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 4, 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 thatit plans to expand the Phase 3 development program 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 4, 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 4, 2019

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Plans to Expand TNX-102 SL Phase 3 Program Beyond PTSD to Include Fibromyalgia

Encouraging FDA Meeting Minutes Support Phase 3 Development of TNX-102 SL 5.6 mg in Fibromyalgia

NEW YORK, April 4, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company focused on developing pharmaceutical products to treat serious neuropsychiatric and central nervous system conditions, and biological products to improve biodefense, announced today the expansion of the TNX-102 SL 5.6 mg program beyond posttraumatic stress disorder (PTSD) to include a Phase 3 development for TNX-102 SL* in fibromyalgia. TNX-102 SL or Tonmya®** is Tonix's lead Phase 3 program in PTSD with the Phase 3 RECOVERY trial actively enrolling military and civilian PTSD participants.

In a recent Clinical Guidance meeting with the U.S. Food and Drug Administration (FDA), Tonix received clear guidance and support to advance the development of TNX-102 SL, a non-opioid centrally-acting analgesic, for the management of fibromyalgia. Acceptable study design features were discussed to establish the safety and efficacy of TNX-102 SL 5.6 mg in a pivotal study to support the fibromyalgia indication.

A lower dose of TNX-102 SL (2.8 mg) taken daily at bedtime was studied previously in fibromyalgia in a Phase 2 study and a Phase 3 study. Both studies showed clinical benefits especially in the quality of sleep improvement, however, primary analyses on pain reduction were not statistically significant. Additional data developed by Tonix in the PTSD program showed that TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) demonstrated acceptable tolerability with additional clinical benefit in pain reduction for trial participants with PTSD. There were no serious and/or unexpected adverse events reported; the most common adverse events were mostly related to local administration site reactions, such as oral hypoaesthesia and abnormal product taste.

Supported by the safety and efficacy findings in PTSD, Tonix believes that increasing the dose of TNX-102 SL from 2.8 mg to 5.6 mg in the new Phase 3 fibromyalgia study may provide clinical evidence to support the 5.6 mg dose as the efficacious dose for the management of fibromyalgia. The registration of TNX-102 SL 5.6 mg for the fibromyalgia indication will be supported by two positive Phase 3 studies, and the long-term safety exposure data from the PTSD program may support the fibromyalgia NDA.

"We are very pleased with the outcomes of our recent discussion with the FDA to advance the fibromyalgia Phase 3 clinical program with TNX-102 SL 5.6 mg with the potential to expand the product labeling beyond PTSD. FDA's acceptance of the well-established safety information of currently marketed oral cyclobenzaprine products and their agreement that TNX-102 SL 5.6 mg long-term exposure data from our PTSD studies may support the fibromyalgia indication is very reassuring. We are looking forward to submit a final Phase 3 protocol and statistical analysis plan for FDA acceptance prior to study initiation." said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. "We have extensive clinical experience and data collected over the past 7 years with TNX-102 SL in fibromyalgia and PTSD studies. In addition to the synergy between these two development programs, we are very pleased with the FDA clear guidance and support to help advancing our lead product candidate, TNX-102 SL, in fibromyalgia and PTSD toward NDA approvals."

Dr. Lederman continued, "There is a pressing need for new drugs to treat patients with fibromyalgia, especially considering that approximately one-third of fibromyalgia patients are on chronic opiates. Tonix could potentially address this need for a non-opiate, non-addictive analgesic for fibromyalgia and possibly other indications in which improvement in sleep quality can indirectly provide clinical benefit to the primary symptoms."

About Fibromyalgia

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric and central nervous system 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 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.

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

***Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL for the treatment of PTSD.*

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, 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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