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 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, NJ 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 13, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the results of a pre-Investigational New Drug Application ("pre-IND") meeting with the U. S. Food and Drug Administration ("FDA") for TNX-1800 (recombinant horsepox virus, live vaccine) as a potential SARS-CoV-2 vaccine to protect against COVID-19. 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 13, 2021, the Company announced that it received the official written response from a pre-IND meeting with the FDA to develop TNX-1800 (as a potential SARS-CoV-2 vaccine to protect against COVID-19. The Company believes written response provides a path to agreements on the design of the Phase 1 study and the overall clinical development plan to qualify TNX-1800 as a vaccine to prevent COVID-19. Based on the response, the Company expects to begin a Phase 1 study of TNX-1800 for the prevention of COVID-19 in the first half of 2022. This pre-IND meeting demonstrates concurrence and clear guidance on the proposed manufacturing, nonclinical pharmacology and toxicology studies, and Phase 1 clinical design for TNX-1800.

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 13, 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: September 13, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Results of Pre-IND Meeting with FDA for TNX-1800 as a Potential Vaccine to Prevent COVID-19

TNX-1800 is a Live Virus Vaccine Designed to Elicit Durable T-cell Immunity

TNX-1800 is a Modified Version of Dr. Edward Jenner's Vaccine that Eradicated Smallpox, Engineered to Express SARS-CoV-2 Spike Protein

In Animal Testing, TNX-1800 Protected Upper and Lower Airways After Challenge with SARS-CoV-2, Suggesting an Ability to Block Forward Transmission

Phase 1 Trial of TNX-1800 for the Prevention of COVID-19 Expected to Start in the First Half of 2022

CHATHAM, NJ, September 13, 2021 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it received the official written response from a Type B pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) to develop TNX-1800 (recombinant horsepox virus, live vaccine) as a potential SARS-CoV-2 vaccine to protect against COVID-19.

Tonix believes the written response provides a path to agreements on the design of a Phase 1 study and the overall clinical development plan to qualify TNX-1800 as a vaccine to prevent COVID-19. Based on the response, the Company expects to begin a Phase 1 study in the first half of 2022.

TNX-1800 is a live virus vaccine based on the horsepox viral vector platform designed to express the SARS-CoV-2 spike protein and 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. The horsepox virus is closely related to the vaccine developed by Dr. Edward Jenner more than 200 years ago that led to the eradication of smallpox.

Seth Lederman, M.D., President and Chief Executive Officer of Tonix, stated, "The pre-IND meeting written response marks an important milestone in the development of TNX-1800. We have obtained FDA concurrence and clear guidance on the proposed manufacturing, nonclinical pharmacology and toxicology studies, and the Phase 1 clinical design." Dr. Lederman continued, "Operation Warp Speed (OWS) vaccines were available very rapidly and have made a huge contribution to the health of the U.S. population, but they have limitations, particularly in terms of the short duration of protection and the likely requirement for boosters. Concerns about durability of protection have led Pfizer and Moderna, the innovators of the two most widely used COVID-19 vaccines in U.S., to file or plan to file for approval of booster shots within eight months after the administration of each vaccine's second dose."

"It's taken longer to develop live virus vaccines relative to the OWS vaccines," Dr. Lederman added, "but live virus vaccines for other viruses have proven to induce durable T cell immunity, prevent serious illness after infection and block forward transmission. These properties have been demonstrated with vaccines against smallpox, chickenpox, mumps, measles, and rubella, among others. We designed TNX-1800 as a potential single dose vaccine using a virus that is closely related to Dr. Jenner's vaccine, which provided long term, even lifetime T cell immunity to smallpox, prevented forward transmission of the smallpox virus, and eradicated that disease."

Dr. Lederman continued, "Unlike smallpox, we do not expect COVID-19 to be eradicated because there are asymptomatic spreaders, a relatively long period when people are infectious before they become symptomatic and numerous animal reservoirs. Like Jenner's smallpox vaccine, we expect TNX-1800 can potentially be scaled up for manufacturing and will not require a costly and cumbersome cold chain for distribution and storage. We expect it will also be glass-sparing, with 100 doses filled per vial."

"Many believe that after the COVID pandemic passes COVID will become endemic, and it will likely remain a long-term concern", Dr. Lederman added. "Because of this, we believe the need for new vaccine technologies will be ongoing and may lead to vaccines that are tailored to each person's health, genetics or age using precision medicine. Ultimately, a childhood vaccination like the MMR for measles, mumps and rubella with long lasting protection may be what's needed to control COVID in the future. Together with an expected strong and durable immune response, ability to manufacture at scale, store and ship in standard refrigeration, a live virus vaccine like TNX-1800 could become a global product."

Anthony Macaluso, Ph.D., Executive Vice President of Strategic Development of Tonix, commented, "We previously reported the positive results of TNX-1800 in animals after a live SARS-CoV-2 challenge. Animals vaccinated with TNX-1800 had undetectable SARS-CoV-2 in their upper and lower airways six days after challenge with SARS-CoV-2. Animals vaccinated with TNX-1800 manifested both neutralizing antibodies and a 'take', which is a

skin reaction to horsepox vaccination that also serves as a validated biomarker of functional T cell immunity."

