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): November 1, 2024

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 November 1, 2024, the Company announced the presentation of data in an oral presentation at the World Vaccine Congress-Europe 2024, held October 28-31, 2024 (the "WVC"). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference. A copy of the presentation is furnished hereto as Exhibit 99.02, and incorporated herein by reference.

The information in this Item 7.01 of 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 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 November 1, 2024, the Company announced the presentation of data at the WVC. The presentation, titled*A Novel, Single-dose, Live, Attenuated, Minimally Replicating Mpox Vaccine*, highlighted positive preclinical efficacy data, demonstrating tolerability in immunocompromised animals, and demonstrated that the Company's TNX-801 vaccine candidate is unable to spread in blood or tissues in these animals, even at an approximately 100-fold higher dose than 20th century vaccinia vaccines.

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, November 1, 2024
99.02	*A Novel, Single-dose, Live, Attenuated, Minimally Replicating Mpox Vaccine*
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: November 1, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Presented Data on Potential Mpox Vaccine TNX-801 at World Vaccine Congress-Europe 2024

New data show tolerability and no evidence of spreading to blood or tissues even at high doses of Tonix's attenuated live-virus, minimally replicating vaccine candidate TNX-801 in immunocompromised animals

TNX-801, has characteristics that align closely with the World Health Organization's (WHO) preferred target product profile (TPP) criteria for mpox vaccines

WHO-declared public health emergency of international concern (PHEIC)[1-4]: Mpox cases of the new clade Ib mpox detected in Sweden, Thailand, Singapore, India, Germany and England

TNX-801 vaccination demonstrated efficacy in protecting animals from lethal challenge with clade I monkeypox and is in development as an mpox vaccine

CHATHAM, N.J., November 1, 2024 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company with marketed products and a pipeline of development candidates, presented data in an oral presentation at the World Vaccine Congress -Europe 2024, held October 28-31, 2024 in Barcelona, Spain. A copy of the Company's presentation is available under the Scientific Presentations tab of the Tonix website at www.tonixpharma.com following the conference.

The presentation titled, "*A Novel, Single-dose, Live, Attenuated, Minimally Replicating Mpox Vaccine*", highlighted positive preclinical efficacy data, demonstrating tolerability in immunocompromised animalsand showed that TNX-801 is unable to spread in blood or tissues in these animals, even at an approximately 100-fold higher dose than 20th century vaccinia vaccines.

TNX-801 is an attenuated live-virus vaccine based on synthesized horsepox that has been shown to provide single-dose immune protection against a monkeypox challenge with better tolerability than 20th century vaccinia live-virus vaccines in animals. TNX-801 has previously been shown to protect animals against lethal challenge with intratracheal clade I monkeypox virus.[1] After a single dose vaccination, TNX-801 prevented clinical disease and lesions and also decreased shedding in the mouth and lungs of animals challenged with clade I monkeypox.[1] These findings are consistent with TNX-801 inducing mucosal immunity and suggest TNX-801 has the ability to block forward transmission. An outbreak of clade I mpox has recently been declared a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO).[2,3] Starting from an outbreak in the Democratic Republic of the Congo, clade I mpox has spread to sixteen Central African Countries and cases have been reported in Sweden, Thailand, Singapore, India, Germany and England. According to the U.S. Centers for Disease Control and Prevention (CDC), and other experts, there is a significant risk that clade I strain may appear in the U.S.[4]

"Data continue to support TNX-801's strong tolerability and efficacy profiles by continually displaying protective immunity to animals with single-dose administration," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "Synthetic biology is an important technology for vaccine development as viral diseases continue to rapidly evolve. The new data demonstrate that TNX-801 is highly attenuated relative to 20th century vaccinia vaccines in in immunocompromised animals.[5] With TNX-801's target profile, favorable shipping and storing requirements and our manufacturing collaboration agreements, we believe TNX-801 is in a strong position to make an impact towards preventing mpox and control mpox epidemics."

In September 2024, Tonix announced that the World Health Organization's (WHO's) preferred target product profile (TPP), released at the WHO sponsored Mpox Research and Innovation Scientific Conference, aligns with the characteristics of TNX-801. Key elements of the WHO draft TPP include single-dose, durable protection, administration without special equipment, and stability at ambient temperature. Other potential beneficial characteristics include the ability to limit forward transmission, use in case-contact vaccination strategies and suitability for use in immunocompromised individuals.

