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): February 8, 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: (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))

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.

Tonix Pharmaceuticals Holding Corp (the "Company") issued a press release announcing the development of a COVID-19 skin test to measure SARS-CoV-2 exposure and T cell immunity. 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 February 8, 2021, the Company announced the development of a COVID-19 skin test to measure SARS-CoV-2 (CoV-2) exposure and T cell immunity, and that it received a written response from the U.S. Food and Drug Administration ("FDA") to a Type B pre-investigational new drug ("IND") meeting package describing its technology and plans to develop a diagnostic skin test, TNX-2100 (SARS-CoV-2 epitope peptide mixtures for intradermal administration), to measure the delayed-type hypersensitivity ("DTH") reaction to CoV-2, the virus that causes COVID-19.

TNX-2100 is designed to measure T cell immunity to CoV-2. There currently is no standardized laboratory test available to measure T cell immune responses to CoV-2. T cell immunity to CoV-2 persists longer than antibody immunity, is sometimes present in the absence of a measurable antibody response and is believed to provide an important element of protection against serious COVID-19 illness after infection with CoV-2.

TNX-2100 has the potential to serve as: 1) a biomarker for cellular immunity and protective immunity, 2) a method to stratify participants in COVID-19 vaccine trials by immune status; 3) an endpoint in COVID-19 vaccine trials, and 4) a biomarker of durability of vaccine protection.

When fully developed, the TNX-2100 skin test is expected to provide information of potential diagnostic, safety and predictive significance in a timely and cost-effective manner, including the durability of immune responses in vaccinated, convalescent and exposed individuals, clusters, workplaces and populations.

TNX-2100 is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130), which are designed to represent different protein

components of the CoV-2 virus. TNX-2110 (CoV-2 multi-antigen peptides) represents multiple proteins from CoV-2. TNX-2120 (CoV-2 spike peptides) represents only the spike protein. TNX-2130 (CoV-2 non-spike peptides) represents non-spike proteins. Each of these three tests is expected to be administered as part of the same procedure, at separate locations on the forearm, and each is expected to elicit a DTH response after approximately 48 hours in individuals with pre-existing T cell immunity to peptides in that mixture. Individuals who have been infected by or exposed to CoV-2 would be expected to respond to all three mixtures. In contrast, a successfully vaccinated individual who has not been exposed or infected by CoV-2 would be expected to respond only to TNX-2120 (CoV-2 spike peptides), since the currently available vaccines only encode spike protein. In the planned clinical protocol for testing TNX-2100, positive skin test controls will be used to confirm that study participants have intact T cell immunity and are not immunodeficient.

The test is designed to be administered in the same way as skin tests for tuberculosis, or TB, sold as Tubersol® or Apisol®, or generically as the Mantoux tuberculin purified protein derivative (PPD) test. A thin gauge needle is used to apply the three separate peptide mixtures into the skin, or intradermally, on the inner surface of the forearm between the wrist and the elbow. The test may be administered in a variety of settings. In a typical positive test, the skin surrounding the injection site is expected to become red, raised and hardened, or "indurated", after approximately 48 hours. Induration above a threshold level would signify a positive result and the diameter of the induration would indicate the amount of T cell immunity to the test peptides. DTH skin test responses are believed to reflect functional *in vivo* immunity. Clinical trials are expected to correlate skin test results with clinical history to inform estimates about the sensitivity and specificity of the test as a marker of T cell immunity in individuals pre- and post-COVID-19 vaccination, who are recovered from COVID-19, and some with active CoV-2 infection.

Based on guidance provided by FDA in their written response, the Company believes it will have the information necessary to respond to queries, and file the IND application in the second quarter of 2021. The Company has manufactured peptides under current good manufacturing process. The Company expects that clinical trials of TNX-2100 can be initiated, upon FDA clearance of the IND application, in the second half of 2021.

Tubersol® is a trademark of Sanofi Pasteur.
Aplisol® is a trademark of JHP Pharmaceuticals, LLC.

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-2100, 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 statements 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 February 8, 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: February 8, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals to Develop COVID-19 Skin Test (TNX-2100) to Measure SARS-CoV-2 Exposure and T Cell Immunity

Pre-IND Meeting Written Response from FDA Provides Guidance on Product Development and Clinical Testing Protocol

Intradermal Test is Designed to Measure SARS-CoV-2 Specific Delayed Type Hypersensitivity (DTH), the Classic Method of Measuring T Cell Immunity to Tuberculosis and Other Pathogens

Multiple Potential Uses Include Functional Measure of T Cell Immunity to SARS-CoV-2; Aid to COVID-19 Diagnosis and Public Health Surveillance; Endpoint for COVID-19 Vaccine Trials

CHATHAM, N.J., February 8, 2021 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced it has received the written response from the U.S. Food and Drug Administration (FDA) to a Type B pre-investigational new drug (IND) meeting package describing its technology and plans to develop a diagnostic skin test, TNX-2100 (SARS-CoV-2 epitope peptide mixtures for intradermal administration), to measure the delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2 (CoV-2), the virus that causes COVID-19.

TNX-2100 is designed to measure T cell immunity to CoV-2. There currently is no standardized laboratory test available to measureT cell immune responses to CoV-2. T cell immunity to CoV-2 persists longer than antibody immunity, is sometimes present in the absence of a measurable antibody response and is believed to provide an important element of protection against serious COVID-19 illness after infection with CoV-2.

