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): December 13, 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 December 13, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that it entered into a research collaboration with Columbia University ("Columbia") focused on advancing recombinant trefoil factor family 2 ("rTFF2")-based therapeutic candidates ("TNX-1700") in the treatment of gastric and colorectal cancers. 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, 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 December 13, 2021, the Company issued a press release announcing that it entered into a research collaboration with Columbia focused on TNX-1700 in the treatment of gastric and colorectal cancers. Data from a previous collaboration with Columbia demonstrated that TNX-1700 detoxifies the tumor microenvironment and potentiates anti-PD1 therapy in a mouse model of colorectal cancer. These findings raise the possibility that a tumor's responsiveness to anti-PD1 therapy may relate to the tumor microenvironment more than to properties of the tumor itself. The Company believes these findings warrant additional work to learn if TNX-1700 detoxifies the tumor microenvironment in human cancer in a way that makes colorectal and gastric cancers responsive to anti-PD-1 therapy.

The new study, which will be conducted by scientists at Columbia under the direction of Timothy Wang, M.D., professor of medicine and Chief of the Division of Digestive and Liver Diseases at Columbia University Vagelos College of Physicians and Surgeons, will use a modified TFF2 peptide with the carboxy-terminal (CTP) domain of the beta subunit of the human chorionic gonadotropin (hCG) fused to a TFF2 protein (TFF2-CTP) as well as Tonix-generated TFF2- albumin fusion proteins, including murine TFF2-murine serum albumin [muTFF2-MSA], human TFF2-human serum albumin [huTFF2-HSA], and rTFF2 domain-swap variant HAS-fusion proteins for their ability to synergize with anti-PD1 in mouse models of gastric and colon cancer.

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 December 13, 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: December 13, 2021

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

Exhibit 99.1

Tonix Pharmaceuticals Announces Research Collaboration with Columbia University to StudyRecombinant Trefoil Factor 2 (rTFF2)-Based Therapy (TNX-1700) for Gastric and Colorectal Cancers

TNX-1700 is Under Development as Monotherapy and in Combination with Anti-PD1 Checkpoint Inhibitor Therapy in Animal Models of Two Challenging Cancers

In Mouse Models, rTFF2 Detoxifies the Tumor Microenvironment, Allows Activation of Cancer-Killing CD8+T Cells and Limits Immune Evasion by Cancer Cells

Study to be Led by Noted Cancer Researcher and Columbia Professor Timothy C. Wang, MD

CHATHAM, N.J., December 13, 2021 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that it has entered into a research collaboration with Columbia University (Columbia) focused on advancing recombinant trefoil factor family 2 (rTFF2)-based therapeutic candidates (TNX-1700) in the treatment of gastric and colorectal cancers.

Tonix licensed worldwide rights to develop and commercialize products related to Columbia's rTFF2 technology in 2019[1], and key patent claims have recently issued in the U.S[2]. The new project, "Development of rTFF2-Based Therapy to Enhance Immuno-Oncology Treatments," is the first sponsored research project of this collaboration. The agreement also gives Tonix the option to exclusively license from Columbia University new therapeutic candidates and other technologies that arise from the research collaboration for further development.

Tonix's President and Chief Executive Officer, Seth Lederman, M.D., said, "Tonix is excited to enter into this new research agreement, which continues our work with Columbia University on the development of TNX-1700 rTFF2-based therapies as monotherapy and for enhancing the performance of anti-PD1 checkpoint inhibitors in treating gastric and colorectal cancers – two tumor types that are known to be notoriously unresponsive to anti-PD1 treatment. In our previous work with Columbia University, we have shown that TNX-1700 detoxifies the tumor microenvironment and potentiates anti-PD1 therapy in a mouse model of colorectal cancer. These findings raise the possibility that a tumor's responsiveness to anti-PD1 therapy may relate to the tumor microenvironment more than to properties of the tumor itself. We believe these findings warrant additional work to learn if TNX-1700 detoxifies the tumor microenvironment in human cancer in a way that makes colorectal and gastric cancers responsive to anti-PD-1 therapy."

The studies will be conducted by scientists at Columbia University under the direction of Timothy Wang, M.D., professor of medicine and Chief of the Division of Digestive and Liver Diseases at Columbia University Vagelos College of Physicians and Surgeons.

