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): October 4, 2021

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.)**

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 October 4, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that it completed the acquisition of its new research and development center ("RDC") facility located in Frederick, Maryland. 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 8.01. Other Events.

On October 4, 2021, the Company announced it completed the acquisition of the RDC facility. The RDC facility is operational with a dedicated staff of scientists and technicians. The main building was constructed as a biosafety level (BSL) -3 facility but has been operating at BSL-2. The Company plans to make appropriate upgrades and seek certification for BSL-3 so that research may be conducted on live SARS-CoV-2- and other pathogens. The Company believes that the recombinant pox virus platform technology underlying its TNX-1800 product candidate and TNX-1800, coupled with its capabilities at its planned development and clinical scale manufacturing facility, will be rapidly deployable for addressing potential novel or emerging pathogens, with simplified distribution and administration relative to modified mRNA-based vaccines. The Company's goal is to be able to design and test new recombinant pox virus vaccines against novel pathogens within 100 days of recognition of a potential emerging pandemic threat.

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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 development of TNX-601 CR, 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 SEC. 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)

Exhibit No.	Description.
99.01	Press release of the Company, dated October 4, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: October 4, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Completion of Acquisition of Infectious Disease R&D Center in Frederick, Maryland

R&D Center is Expected to Accelerate Internal Discovery and Development of Vaccines and Antiviral Drugs Against COVID-19, its Variants and Other Infectious Diseases

Domestic R&D Capability for Vaccines and Antivirals Intended to Support U.S. Pandemic Preparedness

CHATHAM, N.J., October 4, 2021 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced it has completed the acquisition of its new research and development center (RDC) located in Frederick, Md. The approximately 48,000 square foot facility will support Tonix's expanding infectious disease pipeline, including:

- TNX-1800 - a live virus vaccine designed to protect against COVID-19
- TNX-801 - a live virus vaccine designed to protect against smallpox and monkeypox
- TNX-3500 - a small molecule antiviral under development to treat COVID-19
- TNX-2100 - a peptide based skin test to measure functional T cell immunity to SARS-CoV-2

Tonix purchased the RDC from Southern Research, a collaborating partner on TNX-1800 and TNX-801 development.

The center is operational with a dedicated staff of scientists and technicians. The main building was constructed as a biosafety level (BSL) -3 facility but has been operating at BSL-2. Tonix plans to make appropriate upgrades and seek certification for BSL-3 so that research may be conducted on live SARS-CoV-2- and other pathogens.

The RDC in Frederick, Md. will complement Tonix's Advanced Development Center (ADC) being constructed in New Bedford, Mass., and its Commercial Manufacturing Center (CMC) planned in Hamilton, Mont. The ADC will house laboratories dedicated to process analytical development and pilot manufacturing of the Company's vaccine candidates for clinical trials. The CMC is expected to support commercial scale manufacturing of vaccine products.

"The establishment of the RDC is a significant milestone for Tonix and aligns with our strategic focus to support and grow our pipeline of vaccines and antiviral therapeutics," stated Seth Lederman, M.D., President and Chief Executive Officer of Tonix. "We believe that this strategy will enable Tonix to develop vaccines and therapeutics to address the current COVID-19 pandemic, and to be prepared to efficiently combat potential novel or emerging pathogens, termed 'Disease X', that could impact society in the future. We believe that the recombinant pox virus platform technology underlying TNX-1800 and TNX-801, coupled with our capabilities at the RDC and ADC, will be rapidly deployable for addressing Disease X, with simplified distribution and administration, relative to modified mRNA based vaccines. Our goal is to be able to design and test new recombinant pox virus vaccines against novel pathogens within the 100 days of recognition of a potential emerging pandemic threat, consistent with the criteria[1,2] recently set forth by the White House Office of Science and Technology Policy."

[1]https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf
[2]https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/

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 immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes a COVID-19 platform of product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to COVID-19. Tonix's lead vaccine candidate for COVID-19, TNX-1800[1], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) 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 and expects to start a Phase 1 study in humans in the first half of 2022. TNX-3500[2] (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-Investigational New Drug (IND) stage of development. TNX-102 SL[3] (cyclobenzaprine HCl sublingual tablets) is a small molecule drug being developed to treat Long COVID, a chronic condition, and is also in the pre-IND stage. Finally, Tonix is developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to COVID-19. Tonix intends to initiate a first-in-human clinical study of TNX-2100[4] in the fourth quarter of 2021, pending IND clearance. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases. 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 SL[3], is in mid-Phase 3 development for the management of fibromyalgia.

[1]TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox.

[2]TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.

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

[4]TNX-2100 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.

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, the risks related to operating research, development and manufacturing facilities, 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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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