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): January 29, 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.

Tonix Pharmaceuticals Holding Corp. (the "Company") presented preclinical results of TNX-801 in a poster at the 2020 American Society for Microbiology Biothreats Conference (the "Presentation") on January 29, 2020. The Presentation, which may contain nonpublic information, is filed as Exhibit 99.01 hereto and incorporated herein by reference.

Item 8.01. Other Events.

On January 29, 2020, the Company announced preclinical results of TNX-801 and the development of TNX-1200. A copy of the press release discussing these matters is filed as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibits 99.01 and 99.02 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (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 Securities Act of 1933, as amended (the "Securities Act") 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 and Section 21E of the Exchange Act 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
99.02	Press release of the Company, dated January 29, 2020

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: January 29, 2020

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

Exhibit 99.01

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Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox*

Ryan Noyce[1], Landon Westfall[2], Siobhan Fogarty[3], Karen Gilbert[2], Onesmo Mpanju[4], Helen Stillwell[2], Jose Esparza[5], Fusataka Koide[2], David Evans[1], and Seth Lederman[3]

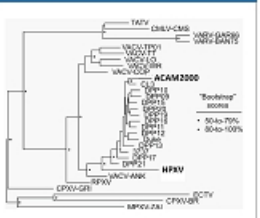
[1]University of Alberta, [2]Southern Research, [3]Tonix Pharmaceuticals, [4]LINQ Pharma Consulting, [5]Institute of Human Virology, U. of Maryland

Introduction

Despite its eradication, smallpox remains a biothreat. While elements of the US military's Global Response Force service troops are vaccinated with clonal, live vaccinia virus (VACV), safety concerns limit its further use in groups like first responders. There is a need for an effective but better tolerated, single dose, live replicating smallpox vaccine. Sequence analysis of polyclonal or legacy smallpox vaccines indicate a common ancestor with horsepox virus (HPXV)[1-2], and suggest that modern VACV diverged in the core viral sequence, and in the accumulation of deletions in the left and right inverted terminal repeats (ITRs) (Figs. 1 and 2). However, it is unknown if the early HPXV-like vaccines, which protected against smallpox, exhibited different safety and efficacy profiles compared to modern VACV. To assess the tolerability and vaccine activity of scHPXV, four groups of macaques were vaccinated with two different doses of scHPXV, one dose of synthetic VACV (sVACV), or vehicle prior to challenge with monkeypox virus (MPXV).

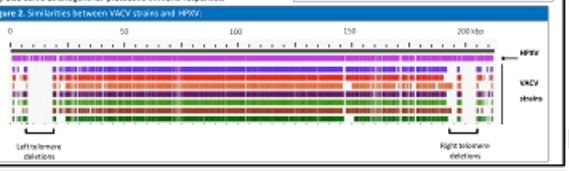
HPXV and VACVs are closely related (Fig. 1). HPXV is an environmental isolate, while VACV vaccines have a variety of telomere deletions (presumably from passage) of approximately 10.7 kb from the left ITR and approximately 5.5 kb from the right ITR (Fig. 2). Consequently, HPXV has additional genes, (relative to VACV vaccines) encoded by "complete" left and right ITRs, that are mostly involved in host immune interactions but may also serve as antigens for protective immune responses.

Figure 1. Phylogenetic relationships between VACV strains and HPXV



Adapted from: Qin et al. J Virol 85:13049 (2011)

Figure 2. Similarities between VACV strains and HPXV



Experimental Procedures

scHPXV and sVACV were assembled using synthetic DNA fragments as described previously in Noyce RS et al.[3] A laboratory isolate of VACV was sequenced using Illumina sequencing technologies to obtain a complete genome sequence, including the terminal hairpin sequences and repeat regions in the inverted terminal repeats (ITRs). This sequence is very similar to VACV (strain ACAM 2000) and has been deposited in Genbank (Accession # **MN974380**). The sVACV genome sequence was also deposited into Genbank (Accession # **MN974381**).

