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Tonix Pharmaceuticals Reports Second Quarter 2016 Financial Results and Provides Programs Update

First Phase 3 Study of TNX-102 SL in Fibromyalgia to Report Topline Results in September

NEW YORK, Aug. 08, 2016 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), announced financial results for the second quarter ended June 30, 2016.

"Our late-stage programs gained significant momentum in the second quarter. We completed enrollment in our flagship Phase 3 fibromyalgia trial, AFFIRM, for which we plan to report topline data in September. AFFIRM, which enrolled 519 fibromyalgia patients, is a randomized, double-blind placebo-controlled study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets), 2.8 mg, dosed at bedtime over twelve weeks. Also, during the second quarter, we reported positive results from our Phase 2 AtEase study of TNX-102 SL in military-related PTSD. The data support that TNX-102 SL, 5.6 mg, is an effective and well tolerated dose in this population. These findings support the advancement of TNX-102 SL, 5.6 mg, for PTSD Phase 3 development," said Seth Lederman, M.D., president and chief executive officer of Tonix. "Our key focus for the third quarter is on our fibromyalgia program, highlighted by the upcoming announcement of topline data from our first Phase 3 AFFIRM study in September, and the ongoing enrollment in our recently initiated second Phase 3 RE-AFFIRM study."

Tonix ended the June 30, 2016 quarter with $31.2 million in cash and cash equivalents and marketable securities, as compared to $27.5 million as of March 31, 2016. During the quarter ended June 30, 2016, Tonix raised approximately $11.8 million in net proceeds from an underwritten offering and through an at-the-market offering. In July 2016, Tonix raised approximately $1.4 million in net proceeds from the fully exercised over-allotment of the underwritten offering.

Recent Clinical Highlights and Upcoming Milestones

TNX-102 SL – Fibromyalgia Program

- Recently completed the clinical phase of the first Phase 3 AFFIRM study.
- Scheduled to report topline results from the AFFIRM study in September.
- Initiated a second Phase 3 RE-AFFIRM clinical study, which is expected to enroll approximately 500 patients at approximately 35 clinical centers in the U.S.
- Presented encouraging results from a retrospective analysis on the Phase 2b BESTFIT

clinical study that demonstrated improvements in multiple domains of fibromyalgia including sleep, pain, and physical function.

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

TNX-102 SL – PTSD Program

- Presented positive results from the Phase 2 AtEase clinical study demonstrating that a 5.6 mg dose is effective and well tolerated for treating military-related PTSD.
- AtEase was the first large, multicenter, adequate well-controlled study that showed promising results with an Investigational New Drug to treat military-related PTSD.
- Phase 3 clinical study, employing a trial design similar to AtEase, is expected to begin enrollment in the first quarter of 2017.

PTSD affects approximately 8.5 million Americans and is a chronic and debilitating condition, in which patients experience nightmares and disturbed sleep, and which is associated with depression and suicide. Individuals who suffer from PTSD experience impaired social functioning, occupational disability, intense anxiety and avoidance, emotional numbness, intense guilt or worry, agitation and an overall poor quality of life. PTSD is sometimes associated with substance abuse and unpredictable or violent behaviors, additional reasons that make it a critical public health concern. PTSD can develop from witnessing or experiencing a traumatic event or ordeal in which there was the threat or actual occurrence of grave physical harm.

TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

Second Quarter Financial Results

Tonix reported a net loss of $9.8 million, or $0.50 per share, for the second quarter of 2016 compared to a net loss of $11.8 million, or $0.73 per share, for the second quarter of 2015. Net loss for the three months ended June 30, 2016, excluding non-cash expenditures of $0.8 million, was $9.0 million, as compared to a net loss of $10.6 million, excluding non-cash expenditures of $1.2 million, for the three months ended June 30, 2015. 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 needed to support these and other corporate development activities.

Tonix reported a net loss of $23.8 million, or $1.23 per share, for the six months ended June 30, 2016 compared to a net loss of $21.4 million, or $1.44 per share, for the six months ended June 30, 2015. Net loss for the six months ended June 30, 2016, excluding non-cash expenditures of $1.7 million, was $22.1 million, as compared to a net loss of $18.8 million, excluding non-cash expenditures of $2.6 million, for the six months ended June 30, 2015. The higher net loss was primarily due to increased research and development expense

during the first quarter of 2016 for clinical studies and research related to TNX-102 SL, as well as higher general and administrative expense needed to support these and other corporate development activities.

Cash used in operations was $8.0 million and $23.5 million for the three and six months ended June 30, 2016, respectively, as compared to $9.2 million and $18.3 million for the three and six months ended June 30, 2015, respectively. At June 30, 2016, Tonix's cash, cash equivalents and marketable securities totaled $31.2 million compared to $43.0 million at December 31, 2015. Management believes that Tonix's existing funds are sufficient to fund its operating expenses and ongoing clinical trials for at least the next 12 months.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and PTSD. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. 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, substantial competition; our possible 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, 2015, as filed with the Securities and Exchange Commission (the "SEC") on March 3, 2016, 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 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,	
	2016	2015	2016	2015
Costs and expenses				

Research and development	$ 7,516	$ 8,871	$ 18,187	$ 15,700
General and administrative	2,320	2,913	5,663	5,780
Total costs and expenses	9,836	11,784	23,850	21,480
Operating loss	(9,836)	(11,784)	(23,850)	(21,480)
Interest income, net	30	21	68	36
Net loss	$ (9,806)	$ (11,763)	$ (23,782)	$ (21,444)
Net loss per common share, basic and diluted	$ (0.50)	$ (0.73)	$ (1.23)	$ (1.44)
Weighted average common shares outstanding, basic and diluted	19,736,434	16,137,898	19,311,931	14,923,934

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

	June 30, 2016	December 31, 2015(1)
Assets		
Cash, cash equivalents and marketable securities	$ 31,246	$ 43,016
Prepaid expenses and other current assets	2,414	3,343
Total current assets	33,660	46,359
Other non-current assets	658	659
Total assets	$ 34,318	$ 47,018
Liabilities and stockholders' equity		
Total liabilities	$ 4,284	$ 6,756
Stockholders' equity	30,034	40,262
Total liabilities and stockholders' equity	$ 34,318	$ 47,018

(1) The condensed consolidated balance sheet for the year ended December 31, 2015 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

Bradley J. Saenger, CPA
Chief Financial Officer
investor.relations@tonixpharma.com
(212) 980-9155 x107

Jessica Smiley
Investor Relations
investor.relations@tonixpharma.com
(212) 980-9155 x185

Edison Advisors (investors)
Tirth Patel
tpatel@edisongroup.com
(646) 653-7035

Dian Griesel Int'l (media)
Susan Forman / Laura Radocaj

sforman@dgicomm.com
iradocaj@dgicomm.com
(212) 825-3210

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