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 15, 2020

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.)**

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))

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. ☐

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

Item 7.01 Regulation FD Disclosure.

The Company will present certain information regarding its vaccine candidates targeting COVID-19 (the "Presentation") at the GEN (Genetic and Engineering News) "NYC Builds Bio+ Vanquishing the Virus" panel on Tuesday, May 19. 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: May 15, 2020

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

Exhibit 99.01

NYC Builds Bio+ Vanquishing the Virus

May 19, 2020 1 – 2 pm

Version P0231 5-19-20 (Doc 0631)

Cautionary Note on Forward-Looking Statements

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; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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.

Potential COVID-19 Vaccine[1]

TNX-1800 (modified horsepox virus)[2,3]

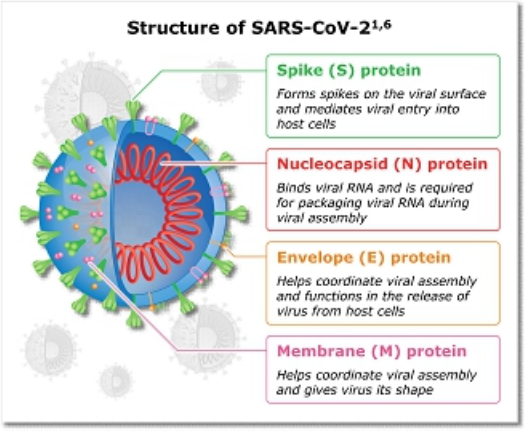
- Pre-clinical and pre-IND stage
- Live virus vaccine designed on our horsepox vaccine platform[4] to express the SARS-CoV-2 Spike (S) protein
- Milestones:
  - 4th Quarter 2020 – Non-human primate testing results expected[5]

[1] COVID-19 = Coronavirus disease 2019
[2] Collaboration with Southern Research and University of Alberta
[3] Experimental new biologic, not approved for any indication
[4] TNX-801 is unmodified horsepox virus, which is in development as a vaccine to protect against smallpox and monkeypox
[5] We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones

Considerations in SARS-CoV-2 Vaccination Strategies: Choice of Antigen

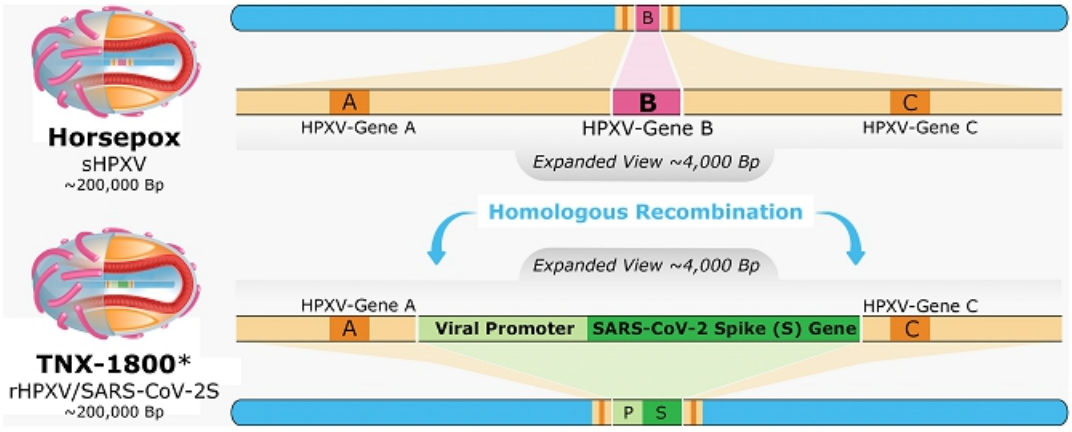
- CoVs are characterized by spike (S) proteins projecting from the virion surface[1]
- Antibodies generated against S proteins in SARS-CoV provide full protection against infection, though the duration of protection is unclear[2,3]

