

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): July 6, 2017

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 Ference Kesner LLP
61 Broadway
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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On July 6, 2017, Tonix Pharmaceuticals Holding Corp. (the “Company”) issued a press release announcing that the Company received conditional acceptance from the U.S. Food and Drug Administration (the “FDA”) for the proposed trade name Tonmya[®] for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the management of posttraumatic stress disorder (“PTSD”). A request for proprietary name review for Tonmya will be submitted once the PTSD New Drug Application (“NDA”) is submitted. The FDA’s final approval of Tonmya is subject to NDA approval.

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 July 6, 2017, issued by Tonix Pharmaceuticals Holding Corp.*](#)

* Furnished herewith.

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: July 6, 2017

By: /s/SETH LEDERMAN

Seth Lederman

Chief Executive Officer



**Tonix Pharmaceuticals Announces Conditional Acceptance of Tonmya® as Proposed Brand Name for TNX-102 SL
(Cyclobenzaprine HCl Sublingual Tablets) for the Treatment of PTSD**

NEW YORK, July 6, 2017 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq:TNXP) (Tonix) a company that is developing innovative pharmaceutical products to address public health challenges today reported that the U.S. Food and Drug Administration (FDA) has conditionally accepted the proposed trade name Tonmya (*ton-MY-ah*) for TNX-102 SL* (cyclobenzaprine HCl sublingual tablets) for the management of posttraumatic stress disorder (PTSD). Tonix recently launched the Phase 3 HONOR study of Tonmya in military-related PTSD, from which topline results are expected to be reported in the second half of 2018. Tonmya was designated a Breakthrough Therapy by the FDA for the treatment of PTSD.

A request for proprietary name review for Tonmya will be submitted once the PTSD New Drug Application (NDA) is submitted. FDA's final approval of Tonmya is subject to NDA approval. A request for review of Tonmya as the proposed name for TNX-102 SL for the management of fibromyalgia has been withdrawn at the FDA. The U.S. Patent and Trademark Office has granted the federal registration of the Tonmya mark.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets)/Tonmya is an investigational new drug and has not been approved for any indication.

About Tonmya and the Phase 3 HONOR Study

Tonmya (cyclobenzaprine HCl sublingual tablets) is a patented sublingual transmucosal formulation of cyclobenzaprine that is in Phase 3 development. PTSD is a serious condition characterized by chronic disability, inadequate treatment options, especially for military-related PTSD, and an overall high utilization of healthcare services that contributes to significant economic burdens. In a Phase 2 study, Tonmya 5.6 mg (2 x 2.8 mg tablets), was found to be effective in treating military-related PTSD, which formed the basis of the Breakthrough Therapy designation granted by the FDA. Tonix is currently conducting a Phase 3 trial of Tonmya in military-related PTSD in the United States, the HONOR study, which is a 12-week randomized, double-blind, placebo-controlled trial evaluating the efficacy of Tonmya 5.6 mg in participants with military-related PTSD. This two-arm, adaptive-design trial is targeting enrollment of up to approximately 550 participants across approximately 35 clinical sites. An unblinded interim analysis will be conducted once the study has accumulated efficacy results from approximately 275 randomized participants. In a recent Cross-Disciplinary Breakthrough Therapy meeting, the FDA confirmed that a single-study NDA approval could be possible if the topline data from the HONOR study are statistically very persuasive. Additional details of the HONOR study are available at www.thehonorstudy.com or <https://clinicaltrials.gov/ct2/show/NCT03062540>. The U.S. Patent and Trademark Office has issued a patent (U.S. Patent No. 9,636,408) protecting the composition and manufacture of the unique Tonmya formulation. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in the patent are important elements of Tonix's proprietary Tonmya composition. This patent is expected to provide Tonmya, upon NDA approval, with U.S. market exclusivity until 2034.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing innovative pharmaceutical products to address major public health challenges. In addition to Tonmya for PTSD, Tonix is developing TNX-601 (tianeptine oxalate), a clinical candidate at pre-IND (Investigational New Drug) application stage, designed as a daytime treatment for PTSD and TNX-801, a live synthetic version of horsepox virus, at the pre-IND application stage, to be developed as a potential smallpox-preventing vaccine.

This press release and further information about Tonix can be found at 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,” “expect,” 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 for the year ended December 31, 2016, as filed with the Securities and Exchange Commission (the “SEC”) on April 13, 2017, 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.

Contacts

Jessica Smiley
Investor Relations
investor.relations@tonixpharma.com
(212) 980-9155 x18

Russo Partners (media)
Rich Allan
rich.allan@russopartnersllc.com
(646) 942-5588
