

November 7, 2017



# Tonix Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Programs Update

*Enrolling Phase 3 HONOR study of Tonmya® (Cyclobenzaprine HCl Sublingual Tablets) in Military-Related PTSD: Interim Analysis Expected 1H18 and Topline Results Expected 2H18*

*Formal FDA Feedback on Manufacturing Data for Tonmya Registration and Commercial Production Strategy Reflects Potential for Early Introduction Upon Successful HONOR Study*

NEW YORK, Nov. 07, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), a company developing innovative pharmaceutical and biological products to address major public health challenges, recently announced financial results for the third quarter ended September 30, 2017. Tonix is in Phase 3 development of Tonmya\*, or TNX-102 SL, a U.S. Food and Drug Administration (FDA)-designated Breakthrough Therapy for the treatment of posttraumatic stress disorder (PTSD).

“Tonix has taken significant steps forward since the beginning of the third quarter in the development of its lead product candidate, Tonmya,” commented Seth Lederman, M.D., President and Chief Executive Officer of Tonix. “In addition to progress in enrolling the Phase 3 HONOR study, we announced conditional acceptance of the proposed trade name Tonmya, the grant of a European method of use patent, and official minutes from the FDA reflecting our readiness to register and proceed to commercial manufacturing of Tonmya upon New Drug Application (NDA) approval. We look forward to the outcome of our planned unblinded interim analysis for the HONOR study in the first half of 2018, with topline results expected in the second half of 2018 for the full study, if needed.”

At September 30, 2017, Tonix had cash and cash equivalents of \$29.3 million. Net cash used in operating activities for the third quarter was \$5.0 million.

## Recent Highlights:

- Received official minutes from a chemistry, manufacturing and controls (CMC) guidance meeting with the FDA regarding CMC data required to support the Tonmya NDA and commercialization production strategy;
- Received notice that European Patent Office issued Patent No. 2,501,234 protecting the use of the active ingredient in Tonmya for the treatment of PTSD;
- Presented at the 2017 Cohen Veterans Care Summit during the Coalition to Heal

Invisible Wounds Panel session, addressing policy incentives to develop new medicines, with focus on small molecule medicines, for the treatment of mental health disorders;

- Presented additional results from the Phase 2 AtEase study and design features of the ongoing Phase 3 HONOR study at the 2017 Military Health System Research Symposium; and
- Received FDA conditional acceptance of the proposed trade name Tonmya(*ton-MY-ah*) for TNX-102 SL for the treatment of PTSD.

*\*Tonmya has been conditionally accepted by the 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.*

### **Third Quarter Financial Results**

Tonix reported a net loss of \$5.8 million, or \$0.77 per share, for the third quarter of 2017, compared to a net loss of \$7.6 million, or \$2.90 per share, for the third quarter of 2016. The net losses for the three months ended September 30, 2017 and 2016 included non-cash expenditures of \$0.5 million and \$0.8 million, respectively. The lower net loss was primarily due to decreased research and development expense for clinical studies and related research, as well as lower general and administrative expense related to these and other corporate development activities.

Tonix reported a net loss of \$15.6 million, or \$2.49 per share, for the nine months ended September 30, 2017 compared to a net loss of \$31.4 million, or \$14.52 per share, for the nine months ended September 30, 2016. The net losses for the nine months ended September 30, 2017 and 2016 included non-cash expenditures of \$1.5 million and \$2.5 million, respectively. The lower net loss was primarily due to decreased research and development expense for clinical studies and research during the nine months ended September 30, 2017, as well as lower general and administrative expense needed to support these and other corporate development activities.

Cash used in operations was \$5.0 million and \$14.2 for the three and nine months ended September 30, 2017, respectively, as compared to \$8.4 million and \$31.9 million for the three and nine months ended September 30, 2016, respectively. At September 30, 2017, cash and cash equivalents totaled \$29.3 million, compared to \$26.1 million at December 31, 2016. Management believes that cash, cash equivalents and marketable securities as of September 30, 2017 are sufficient to fund operating expenses and the Phase 3 HONOR study to completion with up to 550 participants.

Subsequent to September 30, 2017 and through November 3, 2017, Tonix sold an aggregate of 248,340 shares of common stock under a purchase agreement with Lincoln Park Capital Fund, LLC, for gross proceeds of approximately \$1.1 million, at an average selling price of \$4.56 per share.

### **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 United States, 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 45 U.S. sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent 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 <http://www.thehonorstudy.com> or <https://clinicaltrials.gov/ct2/show/NCT03062540>.

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.

### **About Tonix Pharmaceuticals Holding Corp.**

Tonix is developing innovative pharmaceutical and biological products to address major public health challenges. Tonix's lead product candidate, Tonmya, is in Phase 3 development for the treatment of PTSD at bedtime daily. TNX-601 (tianeptine oxalate) is in the pre-IND (Investigational New Drug) application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix is also developing TNX-801, 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](http://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.

**Tonix Pharmaceuticals Reports Third Quarter 2017 Financial Results**  
**TONIX PHARMACEUTICALS HOLDING CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share amounts)  
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Costs and expenses				
Research and development	\$ 3,908	\$ 5,466	\$ 9,708	\$ 23,653
General and administrative	1,927	2,143	6,040	7,806
Total costs and expenses	5,835	7,609	15,748	31,459
Operating loss	(5,835 )	(7,609 )	(15,748 )	(31,459 )
Interest income, net	49	31	118	99
Net loss	\$ (5,786 )	\$ (7,578 )	\$ (15,630 )	\$ (31,360 )
Net loss per common share, basic and diluted	\$ (0.77 )	\$ (2.90 )	\$ (2.49 )	\$ (14.52 )
Weighted average common shares outstanding, basic and diluted	7,508,036	2,613,109	6,287,062	2,160,157

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

	September 30, 2017	December 31, 2016 <sup>(1)</sup>
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 29,310	\$ 26,121
Prepaid expenses and other current assets	896	1,019
Total current assets	30,206	27,140
Other non-current assets	329	370
Total assets	\$ 30,535	\$ 27,510

**Liabilities and stockholders' equity**

Total liabilities	\$	1,855	\$	2,149
Stockholders' equity		<u>28,680</u>		<u>25,361</u>
Total liabilities and stockholders' equity	\$	<u>30,535</u>	\$	<u>27,510</u>

(1) The condensed consolidated balance sheet for the year ended December 31, 2016 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.

**Contacts:**

Jessica Morris (investors)  
 Tonix Pharmaceuticals  
[investor.relations@tonixpharma.com](mailto:investor.relations@tonixpharma.com)  
 (212) 980-9159

Russo Partners (media)  
 Rich Allan  
[rich.allan@russopartnersllc.com](mailto:rich.allan@russopartnersllc.com)  
 (646) 942-5588

Source: Tonix Pharmaceuticals Holding Corp.