Cynomolgus macaques (non-human primates/NHPs) (4 per group), were vaccinated via scarification using a bifurcated needle with 4x10[8] ("high dose") or 5x10[7] ("low dose") PFU of scHPXV, 8x10[8] PFU of sVACV, or phosphate buffered saline (PBS) vehicle (Fig. 3, Table 1). Animals without takes were revaccinated*. Challenge 60 days later with 5x10[7] PFU of MPXV (strain Zaire) s/o the intratracheal (i.t.) route.

Table 1. Experimental Design for scHPXV Dose-Range Finding Study in NHP.

Group	N	Vaccine (Day 0)	Vaccination Dose (PFU)*	Route of Vaccine Administration	IT Challenge Dose (Day 60)
1	4	scHPXV	4x10[8]	Scarification	5x10[7] PFU
2	4	scHPXV	5x10[7]	Scarification	5x10[7] PFU
3	4	sVACV	8x10[8]	Scarification	5x10[7] PFU
4	4	Vehicle	N/A	Scarification	5x10[7] PFU

*A second vaccination by scarification (following procedures and dose volume used on Day 0) was given to four animals that did not show evidence of a take at the vaccination site by Day 7: one scHPXV animal was revaccinated with 5x10[7] PFU scHPXV and the 3 sVACV animals were revaccinated with 2.4x10[8] PFU sVACV. Revaccination of these four animals occurred on Day 14.

Figure 3. Treatment Timeline

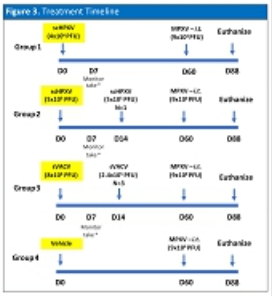
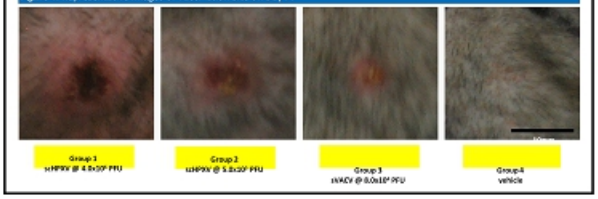


Figure 4. Representative Images of Vaccination Site on Day 7:



Results

Two different doses of scHPXV vaccine were tested: 4 of 4 animals in the 4x10[8] PFU dose, and 3 of 4 animals in the 5x10[7] PFU dose groups exhibited a "take" at Day 7 after a single vaccination. A take is a biomarker of protective immunity. In the sVACV arm only 1 of 4 animals exhibited a take after a single vaccination. The animals that did not present a take were revaccinated on Day 14: the one scHPXV animal was revaccinated with 5x10[7] PFU scHPXV and the 3 sVACV animals were revaccinated with 2.4x10[8] PFU sVACV. All but one of the sVACV animals subsequently produced a take. Tolerability was comparable for scHPXV and sVACV (Figs. 5-6). After MPXV challenge (Figs. 7-9) no lesions were seen in any of the 8 animals vaccinated with scHPXV (Fig. 9). One animal in the sVACV arm died from unrelated causes, but while the 3 remaining animals all had takes, 2 still showed lesions by Day 69 (Fig. 9). Clinical signs of systemic monkeypox infections were seen in all 4 vehicle animals by Day 65. In Figs. 5-9, blue symbols are male animals and red are female.

scHPXV is Tolerated During Vaccination of Macaques

Figure 5. Weights of Macaques During Vaccination Period

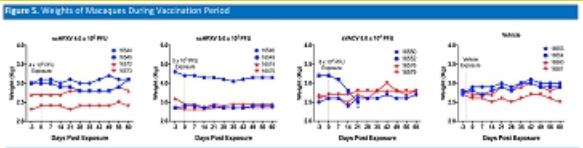
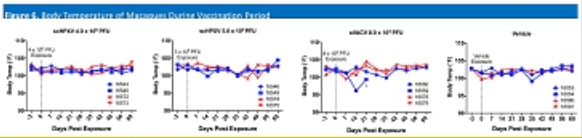


