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): September 23, 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 September 23, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that it is expanding its research collaboration with Columbia University to develop precision medicine techniques for COVID-19 vaccines and therapeutics. 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 September 23, 2021, the Company announced it has expanded its research collaboration with Columbia University. The research collaboration is focused on studying immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were asymptomatic, as well as studying in vitro T cell and antibody responses to SARS-CoV-2, the virus that causes COVID-19. The research is designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation for tailoring vaccines and therapeutics to appropriate individuals with precision medicine.

The two principal investigators for the collaboration are Ilya Trakht, Ph.D., Associate Research Scientist and Sergei Rudchenko, Ph.D., Assistant Professor of Medical Sciences at Columbia University Vagelos College of Physicians and Surgeons. The research has the potential to lead to the isolation, characterization and cloning of therapeutically relevant fully human neutralizing monoclonal antibodies to SARS-CoV-2. Dr. Rudchenko is generating DNA aptamer-based anti-idiotypes to certain monoclonal antibodies identified by Dr. Trakht. Such aptamers have the potential to identify biomarkers for protective CoV-2 immunity and accelerate the design of precision medicine-driven vaccines against COVID-19. Data from the collaboration may provide a roadmap and tools to potentially guide the selection of appropriate individuals for COVID-19 vaccine trials and to help determine which vaccine is appropriate for each individual based on the condition of their immune system or other physiological features.

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 September 23, 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: September 23, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Expands Research Collaboration to Develop Precision Medicine Techniques for COVID-19 Vaccines and Therapeutics

Collaboration Will Continue to Work Towards Identifying Biomarkers for Protective Immunity Against SARS-CoV-2

Immune Correlates of Protection May Support Development of New and Specialized Vaccines to Protect Against COVID-19

Potential for Developing Antibody-Based COVID-19 Therapeutics as a Result of the Collaboration

CHATHAM, N.J., September 23, 2021 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has expanded its research collaboration with Columbia University. The research collaboration is focused on studying immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were asymptomatic, as well as studying in vitro T cell and antibody responses to SARS-CoV-2, the virus that causes COVID-19. The research is designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation for tailoring vaccines and therapeutics to appropriate individuals with precision medicine.

The two principal investigators for the collaboration are Ilya Trakht, Ph.D., Associate Research Scientist and Sergei Rudchenko, Ph.D., Assistant Professor of Medical Sciences at Columbia University Vagelos College of Physicians and Surgeons.

Dr. Trakht is studying T cell and antibody responses in a variety of ways, including at the cellular level by stimulating T cells in vitro with CoV-2 antigens and by generating fully human monoclonal antibodies against SARS-CoV-2. This research has the potential to lead to the isolation, characterization and cloning of therapeutically relevant fully human neutralizing monoclonal antibodies to SARS-CoV-2.

Dr. Rudchenko is generating DNA aptamer-based anti-idiotypes to certain monoclonal antibodies identified by Dr. Trakht. Such aptamers have the potential to identify biomarkers for protective CoV-2 immunity and accelerate the design of precision medicine-driven vaccines against COVID-19.

“Based on the progress and results of the initial phase of these projects, we are excited to expand our research collaboration with Columbia University on these precision medicine technologies and also to potentially develop new monoclonal antibody therapeutics,” stated Seth Lederman, M.D., President and Chief Executive Officer of Tonix. “Data from this collaboration may provide a roadmap and tools to potentially guide the selection of appropriate individuals for COVID-19 vaccine trials and to help determine which vaccine is appropriate for each individual based on the condition of their immune system or other physiological features.”

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 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 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, 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, risks related to our research collaboration efforts, 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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