“We believe TNX-2100 has the potential to measure T cell immunity to CoV-2 and therefore serve as an aid to COVID-19 diagnosis to support patient care, public health surveillance and vaccine trials,” said Seth Lederman, M.D., Tonix’s President and Chief Executive Officer. “Our proposed skin test has the potential to serve as: 1) a biomarker for cellular immunity and protective immunity; 2) a method to stratify participants in COVID-19 vaccine trials by immune status; 3) an endpoint in COVID-19 vaccine trials, and 4) a biomarker of durability of vaccine protection.”

The only currently available methods to detect T cell immunity to CoV-2 require expensive, multi-step sample preparation and *in vitro* T cell stimulation in highly specialized laboratories using methods that have not been amenable to standardization. When fully developed, the TNX-2100 skin test is expected to provide clinicians, patients, employers and public health officials with information of potential diagnostic, safety and predictive significance in a timely and cost-effective manner, including the durability of immune responses in vaccinated, convalescent and exposed individuals, clusters, workplaces and populations.

TNX-2100 is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130), which are designed to represent different protein components of the CoV-2 virus. TNX-2110 (CoV-2 multi-antigen peptides) represents multiple proteins from CoV-2. TNX-2120 (CoV-2 spike peptides) represents only the spike protein. TNX-2130 (CoV-2 non-spike peptides) represents non-spike proteins. Each of these three tests is expected to be administered as part of the same procedure, at separate locations on the forearm, and each is expected to elicit a DTH response after approximately 48 hours in individuals with pre-existing T cell immunity to peptides in that mixture. Individuals who have been infected by or exposed to CoV-2 would be expected to respond to all three mixtures. In contrast, a successfully vaccinated individual who has not been exposed or infected by CoV-2 would be expected to respond only to TNX-2120 (CoV-2 spike peptides), since the currently available vaccines only encode spike protein. In the planned clinical protocol for testing TNX-2100, positive skin test controls will be used to confirm that study participants have intact T cell immunity and are not immunodeficient.

The test is designed to be administered in the same way as skin tests for tuberculosis, or TB, sold as Tubersol® or Aplisol® or generically as the Mantoux tuberculin purified protein derivative (PPD) test. A thin gauge needle is used to apply the three separate peptide mixtures into the skin, or intradermally, on the inner surface of the forearm between the wrist and the elbow. The test may be administered in a variety of settings: ranging from a doctor’s office to a remote outpost without running water or in inclement or extreme weather. In a typical positive test, the skin surrounding the injection site is expected to become red, raised and hardened, or “indurated”, after approximately 48 hours. Induration above a threshold level would signify a positive result and the diameter of the induration would indicate the amount of T cell immunity to the test peptides. DTH skin test responses are believed to reflect functional *in vivo* immunity. Clinical trials are expected to correlate skin test results with clinical history to inform estimates about the sensitivity and specificity of the test as a marker of T cell immunity in individuals pre- and post-COVID-19 vaccination, who are recovered from COVID-19, and some with active CoV-2 infection.

“Based on guidance provided by FDA in their written response, we believe we have the information necessary to respond to queries and file the IND application in the second quarter of 2021,” said Herbert Harris, M.D., Ph.D., Tonix’s Executive Vice President for Translational Medicine. “The Company has manufactured peptides under current good manufacturing process or cGMP. We expect clinical trials of TNX-2100 can be initiated, upon FDA clearance of the IND application, in the second half of 2021.”

In parallel to developing TNX-2100 as a potential diagnostic tool, Tonix is developing TNX-1800, a live replicating vaccine for COVID-19 designed to elicit primarily T cell immunity. Tonix announced positive immune response data in non-human primates in the fourth quarter of 2020 and expects to release data from non-human primate studies involving challenge with SARS-CoV-2 in the first quarter of 2021.

Tubersol® is a trademark of Sanofi Pasteur
Aplisol® is a trademark of Par Pharmaceutical, Inc.

About TNX-2100
TNX-2100 is a diagnostic product candidate in the pre-Investigational New Drug (IND) stage and has not been approved for any indication. Discovered in 1882 by Robert Koch, the DTH reaction has been used for more than a century as a clinical test for T cell-mediated immune reactions[1]. In the 1940s, Landsteiner and Chase demonstrated that the reaction was mediated by the cellular and not the antibody arm of the immune system[2]. When small quantities of antigen are injected intradermally, a hallmark response is elicited which includes induration, swelling and monocytic infiltration into the site of the lesion within 24 to 48 hours. This reaction has been shown to be dependent on the presence of memory T cells. Both the CD4+ and CD8+ T cells have been shown to participate in this response. DTH skin tests have been commonly used to detect T cell responses to tuberculosis, fungal pathogens, and mumps virus.

[1]Black CA. Delayed type hypersensitivity: current theories with an historic perspective.*Dermatol Online J.* 1999;5:7.
[2]Landsteiner K, Chase MW. Studies on the sensitization of animals with simple chemical compounds: vii. Skin sensitization by intraperitoneal injections. *J Exp Med*. 1940;71:237.

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 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, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY, in the second quarter of 2021** and topline data in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. 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 efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801***, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

*TNX-102 SL is an investigational new drug and has not been approved for any indication.
** Pending submission and agreement from FDA on statistical analysis plan.
***TNX-1800 and TNX-801 are investigational new biologics and have 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, 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 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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