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): November 22, 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 November 22, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the publication of "Sangivamycin is highly effective against SARS-CoV-2 in vitro and has favorable drug properties," in JCI Insight (the "Paper"). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, 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 and the Paper, 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 November 22, 2021, the Company announced the publication of a paper entitled "*Sangivamycin is highly effective against SARS-CoV-2 in vitro and has favorable drug properties,*" in JCI Insight. The paper includes *in vitro* studies that show sangivamycin, the active pharmaceutical ingredient in the Company's TNX-3500 product candidate, is a potent antiviral against SARS-CoV-2 and suppresses viral replication in tissue culture with greater efficacy than remdesivir, the active pharmaceutical ingredient in Gilead Sciences, Inc.'s Veklury®. When tested in combination with remdesivir, both drugs had additive rather than competitive effect against SARS-CoV-2. The new data show that TNX-3500 has similar low nanomolar antiviral activity in laboratory-based assays against multiple variants of SARS-CoV-2, including the Delta variant. The Company intends to conduct further nonclinical animal studies prior to submitting an Investigational New Drug application for TNX-3500 and initiating a Phase 1 clinical study.

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 intellectual property rights and protections related to TNX-1700, 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 November 22, 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: November 22, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Publication of Paper on Antiviral SARS-CoV-2 Inhibitor, TNX-3500, in *JCI Insight*

Early Studies in vitro Show that TNX-3500 is a Potent Antiviral Against Multiple Variants of SARS-CoV-2, the Cause of COVID-19, and Potentiates Remdesivir

CHATHAM, NJ, November 22, 2021 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the publication of "*Sangivamycin is highly effective against SARS-CoV-2 in vitro and has favorable drug properties,*" in *JCI Insight*. The paper includes *in vitro* studies that show sangivamycin, the active pharmaceutical ingredient in the Company's (TNX-3500) product candidate, is a potent antiviral against SARS-CoV-2, the cause of COVID-19, and suppresses viral replication in tissue culture with greater efficacy than remdesivir, the active pharmaceutical ingredient of Gilead Sciences, Inc.'s Veklury®. When tested in combination with remdesivir, both drugs had additive rather than competitive effect against SARS-CoV-2. The new data show that TNX-3500 has similar low nanomolar antiviral activity in laboratory-based assays against multiple variants of SARS-CoV-2, including the Delta variant. The article can be accessed at https://insight.jci.org/articles/view/153165.

"We are excited to have the results of this study published, as it demonstrates Tonix's commitment to helping fight COVID-19 and other viral disorders," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix. "We believe that TNX-3500's potency on SARS-CoV-2 inhibition in tissue culture and its tolerability in humans from prior clinical studies support the pursuit of TNX-3500 for further clinical development as a potential COVID-19 therapeutic."

In April 2021, Tonix entered into an exclusive worldwide licensing agreement with OyaGen, Inc. (www.oyageninc.com) to develop TNX-3500 for the treatment of COVID-19 and potentially other viral infections. OyaGen, Inc. discovered sangivamycin's broad-spectrum antiviral effect against Ebola virus, Lassa virus and orthopoxviruses (https://doi.org/10.3390/v13010052) through a collaborative research agreement with National Institute of Allergy and Infectious Disease/National Institute of Health (NIAID/NIH) Integrated Research Facility (IRF-Frederick) at Fort Detrick, Maryland, and the recent findings on SARS-CoV-2 are a product of this collaboration.

Dr. Harold Smith, President and CEO of OyaGen, Inc. stated, "The findings reported in our paper are exciting and reveal significant new understanding of the broad-spectrum antiviral activity of sangivamycin and its *in vitro* activity. Given the rapid global spread of the Delta variant of SARS-CoV-2, we are encouraged that the high potency of sangivamycin against multiple variants of SARS-CoV-2 may provide a much-needed medical countermeasure against current and future variants of coronaviruses. The data produced through a collaborative research agreement with the IRF-Frederick together with prior safety studies in cancer clinical trials suggest that TNX-3500 may be effective in clinical settings and perhaps may enhance the efficacy of other therapeutics through combination antiviral therapy. We are excited to be working with Tonix on the development of TNX-3500 for the treatment of COVID-19."

Tonix intends to conduct further nonclinical animal studies prior to submitting an Investigational New Drug application (IND) and initiating a Phase 1 clinical study.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics 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 COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. 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[1] (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300[2] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800[3], 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 expects to start a Phase 1 study in humans in the second half of 2022. Tonix is also developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study. TNX-3500[5] (sangivamycin, i.v. solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

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

[2] *TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[3] *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. TNX-801 is an investigational new biologic and has not been approved for any indication.*

[4] *TNX-2100 is an investigational new biologic and has not been approved for any indication.*

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

This press release and further information about Tonix can be found atwww.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 the development of TNX-3500, 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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