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): April 22, 2019

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 1608, New York, New York 10022
(Address of principal executive offices) (Zip Code)

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

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 7.01. Regulation FD.

Tonix Pharmaceuticals Holding Corp. (the "Company") announced today that U.S. Food and Drug Administration Breakthrough Therapy Designation remains in effect for its lead product candidate. A copy of the press release announcing this matter is furnished as Exhibit 99.01.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release, dated April 22, 2019

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: April 22, 2019

By: /s/ Seth Lederman

Seth Lederman
Chief Executive Officer

EXHIBIT 99.01

Tonix Pharmaceuticals Announces that Breakthrough Therapy Designation Remains in Effect for Tonmya® for the Treatment of Posttraumatic Stress Disorder

Company Will Meet with FDA in June to Address the "Intent to Rescind" Notice

NEW YORK, April 22, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company developing pharmaceutical products to treat psychiatric and pain conditions, and biological products to improve biodefense, today announced the U.S. Food and Drug Administration (FDA) has withdrawn its previously issued Breakthrough Therapy Designation Rescind letter and confirmed that the Breakthrough Therapy designation granted in December 2016 remains in effect for Tonmya* (cyclobenzaprine HCl sublingual tablets) for the treatment of posttraumatic stress disorder (PTSD), which is in Phase 3 development. Tonix also announced that FDA has reversed itself and granted the Company a meeting in June to present additional data to support continuing Breakthrough Therapy designation.

On December 20, 2018 the FDA issued an Intent to Rescind Breakthrough Therapy Designation letter and provided Tonix the opportunity to request a meeting within 60 days to discuss additional data to support continued Breakthrough Therapy designation for Tonmya for PTSD. Although Tonix made a timely meeting request on February 15, 2019, FDA unexpectedly denied the request and issued Breakthrough Therapy Designation Rescind and Meeting Denied letters on February 26, 2019, without considering the additional data the Company planned to submit prior to the requested meeting. On April 17, 2019, in response to a request for reconsideration by the Company, the FDA acknowledged that FDA should have first provided Tonix the opportunity to discuss the matter and formally withdrew the Breakthrough Therapy Designation Rescind letter and Meeting Denied letter. The FDA granted the Company a meeting in June to discuss the rationale and additional data for continued Breakthrough Therapy designation. Once the meeting has been held and the FDA's review of new information is complete, a determination regarding the status of Tonmya's Breakthrough Therapy designation will be made.

Breakthrough Therapy designation was granted for Tonmya for PTSD based on retrospective analysis of the effect of Tonmya 5.6 mg in the Phase 2 AtEase study in military-related PTSD, which showed a substantial improvement over existing therapies. The Intent to Rescind letter states the FDA's position that "emerging data" on Tonmya from the HONOR study no longer appears to support the continuation of the Breakthrough Therapy designation. At the upcoming June meeting with the FDA, the Company intends to provide additional data and analyses related to the HONOR study and the AtEase study, which the Company believes supports continued Breakthrough Therapy designation.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix commented, "We are pleased to have the opportunity to meet with the FDA to discuss our rationale and present additional data in support of continued Breakthrough Therapy designation for Tonmya for PTSD, our lead development program. In March, we announced the start of enrollment for the Phase 3 RECOVERY trial in civilian and military-related PTSD, and we expect topline data from this trial in the first half of next year."

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat psychiatric and pain conditions, and biological products to improve biodefense through potential medical counter-measures. Tonix's lead program is for the development of Tonmya (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate INDs to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development and the agitation in Alzheimer's program is Phase 2 ready. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but using a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. Phase 1 clinical study selected oral formulation of TNX-601 will be conducted outside of the U.S. in 2019. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

**Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

This press release and further information about Tonix can be found atwww.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, risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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 substantial competition. 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, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, and periodic reports filed with the SEC on or after the date thereof. 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 thereof.

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