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): April 14, 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 1.01 Entry into Material Definitive Agreement

On April 14, 2021, Tonix Pharmaceuticals, Inc. (a wholly owned subsidiary of Tonix Pharmaceuticals Holding Corp. (the "Company")) ("Tonix") and OyaGen, Inc. ("OyaGen") entered into an exclusive License Agreement (the "License Agreement") pursuant to which OyaGen granted to Tonix an exclusive license, with the right to sublicense, certain patents and technical information (collectively, the "Technology") related to an antiviral inhibitor of SARS-CoV-2, sangivamycin, and to develop and commercialize products thereunder (each, a "Product"). OyaGen has also granted Tonix the option to acquire rights to any technology based on the Technology for the prevention or treatment of Covid-19 developed by OyaGen during the term of the License Agreement, and has agreed to facilitate discussions with the intent to enter into an exclusive license of the National Institute of Allergy and Infectious Diseases' ("NIAID") and/or the National Institute of Health's ("NIH) joint interest in certain patent applications related to the Technology.

As consideration for entering into the License Agreement, Tonix has agreed to pay a low-seven digit license fee to OyaGen, and agreed to issue to OyaGen and an affiliated entity an aggregate of 2,752,294 shares of the Company's common stock, par value $0.001 per share (the "Common Stock"). The Common Stock is unregistered and subject to a six-month lock-up and a Shareholder Voting Agreement, dated April 14, 2021 (the "Voting Agreement"), pursuant to which OyaGen and the affiliated entity have agreed to vote the Common Stock on any matter put to a vote of the shareholders of the Company in accordance with management's recommendations. Tonix is obligated to use Commercially Reasonable Efforts, as defined in the License Agreement, to develop and commercialize the Product, subject to specified reversion and revenue sharing rights in the event of Tonix's failure to commercialize a Product within 36 months in the region in which it first receives regulatory approval.

Tonix has agreed to pay OyaGen single-digit royalties on net sales of (i) Products sold by Tonix or a sublicensee and (ii) Product bundles sold together with one or more other products ("Product Bundles") (provided that net sales for Product Bundles shall be determined by mutual agreement of the parties) sold by Tonix or a sublicensee. Royalties on each particular Product are payable on a country-by-country and Product-by-Product basis until the latest of (i) the date of expiration of the last valid claim in the last to expire of the issued patents covered by the License Agreement, and (ii) the expiration of any regulatory exclusivity applicable to such Product in the country in question. Royalties payable on net sales of the Product and Product Bundles may be reduced by 50% of the royalties payable by Tonix to any third party for intellectual property rights which are necessary for the practice of the rights licensed to Tonix under the License Agreement, provided that the royalty payable on a Product or Product Bundle may not be reduced by more than 50%.

Tonix is also obligated to make contingent milestone payments to OyaGen totaling in the mid-seven digits upon the achievement of certain development and approval milestones related to a Product, which shall be payable in cash or Common Stock, at OyaGen's option. Milestone payments payable in Common Stock shall be unregistered and subject to a six-month lock-up and the Voting Agreement. In addition, Tonix shall pay OyaGen 10% of consideration, other than royalty payments and certain other

categories of consideration, payable to Tonix by a sublicensee.

The License Agreement may be terminated by either party for cause and contains customary indemnification provisions.

The foregoing description of the License 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 March 31, 2021. Certain terms of the License Agreement have been omitted from this Form 8-K and will be omitted from the version to be filed as an exhibit to the Form 10-Q.

Item 7.01 Regulation FD Disclosure.

On April 19, 2021, the Company issued a press release announcing that it entered into an exclusive worldwide licensing agreement for an antiviral inhibitor of SARS-CoV-2, TNX-3500 (sangivamycin, formerly OYA1) ("TNX-3500") with OyaGen. 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 April 19, 2021, the Company announced that it entered into an exclusive worldwide licensing agreement for TNX-3500 for the treatment of COVID-19 and potentially other viral disorders with OyaGen. The active ingredient of TNX-3500 has been studied for safety in humans in prior studies on cancer patients at the U.S. National Cancer Institute but has not been approved for marketing in any jurisdiction. TNX-3500 is in the pre-Investigational New Drug phase of development with early data from cell culture infectivity studies with SARS-CoV-2. The Company believes that its potency on SARS-CoV-2 inhibition in tissue culture and its tolerability in humans from prior studies suggests that TNX-3500 may qualify for expedited clinical development. TNX-3500 has shown strong dose-dependent antiviral activity against live SARS-CoV-2 virus in cell culture infectivity studies, and was demonstrated to be approximately 65 times more potent in head to head comparisons at inhibiting SARS-CoV-2 than remdesivir, the active ingredient of Veklury®. In addition, combining TNX-3500 and remdesivir has demonstrated additive activity against SARS-CoV-2 in cell culture infectivity studies. These studies are from unpublished results from OyaGen's collaborative research with the National Institute of Allergy and Infectious Diseases Integrated Research Facility (NIAID-IRF), part of the National Institutes of Health ("NIH"). TNX-3500 inhibits the replication of SARS-CoV-2 and may have other mechanisms of action that affect viral particle release from infected cells.

