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): October 8, 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 October 8, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it entered into an artificial intelligence and machine learning research collaboration with X-Chem, Inc. to potentially accelerate development of the Company's oral broad-spectrum antivirals. 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 October 8, 2024, the Company announced that it entered into an artificial intelligence and machine learning research collaboration with X-Chem, Inc. to potentially accelerate development of the Company's oral broad-spectrum antivirals.

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, October 8, 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: October 8, 2024

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

EXHIBIT 99.01

Tonix Pharmaceuticals Announces AI Collaboration with X-Chem to Develop Broad-Spectrum Antivirals

AI (Artificial Intelligence) and ML (Machine Learning) drug discovery collaboration will accelerate the development of small molecules as orally available host-targeted broad-spectrum medical countermeasures

Host-directed antiviral drugs have the potential to enhance the immune response to viruses from a range of viral families

Tonix was awarded a contract with the U.S. Department of Defense for up to $34 million for the accelerated development of its host-directed broad-spectrum antiviral program TNX-4200

CHATHAM, N.J., October 8, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced that it has entered into an AI and ML research collaboration with X-Chem, Inc. (X-Chem), a leader in small molecule drug discovery, to accelerate development of Tonix's oral broad-spectrum antivirals.

Tonix's TNX-4200 antiviral program focuses on the development of oral CD45 phosphatase inhibitors, with broad-spectrum activity against a range of viral families. As previously disclosed, Tonix entered into a contract with the U.S. Department of Defense's Defense Threat Reduction Agency (DTRA) for up to $34 million to advance the development of Tonix's TNX-4200 broad-spectrum oral antiviral program for medical countermeasures, including an Investigational New Drug (IND) submission and a first-in-human Phase 1 clinical study.

"We are excited to enter into this research collaboration with X-Chem, which we believe will expand our capabilities, and deepen our understanding of host-targeted small molecule therapeutics for a variety of targets," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "With the support of X-Chem's drug discovery AI/ML technology, we expect to optimize the physicochemical properties, pharmacokinetics, and safety attributes of our drug candidates."

"We are excited to partner with Tonix in their pursuit of such important programs in human health, at the intersection of laboratory and *in silico* technology. This collaboration highlights how integrative work continues to leverage the creation of target-specific high-quality data to drive AI drug discovery," said Erin Davis, Ph.D., Chief Technology Officer of X-Chem."

The DTRA contract awarded to Tonix is expected to help fund and accelerate the development of the Company's lead oral host-directed TNX-4200 broad-spectrum antiviral program. The TNX-4200 program aims to reduce viral load and to allow the adaptive immune system to alert the other arms of the immune system to mount a protective response. Tonix plans to leverage previous research on phosphatase inhibitors to optimize lead compounds for therapeutic intervention of biothreat agents.

For the oral broad-spectrum antiviral programs, including TNX-4200, Tonix is utilizing its state-of-the-art research laboratory capabilities, including a Biosafety Level 3 (BSL-3) lab and an Animal Biosafety Level 3 (ABSL-3) facility at its research and development center (RDC) located in Frederick, Md., as well as experienced personnel in-house. The RDC is located in Maryland's 'I-270 biotech corridor' and is close to the center of the U.S. biodefense research community.

About X-Chem, Inc.

X-Chem, Inc. is a leader in small molecule drug discovery services for pharmaceutical and biotech companies. As pioneers of DNA-encoded chemical library (DEL) technology and its integration with proprietary AI technology and computational sciences, X-Chem can accelerate all steps in the discovery process. The company leverages its unique AI/ML approach, market-leading DEL platform, and computationally-driven medicinal chemistry expertise to discover novel small molecule leads against challenging, high-value therapeutic targets. Integrated with X-Chem's extensive chemistry and computational technologies, project teams can deliver clinical candidates with unmatched speed. X-Chem also provides libraries, reagents, and informatic tools to allow DEL operators to get the most of their DEL platform. X-Chem empowers its partners to effectively build drug pipelines from target to clinical candidate, enhanced with AI and extensive data packages.

Further information about X-Chem can be found at www.x-chemrx.com.

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's priority is to submit a New Drug Application (NDA) to the FDA in October 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. TNX-102 SL was generally well tolerated in the Phase 3 program. 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 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 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. 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; their efficacy and safety have not been established 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 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.

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