Dr. Macaluso continued, "The 'take' is considered important because it is otherwise difficult and costly to measure the T cell response to a vaccine. Vaccines that elicit a strong T cell response, like horsepox and closely related vaccinia virus vaccine, have been established to provide long-term, durable immunity and to block forward transmission. In the successful campaign to eradicate smallpox, which was also spread by the respiratory route like COVID-19, the 'take' was used as a biomarker for protective immunity. We believe the absence of detectable CoV-2 in the upper airways shows the potential for TNX-1800 to decrease shedding of virus and is consistent with decreased forward transmission."

Dr. Lederman added, "The reliable durability of vaccine protection from the OWS vaccines is under review[1], leading the makers of the two mRNA vaccines to take steps towards seeking approval of booster shots and setting up the possible need for boosters on a regular basis in the future. The U.S. government has pledged to make available booster shots for the mRNA vaccines available starting on September 20, pending FDA approval. The prospect of boosters poses a challenging and expensive public health policy implementation in the U.S. In contrast to the short duration of protection of the OWS COVID-19 vaccines, live virus vaccines typically provide decades or life-long protective immunity against those diseases. Live virus vaccines activate the immune system in ways that scientists do not completely understand and have not yet been able to recreate with other technologies."

About TNX-1800[l]

TNX-1800 is a live modified horsepox virus vaccine for percutaneous administration that is designed to express the Spike protein of the SARS-CoV-2 virus and to elicit a predominant T cell response. TNX-1800 is based on a horsepox vector, which is a live replicating, attenuated virus that elicits a strong immune response. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been explored as platforms for vaccine development because they possess; (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) readily manufacturable at scale, and (7) ability to provide direct antigen presentation. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, that can be manufactured using conventional cell culture systems, with the potential for mass scale production and packaging in multi-dose vials. Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor horsepox[3-7]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[7]. Molecular analysis shows that horsepox is closer than modern vaccinia vaccines in DNA sequence to the vaccine discovered and disseminated by Dr. Edward Jenner, which protected against smallpox, a respiratory-transmitted disease caused by the orthopox virus, variola.[4-7] Vaccine genome researchers have established the contemporaneous use of horsepox and horsepox-related viruses in the United States as smallpox vaccines in the 1860's, and found a remarkable degree of identity with the circa 1860 U.S. smallpox vaccine VK05 and the 1976 Mongolian horsepox isolate called MNR-76, upon which Tonix's TNX-801 is based.[3,8-10] Tonix's proprietary horsepox vector is believed to be more closely related to Jenner's vaccinia vaccine than modern vaccinia vaccines, which appear to have evolved by deletions and mutations to a phenotype of larger plaque size in tissue culture and greater virulence in mice. The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[11]. Tonix's TNX-1800 vaccine candidate is administered percutaneously using a two-pronged, or "bifurcated" needle. The major cutaneous reaction or "take" to vaccinia vaccine was described by Dr. Edward Jenner in 1796[12] and has been used since then as a biomarker for protective immunity to smallpox, including in the World Health Organization's (WHO) accelerated smallpox eradication program that successfully eradicated smallpox in the 1960's. The "take" is a measure of functional T cell immunity validated by the eradication of smallpox. Tonix reported that immunization with a single dose of TNX-1800 induced "takes" and neutralizing anti-SARS-CoV-2 antibodies in non-human primates. [13]

[1]TNX-1800 is in the pre-IND stage and has not been approved for any indication.

[2]Joint Statement from HHS Public Health and Medical Experts on COVID-19 Booster Shots Statement. URL: www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html

[3]Tulman ER, et al. (2006) J Virol. 80(18):9244-58.PMID:16940536

[4]Qin et al. J. Virol. 89:1809 (2015).

[5]Esparza E, et al Vaccine. (2017) 35(52):7222-7230.

[5]Schrick L et al N Engl J Med (2017); 377:1491-1492

[7]Noyce RS, et al. (2018) PLoS One. 13(1):e0188453

[8]Brinkmann A et al, Genome Biology (2020) 21:286 https://doi.org/10.1186/s13059-020-02202-0

[9]Duggan A et al. Genome Biology (2020) 21:175 https://doi.org/10.1186/s13059-020-02079-z

[10]Esparza J et al. Vaccine. (2020); 38(30):4773-4779.

[11]Trindale GS et al. Viruses (2016) (12). pii: E328. PMID:27973399

[12]Jenner E. "An Inquiry Into the Causes and Effects of the Variole Vaccinae, a Disease Discovered in Some of the Western Counties of England, Particularly Gloucestershire and Known by the Name of the cow-pox." London: Sampson Low, 1798.

[13]Tonix Press Release: "Tonix Pharmaceuticals Reports Positive COVID-19 Vaccine Efficacy Results in Non-Human Primates Vaccinated with TNX-1800

and Challenged with Live SARS-CoV-2. URL: ir.tonixpharma.com/press-releases/detail/1255/tonix-pharmaceuticals-reports-positive-covid-19-vaccine"

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 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], is in mid-Phase 3 development for the management of fibromyalgia. 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[2], 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[2], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox. TNX-3500[3] (sangivamycin) is a small molecule antiviral drug for COVID-19 in the pre-IND stage of development.

[1] TNX-102 SL is an investigational new drug and has not been approved for any indication.
[2] TNX-1800 and TNX-801 are investigational new biologics at the pre-IND stage of development and have not been approved for any indication.
[3] 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, 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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