An optimal SARS-CoV-2 vaccine would also induce a potent T cell response to **improve** viral clearance and **promote** long-lived protection[4,5]



1. Ashour HM, et al. *Pathogens*. 2020;9(186):1-15.
2. Enjuanes L, et al. *Virus Res*. 2008;133(1):45-62.
3. Tang F, et al. *J Immunol*. 2011;186(12):7264-7268.
4. Zhao J, et al. *J Virol*. 2010;84(18):9318-9325.
5. Channappanavar R, et al. *J Virol*. 2014;88(19):11034-11044.
6. The Economist. Accessed March 30, 2020. https://www.economist.com/briefing/2020/03/12/understanding-sars-cov-2-and-the-drugs-that-might-lessen-its-power

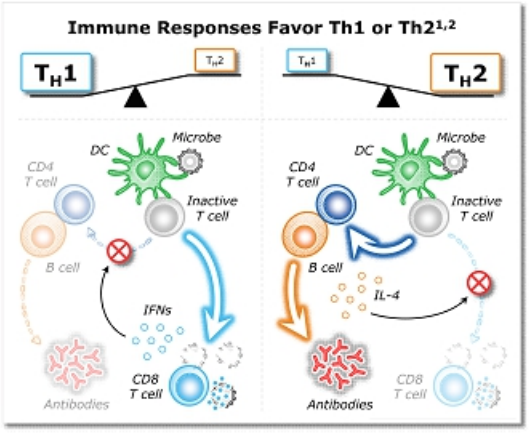
TNX-1800 is Based on a Horsepox Virus (HPXV) Vector Designed to Express SARS-CoV-2 S Protein



*TNX-1800 is at the pre-IND stage of development

The T_H1/T_H2 Decision: The Immune System Chooses a Cellular or Humoral Response

- T_H1 (cellular) and T_H2 (humoral) responses are characterized by unique cytokine patterns[1,2]
- The immune response favors T_H1 or T_H2 immunity, a decision based in part on which cytokines (eg, IFNs or IL-4) are produced early in the adaptive response[1,2]
- Some infections are only well controlled by T_H1 T cell-mediated immunity[1,3]
- In 20 healthy recovered CoV-2 volunteers, only T_H1 T cell-mediated immunity was observed[4]



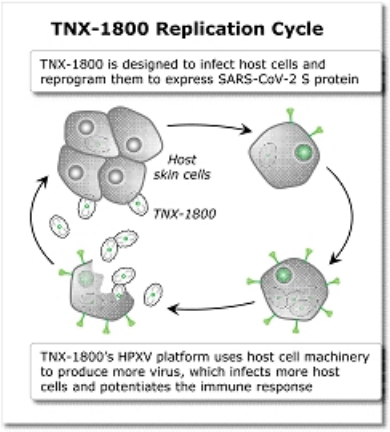
1. Bretscher PA. *Scand J Immunol.* 2014;79(6):361-376.
2. Kalko-GE, et al. *Immunology.* 2006;123(3):328-338.
3. Prompetchara E, et al. *Asian Pac J Allergy Immunol.* 2020;38(1):1-9.
4. Grifoni, A., et al. Cell (2020), doi: https://doi.org/10.1016/j.cell.2020.05.015.

