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): June 18, 2020

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.)**

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))

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 8.01 Other Events.

On June 18, 2020, Tonix Pharmaceuticals Holding Corp. (the "Company") announced an expansion of its strategic collaboration with the Southern Research Institute. A copy of the press release which discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press release of Tonix Pharmaceuticals Holding Corp., dated June 18, 2020

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: June 18, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals and Southern Research Announce Expansion of COVID-19 Vaccine Collaboration

Plan to Produce Blueprint of How the Human Immune System Responds to Infection Caused by SAR-CoV-2, the Virus that Causes COVID-19

Results Expected to Support Tonix's Anticipated Regulatory Filings for TNX-1800, a Live Replicating Virus Vaccine Designed to Elicit T Cell Immunity in Addition to Antibodies

NEW YORK, June 18, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, announced today an expansion of its strategic collaboration with Southern Research to include a study of T cell immune responses to SARS-CoV-2 in volunteers who have recovered or remain asymptomatic after exposure to COVID-19. The research is part of an ongoing and broader collaboration between Tonix and Southern Research to develop and conduct animal testing of Tonix's TNX-1800, which is a live replicating virus vaccine designed to protect against COVID-19. The data will support the interpretation of animal trial results with TNX-1800, which are expected in the fourth quarter of 2020 and subsequent human trials.

"More than 200 years of vaccine experience, beginning with Dr. Edward Jenner's landmark discoveries with horsepox and cowpox vaccines, have shown that T cell eliciting vaccines are particularly effective against viruses," said Seth Lederman, M.D., President and CEO of Tonix. "We believe that protective vaccines against the SARS-CoV-2 virus will be similar in that regard. The data we plan to collect from recovered and asymptomatic COVID-19 volunteers will inform vaccine development on how to safely provide to vaccine recipients the same immune responses that others got from recovering from actual CoV-2 infection. If approved by the U.S. Food and Drug Administration (FDA) for use in healthy, non-pregnant adults without moderate or severe eczema, TNX-1800 would feature single-dose immunity without the use of adjuvants, ease of manufacturing on readily available systems, and glass-sparing distribution since we believe 100 doses of TNX-1800 could be packaged in a single vial. Our goal with TNX-1800 is to develop a vaccine that is well tolerated, produces strong, long-lasting immunity, and can be rapidly and broadly deployed."

Dr. Lederman, a former tenured professor at Columbia Medical School, who has made original contributions to immunology and virology, continued, "Tonix's TNX-1800 is based on a virus that we believe is closely related to Dr. Jenner's first vaccine. Vaccines that descended from Dr. Jenner's vaccine were used to eradicate smallpox globally, the only virus ever successfully eradicated. Smallpox was spread through the respiratory route, but it was eradicated with a vaccine administered in the arm. Tonix's lead COVID-19 vaccine candidate, TNX-1800, is designed to elicit a predominant T cell response, with some antibody response, while three other early candidates in the Company's vaccine portfolio are designed to elicit almost pure T cell responses." Dr. Lederman added, "The features of a protective immune response to SARS-CoV-2 remain unknown. But since SARS-CoV-2 is a virus, we believe that T cell responses, in particular T Helper Type 1, or TH1 responses, will play an important if not dominant role in protecting against serious illness from COVID-19. These studies will provide us with a blueprint for interpreting the results of planned animal and human studies with TNX-1800."

Raj Kalkeri, Ph.D., from Southern Research and technical lead for this study, said, “This is groundbreaking research with regards to COVID-19. As scientists, we know that the most successful vaccines mimic and potentiate how the immune system responds to an invader. This additional work we are doing with Tonix will add focus to that objective. We are looking forward to a timely completion of this study, utilizing readouts from a variety of assays that can provide information about TH1 or other types of immunity.”

An expert team of scientists from Southern Research, including Raj Kalkeri, Ph.D., Elizabeth Wonderlich, Ph.D., John Farmer, Ph.D. and Fusataka Koide, Director of Virology, is working on this collaboration.

About TNX-1800, TNX-1810, TNX-1820, TNX-1830 and TNX-801*

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 that causes COVID-19 and to elicit a predominant T cell response. TNX-1810, TNX-1820 and TNX-1830 are modified horsepox viruses that are designed to express different SARS-CoV-2 proteins than Spike and to elicit almost pure T cell responses. TNX-801 is a live horsepox virus vaccine [1]. Horsepox and vaccinia are closely related orthopoxviruses that are believed to share a common ancestor. 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. Relative to vaccinia, horsepox has substantially decreased virulence in mice[1]. TNX-801 vaccinated macaques showed no overt clinical signs after monkeypox challenge[2]. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, which can be manufactured on conventional cell culturing systems, with the potential for mass scale production.

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

[2]Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA. (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

*TNX-801 and TNX-1800 are in the pre-IND stage and have not been approved for any indication

About Southern Research

Founded in 1941, Southern Research (SR) is an independent, 501(c)(3) nonprofit, scientific research organization with more than 400 scientists and engineers working across four divisions: Drug Discovery, Drug Development, Engineering, and Energy & Environment. SR supports the pharmaceutical, biotechnology, defense, aerospace, environmental, and energy industries. SR works on behalf of the National Cancer Institute, National Institutes of Health, the U.S. Department of Defense, the U.S. Department of Energy, NASA, major aerospace firms, utility companies, and other private and government organizations. SR pursues entrepreneurial and collaborative initiatives to develop and maintain a pipeline of intellectual property and innovative technologies that positively impact real-world problems. SR is developing 18 drugs to combat various forms of cancer, ALS, Alzheimer’s, diabetes, kidney disease, Parkinson’s and tuberculosis, among others. SR has developed 20 other drugs, including seven FDA-approved cancer drugs —a number rivaling any other U.S. research institute. SR is headquartered in Birmingham, Alabama with additional laboratories and offices in Wilsonville, Alabama; Frederick, Maryland; Cartersville, Georgia; and Houston, Texas.

Further information about SR can be found athttps://southernresearch.org.

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 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'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 first quarter of 2021. 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 cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR (tianeptine 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 and TNX-1300 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

This press release and further information about Tonix can be found atwww.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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