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): June 1, 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 June 1, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing that the U.S. Patent and Trademark Office ("USPTO") issued U.S. Patent No. 11,345,896 entitled "Synthetic Chimeric Poxviruses" on May 31, 2022 (the "Patent"). 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 June 1, 2022, the Company announced that the USPTO issued the Patent on May 31, 2022. This patent, entitled "Synthetic Chimeric Poxviruses," includes claims covering synthetic horsepox virus, the basis for the Company's TNX-801 vaccine in development to protect against monkeypox and smallpox, and for the Company's Recombinant Pox Virus (RPV) platform to protect against other pathogens, including SARS-CoV-2. This patent is expected to provide the Company with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments.

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 Share Repurchase Program, intellectual property rights and protections related to TNX-801, 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 June 1, 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: June 1, 2022

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Issuance of U.S. Patent for TNX-801 Smallpox and Monkeypox Vaccine and Recombinant Pox Virus (RPV) Platform Technology

Strengthens Patent Portfolio Protecting Horsepox-Based Live Virus Vaccines

TNX-1840 and TNX-1850 are Potential RPV Vaccines Designed to Protect Against COVID-19

Confirms Leadership Position in Synthetic Biology

Statutory Term of New Patent Expected to Provide Exclusivity Until 2037

CHATHAM, N.J., June 1, 2022 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, announced today that the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 11,345,896 to the Company on May 31, 2022. This patent, entitled "Synthetic Chimeric Poxviruses," includes claims covering synthetic horsepox virus, the basis for the Company's TNX-801[1] vaccine in development to protect against monkeypox and smallpox and for the Company's Recombinant Pox Virus (RPV) platform to protect against other pathogens, including SARS-CoV-2. This patent is expected to provide Tonix with U.S. market exclusivity until 2037, excluding any possible patent term extensions or patent term adjustments.

"This patent is an important milestone in protecting our expanding pipeline of vaccines that address known and potentially novel pathogens," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "TNX-801 is a horsepox-based live virus vaccine currently in development to protect against monkeypox and smallpox. TNX-1840[1] and TNX-1850[1] are designed to express the spike proteins from the SARS-CoV-2 omicron and BA.2 variants, respectively. Horsepox was one of the first few viruses ever generated by synthetic biology and remains among the largest. As we prepare to advance horsepox-based live virus vaccines into clinical development, we are excited to have this new patent as an important element of our patent estate."

About TNX-801, TNX-1840 and TNX-1850

TNX-801 is a live virus vaccine based on synthesized horsepox[2,3]. Tonix is developing TNX-801 for percutaneous administration as a vaccine to protect against monkeypox and smallpox. Tonix has previously reported positive data from a monkeypox challenge study in non-human primates[4]. Tonix is also developing TNX-1840 and TNX-1850 (horsepox-based live virus vaccines) for the prevention of COVID-19. TNX-1840 and TNX-1850 are designed to express the spike protein from the omicron and BA.2 variants of SARS-CoV-2, respectively. Tonix has previously reported positive data from a SARS-CoV-2 challenge study in non-human primates in which animals were vaccinated with TNX-1800, a horsepox-based vaccine expressing spike protein from the Wuhan strain[5]. Tonix's TNX-801 was synthesized[2] based on the sequence of the 1976 natural isolate Mongolian horsepox clone MNR-76[3]. Molecular analysis of DNA sequences suggests that TNX-801 is closer than modern smallpox vaccines to the vaccine discovered and disseminated by Dr. Edward Jenner in 1798[6-8]. For example, recent studies[9,10] have shown approximately 99.7% colinear identity between TNX-801 and the circa 1860 U.S. smallpox vaccine VK05.[11] The small plaque size in culture of TNX-801 appears identical to the U.S. Centers for Disease Control publication of the natural isolate[12]. Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Dr. Edward Jenner invented vaccination in 1798 and the procedure was called "vaccination" because 'cow' is '*vacca*' in Latin and the inoculum material was initially obtained from lesions on the udders of cows affected by a mild disease known as cowpox. However, Dr. Jenner suspected that cowpox originated from horses.[8] Subsequently, Dr. Jenner and others immunized against smallpox using material directly obtained from horses. The use of vaccines from horses was sometimes called 'equination' from the Latin '*equus*' which means 'horse'[13]. Equination and vaccination were practiced side-by-side in Europe[13,14].