Figure 6. Body Temperature of Macaques During Vaccination Period



scHPXV Protects Macaques from Intratracheal MPXV Challenge

Figure 7. Weight Change

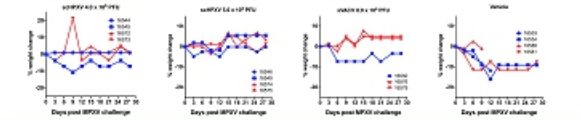
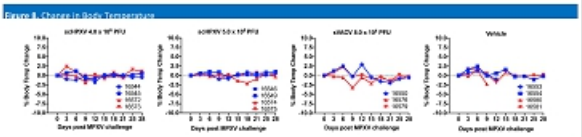
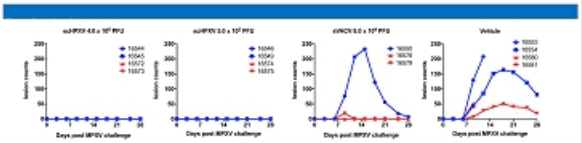


Figure 8. Change in Body Temperature





Conclusions

- HPXV virus is closely related to VACV vaccines
- HPXV is an environmental isolate and molecular analysis indicates that HPXV has not undergone deletions (with "complete" left and right ITRs)
- HPXV has additional genes, relative to VACV vaccines, that could be related to host range and immune interactions
- Molecular analysis suggests HPXV is closer to the vaccine discovered and disseminated by Dr. Edward Jenner than modern VACV swarms and strains[1,4] (in terms of left and right ITRs and core viral sequence)
- Tolerability of scHPXV (high dose) is comparable to sVACV at low dose
- Protection of scHPXV and sVACV was comparable (all 8 scHPXV-vaccinated animals and all 3 sVACV-vaccinated animals survived and recovered)
- scHPXV had higher rates of "take" (4/4 high dose and 3/4 low dose animals) than sVACV (1/3 animals) after a single vaccination ("take" is a biomarker of protective and sterilizing immunity)
- scHPXV induced sterilizing immunity (no lesions) in all 8 animals (4 high dose and 4 low dose), while sVACV (low dose) provided sterilizing immunity to only one of three animals
- scHPXV's additional genes, relative to sVACV may modulate host immune interactions and one or more may serve as antigens for protective immunity

References Cited: [1]Schrick L et al. *N Engl J Med* (2017) 377:1491; [2]Qin et al. *J Virol* 85:13049 (2011). [3]Noyce RS et al, *PLoS One* 13:e0188453 (2018). [4]Esparza, J. et al., *Vaccine* 35:7222 (2017).

American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA.

*The study design was reviewed by the Institutional Animal Care and Use Committee (IACUC) at Southern Research – Funded by Tonix Pharmaceuticals

Exhibit 99.02

Tonix Pharmaceuticals Presented Results from a Preclinical Study of TNX-801, a Potential Vaccine to Prevent Smallpox and Monkeypox, in a Poster Presentation at the 2020 American Society for Microbiology (ASM) Biothreats Conference

NEW YORK, January 29, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, presented preclinical results of TNX-801 (live virus vaccine for percutaneous administration) to potentially prevent smallpox and monkeypox in a poster at the 2020 ASM Biothreats Conference held January 28-30, 2020 in Arlington, Va. The poster, titled "Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox" includes preclinical safety and efficacy analyses of TNX-801. The poster can be found on the Scientific Presentations page of Tonix's website.

