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 5, 2022

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 Capital 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 April 5, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that it entered into a new preclinical research agreement with Kansas State University ("K-State") to extend the research being performed under its original agreement with K-State to develop a live-virus vaccine against COVID-19. Tonix and K-State are working together to develop a vaccine candidate for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform, bovine parainfluenza virus and also to test the effect of co-expression of the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity. 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 April 5, 2022, the Company issued a press release announcing that it entered into a new preclinical research agreement with K-State to extend its original agreement with K-State to develop a live-virus vaccine against COVID-19. The Company and K-State are working together to develop a vaccine candidate, TNX-2300, for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform, bovine parainfluenza virus, and also to test the effect of co-expression of the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity. Modern live virus vaccines for COVID-19 in development use a vector system to present SARS-CoV-2 protein antigens. K-State is studying bovine parainfluenza virus as the vector. A traditional live virus vaccine approach would use a weakened version of SARS-CoV-2, but SARS-CoV-2 contains genes that weaken the immune response by thwarting innate immunity. In the first completed phase of the research project, K-State showed that vaccinating hamsters with bovine parainfluenza virus expressing SARS-CoV-2 spike protein elicited antibody responses to the SARS-CoV-2 spike protein. The Company's goal in utilizing bovine parainfluenza virus as a live virus vaccine vector is to develop a COVID-19 vaccine that is well tolerated, produces durable immunity, prevents forward transmission and can be rapidly and broadly deployed.

The research is being directed by Dr. Waithaka Mwangi, Kansas State University, Department of Diagnostic Medicine/Pathobiology. In addition, K-State has granted the Company an option for an exclusive license for the clinical and commercial use of K-State's intellectual property associated with coronavirus vaccines under this relationship.

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-2300, 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 5, 2022
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: April 5, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Extension of Sponsored Research Agreement with Kansas State University to Develop Live-Virus Vaccine Against COVID-19

TNX-2300, a Live Virus Vaccine Based on a Bovine Parainfluenza Virus Vector, in Development to Protect Against COVID-19
Co-Expression of the CD40-Ligand Will be Tested to Direct Immune Response

CHATHAM, N.J., April 5, 2022 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced a new preclinical research agreement with Kansas State University (K-State) to extend the research being performed under its original agreement. Tonix and K-State are working together to develop a vaccine candidate for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform, bovine parainfluenza virus, and also to test the effect of co-expression of the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity.

"Vaccines based on live replicating viruses trigger the immune system by direct stimulation of T cells, with the potential to elicit strong, long-lasting and durable immunity," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "There are currently well over 300 potential COVID-19 vaccines in various stages of develpment[1], but relatively very few utilize live replicating viral platforms. TNX-2300* is a live replicating virus vaccine designed to elicit T cell immunity."

Dr. Lederman continued, "Modern live virus vaccines in development for COVID-19 use a vector system to present SARS-CoV-2 protein antigens. K-State is studying bovine parainfluenza virus as the vector. A traditional live virus vaccine approach would use a weakened version of SARS-CoV-2, but SARS-CoV-2 contains genes that weaken the immune response by thwarting innate immunity. In the first completed phase of the research project, K-State showed that vaccinating hamsters with bovine parainfluenza virus expressing SARS-CoV-2 spike protein elicited antibody responses to the SARS-CoV-2 spike protein. Our goal in utilizing bovine parainfluenza virus as a live virus vaccine vector is to develop a COVID-19 vaccine that is well tolerated, produces durable immunity, prevents forward transmission and can be rapidly and broadly deployed."

Under the extended research agreement, K-State will continue to advance preclinical development of a live replicating virus vaccine to protect against COVID-19 based on bovine parainfluenza virus and also to test the effect of co-expression of the CD40-ligand.

Attenuated bovine parainfluenza virus has previously been shown to be an effective antigen delivery vector in humans[2-7]. Notably and most importantly, following extensive testing in non-human primates, the attenuated BPI3V was shown to be well tolerated, infectious, immunogenic, and stable in infants and children[3,6]. The vector is well suited for mucosal immunization using a nasal atomizer, but it can also be delivered parenterally. The technology also includes a molecular stimulant called CD40-ligand, which triggers strong immunity, including T cell responses. TNX-2300 is designed to potentially stimulate immunity against the SARS-CoV-2 spike protein. The research is being directed by Dr. Waithaka Mwangi, Kansas State University, Department of Diagnostic Medicine/Pathobiology, who is the inventor of the new technology. In addition, K-State has granted Tonix an option for an exclusive license for the clinical and commercial use of K-State's intellectual property associated with coronavirus vaccines under this relationship.

**TNX-2300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[1] *World Health Organization, https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines, COVID-19 - Landscape of novel coronavirus candidate vaccine development worldwide, March 2022.*
[2] *Liang, B., et al., J. Virol. 2016. 90:10022.*
[3] *Karron, R. A., et al., Vaccine. 2012. 30:3975.*
[4] *Haller, A. A., et al., J. Gen Virol. 2003. 84:2153.*
[5] *Schmidt, A. C., et al., J. Virol. 2001. 75:4594.*
[6] *Karron, R. A., et al., J. Infec. Diseases. 1995. 171:1107.*
[6] *Haller, A. A., et al., J. Virol. 2000. 74:11626.*

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 composed of immunology, rare disease, infectious disease, and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500[1] which is a humanized monoclonal antibody targeting CD40-ligand being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the second half of 2022. Tonix's rare disease portfolio includes TNX-2900[2] for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan-Drug Designation by the FDA. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox called TNX-801[3], next-generation vaccines to prevent COVID-19, an antiviral to treat COVID-19, and a potential treatment for Long COVID. Tonix's lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850[4], which are live virus vaccines based on Tonix's recombinant pox vaccine (RPV) platform. 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. TNX-102 SL[6], (cyclobenzaprine HCl sublingual tablets), is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition. Tonix expects to initiate a Phase 2 study in Long COVID in the first half of 2022. 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, is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study expected to start in the first half of 2022. Finally, TNX-1300[7] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the first half of 2022.

[1] *TNX-1500 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[2] *TNX-2900 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.*

[3] *TNX-801 is a live horsepox virus vaccine for percutaneous administration in development to protect against smallpox and monkeyox. TNX-801 is an investigational new biologic and has not been approved for any indication.*

[4] *TNX-1840 and TNX-1850 are live horsepox virus vaccines for percutaneous administration, in development to protect against COVID-19. TNX-1840 and TNX-1850 are designed to express the SARS-CoV-2 spike protein from the omicron and BA.2 variants, respectively. TNX-1840 and TNX-1850 are investigational new biologics at the pre-IND stage of development and have 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.*

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

[7] *TNX-1300 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 the development of TNX-2300; the 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, 2021, as filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2022, 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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