

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): March 19, 2020

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.)

509 Madison Avenue, Suite 1608, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

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 Global 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.

Tonix Pharmaceuticals Holding Corp (the “Company”) will present certain information regarding its product candidate, TNX-1800, being developed as a potential COVID-19 vaccine, based on its horsepox vaccine vector platform, to the World Health Organization (the “Presentation”) on March 20, 2020. The Presentation, which may contain nonpublic information, is filed as Exhibit 99.01 hereto and incorporated herein by reference.

The information in 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 it 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.

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 Securities and Exchange Commission. 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	Presentation by the Company

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: March 19, 2020

By: /s/ Bradley Saenger

Bradley Saenger
Chief Financial Officer



WHO Presentation – COVID Vaccine Manufacturers

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March 20, 2020

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Cautionary Note on Forward-Looking Statements

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Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are “forward-looking statements” as defined by 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” 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 failure to obtain U.S. Food and Drug Administration clearances or approvals and noncompliance with its regulations; our need for additional financing; substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, and periodic reports and current 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.



Public Health and Biodefense Preclinical Pipeline¹

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Pipeline Product	Targeted Indication(s)	Category
TNX-1800² Live modified horsepox virus (rHPXV/SARS-CoV2-S ³) vaccine from cell culture	COVID-19 ⁴ preventing vaccine	Public Health
TNX-801⁵ Live horsepox virus (sHPXV ⁶) vaccine from cell culture	Smallpox and monkeypox preventing vaccine	Biodefense
TNX-1200 Live vaccinia virus (sVACV ⁷) vaccine from cell culture	Smallpox and monkeypox preventing vaccine	Biodefense

¹ Experimental new medicines and biologics, not approved for any indication

² Collaboration with Southern Research

³ Designed to express SARS-CoV-2 Spike (S) protein

⁴ COVID-19 = Coronavirus disease 2019

⁵ Collaboration with David Evans and Ryan Noyce at Univ. of Alberta, Canada

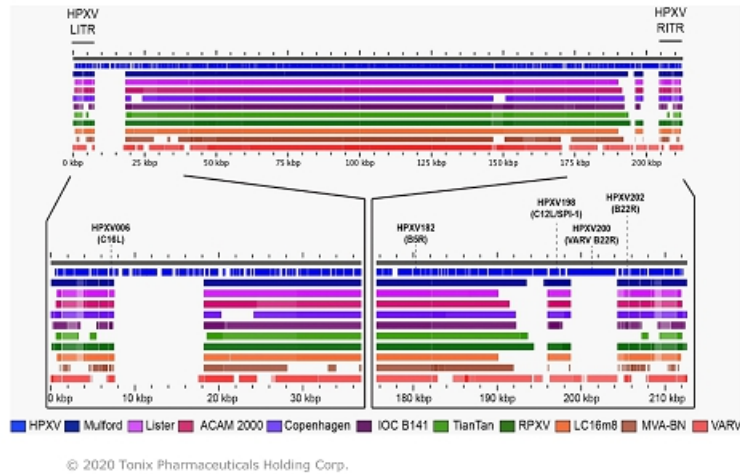
⁶ Synthesized horsepox

⁷ Synthesized vaccinia



Relationship Between Horsepox, Certain Vaccinia Strains and Variola

Legend: Alignment of orthopoxvirus genomes and location of horsepox (HPXV) genes within telomeres. Orthopoxvirus genomes were aligned using the program GView (<https://server.gview.ca>). The actual nucleotide sequence of each gene within the genome was compared to the coding sequence (CDS) of each gene within the horsepox (HPXV) reference genome (NCBI Accession DQ792504) and the following orthopoxvirus genomes (VACV Mulford 1902 - MF477237; VACV Lister - AY678276; VACV ACAM2000 - AY313847; VACV Copenhagen - M35027; VACV IOC-B141 - KT184690; VACV TianTan - KC207810; Rabbitpox virus (RPXV) Utrecht - AY484669; MVA-BN - DQ983238; VACV LC16m8 - AY678275; Variola virus (VARV) (Bangladesh 1975 - L22579). The white gaps in the HPXV reference sequence represent non-coding sequences within the genome. The percent identity (PID) cutoff was set to 85%, meaning that only matches with PID values over 85% are displayed. Abbreviations: BLAST = Basic Local Alignment Search Tool; LITR = left inverted terminal repeat; RITR= right ITR.





