

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 17, 2024

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(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 17, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it received the first payment from the Defense Threat Reduction Agency ("DTRA"), an agency within the U.S. Department of Defense, to develop small molecule broad-spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. 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 17, 2024, the Company announced that it received the first payment from DTRA to develop small molecule broad-spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments.

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.
	<u>99.01</u>	<u>Press Release of the Company, October 17, 2024</u>
	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 17, 2024

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

Tonix Pharmaceuticals Receives First Contract Payment from U.S. Department of Defense for Accelerated Development of Broad-Spectrum Antivirals with the Defense Threat Reduction Agency (DTRA)

First payment received under Tonix's contract with the Defense Threat Reduction Agency (DTRA), for up to \$34 million over five years

CHATHAM, N.J., October 17, 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, received its first payment from the Defense Threat Reduction Agency (DTRA), an agency within the U.S. Department of Defense (DoD), to develop small molecule broad-spectrum antiviral agents for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. The previously announced award from DTRA is for up to \$34 million over five years.

“This award provides important validation and substantial non-dilutive funding for our ongoing research to advance our antiviral discovery program,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals “With biological adaptations and mutations happening to viruses rapidly across the globe, this research will be crucial in order to protect lives in the event biological threats are introduced onto the battlefield.”

The \$34.0 million five-year contract will help fund and accelerate the development of the Company's broad-spectrum antiviral program, which has the potential to reduce viral load and 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, specifically compounds that target CD45, to optimize lead compounds for therapeutic intervention of biothreat agents and provide the government with a complete and cost-effective solution for a broad-spectrum medical countermeasure. Tonix's premise is that partial inhibition of CD45 will provide optimal antiviral protection while requiring lower plasma drug concentrations, a lower dose, and a better safety profile.

Tonix will utilize its state-of-the-art research laboratory capabilities, including a Biosafety Level 3 (BSL-3) lab at its research and development center (RDC) facility 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 Defense Threat Reduction Agency (DTRA)

The Defense Threat Reduction Agency (DTRA), an agency within the United States Department of Defense (DoD) is both a Defense Agency and Combat Support Agency with two distinct yet highly integrated roles countering Weapons of Mass Destruction (WMD) and emerging threats. Its origins stretch back to World War II and the Manhattan Project, but today the agency encompasses a wide variety of strategic and operational functions that deter, prevent, and ultimately prevail against these unique threats. DTRA enables the Department of Defense (DoD), the United States Government and international partners to counter and deter weapons of mass destruction (WMD) and emerging threats. DTRA provides cross-cutting solutions to enable the Department of Defense, the United States Government, and international partners to deter strategic attack against the United States and its allies; prevent, reduce, and counter WMD and emerging threats; and prevail against WMD-armed adversaries in crisis and conflict. DTRA's continued effort to enhance the combat support mission also advances public health services by developing innovative technologies that protect against biological threats. For more information, visit www.dtra.mil.

Tonix Pharmaceuticals Holding Corp.**

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders, and its priority is to progress TNX-102 SL, a product candidate for which an NDA was submitted based on two statistically significant Phase 3 studies 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 and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation and its development is supported by a grant from the U.S. National Institute of Drug Abuse and Addiction (NIDA). Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified 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, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) 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. 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. 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.

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