Advantages of Live, Replicating HPVX as a Vector Platform for Vaccines

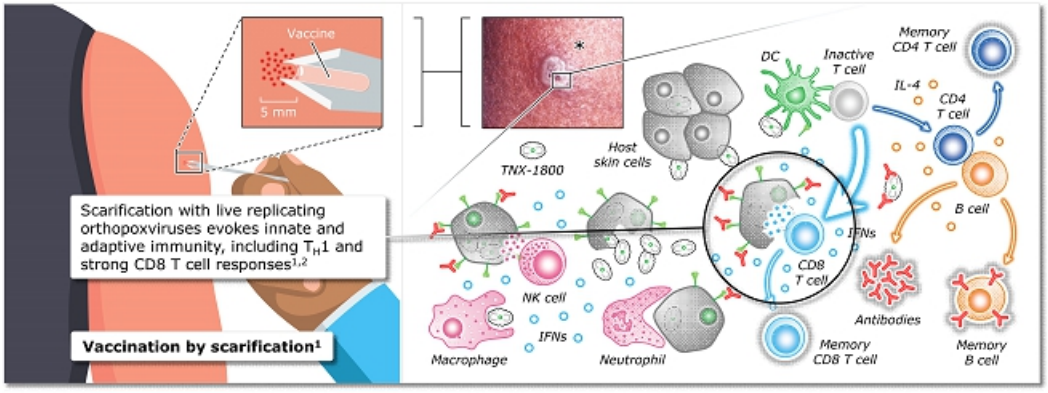
- TNX-1800–infected host cells are designed to produce SARS-CoV-2 S protein, activating an immune response against those proteins
- TNX-1800 is based on a live, replicating vaccine (HPXV) platform, which induces a robust immune response

HPXV can serve as a platform for general vaccine development:

- ✓ *Capacity for large and diverse viral DNA inserts*
- ✓ *Vaccines can be rapidly generated and readily manufactured at scale*



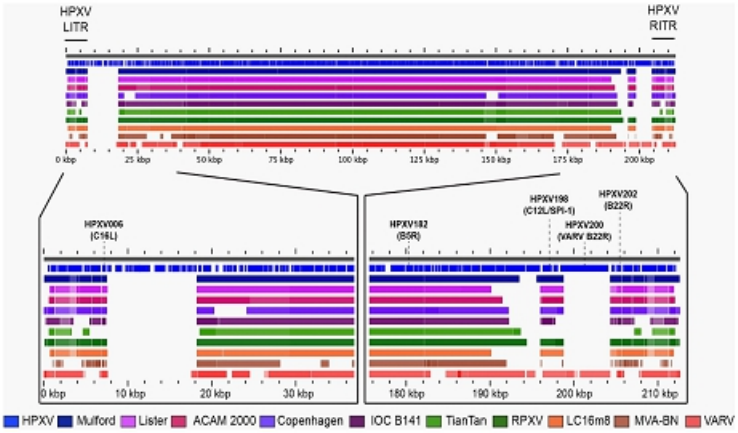
TNX-1800 is Designed to Induce Robust T_H1 Cellular Immunity



*Example of major cutaneous reaction, or "take," resulting from a replication-competent live-virus vaccine delivered via scarification, indicating successful vaccination[1,3]

1. Fulginiti VA, et al. *Clin Infect Dis.* 2003;37(2):241-250.
2. Liu L, et al. *Nature Med.* 2010;16(2):224-228.
3. Centers for Disease Control and Prevention. Accessed April 15, 2020. https://phil.cdc.gov/Details.aspx?pid=3276

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 (ITR); RITR= right ITR.



Development of TNX-1800 as a COVID-19 Vaccine

Collaboration with Southern Research

- Southern Research will develop and test TNX-1800, which is designed to express Spike (S) protein from the virus that causes COVID-19, which is called SARS-CoV-2.
- We plan to test whether vaccination of animals with TNX-1800 will elicit an immune response to the S protein from SARS-CoV-2 and if so, whether such an immune response will protect mice and non-human primates against a challenge with SARS-CoV-2 virus
- We expect to receive data from small animal experiments and from primates in the fourth quarter of 2020[1]

Further Development

- The further development of TNX-1800 for human clinical trials will require manufacturing according to Good Manufacturing Practice, or GMP
- TNX-1810, TNX-1820 and TNX-1830[2] are in early development as vaccines to elicit almost pure T cell responses vaccines

[1]We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones
[2]TNX-1810, -1820 and -1830 are experimental new biologics, at the pre-IND and pre-clinical stage of development and are not approved for any indication

TONIX PHARMACEUTICALS

NASDAQ: TNXP

Thank you!