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 28, 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 July 28, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") announced a collaboration with the Kenya Medical Research Institute ("KEMRI") to plan, seek regulatory approval for and conduct a Phase 1 clinical study in Kenya to develop the Company's TNX-801 product candidate as a vaccine to protect against monkeypox and smallpox. 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 July 28, 2022, the Company announced a collaboration with KEMRI to plan, seek regulatory approval for and conduct a Phase 1 clinical study in Kenya to develop TNX-801 as a vaccine to protect against monkeypox and smallpox. The study is expected to start in the first half of 2023.

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 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 July 28, 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: July 28, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Collaboration with Kenya Medical Research Institute to Develop TNX-801 in Kenya as a Vaccine for the Prevention of Monkeypox and Smallpox Infection

Phase 1 Clinical Study Expected to be Initiated in Kenya in the First Half of 2023

World Health Organization Has Declared Monkeypox a Global Health Emergency

CHATHAM, N.J., July 28, 2022 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced a collaboration with the Kenya Medical Research Institute (KEMRI) to plan, seek regulatory approval for and conduct a Phase 1 clinical study in Kenya to develop TNX-801[1] as a vaccine to protect against monkeypox and smallpox. The study is expected to start in the first half of 2023.

"We are excited to collaborate with KEMRI on the clinical development of TNX-801 as a vaccine to protect against monkeypox and smallpox in Kenya," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. Since ending routine vaccination for smallpox in the 1960's, monkeypox has emerged as a growing problem among people in West and Central Africa. People who received the live virus vaccine for smallpox prior to eradication appear to maintain durable protective immunity against monkeypox. TNX-801 is a live virus vaccine that we believe is closer to the smallpox vaccines used in the U.S. and Europe before 1900 than the modern vaccinia smallpox vaccines. TNX-801 has reduced virulence in animals, and we believe it has the potential for widespread use to protect against monkeypox."

"KEMRI is excited to plan this clinical trial with Tonix, and ultimately to lead the trial," said Professor Samuel Kariuki, Director General and CEO of KEMRI. "Monkeypox has spread in Central and West Africa, and there's a concern that we could begin seeing cases in the Eastern and Central Africa or from foreign travelers. Recently, monkeypox has been reported in over 30 countries outside of Africa that were not endemic for monkeypox virus. We are grateful that Tonix is committed to sponsoring clinical studies and making TNX-801 available for this important problem."

Professor Matilu Mwau, PhD, of KEMRI said, "The recent global outbreak of monkeypox has exemplified the need to be prepared with a vaccine that is efficacious, that provides for durable immunity and that blocks forward transmission. Tonix's live virus vaccine technology is designed to achieve these outcomes. The West African strain which has recently spread outside of Africa has a low fatality rate, but the Central African strain is reportedly fatal in approximately 10% of infected individuals. We want Kenya to be prepared with a vaccine that provides protection and can be widely deployed without the need for sterile injections or ultra-cold shipping and storage."

About TNX-801

TNX-801 is a live virus vaccine based on synthesized horsepox[2,3]. Tonix is developing TNX-801 for percutaneous administration as a vaccine to protect against monkeypox and smallpox. TNX-801 was developed as part of research collaboration between Tonix and Professor David Evans, Ph.D. and Ryan Noyce, Ph.D., the Department of Cell Biology, University of Alberta. Tonix has previously reported positive data from a monkeypox challenge study in non-human primates[4]. Tonix's TNX-801 was synthesized[2] based on the sequence of the 1976 natural isolate Mongolian horsepox clone MNR-763. Molecular analysis of

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DNA sequences suggests that TNX-801 is closer than modern smallpox vaccines to the vaccine discovered and disseminated by Dr. Edward Jenner in 1798[6-8]. For example, recent studies[9,10] have shown approximately 99.7% colinear identity between TNX-801 and the circa 1860 U.S. smallpox vaccine VK05[11]. The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[12] Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Dr. Edward Jenner invented vaccination in 1798 and the procedure was called "vaccination" because 'cow' is 'vacca' in Latin and the inoculum material was initially obtained from lesions on the udders of cows affected by a mild disease known as cowpox. However, Dr. Jenner suspected that cowpox originated from horses[8]. Subsequently, Dr. Jenner and others immunized against smallpox using material directly obtained from horses. The use of vaccines from horses was sometimes called 'equination' from the Latin 'equus' which means 'horse'[13]. Equination and vaccination were practiced side-by-side in Europe[13,14].

About Monkeypox

Monkeypox[15] is a contagious disease caused by infection with monkeypox virus, a virus closely related to variola virus, which causes smallpox. Monkeypox virus belongs to the Orthopoxvirus genus in the family Poxviridae. The Orthopoxvirus genus also includes variola virus (which causes smallpox), vaccinia virus (used in the smallpox vaccine), and cowpox virus. After routine smallpox vaccination was stopped in about 1970, monkeypox has become a growing problem in Africa. Recently more than 16,000 cases have been identified outside of Africa[17].

About the Kenya Medical Research Institute (KEMRI)

The Kenya Medical Research Institute is a State Corporation established in 1979 as a Research Institute under the Science and Technology (Repealed) Act, Cap 250 Laws of Kenya and operates as such under Legal Notice No. 35 of March 2021. KEMRI's vision is to be the leading centre of excellence in research for human health. The mission is to improve human health and quality of life through research, capacity building, innovation and service delivery. KEMRI has grown from its humble beginning over 40 years ago to become a regional leader in human health research. KEMRI is the Medical Research arm of the Government of Kenya. It provides advice to the Ministry on various aspects of healthcare and delivery. National diseases surveillance and rapid response capacity for major disease outbreaks (including, Cholera, Chikungunya Virus, H1N1 Flu, Yellow Fever, Rift Valley Fever, Ebola, and Aflatoxicosis. In line with constitutional requirements, KEMRI has developed a comprehensive framework under which the Institute has devolved its research activities and services, through seven regional clusters that serves the forty seven counties under the strategic pillar of health research in the context of devolution.

About Tonix Pharmaceuticals Holding Corp.[1]

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product

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candidates. Tonix'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 (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the third quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is mid-Phase 2 and has been granted Breakthrough Therapy Designation by the FDA. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the second half of 2022. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan-Drug Designation by the FDA. TNX-601 ER (tianeptine hemioxalate extended-release tablet) is being developed as an antidepressant in the U.S., with a Phase 2 study expected to be initiated in first quarter of 2023 pending IND clearance. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, 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 first half of 2023. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. Tonix's lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform.

[1]*All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

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

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

[4]*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)*

[5]*Tonix Press Release March 16, 202a https://ir.tonixpharma.com/news-events/press-releases/detail/1255/tonix-pharmaceuticals-reports-positive-covid-19-vaccine.*

[6]*Schrick L et al. N Engl J Med. (2017) 377:1491.*

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

[8]*Jenner E. "An Inquiry Into the Causes and Effects of the Variolae 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.*

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

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

[11]*Tonix press release. Dec 4, 2020 https://ir.tonixpharma.com/news-events/press-releases/detail/1236/vaccine-genome-researchers-report-99-7-colinear-identity.*

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

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

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

[15] *www.cdc.gov/poxvirus/monkeypox/about.html*

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[16] *Mandavilli, A. The New York Times. May 26, 2020. "Who is protected against monkeypox".*

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 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 799-8599

Olipriya Das, Ph.D. (media)
Russo Partners
Olipriya.Das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)
ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505