TNX-801 (live horsepox virus vaccine for percutaneous (scarification) administration)

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Vaccine based on sequence of isolated horsepox clone^{1,2}

- No new gene elements and coding sequence is identical to environmental horsepox isolate
- May be considered "primordial" since Left and Right ITRs are "complete"
- In contrast, modern vaccinia strains contain deletions and mutations

Small plaque size in culture

- Appears similar to CDC publication of 1976 horsepox isolate³

Substantially decreased virulence in mice²

- Relative to a vaccinia vaccine strain

Protects macaques from monkeypox⁴

- No overt sign of clinical symptoms and no lesions in 8/8 animals at two doses of TNX-801

Historical evidence for horsepox-like vaccines

- Jenner and others demonstrated their horse originated vaccine was protective against variola in challenge studies with variola (what was then called "variolation")
- Used when smallpox was endemic

Horsepox has not been reported in >40 years

- Improved hygiene in animal husbandry led to its elimination
- Probable natural hosts are rodents
- Horse-to-cow transmission by human vector reported by Jenner

¹Tulman ER, et al. (2006) *J Virol*. 80(18):9244-58. PMID:16940536

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

³Trindale GS et al. *Viruses* (2016) (12). pii: E328. PMID:27973399

⁴Noyce, 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/10929ac27f4fb5f5204f5c41659a121.pdf>)



Potential for Use of Horsepox as a Vector Platform for a SARS-CoV-2 Vaccine

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Horsepox can be engineered to express foreign genes and serve as a platform for vaccine development

- Large packaging capacity for exogenous DNA inserts (i.e. encoding antigens)
- Precise virus-specific control of exogenous gene insert expression
- Lack of persistence or genomic integration in the host
- Strong immunogenicity as a vaccine
- Ability to rapidly generate vector/insert constructs
- Readily manufacture at scale
- Live, replicating vaccine – direct antigen presentation

Potential advantages of horsepox over vaccinia

- Maintains strong immunogenicity with potentially improved tolerability
- Relative to non-replicating vaccinia, horsepox's replication in human cells provides direct antigen presentation by Class I MHC
- Horsepox may behave differently as a vector, in part because of its different repertoire of genes that modulate immune responses and host range

Strong immunogenicity for adaptive and innate immunity – believed important in SARS

- Humoral immunity against Spike protein is sufficient to protect against SARS-CoV in mice^{1,2}
- T cells are sufficient to clear SARS-CoV in mice³
- T cells can protect mice from SARS-CoV after vaccination with vaccinia-virus encoding a SARS Spike protein peptide^{3,4}
- T cell response to Spike protein is durable (>1 year) in humans post-SARS⁵
- Innate immunity can clear SARS-CoV from mice⁶
- Interferon responses are important for mice to limit SARS-CoV in mice⁷

¹Yang ZY, et al. (2004) *Nature*;428:561–564.

²Enjuanes L, et al. (Review) (2008) *Virus Res.* 133:45–62.

³Zhao J et al. (2010) *J Virol* 84(18):9318-9325.

⁴Channappanavar R, et al. (2014) *J Virol* 88(19):11034–11044.

⁵Yang L-T et al. (2006) *Clinical Immunology* 120, 171–178.

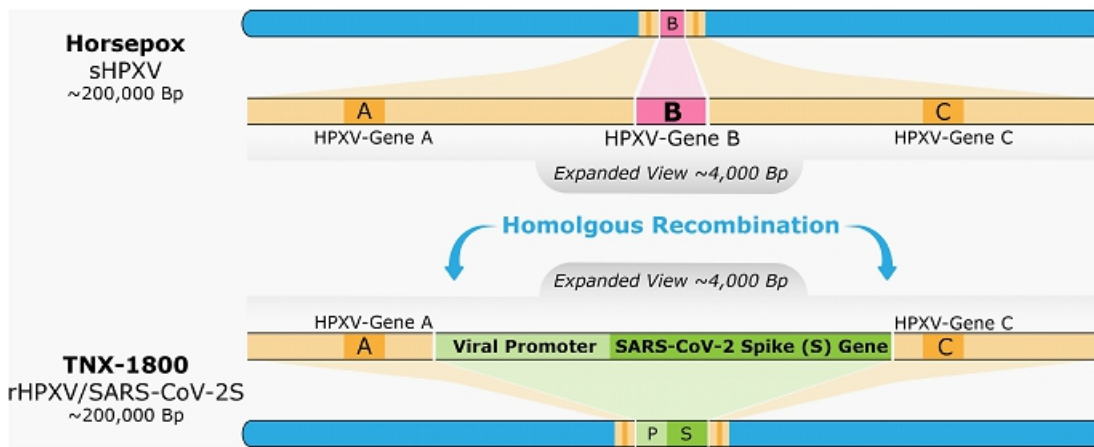
⁶Glass WG, et al. (2004) *J Immunol.* 173:4030–4039.

⁷Hogan RJ, et al. (2004) *J Virol.* 78:11416–11421.



TNX-1800 is Designed to Express SARS-CoV-2 Spike Protein

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Thank you!