TNX-3500 has demonstrated broad-spectrum antiviral activity in laboratory-based assays against the coronaviruses SARS-CoV-2 and MERS-CoV. TNX-3500 also demonstrated that it acts as a dual target specific antiviral against filoviruses such as Ebola virus in cell culture infectivity studies. TNX-3500 was studied in the U.S. at the National Cancer Institute, part of NIH, as an investigational new drug for treating cancer in the 1960s. Studies at that time demonstrated safety in nonhuman primates and human adults when dosed daily or weekly. TNX-3500 was demonstrated in studies in mice to persist in tissues for greater than 12 days following a single dose. The Company believes that its long half-life in tissues suggests that a single dose or weekly dosing may be sufficient for antiviral treatments.

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-3500, 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 April 19, 2021

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: April 19, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Enters into Exclusive Worldwide Licensing Agreement with OyaGen to Develop Antiviral SARS-CoV-2 Inhibitor, TNX-3500, for the Treatment of COVID-19

Early Studies Show TNX-3500 Significantly Inhibits
SARS-CoV-2, the Cause of COVID-19, and Potentiates Remdesivir

CHATHAM, NJ, April. 19, 2020 - Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, and OyaGen, Inc. (OyaGen), a pre-clinical biotechnology research company, announced today an exclusive worldwide licensing agreement for an antiviral inhibitor of SARS-CoV-2, TNX-3500 (sangivamycin, formerly OYA1), for the treatment of COVID-19 and potentially other viral disorders. The active ingredient of TNX-3500 has been studied for safety in humans in prior studies on cancer patients at the U.S. National Cancer Institute but has not been approved for marketing in any jurisdiction.

“We are excited to expand our pipeline and we look forward to developing TNX-3500 as a potential treatment for COVID-19 and emerging variants,” said Seth Lederman, M.D., Tonix's President and Chief Executive Officer. “TNX-3500 is in the pre-Investigational New Drug (IND) phase of development with encouraging early data from cell culture infectivity studies with SARS-CoV-2. We believe that its potency on SARS-CoV-2 inhibition in tissue culture and its tolerability in humans from prior studies suggests that TNX-3500 may qualify for expedited clinical development.”

Harold Smith, PhD, Chief Executive Officer and founder of OyaGen andprofessor of biochemistry and biophysics at the University of Rochester, School of Medicine and Dentistry said, “TNX-3500 has shown strong dose-dependent antiviral activity against live SARS-CoV-2 virus in cell culture infectivity studies. TNX-3500 was demonstrated to be approximately 65 times more potent in head to head comparisons at inhibiting SARS-CoV-2 than remdesivir, the active ingredient of Veklury®. In addition, combining TNX-3500 and remdesivir has demonstrated additive activity against SARS-CoV-2 in cell culture infectivity studies. These studies are from unpublished results from OyaGen’s collaborative research with the National Institutes of Allergy and Infectious Diseases Integrated Research Facility (NIAID-IRF), part of the National Institutes of Health. TNX-3500 inhibits the replication of SARS-CoV-2 and may have other mechanisms of action that affect viral particle release from infected cells.”

Dr. Smith continued, “We’re delighted to partner with Tonix on the development of TNX-3500 because we believe Tonix to be ideally capable to bring this program to the clinic and position it for worldwide commercialization in the rapidly evolving and highly competitive area of SARS-CoV-2 inhibitors.”

Under the terms of the agreement, Tonix has been granted an exclusive license from OyaGen for technology and patents related to TNX-3500 and other related compounds. Tonix will conduct further studies to test the safety and efficacy of TNX-3500 in treating COVID-19 as necessary to support regulatory approval.

About TNX-3500

TNX-3500 (sangivamycin) has demonstrated broad-spectrum antiviral activity in laboratory-based assays against the coronaviruses SARS-CoV-2 and MERS-CoV. Sangivamycin also demonstrated that it acts as a dual target specific antiviral against filoviruses such as Ebola virus in cell culture infectivity studies. TNX-3500 was studied in the U.S. at the National Cancer Institute (NCI), part of NIH, as an investigational new drug for treating cancer in the 1960s. Studies at that time demonstrated safety in nonhuman primates and human adults when dosed daily or weekly. TNX-3500 was demonstrated in studies in mice to persist in tissues for greater than 12 days following a single dose. Its long half-life in tissues suggests that a single dose or weekly dosing may be sufficient for antiviral treatments.

About OyaGen, Inc.

OyaGen is a privately held biotechnology company located in Rochester, New York. OyaGen is focused on the identification and early development of novel therapeutics for the treatment of viral diseases, such as those caused by HIV, coronavirus, and Ebola virus.

Further information about OyaGen can be found atwww.oyageninc.com.

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 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], is in mid-Phase 3 development for the management of fibromyalgia, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY, in the third quarter of 2021[2] and topline data in the fourth quarter of 2021. 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 [3], 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[3], a 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]Pending agreement from FDA on statistical analysis plan.
[3]TNX-1800 and TNX-801 are investigational new biologics and have 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, 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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