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): August 26, 2024

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 August 26, 2024, Tonix Pharmaceuticals Holding Corp (the "Company") announced a collaboration with Bilthoven Biologicals ("BBio") to advance the Company's TNX-801 vaccine candidate by developing manufacturing processes in preparation for potential GMP manufacturing of TNX-801. 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 August 26, 2024, the Company announced a collaboration with BBio to advance TNX-801 by developing manufacturing processes in preparation for potential GMP manufacturing of TNX-801.

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, August 26, 2024
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: August 26, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals and Bilthoven Biologicals to Collaborate on Advancing Development of Tonix's Mpox Vaccine, TNX-801

World Health Organization declared spread of mpox in multiple African countries a public health emergency of international concern (PHEIC) for the second time in two years

Worldwide availability and affordability of single-dose mpox vaccine with durable protection will be required to address global health emergency

The newest Clade 1 strain represents a new global threat with mortality up to 10%

Bilthoven Biologicals to develop manufacturing processes in preparation for potential GMP manufacturing

CHATHAM, N.J., August 26, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, and Bilthoven Biologicals (BBio), part of the world's largest vaccine manufacturer the Cyrus Poonawalla Group, which includes the Serum Institute of India, today announced a collaboration to advance TNX-801, Tonix's mpox vaccine candidate. TNX-801 (recombinant horsepox virus) is a live replicating, attenuated virus vaccine based on horsepox in preclinical development to prevent mpox and smallpox.

TNX-801 is based on technology that has the potential to be used as a viral vector platform from which recombinant versions can be developed to protect against other infectious diseases. BBio is a global vaccine company, producing prophylactic vaccines as well as vaccines for therapeutic use. BBio has been selected by the European Union for its pandemic preparedness program of 'ever warm' vaccine manufacturing companies.

TNX-801 has demonstrated in animal models to provide immune protection with better tolerability than vaccines based on 20th century vaccinia viruses. Preclinical studies have shown positive efficacy data, demonstrating that TNX-801 protected non-human primates against lethal challenge with intratracheal Clade 1 monkeypox virus. After a single dose vaccination, TNX-801 prevented clinical disease and lesions and decreased shedding in the mouth and lungs of non-human primates. These findings are consistent with mucosal immunity and suggest the ability to block forward transmission.

On August 14, 2024, the World Health Organization (WHO) determined that the upsurge of mpox in a growing number of countries in Africa constitutes a public health emergency of international concern, the second such declaration in the past two years called in response to an mpox outbreak. The current outbreak was caused by Clade 1 monkeypox virus, while the 2022 outbreak was caused by Clade 2 monkeypox virus. The global mpox outbreak from Clade 2, which commenced in 2022, has affected over 90,000 persons in countries where mpox had previously not been endemic, including Europe and the U.S. The spread of Clade 2b mpox in 2022 underscores the pandemic potential of the disease. In several Central African countries, including the Democratic Republic of the Congo, mpox is currently endemic, with the Clade 1 showing a mortality rate of up to 10%.

"The recent mpox outbreak exemplifies precisely why we built the pandemic preparedness facility at BBio," saidJurgen Kwik, Chief Executive Officer of Bilthoven Biologicals. "The establishment of the 'ever-warm' facility for pandemic preparedness underscores the critical importance of readiness in the face of global health emergencies, such as mpox. This collaboration encapsulates the essential role of the facility in bolstering pandemic preparedness and response capabilities."

"We look forward to collaborating with BBio and to accelerating the development of our vaccine candidate to prevent mpox," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-801 is administered with a single dose, which we believe will improve acceptance and eliminate partial vaccination compared to the current two-dose regimens. We believe TNX-801 can be rapidly scaled up for manufacturing and can be distributed and stored without a costly and cumbersome ultra-cold supply chain. TNX-801 has the potential to make a global impact on mpox and the risk of smallpox because of its durable T-cell immune response, the potential to manufacture at scale, and the use of a lower dose than non-replicating vaccines."