In August 2024, Tonix announced a collaboration with Bilthoven Biologics (Bbio) to develop GMP manufacturing processes for its mpox vaccine. Bbio is part of the world's largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

About TNX-801*

TNX-801 is a live replicating attenuated vaccine based on horsepox that is believed to provide immune protection with better tolerability than 20th century vaccinia viruses. As previously disclosed, TNX-801 protected animals against lethal challenge with intratracheal clade I monkeypox virus.[1] After a single dose vaccination, TNX-801 prevented clinical disease and lesions and also decreased shedding in the mouth and lungs of non-human primates.[1] The Findings are consistent with mucosal immunity and suggest the ability to block forward transmission, similar to Dr. Edward Jenner's vaccinia vaccine, which eradicated smallpox and kept mpox out of the human population. On August 26, 2024, Tonix announced a collaboration to develop GMP manufacturing processes for its mpox vaccine with Bilthoven Biologics (Bbio), part of the world's largest vaccine manufacturer, the Cyrus Poonawalla Group, which also includes the Serum Institute of India.

On the horsepox platform, Tonix is developing TNX-1800 (horsepox expressing SARS-CoV-2 spike protein) for protecting against COVID-19. TNX-1800 is an engineered version of horsepox that expresses the spike protein of SARS-CoV-2. In preclinical studies of TNX-1800 highlighted in the presentation, TNX-1800 was tested for immunogenicity and efficacy of TNX-1800 in nonhuman primates following a SARS CoV-2 challenge. [6,7] TNX-1800 vaccination results in a neutralizing antibody response that was associated with significant reduction in virus replication/shedding in the respiratory tract and tolerability. [2,3] TNX-1800 was selected by the NIH's, Project NextGen for inclusion in clinical trials as part of a select group of next generation COVID-19 vaccine candidates with the intent to identify promising vaccine platforms. NIH plans to conduct a Phase 1 trial of TNX-1800 and cover the full cost of the study, while Tonix provides the vaccine candidate.

About Mpox*

On August 14, 2024, the WHO determined that the upsurge of mpox in a growing number of countries in Africa constitutes a public health emergency of international concern, the second such declaration in the past two years called in response to an mpox outbreak. The current outbreak was caused by clade I monkeypox virus, while the 2022 outbreak was clade II monkeypox virus. The global mpox outbreak, which commenced in 2022 has affected over 90,000 persons in countries where mpox had previously not been endemic, including Europe and the US. The spread of clade IIb strain mpox in 2022 underscores the pandemic potential of mpox. Unlike clade IIb mpox, the clade I strain of mpox appears to be spreading to countries neighboring the Democratic Republic of the Congo. According to the U.S. Centers for Disease Control and Prevention (CDC), and other experts, there is a significant risk that the deadlier clade I strain may appear in the U.S.[4]

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders, and its priority is to progress TNX-102 SL, a product candidate for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia. The FDA has granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation and its development is supported by a grant from the U.S. National Institude of Drug Abuse and Addiction. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix also has product candidates in development in the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents targeting CD45 for the prevention or treatment of infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, MD. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

This press release and further information about Tonix can be found at www.tonixpharma.com.

[1]Noyce RS, et al. Viruses. 2023 Jan 26;15(2):356. Doi: 10.3390/v15020356. PMID: 36851570; PMCID: PMC9965234

[2]WHO Press Release August 14, 2024. "WHO Director-General declares mpox outbrfeak a public health emergency of international concern". URL: www.who.int/news/item/14-08-2024-who-director-general-declares-mpox-outbreak-a-public-health-emergency-of-international-concern (accessed 8-15-24)

[3]McQuiston JH, et al. *U.S. Preparedness and Response to Increasing Clade I Mpox Cases in the Democratic Republic of the Congo* 2024, MMWR Morbi Mortal Wkly Rep: United States. p. 435-440

[4]CDC. 2022-2023 Mpox: US Map and Case Count.

[5]Trefry, SV et al. bioRxiv 2023.10.25.564033; doi: https://doi.org/10.1101/2023.10.25.564033

[6]Awashti M et al *Vaccines* (Basel). 2023 11(11):1682. doi: 10.3390/vaccines11111682.PMID: 38006014

[7]Awasthi M, et al. *Viruses*. 2023 15(10):2131. doi: 10.3390/v15102131. PMID: 37896908; PMCID: PMC10612059.

