

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): June 13, 2019

**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 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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TNXP	The NASDAQ Global Market

**Item 8.01 Other Events.**

Tonix Pharmaceuticals Holding Corp. (the “Company”) announced that the China National Intellectual Property Administration issued Chinese Patent No. ZL 201480024011.1 to the Company on April 16, 2019. A copy of the press release discussing this matter is filed as Exhibit 99.01, and incorporated by reference, in this report.

*Forward-Looking Statements*

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company’s product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management’s current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, “expect,” “anticipate,” “intend,” “plan,” “believe,” “estimate,” “potential,” “predict,” “project,” “should,” “would” and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company’s filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

**Item 9.01 Financial Statements and Exhibits.**

(d)	<b>Exhibit No.</b>	<b>Description.</b>
	99.01	<a href="#">Press Release dated June 13, 2019, issued by the Company</a>

**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: June 13, 2019

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

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**Tonix Pharmaceuticals Announces Issuance of Patent in China for the Composition and Formulation of TNX-102 SL**

***Patent Expected to Provide Intellectual Property Protection until 2034 in China***

NEW YORK, June 13, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company focused on developing small molecules and biologics to treat psychiatric, pain and addiction conditions as well as to improve biodefense, today announced that the China National Intellectual Property Administration issued Chinese Patent No. ZL 201480024011.1 to the Company on April 16, 2019. This patent, "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride," is directed to a unique eutectic that characterizes TNX-102 SL\*, and claims pharmaceutical compositions containing that eutectic and methods of making those compositions.

Tonix's proprietary eutectic formulation of cyclobenzaprine, or TNX-102 SL, is designed for long-term daily use at bedtime and sublingual (under-the-tongue) administration, which facilitates transmucosal absorption of cyclobenzaprine and bypasses first pass liver metabolism. Marketed cyclobenzaprine drug products are limited to short-term use (two to three weeks) and indicated for oral ingestion, which results in significant liver metabolism. Sublingual TNX-102 SL has a different pharmacokinetic profile than marketed oral cyclobenzaprine drug products. TNX-102 SL is being developed as a treatment for three indications: posttraumatic stress disorder (PTSD), fibromyalgia and agitation in Alzheimer's disease. Marketed oral cyclobenzaprine products are indicated for the relief of muscle spasm.

**About Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat psychiatric, pain and addiction 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. TNX-102 SL for the treatment of PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate Investigational New Drug applications (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-1300\*\*\* (double-mutant cocaine esterase) is being developed under an IND and is in Phase 2 development for the treatment of cocaine intoxication. TNX-1300 is a recombinant protein enzyme produced through rDNA technology in E. coli bacteria. TNX-1300 for cocaine intoxication has FDA Breakthrough Therapy designation. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by 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. Data is expected in the second half of 2019 for a Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 that is being conducted outside of the U.S. TNX-801 (live virus vaccine for percutaneous (scarification) administration) 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.*

\*\*\**TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has not been approved for any indication.*

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

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## **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 on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

## **Contacts**

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