

August 8, 2014



# **Tonix Pharmaceuticals Reports Second Quarter 2014 Financial Results**

## **Clinical Programs in Fibromyalgia and Post-Traumatic Stress Disorder Remain On Track**

NEW YORK, Aug. 8, 2014 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) today announced its financial results for the quarter ended June 30, 2014.

"In the second quarter, we continued to successfully execute against our strategic clinical and corporate development plans. Perhaps most significantly, in May we announced the completion of enrollment in our BESTFIT trial, a potentially pivotal clinical study evaluating TNX-102 SL in patients with fibromyalgia. Meeting this milestone keeps us on track to announce top-line data in the fourth quarter of this year," said Seth Lederman, M.D., president and chief executive officer. "Also in the second quarter, the United States Food and Drug Administration (FDA) cleared our Investigational New Drug application for post-traumatic stress disorder (PTSD), allowing us to proceed with our planned Phase 2 study, the AtEase Trial, which will evaluate TNX-102 SL in patients suffering from PTSD. In addition, we appointed key additions to the senior management and core development team. We are well equipped to advance and expand our development programs."

### **Second Quarter Financial Results**

For the three months ended June 30, 2014, Tonix reported a net loss of \$6.0 million, or \$0.61 per share, as compared to a net loss of \$2.1 million, or \$0.95 per share, for the second quarter of 2013. The increase in net loss is primarily due to an increase in research and development expense. At June 30, 2014, Tonix's cash totaled \$43.9 million as compared to \$8.2 million at December 31, 2013. This cash balance excludes approximately \$7.2 million in net proceeds from the sale of shares of common stock in a registered direct offering that closed in July.

### **Recent Corporate Highlights**

#### **Fibromyalgia Clinical Program**

- Completed Enrollment in BESTFIT Trial of TNX-102 SL for Fibromyalgia

#### **Post-Traumatic Stress Disorder Clinical Program**

- IND for TNX-102 SL in PTSD Cleared by the FDA

#### **Personnel Appointments**

- Chief Medical Officer - Gregory M. Sullivan, M.D.
- Senior Vice President of Clinical Development and Regulatory Affairs - Donald J. Kellerman, Pharm.D.
- Senior Vice President of Commercial Planning and Development - Ronald R. Notvest, Ph.D.

## Financial

- Completed Registered Direct Offering of \$7.8 Million

## About Tonix Pharmaceuticals Holding Corp.

Tonix develops innovative prescription medicines for common disorders of the central nervous system that represent new treatment paradigms. Fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache are characterized by inadequate treatment options, dissatisfaction among patients and physicians, and significant economic impact. Tonix is currently conducting the first potentially pivotal trial of TNX-102 SL in fibromyalgia, the BESTFIT trial (BEddtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy). Tonix expects to begin a Phase 2 trial of TNX-102 SL in PTSD, the AtEase Trial, in the fourth quarter of 2014. Tonix designed TNX-102 SL to target non-restorative or disturbed sleep in a chronic bedtime treatment regimen as a means of decreasing pain and other symptoms in fibromyalgia and improving PTSD symptoms. Tonix's second clinical stage investigational new drug, TNX-201, is in development for episodic tension-type headache, and Tonix expects to begin clinical studies of TNX-201 in the first quarter of 2015. To learn more, please visit [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" 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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 filed with the SEC on March 28, 2014 and future periodic reports filed with the Securities and Exchange Commission. All of the Company'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.*

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except share data)

(Unaudited)

|                                                                | Three Months Ended |           | Six Months Ended |           |
|----------------------------------------------------------------|--------------------|-----------|------------------|-----------|
|                                                                | June 30,           |           | June 30,         |           |
|                                                                | 2014               | 2013      | 2014             | 2013      |
| Costs and expenses:                                            |                    |           |                  |           |
| Research and development                                       | \$4,075            | 944       | 7,625            | 1,685     |
| General and administrative                                     | 1,974              | 1,142     | 3,593            | 2,402     |
| Total operating expenses                                       | 6,049              | 2,086     | 11,218           | 4,087     |
| Operating loss                                                 | (6,049)            | (2,086)   | (11,218)         | (4,087)   |
| Interest and other financing costs, net                        | 5                  | --        | 10               | --        |
| Net loss                                                       | \$(6,044)          | (2,086)   | (11,208)         | (4,087)   |
| Net loss per common share - basic and diluted                  | \$(0.61)           | (0.95)    | (1.20)           | (1.88)    |
| Weighted average common shares outstanding - basic and diluted | 9,923,184          | 2,186,537 | 9,324,020        | 2,172,921 |

**TONIX PHARMACEUTICALS HOLDING CORP.****CONDENSED CONSOLIDATED BALANCE SHEET DATA**

(in thousands)

(Unaudited)

|                                             | June 30, | December 31, |
|---------------------------------------------|----------|--------------|
|                                             | 2014     | 2013 (1)     |
| <b>Assets</b>                               |          |              |
| Cash                                        | \$43,870 | 8,202        |
| Prepaid expenses and other current assets   | 946      | 429          |
| Total current assets                        | 44,816   | 8,631        |
| Other non-current assets                    | 249      | 105          |
| Total assets                                | \$45,065 | 8,736        |
| <b>Liabilities and stockholders' equity</b> |          |              |
| Total liabilities                           | \$2,401  | 2,224        |
| Stockholders' equity                        | 42,664   | 6,512        |
| Total liabilities and stockholders' equity  | \$45,065 | 8,736        |

The condensed consolidated balance sheet for the year ended December 31, 2013 has been derived from the (1) 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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**Source: Tonix Pharmaceuticals Holding Corp.**