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; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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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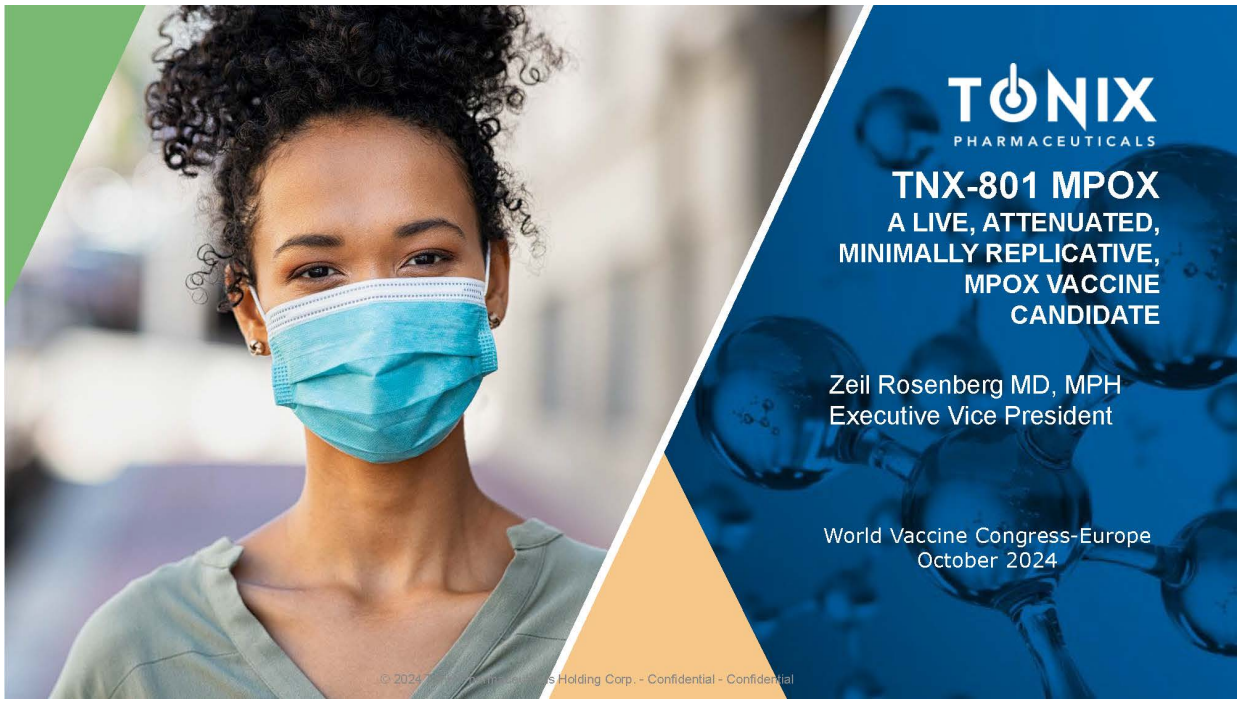
Exhibit 99.02



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, the risks related to 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. 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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.

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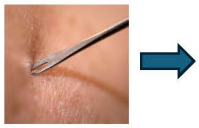
In 1796, Jenner Successfully Used Vaccination to Protect Against Smallpox

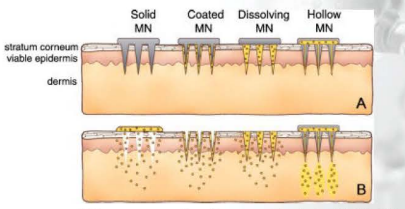
Jenner believed "vaccinia" was spread from horses to cows by farriers

Next Gen sequencing shows horsepox was used as a vaccine in 19th century

- **Skin reaction called "take" also described first by Jenner**



Take



Microneedle Array Patch (MAP)

- Biomarker of protection[2]
- Measure of T cell immunity

[1]Fulginiti VA, et al. *Clin Infect Dis.* 2003;37(2):241-250.
[2]Centers for Disease Control and Prevention. Accessed April 15, 2020. https://phil.cdc.gov/Details.aspx?pid=3276
Kim et al Advanced Dru Delivery Reviews 64(14)2012 1457-1568

