

March 3, 2015



# Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2014 Financial Results

NEW YORK, March 3, 2015 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) announced financial results for the fourth quarter and full year ended December 31, 2014. Tonix filed its Annual Report on Form 10-K for fiscal year 2014 on Friday, February 27, 2015.

"Over the last year, Tonix has evolved into a company with a portfolio of clinical programs in three significantly under-served central nervous system conditions," said Seth Lederman, M.D., president and chief executive officer of Tonix. "Following our recent capital raise, we expect our cash position to enable us to report key clinical results in fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache."

## Recent Business Highlights and Upcoming Milestones

- ***Announced FDA acceptance of Phase 3 trial design for TNX-102 SL in fibromyalgia.*** Following Tonix's report of top line results of the Phase 2b BESTFIT study in fibromyalgia this past September, in which TNX-102 SL (cyclobenzaprine HCl sublingual tablet) met statistical significance in the 30% pain responder rate at Week 12, a declared secondary endpoint, Tonix received written acceptance from the FDA to use this analysis as the primary endpoint in its prospective 500-patient Phase 3 AFFIRM trial, set to begin in the second quarter of 2015. Tonix expects to report top line results from AFFIRM in the second half of 2016. If approved, TNX-102 SL would be the first medicine for fibromyalgia to target non-restorative sleep and would be highly differentiated from currently marketed drug products.
- ***Commenced Phase 2 AtEase trial of TNX-102 SL in post-traumatic stress disorder.*** The AtEase trial commenced enrolling patients with military-related PTSD in January 2015, and Tonix expects to report top line results from this trial in the first half of 2016. If the primary outcome measure in the AtEase trial is achieved, it could qualify as one of the two pivotal studies required to support a New Drug Application for TNX-102 SL for the management of PTSD. If approved, TNX-102 SL would be the first medicine for PTSD to target poor sleep quality and would be highly differentiated from approved antidepressants that are also indicated for PTSD.
- ***Reported clinical progress on TNX-201, in development for episodic tension-type headache.*** In the fourth quarter of 2014, Tonix successfully completed a Phase 1 safety, tolerability, and pharmacokinetic study of TNX-201 ((R)-isometheptene). A

double-blind, randomized, placebo-controlled Phase 2 trial in episodic tension-type headache will be initiated in the second quarter of 2015. Tonix expects to report top line results from this trial in the fourth quarter of 2015. If approved, TNX-201 would be the first new medicine for episodic tension-type headache in over 40 years and would be highly differentiated from current prescription drug products that contain barbiturates.

- ***Elucidated the pharmacologic mechanism of TNX-201.*** Tonix research has revealed that TNX-201 is a specific agonist of the imidazoline-1 ( $I_1$ ) receptor. The  $I_1$  receptor is a receptor expressed in the brain that normally modulates pain perception and signal transmission, and the targeting of  $I_1$  appears to represent a novel strategy for the development of analgesics.
- ***Completed financing with premier life science institutional investors.*** In February 2015, Tonix raised approximately \$29 million in net proceeds from an offering of common stock underwritten by Roth Capital Partners, Oppenheimer & Co., and Janney Montgomery Scott, including a partial exercise of the over-allotment option. Investors in the offering included Broadfin Capital LLC, Deerfield Management Company, L.P., Sabby Management LLC and others.
- ***Created efficient international business structure.*** In the fourth quarter of 2014, Tonix formed two Irish subsidiaries, Tonix Pharma Holdings Limited ("Tonix International Holding") and Tonix Pharma Limited ("Tonix Ireland"). Tonix International Holding is managed and controlled in Bermuda and Tonix Ireland is managed and controlled in Ireland. Tonix International Holding was granted a non-exclusive right to exercise certain product technologies and related intangible rights related to and including TNX-102 SL and TNX-201 and other products. Tonix Ireland is managing the supply chain for TNX-102 SL and TNX-201 and other products.

## **Fourth Quarter and Full Year Financial Results**

Tonix reported a net loss of \$9.0 million, or \$0.83 per share, for the fourth quarter of 2014 compared to a net loss of \$3.7 million, or \$0.74 per share, for the fourth quarter of 2013. For the year ended December 31, 2014, Tonix reported a net loss of \$27.6 million, or \$2.77 per share, compared to a net loss of \$10.9 million, or \$3.37 per share, for the comparable period of 2013. At December 31, 2014, Tonix's cash totaled \$38.2 million compared to \$8.2 million at December 31, 2013.

## **About Tonix Pharmaceuticals**

Tonix Pharmaceuticals is a clinical-stage pharmaceutical company dedicated to the development of novel medicines for common yet challenging disorders of the central nervous system, including fibromyalgia, post-traumatic stress disorder, and episodic tension-type headache. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. To learn more, please visit [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 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 filed with the SEC on February 27, 2015 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.*

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

|                                                               | Three Months<br>ended December 31, |         | Twelve Months<br>ended December 31, |          |
|---------------------------------------------------------------|------------------------------------|---------|-------------------------------------|----------|
|                                                               | 2014                               | 2013    | 2014                                | 2013     |
|                                                               | (unaudited)                        |         |                                     |          |
| Costs and expenses                                            |                                    |         |                                     |          |
| Research and development                                      | \$5,775                            | 1,328   | \$18,617                            | 4,650    |
| General and administrative                                    | 3,229                              | 2,381   | 9,039                               | 6,238    |
| Total costs and expenses                                      | 9,004                              | 3,709   | 27,656                              | 10,888   |
| Operating loss                                                | (9,004)                            | (3,709) | (27,656)                            | (10,888) |
| Interest income, net                                          | 15                                 | 2       | 40                                  | 4        |
| Net loss                                                      | \$(8,989)                          | (3,707) | \$(27,616)                          | (10,884) |
| Net loss per common share, basic and diluted                  | \$(0.83)                           | (0.74)  | \$(2.77)                            | (3.37)   |
| Weighted average common shares outstanding, basic and diluted | 10,776                             | 5,007   | 9,986                               | 3,231    |

(1) The condensed consolidated statements of operations for the years ended December 31, 2014 and 2013 have been derived from the audited financial statements but do not include all of 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, | December 31, |
|--|--------------|--------------|
|  | 2014         | 2013         |

**Assets**

|                                           |          |         |
|-------------------------------------------|----------|---------|
| Cash                                      | \$38,184 | \$8,202 |
| Prepaid expenses and other current assets | 852      | 429     |
| Total current assets                      | 39,036   | 8,631   |
| Non-current assets                        | 506      | 105     |
| Total assets                              | \$39,542 | \$8,736 |

**Liabilities and stockholders' equity**

|                                            |          |         |
|--------------------------------------------|----------|---------|
| Total liabilities                          | \$3,450  | \$2,224 |
| Stockholders' equity                       | 36,092   | 6,512   |
| Total liabilities and stockholders' equity | \$39,542 | \$8,736 |

(1) The condensed consolidated balance sheets for the years ended December 31, 2014 and 2013 have been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

**Source: Tonix Pharmaceuticals**

CONTACT: For additional information contact:

Tonix Pharmaceuticals Holding Corp.  
Leland Gershell  
Chief Financial Officer  
(212) 980-9155 x104  
leland.gershell@tonixpharma.com

Martini Communications  
Amy Martini (investors)  
amartini@martinicomunications.com

Dian Griesel Int'l.  
Susan Forman/Laura Radocaj (media)  
(212) 825-3210  
sforman@dgicomm.com  
lradocaj@dgicomm.com

Source: Tonix Pharmaceuticals Holding Corp.