Cynomolgus macaques (four per group), were vaccinated with either high dose or low dose TNX-801, TNX-1200 (live virus vaccine based on synthesized vaccinia, or sVACV), or vehicle control. The poster presentation reports that all animals (eight of eight) vaccinated with TNX-801 were fully protected with sterilizing immunity from a challenge with intra-tracheal monkeypox. In contrast, two of three evaluable animals vaccinated with TNX-1200, and all animals who received the vehicle control, developed monkeypox lesions after challenge. In addition, after a single vaccination, four of four animals vaccinated with high dose of TNX-801 and three of four animals vaccinated with a low dose of TNX-801 responded with a cutaneous reaction called a "take" that is a biomarker of protective immunity in immunocompetent individuals in campaigns to control smallpox contagion. In contrast, only one of three animals vaccinated with a low dose of TNX-1200 responded with a take. The vaccinations with TNX-801 or TNX-1200 were well tolerated. TNX-801 and TNX-1200 are in the pre-clinical and pre-Investigational New Drug (IND) application stage of development. Tonix is developing TNX-801 and TNX-1200 as potential smallpox preventing vaccines for the U.S. strategic national stockpile and as monkeypox preventing vaccines for areas where monkeypox is a growing problem.

About TNX-801 and TNX-1200

TNX-801 is a live virus vaccine based on synthesized horsepox (sHPXV). TNX-1200 is a live virus vaccine based on synthesized vaccinia (sVACV). HPXV virus is closely related to VACV vaccines. Molecular analysis suggests that TNX-801 is closer than modern vaccines in DNA sequence[1,2] to the vaccine discovered and disseminated by Dr. Edward Jenner. Molecular analysis indicates that HPXV has "complete" left and right inverted terminal repeats (ITRs) while different VACV isolates have a variety of deletions in the left and right ITRs. Therefore, TNX-801 has additional genes, relative to VACV vaccines, that may play roles in host immune interactions and one or more or such proteins may serve as antigens for protective immunity. Both TNX-801 and TNX-1200 were assembled using synthetic DNA fragments[3]. TNX-1200 was based on a complete genome sequence of a laboratory isolate of VACV, including the terminal hairpin sequences and the repeat regions in the ITRs. The sequence of this laboratory isolate of VACV (Genbank Accession # MN974380)) is very similar to the published sequence of VACV strain ACAM2000®[4]. Also deposited in Genbank are the TNX-1200 sequence (Accession # MN974381) and the TNX-801 sequence (Accession # KY349117.1).

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

[2]Qin *et al.* J. Virol. 89:1809 (2015).1Noyce RS et al, PLoS One. (2018) 13:e0188453.

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

[4]ACAM2000 is a registered trademark of Emergent Product Development Gaithersburg Inc.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing small molecules and biologics to treat psychiatric, pain and addiction conditions. Tonix's lead product candidate, TNX-102 SL*, is in Phase 3 development as a bedtime treatment for posttraumatic stress disorder (PTSD) (trade name Tonmya**) and fibromyalgia. The Phase 3 RECOVERY trial (P302) in PTSD is currently enrolling and results from an interim analysis for a potential sample size adjustment are expected in the first quarter of 2020 and topline data are expected in the second quarter of 2020 if the sample size remains the same. TNX-102 SL for PTSD has U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation. The Company has started enrollment in the Phase 3 RELIEF trial in fibromyalgia. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation and the development for AUD is in the pre-Investigational New Drug (IND) application stage. TNX-601 CR (tianeptine oxalate controlled-release tablets) is in development as a daytime treatment for PTSD, as well as for depression. The first efficacy study will be performed outside the U.S. and it is expected to be IND-ready in 2020. TNX-1600 (a triple reuptake inhibitor) is a third product candidate being developed for PTSD, as a daytime treatment. Tonix's programs for treating addiction conditions also include TNX-1300*** (double-mutant cocaine esterase), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy Designation. Tonix's preclinical pipeline includes TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers. Finally, TNX-701 (undisclosed small molecule) to prevent radiation effects is being advanced as a medical countermeasure to improve biodefense.

*TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has not been approved for any indication.

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL for the treatment of PTSD.

***TNX-1300 (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution) is an investigational new biologic and has 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 failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2018, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2019, and periodic reports on Form 10-Q filed with the SEC on or after the date thereof. Tonix does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Contacts

Bradley Saenger (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505