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): December 12, 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 December 12, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it obtained an exclusive license from Curia Global, Inc. ("Curia") for the development of three humanized murine monoclonal antibodies ("mAbs") for the treatment or prophylaxis of SARS-CoV-2 infection. 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 December 12, 2022, the Company announced that it obtained an exclusive license from Curia for the development of three humanized murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection. The Company believes that the licensing of these mAbs strengthens its pipeline of next-generation therapeutics to treat COVID-19, which is caused by SARS-CoV-2. The Company believes that murine mAbs have the potential for neutralizing a broader spectrum of SARS-CoV-2 variants and may be harder for SARS-CoV-2 to evade.

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 December 12, 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: December 12, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Exclusive License of Potential Therapeutic or Preventative Humanized anti-SARS-CoV-2 Monoclonal Antibodies from Curia Global, Inc.

Immunocompromised Individuals, Including Organ Transplant Recipients, are at Increased Risk of Severe COVID-19 and Poor Clinical Outcomes

SARS-CoV-2 has Mutated to Evade the Existing EUA-Approved Therapeutic Monoclonal Antibody Therapies

CHATHAM, N.J., December 12, 2022 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced that it has obtained an exclusive license from Curia Global, Inc., a leading contract research, development and manufacturing organization, for the development of three humanized murine monoclonal antibodies (mAbs) for the treatment or prophylaxis of SARS-CoV-2 infection. SARS-CoV-2 is the cause of COVID-19.

"We believe that the licensing of these mAbs strengthens our pipeline of next-generation therapeutics to treat COVID-19," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Immunocompromised individuals, including organ transplant recipients, are at increased risk of severe COVID-19 and poor clinical outcomes[1]. Although five monoclonal antibody products, containing seven distinct monoclonal antibodies, have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for either treatment or prophylaxis of COVID-19, only a single product, Evusheld®, is still recommended for use as a prophylaxis by the National Institutes of Health COVID-19 Treatment Guidelines Panel or FDA[2,3]. Moreover, concerns have been raised about the ongoing ability of Evusheld® to prophylax in the face of new variants[4]. We believe there is a need for second generation mAb treatments and prophylactics for COVID-19[5]. To date, the EUA-approved products have been derived from the blood of COVID-convalescent patients or a humanized mouse[6,7]. The Company believes that humanized murine monoclonal antibodies discovered by Curia and licensed by Tonix represent a potential new approach to treating SARS-CoV-2 infection. The Company believes that murine monoclonal antibodies have the potential for neutralizing a broader spectrum of SARS-CoV-2 variants and may be harder for SARS-CoV-2 to evade as we face a 'variant soup' from both convergent and divergent evolution."[8]

Brian Zabel, Ph.D., Senior Director at Curia said, "We are excited to work with Tonix because of their commitment to developing therapeutics to COVID-19. Murine monoclonal antibodies represent a different approach and one that has the potential to generate high affinity antibodies that recognize different epitopes on the SARS-CoV-2 spike protein. Mice have a different repertoire of antibodies and the Curia technology for generating antibodies optimizes the selection of appropriate B cells by the timing of immunization, harvesting approach and screening platform."

Seth Lederman added, "The potential therapeutic antibodies licensed leverage our expanding internal development and manufacturing capabilities for biologics. These murine monoclonal antibodies and their humanized counterparts build on a base of knowledge from the fully human monoclonal antibody platform, TNX-3600, which we are developing with Columbia University."

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[1] Haidar G, Mellors JW. Improving the Outcomes of Immunocompromised Patients With Coronavirus Disease 2019.*Clin Infect Dis.* 2021;73(6):e1397-e1401. Doi:10.1093/cid/ciab397

[2] https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/ - accessed Nov 3, 2022

[3] FDA Updates on Bebtelovimab www.fda.gov/drugs/drug-safety-and-availability/fda-updates-bebtelovimab- Accessed Nov 4, 2022

[4] Wu, K.J. October 29, 2022. *The Atlantic.* "The End of Evusheld: If you're immunocompromised, this … isn't great." www.theatlantic.com/health/archive/2022/10/covid-variants-antibody-treatments-immunocompromised/671929/

[5] Madison Muller, M. November 16, 2022. *Bloomberg*. "Doctors Are Running Out of Antibody Drugs to Treat Covid as Virus Mutates."www.bloomberg.com/news/articles/2022-11-16/covid-s-mutations-leave-doctors-with-far-fewer-antibody-drugs-to-treat-virus?

[6] Hansen J et al. *Science*. 2020 Aug 21;369(6506):1010-1014. Doi: 10.1126/science.abd0827

[7] Asdaq, S.M.B. et al. A Patent Review on the Therapeutic Application of Monoclonal Antibodies in COVID-19*Int. J. Mol. Sci.* 2021, 22, 11953. https://doi.org/10.3390/ijms222111953

[8] Callaway, E. Oct 28 2022. *Nature (News)*. COVID 'variant soup' is making winter surges hard to predict: Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6

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 a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the second quarter of 2023. 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 first quarter of 2023. 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 first quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first 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 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, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. 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.

* *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.

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.

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