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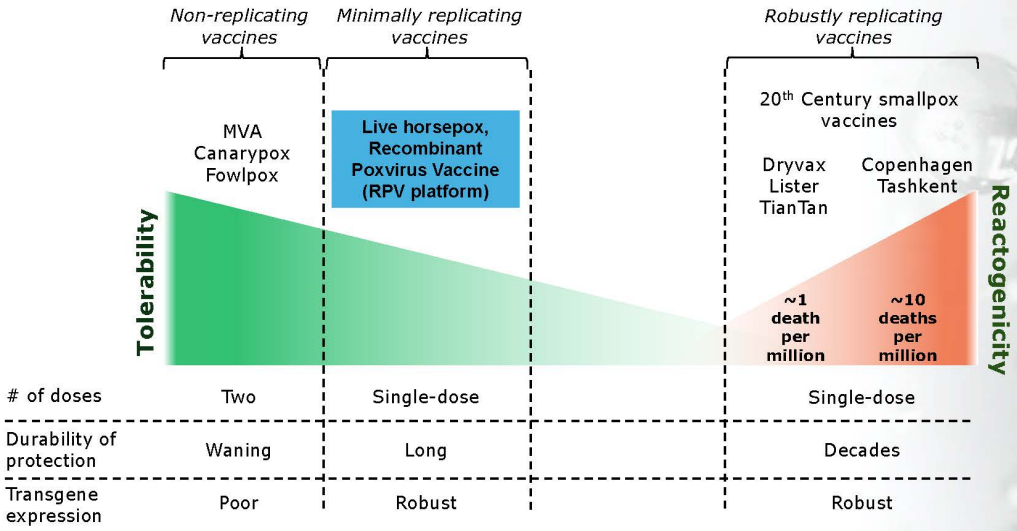
ILLUSTRATIVE SAFETY SPECTRUM OF POX-BASED VACCINE VECTORS OPTIMIZING LIVE VIRUS VACCINES



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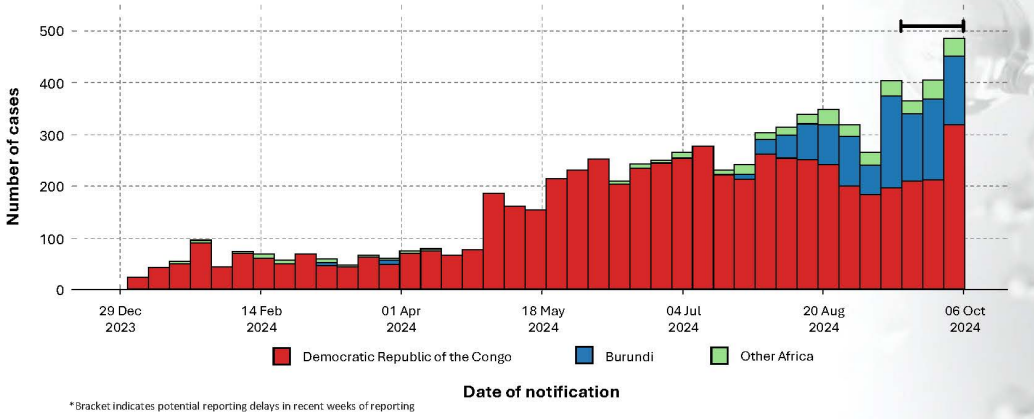
EPIDEMIC CURVE OF WEEKLY REPORTED CONFIRMED MPOX CASES IN AFRICA JANUARY 1- OCTOBER 6, 2024



*Bracket indicates potential reporting delays in recent weeks of reporting

Adapted from Mutli-country outbreak of Mpox, external situation report #40. World Health Organization. Updated October 13, 2024. Accessed October 22, 2024. https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox--external-situation-report-40--13-october-2024.

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MPOX VACCINE LANDSCAPE

Vaccine	Company	Phase	Presentation	Comment
TNX-801*	Tonix	Pre-IND written response from FDA in Aug 2023	Single dose: Microneedle patch	Minimally replicating live virus May block forward transmission Expected thermostability Expected long durability (decades) Increased accessibility (patch)
MVA-BN	Bavarian Nordic	FDA Approved	Two dose IM	Waning antibody (6-12 months)[1] High Cost Limited manufacturing Refrigeration required
ACAM2000	Emergent	FDA Approved No WHO EUL	Single dose: Bifurcated needle	Robustly replicating live virus Hx of associated myopericarditis[2] Unlikely broad use
LC16m8	KM Biologics/ Japan	Approved Japan No WHO EUL	Single dose: Bifurcated needle	Virus reversion risk Application not approved by FDA Limited manufacturing

*TNX-801 is in the pre-IND stage of development and has not been approved for any indication [1]Collier AT, et al. *JAMA* (2024)
[2]Shrestha AB et al. *Annals of Medicine & Surgery(London)(2023)*