Dr. Wang said, "Over the last decade, cancer therapy has been notable for improvements in treatment with the successful introduction of immune-oncology drugs that overcome immune checkpoints such as PD1-PDL1 to harness the power of the host's adaptive immune system. However, despite these successes, most solid tumors show significant resistance to immune therapies, in part due to the presence of immune suppressor cells such as myeloid derived suppressor cells (MDSCs). The new project will focus on rTFF2 in gastric and colorectal cancer models using rTFF2 to suppress MDSCs."

[1] *Tonix Pharmaceuticals Announces Licensing Agreement with Columbia University for the Development of Recombinant Trefoil Family Factor 2 (rTFF2), or TNX-1700, for the Treatment of Gastric and Pancreatic Cancers :: Tonix Pharmaceuticals Holding Corp. (TNXP)*

[2] *The U.S. Patent and Trademark Office issued U.S. Patent No. 11,167,010 on November 9, 2021.*

Dr. Wang is an expert in the molecular mechanisms of carcinogenesis whose research has focused on the carcinogenic role of inflammation in modulating stem cell functions. Dr. Wang demonstrated that knocking out the TFF2 gene in mice leads to faster tumor growth and that overexpression of TFF2 markedly suppresses tumor growth by curtailing the homing, differentiation, and expansion of MDSCs to allow activation of cancer-killing CD8+ T cells[3]. He went on to show that a novel engineered form of rTFF2 (TFF2-CTP) had an extended half-life *in vivo* and was able to suppress MDSCs and tumor growth in an animal model of colorectal cancer. More recently, he has shown in gastric cancer models that suppressing MDSCs using chemotherapy enhances the effectiveness of anti-PD1 therapy and significantly reduces tumor growth.[4] Dr. Wang proposed the concept of employing rTFF2 in combination with other therapies in cancer prevention and early treatment.

The new study will use modified TFF2 peptide with the carboxy-terminal (CTP) domain of the beta subunit of the human chorionic gonadotropin (hCG) fused to a TFF2 protein (TFF2-CTP) as well as Tonix-generated TFF2- albumin fusion proteins, including murine TFF2-murine serum albumin [muTFF2-MSA], human TFF2-human serum albumin [huTFF2-HSA], and rTFF2 domain-swap variant HAS-fusion proteins for their ability to synergize with anti-PD1 in mouse models of gastric and colon cancer.

About Trefoil Factor 2 (TFF2)

TFF2 is a small, secreted protein, encoded by the TFF2 gene in humans, that is expressed in gastrointestinal mucosa where it functions to protect and repair mucosa. TFF2 is also expressed at low levels in splenic immune cells and is now appreciated to have intravascular roles in spleen and in the tumor microenvironment. In gastric cancer, TFF2 is epigenetically silenced, and TFF2 is suggested to be protective against cancer development through several mechanisms. A poster, titled "Stabilized recombinant trefoil factor 2 (TFF2-CTP) enhances anti-tumor activity of PD-1 blockade in mouse models of colorectal cancer," was presented at the American Association for Cancer Research (AACR) conference as a collaboration between Tonix and Columbia University in 2020[5] and includes data from a preclinical study which investigated the role of PD-L1 in colorectal tumorigenesis and evaluated the utility of targeting myeloid-derived suppressor cells (MDSCs) in combination with PD-1 blockade in mouse models of colorectal cancer. The data show that anti-PD-1 monotherapy was unable to evoke anti-tumor immunity in this model of colorectal cancer, but TFF2-CTP augmented the efficacy of anti-PD-1 therapy. Anti-PD-1 in combination with TFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice. Tonix is developing TNX-1700 (rTFF2-CTP) for the treatment of gastric and colon cancers under a license from Columbia University. Columbia was recently granted patent claims, which, excluding possible patent term extensions, is expected to provide U.S. market exclusivity until April 2, 2033.

[3] *Dubeykovskaya ZA et al, Nat Commun 2016*

[4] *Kim W et al, Gastroenterology 2021*

[5] *Tonix Pharmaceuticals Announces Results from Preclinical Study of TNX-1700 Presented in a Poster at AACR Virtual Annual Meeting 2020 :: Tonix Pharmaceuticals Holding Corp. (TNXP)*

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 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 in the first quarter of 2022. 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 initiate 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 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 the research collaboration with Columbia and the development of TNX-1700, 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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