Dr. Lederman added, "The worldwide availability of an affordable, safe and effective single dose mpox vaccine is essential given the pandemic potential of the disease. Successful development of TNX-801 will establish the foundation for potentially expanding the viral vector platform, for which recombinant versions can be developed to protect against other infectious diseases and future outbreaks. Our TNX-1800 vaccine (recombinant horsepox virus expressing SARS-CoV-2 spike) in development to protect against COVID-19 was selected by the U.S. National Institutes of Health for Project NextGen."

About TNX-801

TNX-801 (recombinant horsepox virus) is a live virus vaccine based on horsepox in pre-clinical development to prevent mpox and smallpox. Tonix reported positive preclinical efficacy data, demonstrating that TNX-801 vaccination protected non-human primates against lethal challenge with monkeypox.[1] Tonix has received official written response from a Type B pre-Investigational New Drug Application (IND) meeting with the U.S. Food and Drug Administration (FDA) to develop TNX-801 as a potential vaccine to protect against mpox disease and smallpox.[2] Tonix believes the FDA feedback provides a path to agreement on the design of a Phase 1 /2 study and the overall clinical development plan. More than 90,000 people contracted mpox globally. during the 2022-23 epidemic.[3] The June 2023 cluster of mpox in Chicago revealed breakthrough cases of the disease in individuals who had been vaccinated with the currently authorized non-replicating vaccine, which is administered in two doses.[4] In contrast, TNX-801 is delivered percutaneously with only one dose and therefore may achieve higher rates of community protection by eliminating drop-out between doses and limiting forward transmission. Moreover, relying on only one approved mpox vaccine at present is a risk for the global supply chain that has already led to insufficient availability of vaccines to meet global health needs, especially in Africa. TNX-801 has the potential to make a global impact on mpox and the risk of smallpox because of its durable T-cell immune response, the potential to manufacture at scale, and the use of a lower dose than non-replicating vaccines.

[1]Noyce RS, et al. *Viruses*. 2023;15(2):356. https://doi.org/10.3390/v15020356

[2]TNX-801 PR pre-IND meeting 8/20/23: https://ir.tonixpharma.com/news-events/press-releases/detail/1417/tonix-pharmaceuticals-announces-results-of-pre-ind-meeting

[3]CDC. (2022-2023). Mpox Outbreak Global Map https://www.cdc.gov/poxvirus/mpox/response/2022/world-map.html

[4]Faherty EA, et al. *MMWR Morb Mortal Wkly Rep.* 2023;72:696–698. http://dx.doi.org/10.15585/mmwr.mm7225a6.

About Bilthoven Biologicals (BBio)

BBio is a Netherlands-based end-to-end vaccine manufacturer of viral and bacterial vaccines. The company has a long-standing track record in supplying vaccines to European markets and global health partners such as UNICEF, PAHO and WHO/GAVI. With the manufacturing of polio vaccines, BBio is key contributor to the worldwide program to eradicate polio. BBio is also acting as contract manufacturer of vaccines used as cancer treatment, which is registered and supplied to the European market for the treatment of bladder cancer.

BBio is a carve-out of the former Netherlands Vaccine Institute and was acquired by Serum Institute of India in 2012 and employs a little over 500 people. BBio is covering the

full vaccine manufacturing value chain with its facilities in Bilthoven on Utrecht Science Park Bilthoven.

For more information, please visit www.bbio.nl

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years to develop TNX-4200 small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. The company's Good Manufacturing Practice (GMP)-capable advanced manufacturing facility in Dartmouth, MA was purpose-built to manufacture TNX-801 and the GMP suites are ready to be reactivated in case of a national or international emergency. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development, designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease and infectious disease, including a vaccine for mpox, TNX-801. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

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; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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.

Tonix Pharmaceuticals Investor Contact

Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

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

Tonix Pharmaceuticals Media Contact

Ray Jordan
Putnam Insights
ray@putnaminsights.com
(949) 245-5432
