

August 10, 2015



# Tonix Pharmaceuticals Reports Second Quarter 2015 Financial Results and Provides Program Update

## Key Clinical Results in Fibromyalgia, Post-Traumatic Stress Disorder, and Tension Headache to be Reported in 2016

NEW YORK, Aug. 10, 2015 (GLOBE NEWSWIRE) --[Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) ("Tonix"), a clinical-stage pharmaceutical company developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, announced financial results for the second quarter ended June 30, 2015.

"In the first half of this year, we achieved our goal of initiating efficacy studies in tension headache, post-traumatic stress disorder, and fibromyalgia, all large therapeutic indications. We look forward to reporting results from each of these three trials in 2016 as we advance our programs through the clinical development process," said Seth Lederman, M.D., Tonix's chairman and CEO.

Tonix ended the June 30, 2015 quarter with \$48.7 million in cash and cash equivalents. Tonix raised \$18.7M in net proceeds from an underwritten offering completed in July 2015.

### Recent Clinical Highlights and Upcoming Milestones

- *Tonmya™ (cyclobenzaprine HCl sublingual tablets, 2.8 mg) – fibromyalgia*
  - We commenced the 500-patient Phase 3 AFFIRM clinical study in fibromyalgia in May 2015.
  - AFFIRM is a randomized, double-blind, placebo-controlled, 12-week trial of Tonmya taken sublingually at bedtime daily.
  - The primary efficacy endpoint is a 30% pain responder analysis at week 12.
  - We expect to report top-line results in the second half of 2016.

Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. To learn more, please visit [www.affirmstudy.com](http://www.affirmstudy.com).

- *TNX-102 SL (cyclobenzaprine HCl sublingual tablets) – post-traumatic stress disorder*
  - We commenced the 220-patient Phase 2 AtEase clinical study in military-related PTSD in January 2015.

- AtEase is a randomized, double-blind, placebo-controlled, 12-week trial of TNX-102 SL 2.8 mg and 5.6 mg taken sublingually at bedtime daily.
- The primary efficacy endpoint will evaluate performance of TNX-102 SL 2.8 mg on the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5).
- We expect to report top-line results in the first half of 2016.

PTSD afflicts approximately 8.5 million Americans, and its prevalence in the military population is higher than that among civilians. Both of the drugs approved by the U.S. Food and Drug Administration (FDA) for this disorder lack evidence of efficacy in combat-related PTSD and carry suicidality warnings. To learn more, please visit [www.ateasestudy.com](http://www.ateasestudy.com).

- *TNX-201 (dexisometheptene mucate) – episodic tension-type headache*
  - A randomized, double-blind, placebo-controlled Phase 2 proof-of-concept (POC) study in episodic tension-type headache is underway and will evaluate the potential benefit of TNX-201 according to a variety of efficacy measures, as well as safety and tolerability.
  - The target enrollment is 200 patients, and we expect to report top-line results in the first quarter of 2016.

Millions of Americans suffer from episodic tension-type headache, yet prescription medications are limited for the many who find over-the-counter options to be inadequate. All of the FDA-approved prescription drugs for this condition contain a barbiturate, and no new prescription medication for tension-type headache has been approved in over 40 years. To learn more, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02423408).

## **Second Quarter Financial Results**

For the three months ended June 30, 2015, Tonix reported a net loss of \$11.8 million, or \$0.73 per share, as compared to a net loss of \$6.0 million, or \$0.61 per share, for the second quarter of 2014. The higher net loss was primarily due to increased research and development expense for clinical studies and related research as well as increased general and administrative expense to support these and other corporate development activities. Cash used in operations was \$18.3 million for the six months ended June 30, 2015, as compared to \$9.8 million for the six months ended June 30, 2014. At June 30, 2015, Tonix's cash and cash equivalents totaled \$48.7 million as compared to \$38.2 million at December 31, 2014.

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

Tonix is dedicated to the invention and development of novel pharmaceutical products for medical conditions that it believes have broad societal impact, that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's Tonmya is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

## Cautionary Note on 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" 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, 2014 and Quarterly Report on Form 10-Q for the period ended June 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and August 7, 2015, respectively, 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<br>30, |                  | Six Months Ended June<br>30, |                   |
|---|--------------------------------|------------------|------------------------------|-------------------|
|   | 2015                           | 2014             | 2015                         | 2014              |
| Costs and expenses  |                                |                  |                              |                   |
| Research and development                                      | \$8,871                        | \$4,075          | \$15,700                     | \$7,625           |
| General and administrative                                    | 2,913                          | 1,974            | 5,780                        | 3,593             |
| Total costs and expenses                                      | 11,784                         | 6,049            | 21,480                       | 11,218            |
| Operating loss  | (11,784)                       | (6,049)          | (21,480)                     | (11,218)          |
| Interest and other financing costs, net                       | 21                             | 5                | 36                           | 10                |
| Net loss  | <u>\$(11,763)</u>              | <u>\$(6,044)</u> | <u>\$(21,444)</u>            | <u>\$(11,208)</u> |
| Net loss per common share, basic and diluted                  | <u>\$(0.73)</u>                | <u>\$(0.61)</u>  | <u>\$(1.44)</u>              | <u>\$(1.20)</u>   |
| Weighted average common shares outstanding, basic and diluted | <u>16,137,898</u>              | <u>9,923,184</u> | <u>14,923,934</u>            | <u>9,324,020</u>  |

## TONIX PHARMACEUTICALS HOLDING CORP. CONDENSED CONSOLIDATED BALANCE SHEETS

**(in thousands)**  
**(Unaudited)**

|   | <u>June 30, 2015</u> | <u>December 31,<br/>2014(1)</u> |
|---|----------------------|---------------------------------|
| <b>Assets</b>                               |                      |                                 |
| Cash and cash equivalents                   | \$48,737             | \$38,184                        |
| Prepaid expenses and other current assets   | 1,577                | 852                             |
| Total current assets                        | 50,314               | 39,036                          |
| Other non-current assets                    | 614                  | 506                             |
| Total assets                                | <u>\$50,928</u>      | <u>\$39,542</u>                 |
| <b>Liabilities and stockholders' equity</b> |                      |                                 |
| Total liabilities                           | \$4,684              | \$3,450                         |
| Stockholders' equity                        | 46,244               | 36,092                          |
| Total liabilities and stockholders' equity  | <u>\$50,928</u>      | <u>\$39,542</u>                 |

(1) The condensed consolidated balance sheet for the year ended December 31, 2014 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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