders' equity		
Total liabilities	$ 2,655	$ 2,138
Stockholders' equity	23,664	24,616
Total liabilities and stockholders' equity	$ 26,319	$ 26,754

[1] *The condensed consolidated balance sheets for the years ended December 31, 2018 and 2017 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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Source: Tonix Pharmaceuticals Holding Corp.