

**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): May 31, 2023**

**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 May 31, 2023, the Company announced an upcoming oral presentation by Ryo Otsuka, Ph.D., and poster presentation by Kohei Kinoshita, M.D., at the 2023 American Transplant Congress being held June 3, 2023 to June 7, 2023 ("ATC"). 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 May 31, 2023, the Company announced an upcoming oral presentation by Dr. Otsuka, and poster presentation by Dr. Kinoshita, at the ATC. Both presenters are faculty members at the Center for Transplantation Sciences, Massachusetts General Hospital, and collaborators of the Company. The research involves studies of the Company's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) product candidate for the prevention of renal and cardiac allograft rejection. A copy of the presentation and poster will be made available on the Company's website.

**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	Description.
	No.	
	<a href="#"><u>99.01</u></a>	Press Release of the Company, May 31, 2023
	104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: May 31, 2023

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

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## **Tonix Pharmaceuticals Announces Presentations Involving TNX-1500 (anti-CD40L mAb) at the 2023 American Transplant Congress**

*Research Directed by Faculty of the Center for Transplantation Sciences, Massachusetts General Hospital*

CHATHAM, N.J., May 31, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an upcoming oral presentation by Ryo Otsuka, Ph.D., and poster presentation by Kohei Kinoshita, M.D at the 2023 American Transplant Congress (ATC). Both presenters are faculty members at the Center for Transplantation Sciences, Massachusetts General Hospital, and collaborators of Tonix. The Congress is being held June 3-7, 2023, in San Diego, Calif. The research involves studies of Tonix's TNX-1500 (Fc-modified anti-CD40L monoclonal antibody) for the prevention of renal and cardiac allograft rejection. A copy of the presentation and poster will be made available on the [Scientific Presentations](#) page of the Tonix website at [www.tonixpharma.com](http://www.tonixpharma.com) following the congress.

### **Oral Presentation Details**

Title: Fc-Modified Anti-Cd154 Mab Induced Long Term Renal Allograft Survival without Thromboembolic Complications  
Authors: R. Otsuka, G. Lassiter, T. Hirose, A. Karadagi, T. Tomosugi, I. Rosales, T. Kawai  
Date: Tuesday, June 6, 2023  
Time: 6:00 p.m. PT  
Location: Ballroom 6E Upper Level, San Diego Convention Center, San Diego, Calif.  
Number: Presentation 544

### **Poster Presentation Details**

Title: aCD154mAb (TNX-1500) Alone, or in Combination with Rapamycin, MMF, or aCD28mAb (VEL-101) Prolongs Cynomolgus Cardiac Allograft Survival  
Authors: K. Kinoshita, A. Maenaka, Z. Habibabady, G. McGrath, R. Chaban, I. Iieka, M. Ma, V. Diaz, I. Rosales, S. Fogarty, P. Maguire, B. Daugherty, S. Lederman, R. Pierson III  
Date: Saturday, June 3, 2023  
Time: 5:30 – 7:30 p.m. PT  
Location: Exhibit Halls A & B1, San Diego Convention Center, San Diego, Calif.  
Number: Poster Board A030

### **Tonix Pharmaceuticals Holding Corp.\***

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 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 topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth quarter of 2023. TNX-4300 (estianeptine) is a small molecule oral therapeutic in preclinical development to treat MDD, Alzheimer's disease and Parkinson's disease. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the third quarter of 2023. 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. 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 (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the second half of 2023. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

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

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://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, 2022, as filed with the Securities and Exchange Commission (the “SEC”) on March 13, 2023, 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**

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