

**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 16, 2020

**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.)

509 Madison Avenue, Suite 1608, New York, New York 10022  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

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))

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.

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

**Item 8.01 Other Events.**

On July 16, 2020, Tonix Pharmaceuticals Holding Corp. (the “Company”) announced that it entered a research collaboration and option agreement with Columbia University.

A press release issued by the Company which discusses this matter is included as Exhibit 99.01 hereto.

*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 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 9.01 Financial Statements and Exhibits.**

(d)	<b>Exhibit No.</b>	<b>Description.</b>
	<u>99.01</u>	<u>Press release of Tonix Pharmaceuticals Holding Corp., dated July 16, 2020</u>

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**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 16, 2020

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

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

*Dissecting the Immune Response to SARS-CoV-2 in Healthy Recovered or Asymptomatic Volunteers  
May Lead to Biomarkers for Tailoring COVID-19 Vaccines and Therapeutics*

*Potential for Human Monoclonal Antibody COVID-19 Therapeutics to be Developed as a Result of the Collaboration*

NEW YORK, July 16, 2020 - Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has entered into a research collaboration and option agreement with Columbia University focused on studying the immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were asymptomatic. The research collaboration will focus on T cell and antibody responses to SARS-CoV-2 (CoV-2), the virus that causes COVID-19 at the cellular level including human monoclonal antibodies and anti-idiotypes. The research is designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation upon which to target vaccines and therapeutics to appropriate individuals by 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's project will study 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 CoV-2. The project, directed by Dr. Trakht, has the potential to lead to the isolation and characterization of therapeutically relevant fully human monoclonal antibodies to CoV-2. Dr. Rudchenko's project will generate DNA aptamer-based anti-idiotypes to certain of the monoclonal antibodies identified by Dr. Trakht. Such aptamers have the potential to identify biomarkers for protective CoV-2 immunity and to lead to accelerated precision medicine-driven vaccines designed to protect against COVID-19.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals, said, "We expect that more than one COVID-19 vaccine will ultimately be approved by the Food and Drug Administration (FDA), and a challenge for future research will be to determine which vaccine is appropriate for each individual. Data from this collaboration will provide a roadmap and tools to potentially guide these recommendations. This work may also guide the selection of appropriate individuals for COVID-19 vaccine trials, such as for Tonix's TNX-1800, based on a live replicating vector platform, which is designed to confer durable T cell immunity. It is also possible that new COVID-19 vaccines can be designed which will be tailored to individuals by precision medicine. We are excited to work with our collaborators at Columbia University on these precision medicine technologies and also to potentially develop new monoclonal antibody therapeutics."

Dr. Trakht said, "T cell responses to SARS-CoV-2 have only recently been reported, so there is much that we hope to learn and to contribute to the understanding of the systemic immune response to COVID-19. We are excited to exploit our fully human monoclonal antibody system to characterize the antibody response to SARS-CoV-2 infection and the potential for developing antibody-based immunotherapeutics.

Dr. Rudchenko said, "The anti-idiotypic aptamer tools that we plan to develop will characterize the immune responses in healthy people who have recovered or were asymptomatic from SARS-CoV-2 infection, which are relevant for developing therapeutics and vaccines. A goal for future research will be to use these tools to distinguish SARS-CoV-2-specific immunity in COVID-19 patients who suffered poor outcomes. My colleague, Dr. Trakht's system to make human monoclonal antibodies is particularly well suited to evaluate individuals' antibody responses at a high level of detail in the context of accelerating precision medicine approaches to vaccines and therapeutics."

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## 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 central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800\*, 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 expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801\*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix is also developing TNX-2300\*, a second live replicating vaccine candidate for the prevention of COVID-19, but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL\*\*, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) application stage. Tonix's programs for treating addiction conditions also include TNX-1300\* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR\*\* (tiapentine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900\*\*, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600\*\* (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD; TNX-1500\* (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions; and TNX-1700\* (rTFF2), a biologic being developed to treat gastric and pancreatic cancers.

\*TNX-1800, TNX-801, TNX-2300, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

\*\*TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have not been approved for any indication.

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, and periodic reports filed with the SEC on or after the date thereof. All of 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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