UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): August 10, 2015

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada (State or Other Jurisdiction of Incorporation) 001-36019 (Commission File Number) 26-1434750 (IRS Employer Identification No.)

509 Madison Avenue, Suite 306, New York, New York 10022 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

Copy of correspondence to:

Marc J. Ross, Esq. James M. Turner, Esq. Sichenzia Ross Friedman Ference LLP 61 Broadway, 32nd Floor New York, New York 10006 Tel: (212) 930-9700 Fax: (212) 930-9725

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2015, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the second fiscal quarter ended June 30, 2015. A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report. The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits.
- 99.01 Press Release, dated August 10, 2015, issued by Tonix Pharmaceuticals Holding Corp.



SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: August 10, 2015

By: <u>/s/ LELAND GERSHELL</u> Leland Gershell Chief Financial Officer



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, NY – August 10, 2015 – <u>Tonix Pharmaceuticals Holding Corp.</u> (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 <u>www.affirmstudy.com</u>.

- 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 <u>www.ateasestudy.com</u>.

- 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 overthe-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 <u>www.clinicaltrials.gov</u> (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.

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)

	Tł	Three Months Ended June 30,				Six Months Ended June 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	\$	(11,763)	\$	(6,044)	\$	(21,444)	\$	(11,208)		
Net loss per common share, basic and diluted	\$	(0.73)	\$	(0.61)	\$	(1.44)	\$	(1.20)		
Weighted average common shares										
outstanding, basic and diluted		16,137,898		9,923,184		14,923,934		9,324,020		

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

	June 30		December 31, 2014(1)	
Assets				
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	\$	50,928	\$	39,542
Liabilities and stockholders' equity				
Total liabilities	\$	4,684	\$	3,450
Stockholders' equity		46,244		36,092
Total liabilities and stockholders' equity	\$	50,928	\$	39,542

(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.

Source: Tonix Pharmaceuticals Holding Corp.

Contact:

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

Jenene Thomas Communications (investors) Jenene Thomas (908) 938-1475 jenene@jenenethomascommunications.com

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