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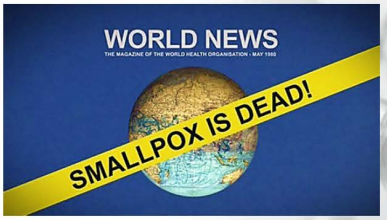
RING VACCINATION (SURVEILLANCE-CONTAINMENT)

- Aggressive case-finding followed by vaccination of all known and possible contacts to seal off outbreak from rest of population.
- Used during smallpox eradication campaign first in Nigeria, led to the disappearance of smallpox in Nigeria although population coverage was <50%.[1,2]
- Low likelihood of success with a two-dose strategy due to population movement, drop-out, etc.



[1]Belangia (2002) *Clin Med Res. April;(1):87-92*
[2]Fenner et al . *(1982) Smallpox and Its Eradication. WHO: Geneva.*

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U.S. NATIONAL ACADEMIES OF SCIENCE
RECOMMEND SINGLE DOSE ORTHOPOX VIRUS VACCINES BE DEVELOPED

(2-2) Smallpox vaccines that have improved safety across different population subgroups and are available as a single dose would support faster and more effective response to contain smallpox and other orthopoxvirus outbreaks. The development of novel smallpox vaccines using multi-vaccine platforms (i.e., use common vaccine vectors, manufacturing ingredients, and processes) would improve the capacity for rapid vaccine production in response to a smallpox event and reduce the need for stockpiling in the SNS at current levels.

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WHO SAGE TARGET PRODUCT PROFILE (TPP)MPOX VACCINE

Vaccine characteristic	Preferred	Critical or Minimal[2]
Indication for use	People at risk of exposure to monkeypox virus in an outbreak: Prevention of mpox disease People exposed to monkeypox virus: Prevention of mpox disease and reduction of severe mpox disease. Prevention of mpox disease transmission	People at risk of exposure to monkeypox virus in an outbreak: Prevention of mpox disease People exposed to monkeypox virus: Prevention of mpox disease and/or reduction of severe mpox disease
Contraindication	Minor (e.g., hypersensitivity or linked to specific adverse events).	Limited contraindications may include severely immunocompromised patients
Target population	Adults, children, and infants Data to support administration to special populations such as those who are pregnant, lactating, or immunocompromised	Adults
Safety/Reactogenicity	Minimal reactogenicity No serious ADRs	Up to mild-moderate reactogenicity Serious adverse events occurring only in rare circumstances
Measures of Efficacy	Efficacy point estimate >90% Direct evidence of efficacy against disease caused by relevant monkeypox clades, preferably generated through randomized clinical trials	Efficacy point estimate >60% Animal studies, immune responses[3], and/or observational data supporting efficacy against mpox Additionally strong evidence of efficacy against smallpox if available would be supportive
Dose regimen	Single dose	Two or fewer doses for primary regimen Boosters are acceptable

WHO Target Product Profiles for mpox Vaccines, Version 1, August 16, 2024

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viruses

MDPI

Article

Single Dose of Recombinant Chimeric Horsepox Virus (TNX-801) Vaccination Protects Macaques from Lethal Monkeypox Challenge

Ryan S. Noyce [1], Landon W. Westfall [2,†], Siobhan Fogarty [3], Karen Gilbert [2], Onesmo Mpanju [4], Helen Stillwell [3,‡], José Esparza [5], Bruce Daugherty [3], Fusataka Koide [2], David H. Evans [1] and Seth Lederman [3,*]

Noyce et al 2023 Viruses Jan 26;15(2):356

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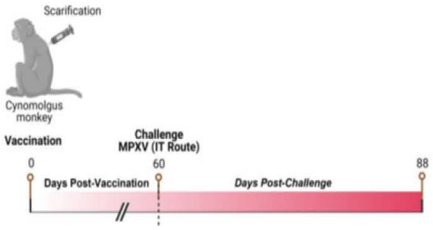
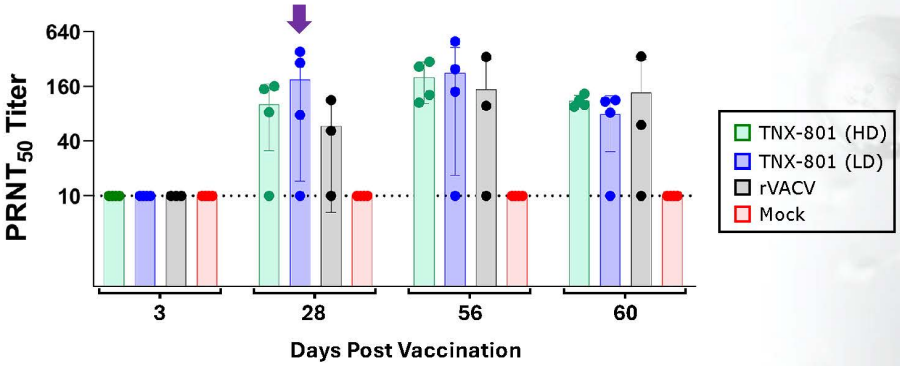
IMMUNOGENICITY AND EFFICACY IN NHP – STUDY DESIGN