About the Recombinant Pox Virus (RPV) Platform

Horsepox virus and vaccines based on its use as a vector are live replicating viruses that elicit strong immune responses. Live replicating orthopoxviruses, like vaccinia or horsepox, can be engineered to express foreign genes and have been exploited as platforms for vaccine development because they possess; (1) large packaging capacity for exogenous DNA inserts, (2) precise virus-specific control of exogenous gene insert expression, (3) lack of persistence or genomic integration in the host, (4) strong immunogenicity as a vaccine, (5) ability to rapidly generate vector/insert constructs, (6) manufacturable at scale, and (7) ability to provide direct antigen presentation. Relative to vaccinia, horsepox has substantially decreased virulence in mice[2]. Horsepox-based vaccines are designed to be single dose, vial-sparing vaccines, that can be manufactured using conventional cell culture systems, with the potential for mass scale production and packaging in multi-dose vials. Tonix's TNX-801 and RPV vaccine candidates are administered percutaneously using a two-pronged, or "bifurcated" needle. The major cutaneous reaction or "take" to vaccinia vaccine was described by Dr. Edward Jenner in 1796 and has been used since then as a biomarker for protective immunity to smallpox, including in the World Health Organization's (WHO) accelerated smallpox eradication program that successfully eradicated smallpox in the 1960's. The "take" is a measure of functional T cell immunity validated by the eradication of smallpox, a respiratory-transmitted disease caused by variola.

About Monkeypox and Smallpox

Monkeypox[15] and smallpox[16] are diseases in humans called by the monkeypox and smallpox (or variola) viruses, respectively. Monkeypox and variola are closely related orthopox viruses. Vaccination against smallpox with live virus vaccines based on horsepox or vaccinia protects against monkeypox. After routine smallpox vaccination was stopped in about 1970, monkeypox has become a growing problem in Africa. Recently approximately 300 cases have been identified outside of Africa.[17] Smallpox is considered eradicated, but there are concerns about malicious reintroduction.

About Tonix Pharmaceuticals Holding Corp.[1]

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 first quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the second quarter of 2022. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the second quarter of 2022. TNX-1300 has been granted Breakthrough Therapy Designation by the FDA. Finally, 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 second half of 2022. 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 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 half of 2022. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox called TNX-801, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. Tonix's lead vaccine candidates for COVID-19 are TNX-1840 and TNX-1850, which are live virus vaccines based on Tonix's recombinant pox vector (RPV) live virus vaccine platform.

[1] *All of Tonix's product candidates are investigational new drugs or biologics and none have been approved for any indication*

[2] *Noyce RS, et al. (2018) PLoS One. 13(1):e0188453*

[3] *Tulman ER, et al. (2006) J Virol. 80(18):9244-58.PMID:16940536*

[4] *Noyce, RS, et al. Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox* Presented as a poster at the American Society of Microbiology BioThreats Conference – January 29, 2020, Arlington, VA.* (https://content.equisolve.net/tonixpharma/media/10929ac27f4fb5f5204f5cf41d59a121.pdf)

[5] *Tonix Press Release March 16, 202a https:// /ir.tonixpharma.com/news-events/press-releases/detail/1255/tonix-pharmaceuticals-reports-positive-covid-19-vaccine*

[6] *Schrick L et al. N Engl J Med. (2017) 377:1491.*

[7] *Qin et al. J. Virol. 89:1809 (2015).*

[8] *Jenner E. "An Inquiry Into the Causes and Effects of the Variole Vaccinae, a Disease Discovered in Some of the Western Counties of England, Particularly Gloucestershire and Known by the Name of the cow- pox." London: Sampson Low, 1798.*

[9] *Brinkmann A et al, Genome Biology (2020) 21:286 https://doi.org/10.1186/s13059-020-02202-0*

[10] *Duggan A et al. Genome Biology (2020) 21:175* https://doi.*org/10.1186/s13059-020-02079-z*

[11] *Tonix press release. Dec 4, 2020 https://ir.tonixpharma.com/news-events/press-releases/detail/1236/vaccine-genome-researchers-report-99-7-colinear-identity*

[12] *Trindale GS et al. Viruses (2016) (12). Pii: E328. PMID:27973399*

[13] *Esparza E, et al Vaccine. (2017) 35(52):7222-7230.*

[14] *Esparza J et al. Vaccine. (2020); 38(30):4773-4779.*

[15] *www.cdc.gov/poxvirus/monkeypox/about.html*

[16] *www.cdc.gov/smallpox/research/*

[17] *Mandavilli, A. The New York Times. May 26, 2020. "Who is protected against monkeypox"*

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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