

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): July 26, 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, Suite 101, 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 1.01 Entry into Material Definitive Agreement.**

On July 26, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") entered into a Purchase and Sale Agreement (the "Agreement") with Southern Research for the sale of an approximately 48,000 square foot research and development facility in Frederick, Maryland (the "Property") for a purchase price of \$17.5 million. The Company may terminate the Agreement prior to the closing of the sale of the Property subject to certain contingencies. The Property is intended to support the Company's infectious disease pipeline.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Agreement, which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2021.

*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 research and development facilities, 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 7.01 Regulation FD Disclosure.**

On July 27, 2021, the Company issued a press release announcing that it entered into the Agreement. 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.**

As of June 30, 2021, the Company had working capital of approximately \$169.2 million, an accumulated deficit of approximately \$311.7 million, and held unrestricted cash and cash equivalents of approximately \$165.7 million. The Company had approximately 346.4 million shares of common stock outstanding as of June 30, 2021.

**Item 9.01 Financial Statements and Exhibits.**

(d)	<b>Exhibit No.</b>	<b>Description.</b>
	<u>99.01</u>	<u>Press release of the Company, dated July 27, 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: July 27, 2021

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

## **Tonix Pharmaceuticals Announces Agreement to Acquire Infectious Disease R&D Facility to Accelerate Development of Vaccines and Antiviral Drugs**

*R&D Facility in Frederick, MD is Expected to Provide Internal Capacity to Discover and Develop Vaccines and Antiviral Drugs Against COVID-19, its Variants and Other Infectious Diseases*

*Facility, Currently Owned and Operated by Tonix Partner Southern Research, has Housed Research Relating to Tonix's COVID-19 Vaccine Candidate, TNX-1800 and Smallpox and Monkeypox Vaccine Candidate, TNX-801*

CHATHAM, N.J., July 27, 2021 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the signing of a Purchase and Sale Agreement to acquire an approximately 48,000 square foot research and development (R&D) facility in Frederick, MD to support Tonix's expanding infectious disease pipeline, including TNX-1800, a live replicating viral vaccine designed to protect against COVID-19, TNX-801, a live vaccine designed to protect against smallpox and monkeypox, and TNX-3500, a small molecule antiviral to inhibit replication of SARS-CoV-2.

Tonix agreed to purchase the R&D facility from Southern Research, a research collaboration partner for TNX-1800 and TNX-801 development. The facility currently operates at biosafety level 2 (BSL-2) containment. Pending transfer and approval of relevant permits, Tonix expects the transaction to close and the facility to be operational in the fourth quarter of 2021. Southern Research plans to consolidate its research activities at its Birmingham, AL campus. Tonix and Southern Research plan to continue those aspects of their collaboration on the development of vaccines and antivirals that are ongoing at the Birmingham, AL campus.

"The Frederick facility will be a major expansion of our R&D capabilities," stated Seth Lederman, M.D., President and Chief Executive Officer of Tonix. "We believe this facility will ensure adequate resources and capacity to support and grow our pipeline of vaccines and antiviral therapeutics. In addition, we view control of in-house facilities as a strategic capability to ensure the speed and efficiency with which we can develop vaccines and antiviral products in the future against known, emerging or novel pathogens."

Dr. Lederman continued, "While COVID-19 has the appearance of being controlled in certain geographic centers, reports of increasing infections in both unvaccinated and vaccinated individuals, primarily related to new variants, have led to new mask mandates and restrictions in parts of the U.S. as well as new lockdowns and other restrictions in Europe and elsewhere. These concerning trends point to an urgent need for more robust vaccine technology and better overall preparedness. The COVID-19 pandemic revealed weaknesses in the U.S. domestic capability to conduct infectious disease R&D and produce vaccines and therapeutics, particularly in the setting of an interrupted global supply chain. We believe our planned capabilities at the Frederick facility will provide greatly needed domestic resources. The facility is ideally located in Maryland's 'biotech corridor', which is rich in highly skilled talent, and is also close to the center of the U.S. biodefense research community."

Josh Carpenter, PhD, Chief Executive Officer of Southern Research stated, "We are delighted that Tonix will be acquiring the Frederick research campus. This is another chapter in a robust partnership that will be made even stronger. We have enjoyed partnering with Tonix on TNX-1800 and TNX-801 vaccine projects and look forward to continued collaboration on these projects, as well as TNX-3500 with work performed at our Birmingham campus."

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Tonix's Frederick R&D facility will complement its Advanced Development Center (ADC) being constructed in New Bedford, MA and the Commercial Manufacturing Center (CMC) that Tonix is planning in Hamilton, MT. The ADC will house laboratories dedicated to process analytical development and pilot manufacturing of its vaccine candidates. The CMC is expected to support commercial scale manufacturing of vaccine products.

### **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 SL<sup>1</sup>, is in mid-Phase 3 development for the management of fibromyalgia. 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-1800<sup>2</sup>, 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-801<sup>2</sup>, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox. TNX-3500<sup>3</sup> (sangivamycin) is a small molecule antiviral drug in the pre-IND stage of development.

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

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

<sup>3</sup>TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.

## About Southern Research

Founded in 1941, Southern Research (SR) is an independent, 501(c)(3) nonprofit affiliated with the University of Alabama at Birmingham. SR is an applied scientific research organization with more than 400 scientists and engineers working across four divisions: CRO services, Drug Discovery, Energy Storage, and Engineering. SR has supported the pharmaceutical, biotechnology, defense, aerospace, environmental, and energy industries. SR works on behalf of the National Institutes of Health, the U.S. Department of Defense, the U.S. Department of Energy, NASA and other major aerospace firms, utility companies, and other external academic, industry and government agencies. SR pursues entrepreneurial and collaborative initiatives to develop and maintain a pipeline of intellectual property and innovative technologies that positively impact real-world problems. SR has numerous ongoing drug discovery programs, which encompass drug discovery programs to combat various forms of cancer, Alzheimer's, schizophrenia, opioid use disorder, human immunodeficiency virus, disease, Parkinson's, tuberculosis, influenza, and others. SR's strong history, which includes nearly 80 years of successful collaborations to solve complex problems, has led to the discovery of seven FDA-approved cancer drugs—a number rivaling any other U.S. research institute. Furthermore, experts at SR are well-equipped to assist with the challenging landscapes of drug design and development technologies and market viability. SR is headquartered in Birmingham, Alabama.

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Further information about SR can be found at <https://southernresearch.org>

## 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 development of R&D 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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