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): October 21, 2014

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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

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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 8.01 Other Events.

On October 21, 2014, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that the Company has received clearance from the U.S. Food and Drug Administration of its Investigational New Drug application to study TNX-201 for the treatment of episodic tension-type headache. A clinical pharmacology study of TNX-201 in healthy volunteers will commence and be completed before the end of 2014.

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 October 21, 2014, 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: October 21, 2014

By: */s/ LELAND GERSHELL*
Leland Gershell
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Receives IND Clearance for TNX-201 in Episodic Tension-Type Headache

TNX-201 to be Evaluated in Clinical Trial This Quarter

NEW YORK – October 21, 2014 – Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) announced today that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to study TNX-201 for the treatment of episodic tension-type headache. Tonix will evaluate the safety, tolerability, and pharmacokinetics of TNX-201 in a healthy volunteers study to be completed before the end of 2014.

"We are developing TNX-201 with the goal of providing a new prescription medication for the millions of U.S. adults who suffer from episodic tension-type headache. For many, the existing treatment options are not adequately effective. Furthermore, all of the approved prescription drugs contain the barbiturate butalbital. Barbiturates are known to impair alertness, and carry risk of dependence and addiction," said Seth Lederman, M.D., chairman and chief executive officer of Tonix. "With TNX-201 to enter clinical development ahead of schedule, we expect to complete this first-in-man pharmacology and pharmacokinetics study before the end of this year."

TNX-201 is a single isomer of isometheptene (IMH), which has an extensive history of use as a prescription pharmaceutical in the U.S. as a mixture of two mirror-image isomers, also known as a racemic mixture. Racemic IMH was a Drug Efficacy Study Implementation (DESI) ingredient that has been marketed as prescription single-agent and combination drug products for the relief of tension and vascular headaches without an approved New Drug Application for many decades. Tonix proprietary research has shown that one isomer of IMH, TNX-201, is believed to be primarily responsible for the efficacy associated with racemic IMH for the treatment of headache. Furthermore, TNX-201 may possess favorable safety and tolerability relative to both the other isomer and to the racemic mixture, and potentially have an improved clinical profile as compared to the unapproved racemic IMH for headache indications.

About Episodic Tension-Type Headache

Episodic tension-type headache is the most common type of headache. It is estimated that approximately 30% of U.S. adults experience frequent episodic tension-type headaches (one to 15 headaches per month over a three-month period). Tension-type headache pain is often described as a constant pressure on both sides of the head, and typically lasts for several hours.

About Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals is a clinical-stage company developing first-in-class medicines for common disorders of the central nervous system, including fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. Tonix's lead candidate, TNX-102 SL, is intended to be a first-line treatment for fibromyalgia and for PTSD. A Phase 2b trial of TNX-102 SL in fibromyalgia (BESTFIT) has been completed, and Tonix is preparing to initiate a Phase 3 program to support registration. A Phase 2 trial of TNX-102 SL in PTSD (AtEase) is expected to begin in the fourth quarter of 2014. Tonix plans to enter TNX-201 into clinical development for patients with episodic tension-type headache in the fourth quarter of 2014. To learn more, please visit 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.

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