

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 24, 2021

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.)

26 Main Street, Chatham, New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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))

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

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 Disclosure.

On June 24, 2021, Tonix Pharmaceuticals Holding Corp. (the “Company”) issued a press release announcing the advancement of the construction of its commercial-scale manufacturing facility to develop and manufacture vaccines in Ravalli County, Montana. A copy of the press release is furnished as Exhibit 99.01 hereto and incorporated herein by reference.

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 they 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	Description.
No.		
<u>99.01</u>	<u>Press release of the Company, dated June 24, 2021</u>	

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 24, 2021

By: /s/ Bradley Saenger

Bradley Saenger

Chief Financial Officer

FOR IMMEDIATE RELEASE
June 24, 2021

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COMMERCIAL SCALE VACCINE MANUFACTURING FACILITY ADVANCES IN THE BITTERROOT

Hamilton to Welcome Tonix Pharmaceuticals to the Valley's Biotech Corridor

(HAMILTON, Mont.) — Dr. Seth Lederman, CEO of Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, said today that plans are advancing to construct a commercial-scale manufacturing facility to develop and manufacture vaccines in the Bitterroot Valley.

During a roundtable discussion today in Hamilton hosted by the Ravalli County Economic Development Authority (RCEDA), Lederman and community leaders announced a new public/private sector collaboration between Ravalli County and Tonix Pharmaceuticals that will bring more high-tech bioscience jobs to the Bitterroot Valley. Lederman said he was pleased that the Hamilton City Council voted in April to ensure that critical infrastructure will be available to Tonix once the construction phase is complete. Tonix's new manufacturing site will be constructed on 44 acres of land designated by Ravalli County as a Target Economic Development District (TEDD), which allows for tax money generated at the site to be used for building infrastructure inside the district.

Attendees included Lederman, Rocky Mountain Lab Associate Director Dr. Marshall Bloom, Hamilton Mayor Dominic Farrenkopf, Ravalli County Commissioner Greg Chilcott, and RCEDA board chair Ryan Oster. The panel met to discuss recent developments in a longstanding effort to turn southwest Montana into a renowned biotech corridor. Tonix joins the U.S. National Institutes of Health's Rocky Mountain Laboratories (RML) in Hamilton, which is an internationally recognized leader in vaccine development and virology research. GlaxoSmithKline (GSK) also has a vaccine manufacturing facility in Hamilton.

Lederman has said that once the facility is completed, Tonix expects to create many high-tech bioscience jobs. The new Montana facility is intended to develop and produce Tonix's vaccine candidates, including TNX-1800, a potential COVID-19 vaccine.

“One of the things that the COVID-19 pandemic exposed was major shortcomings in U.S. domestic vaccine development and manufacturing capabilities,” said **Seth Lederman**, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. “Tonix is striving to be a pioneer in American made vaccine development and production. We believe it is vital to bring these skills and high-tech jobs back to the U.S. both in the fight against the COVID-19 pandemic and its long lasting effects, and to prepare for prospective future pandemics. Building our new Montana facility demonstrates our dedication to the development of our vaccines and creating good American jobs. We are excited to be at the forefront of this exciting time in domestic manufacturing and biotech in Montana, and we look forward to continued collaboration with the community partners here in the Bitterroot valley.”

“This is an unprecedented opportunity for economic development in Montana, and Ravalli county in particular,” said **Julie Foster**, the Executive Director of the Ravalli County Economic Development Authority (RCEDA). “We’re excited that we were able to work in collaboration with the city, county and the folks at Tonix to move this project forward and bring more good jobs to the Bitterroot Valley.”

In addition to a COVID-19 vaccine, Tonix is also developing a diagnostic test for T cell immunity to COVID-19, as well as an antiviral therapeutic for COVID-19. Tonix also announced earlier this week that it plans to develop TNX-102 SL, currently in phase 3 development for fibromyalgia, as a potential treatment for Long COVID Syndrome. The disease's symptoms include pain, sleep disturbance, fatigue, and brain fog, which are also seen in fibromyalgia. Tonix plans to meet with the U.S. Food and Drug Administration (FDA) in the third quarter of 2021 to determine the design of a pivotal phase 2 study. Some studies have indicated that Long COVID Syndrome, officially called Post-Acute Sequelae of COVID-19 (PASC), can occur in more than 30% of COVID-19 patients that have recovered.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix’s portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The Company’s CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead CNS candidate, TNX-102 SL¹, is in mid-Phase 3 development for the management of fibromyalgia, with positive data from the Phase 3 RELIEF study reported in December 2020. The Company expects interim data from the second Phase 3 study, RALLY, in the third quarter of 2021 and topline data in the first quarter of 2022. Tonix’s immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix’s lead vaccine candidate, TNX-1800², is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix reported positive efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801², live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

¹ TNX-102 SL is an investigational new drug and has not been approved for any indication.

² TNX-1800 and TNX-801 are investigational new biologics and have not been approved for any indication.

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; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; 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, 2019, as filed with the Securities and Exchange Commission (the “SEC”) on March 24, 2020, 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.