Vaccination					Challenge		
Group	Vaccine	N	Dose (Log_{10} PFU)	Route	*Virus*	*Dose (Log_{10} PFU)*	*Route*
1	TNX-801 (High)	4	6.6	Percutaneous	*MPXV Clade I*	*5.0*	*IT*
2	TNX-801 (Low)	4	5.7	Percutaneous			
3	rVACV*	4	5.0	Percutaneous			
4	Mock	4	-	Percutaneous			

*rVACV = Synthetic vaccinia virus (VACV) similar to ACAM2000 (FDA approved smallpox and mpox vaccine)
Noyce RS, Lederman, Evans et al. 2018 PloS ONE 13 e188453



IMMUNOGENICITY: NEUTRALIZING ANTIBODY ($PRNT_{50}$ ASSAY)



100% Seroconversion and 88% of TNX-801 vaccinated NHPs had neutralizing antibody responses 8- to 50-fold from baseline

Noyce et al 2023 Viruses Jan 26;15(2):356

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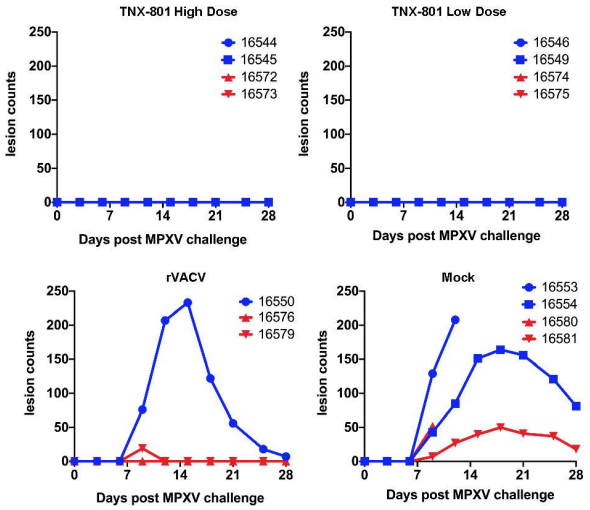
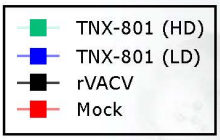
CLINICAL SIGNS (LESIONS) AFTER MPXV CHALLENGE





No lesions observed after MPXV challenge in any of the vaccinated animals

[1]Noyce RS, et al. *Viruses*. 2023 Jan 26;15(2):356. doi: 10.3390/v15020356. PMID: 36851570; PMCID: PMC9965234.

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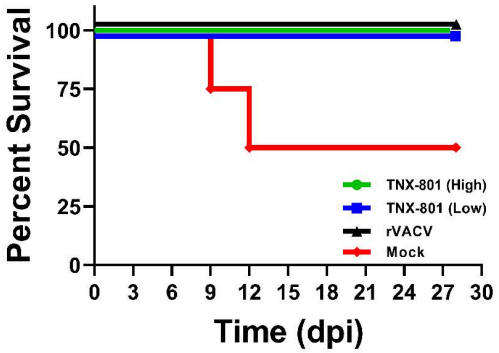
CLINICAL DISEASE: LETHALITY



100% survival in TNX-801 vaccinated animals

Noyce et al 2023 Viruses Jan 26;15(2):356

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AMERICAN SOCIETY FOR MICROBIOLOGY | mSphere

Biotechnology | Research Article

Recombinant chimeric Horsepox virus (TNX-801) is attenuated relative to Vaccinia virus strains in both *in vitro* and *in vivo* models

