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): February 13, 2023

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 February 13, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it exercised an option to obtain an exclusive license from The Trustees of Columbia University in the City of New York ("Columbia") for the development of a portfolio of both fully human and 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 February 13, 2023, the Company announced that it exercised an option to obtain an exclusive license from Columbia for the development of a portfolio of both fully human and murine mAbs for the treatment or prophylaxis of SARS-CoV-2 infection, including the Company's TNX-3600 and TNX-4100 product candidates, respectively. The licensed mAbs were developed as part of a research collaboration and option agreement between the Company and Columbia. TNX-3600 are fully human mAbs generated from SARS-CoV-2+ asymptomatic individuals or COVID-19 convalescent patients. TNX-4100 are murine mAbs and their humanized counterparts generated from mice immunized with SARS-CoV-2 spike protein. The Company believes that murine mAbs, such as TNX-4100, have the potential to generate high affinity antibodies that recognize different epitopes on the SARS-CoV-2 spike protein.

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 February 13, 2023
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: February 13, 2023

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Exclusive License of Potential Therapeutic or Preventative Fully Human and Murine Anti-SARS-CoV-2 Monoclonal Antibodies

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 Formerly EUA-Approved Monoclonal Antibody Therapies and Preventatives

CHATHAM, N.J., February 13, 2023 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced that it has exercised an option to obtain an exclusive license from Columbia University for the development of a portfolio of fully human (TNX-3600) and murine (TNX-4100) monoclonal antibodies (mAbs) for the treatment or prophylaxis of SARS-CoV-2 infection. SARS-CoV-2 is the cause of COVID-19. The licensed mAbs were developed as part of a research collaboration and option agreement between Tonix and Columbia University, originally announced in 2020.

"The licensing of these mAbs strengthens our expanding pipeline of next-generation therapeutics to treat and prevent 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]. We believe there is a need for second-generation mAb treatments and prophylactics[2,3] to protect this population."

Although five mAb products containing seven distinct mAbs received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for either treatment or prophylaxis of COVID-19, none remain useful or available since January 26, 2023, when the FDA announced that the last remaining mAb, Evusheld®, is no longer authorized[4]. Previously, either the National Institutes of Health COVID Treatment Guidelines Panel or FDA had removed recommendations or approvals for the other mAbs[5,6].

Ilya Trakht, Ph.D., Associate Research Scientist at Columbia University Vagelos College of Physicians and Surgeons said, "We are excited to work with Tonix because of its commitment to developing therapeutics for COVID-19. Our antibody platform has proven robust and capable of rapidly making therapeutically relevant fully human mAbs to SARS-CoV-2. We have also generated murine mAbs, which represent a new approach. 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 as we face a multitude of variants."

To date, the formerly EUA-approved products were derived from the blood of COVID-convalescent patients or humanized mice[7-9]. The fully human mAbs generated by Columbia University, TNX-3600, have been isolated using a proprietary system involving a human hybridoma fusion partner.

The Company believes that murine mAbs, such as TNX-4100, have the potential to generate high affinity antibodies that recognize different epitopes on the SARS-CoV-2 spike protein. This is because mice have a different repertoire of antibodies than humans and the technology for generating antibodies optimizes the selection of appropriate B cells by the timing of immunization, harvesting approach and screening platform.

Dr. Lederman added, "The potential therapeutic antibodies licensed from Columbia University leverage our expanding internal development and manufacturing capabilities for biologics. These fully human and murine mAbs and their humanized counterparts build on a base of knowledge from a distinct murine mAb

platform in development, TNX-3800, from which we have licensed three humanized mAbs from Curia Global."

About TNX-3600

TNX-3600 are fully human mAbs generated from SARS-CoV-2+ asymptomatic individuals or COVID-19 convalescent patients, on which Tonix is collaborating with Columbia University. Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants, we seek to contribute to a broad set of mAbs that can be scaled up quickly and potentially combined with other mAbs for the treatment or prophylaxis of SARS-CoV-2 infection.

About TNX-4100

TNX-4100 are murine mAbs and their humanized counterparts generated from mice immunized with SARS-CoV-2 spike protein, on which Tonix is collaborating with Columbia University. Since mice have a different repertoire of antibodies than humans, murine mAbs have the potential for neutralizing a broader spectrum of SARS-CoV-2 variants than fully human mAbs.

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. 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 second quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is being studied in a potential pivotal Phase 2 study that initiated enrollment in the first quarter of 2023 and for which interim data is expected in the fourth 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 second quarter of 2023. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801; a next-generation vaccine to prevent COVID-19, TNX-1850; a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600; and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800; and a class of broad-spectrum small molecule oral antivirals, TNX-3900. 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 the second half of 2023.

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

[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]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?

[3]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

[4]https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-evusheld-not-currently-authorized-emergency-use-us – Accessed Feb 7, 2023

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

[6]"FDA Updates on Bebtelovimab" – "This information shows that bebtelovimab is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1." – www.fda.gov/drugs/drug-safety-and-availability/fda-updates-bebtelovimab- Accessed Nov 4, 2022

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

[8]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

[9]Vir isolated sotrovimab from the blood of a SARS-CoV-1 patient

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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