Stephanie V. Trefry,[1] Mayanka Awasthi,[1] Christy N. Raney,[1] Amy L. Cregger,[1] Chase A. Gonzales,[1] Brittney L. Layton,[1] Robert N. Enamorado,[1] Nelson A. Martinez,[1] Deborah S. Gohegan,[1] Masoudeh Masoud-Bahnamiri,[1] Jennifer Y. Cho,[1] Dawn M. Myscofski,[1] Tinoush Moulaei,[1] Natasza E. Ziółkowska,[1] Scott J. Goebel,[1] Seth Lederman,[1] Sina Bavari,[1] Farooq Nasar[1]

Accepted, publication in press

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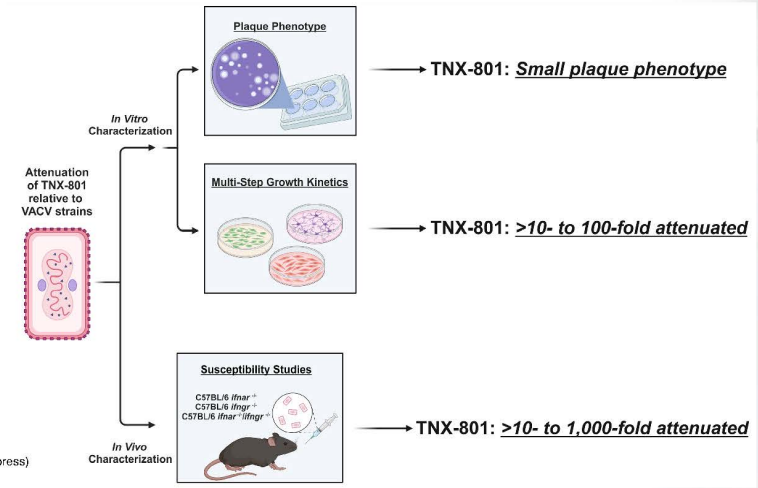
TNX-801 IS 10-TO-1,000-FOLD LESS VIRULENT THAN "MODERN" VACCINIA



Trefry S et al mSphere 2024 (in press)

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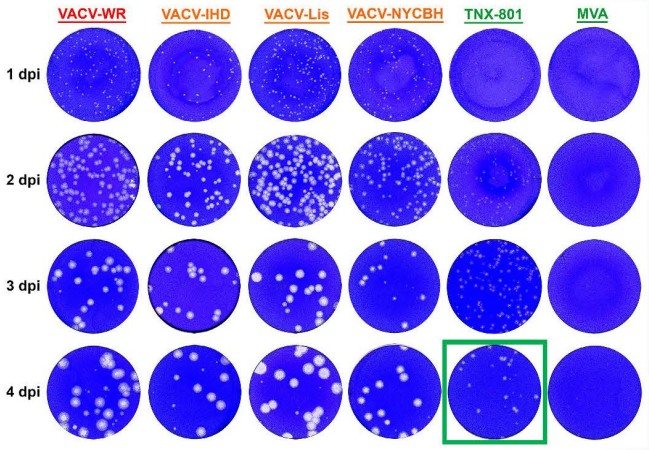
TNX-801 PLAQUE PHENOTYPE IN BSC-40 CELLS



Trefry S et al mSphere 2024 (in press)

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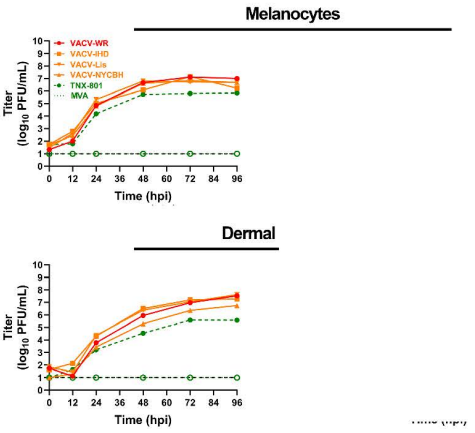
TNX-801 MINIMALLY REPLICATIVE: KINETICS IN PRIMARY HUMAN CELLS (DERMAL TRACT)

Plaque Assay



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TNX-801: *~30- to 120-fold* more attenuated than VACV based vaccines

Trefry S et al mSphere 2024 (in press)

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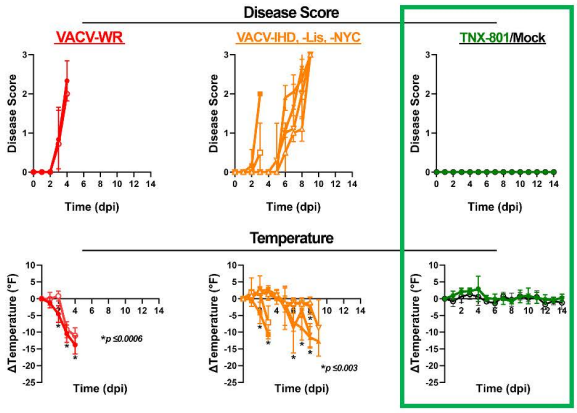
TNX-801 CHARACTERIZATION IN IMMUNOCOMPROMISED MOUSE MODEL
C57BL/6 *Ifnar* $^{-/-}$/*Ifngr* $^{-/-}$



TNX-801 infection did not produce any clinical disease

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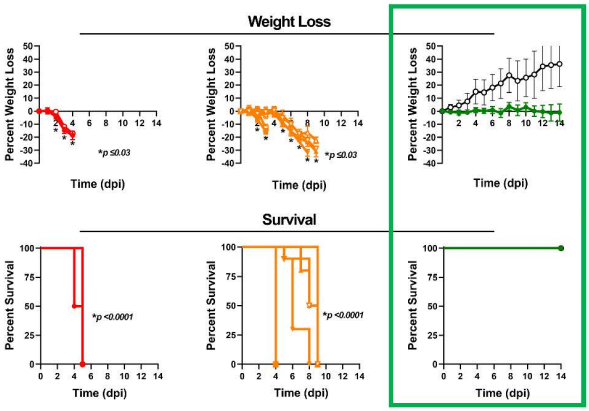

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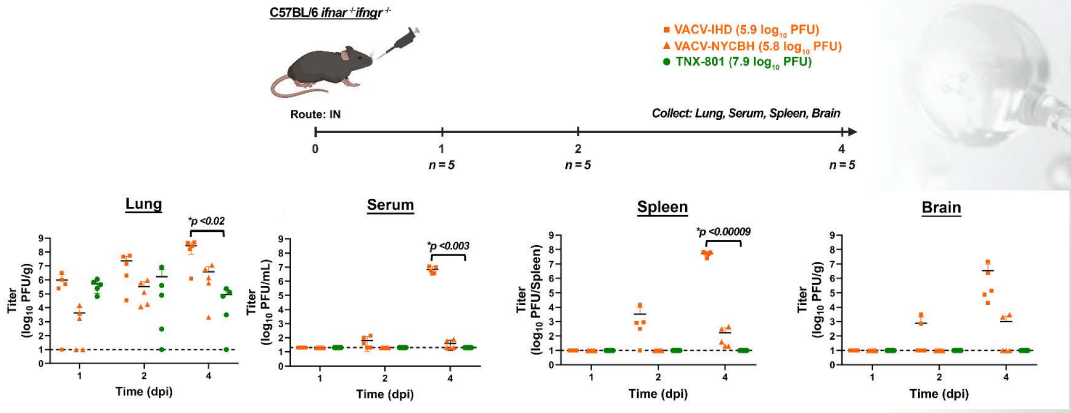
TNX-801 AT 100-FOLD HIGHER DOSE IS UNABLE TO CAUSE DISSEMINATED INFECTION



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PREFERRED WHO SITE LOCATION PHASE 1: AFRICA

Meeting summary: Vaccine Gaps Panel Discussion

- **effectiveness** studies, modifiers: HIV, malnutrition, other infections; Data on post-exposure efficacy. Fractional dosing, single dose efficacy. Clade-specific data
- Collection of real world **safety** data via active surveillance, using standardized definitions.
- Data to support vaccine use in **special populations** esp. where data aren't yet available e.g., peds, IC, pregnancy. Correlates of protection data to support other decisions
- Strategies: randomized deployment (e.g., 1 vs 2 doses, IM vs ID), test negative, vaccination registries to do appropriate follow-up, ring vaccination immediate vs. delayed., immunobridging
- Implementation:
  - Phase I studies should be done in Africa.
  - Use existing platforms & consortia.
  - Need for coordinated large studies, not lots of small studies (Africa is the only place to study multiple clades).

AfricaCDC Centre for Disease Control · CEPI · NIH National Institute of Allergy and Infectious Diseases · World Health Organization

A coordinated research roadmap - Mpox virus: Immediate research next steps to contribute to control the outbreak Aug 29-30 2024 WHO/CEPI/NIH/Africa CDC

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Agreement with KEMRI in Process to Jointly Develop Early-Stage Clinical Trials for TNX-801 in Kenya

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