TONIX PHARMACEUTICALS

TNX-801 & TNX-1850
Vaccine Platform

NASDAQ: TNXP

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INFECTIOUS DISEASE: KEY CANDIDATES

Live Virus Vaccines: Development Rationale

- **Control of smallpox, measles, mumps, rubella, chickenpox and other viral conditions**
  - Prevent forward transmission
- **Effective in eliciting durable or long-term immunity**
- **Economical to manufacture at scale**
  - Low dose because replication amplifies dose *in vivo*
  - Single shot administration
- **Standard refrigeration required for shipping and storage**
- **Live virus vaccines are the oldest vaccine technology**
  - Starting with Edward Jenner's smallpox vaccine, the first vaccine, eradicated smallpox

TNX-801: Smallpox and Monkeypox Vaccine
Live Virus Platform Development Program

APPLICATION OF LIVE VIRUS PLATFORM

- TNX-801 is a cloned version of horsepox[1] (without any insert) purified from cell culture
- In addition to being a potential addition to the U.S. Strategic National Stockpile, TNX-801 will support recognition of the RPV/horsepox platform

ANIMAL TESTING OF TNX-801 WITH SOUTHERN RESEARCH INSTITUTE

- Non-human primate monkeypox challenge testing: positive data reported in 1Q 2020[2]

DEVELOPED IN COLLABORATION WITH UNIVERSITY OF ALBERTA

- Proprietary synthetic biology approach and vector system

Patents Filed

DEVELOPMENT PROGRAM

Market Entry: Smallpox and Monkeypox Vaccine

Status: Preclinical, Pre-IND

Next Steps: Developing GMP manufacturing for TNX-801; Initiate Phase 1 Trial, 1H 2023 in Keyna

*TNX-801 is in the pre-IND stage of development and has not been approved for any indication.

[1]Noyce RS, et al. Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments. PLoS One. 2018 Jan 19;13(1):e0188453.
[2]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)

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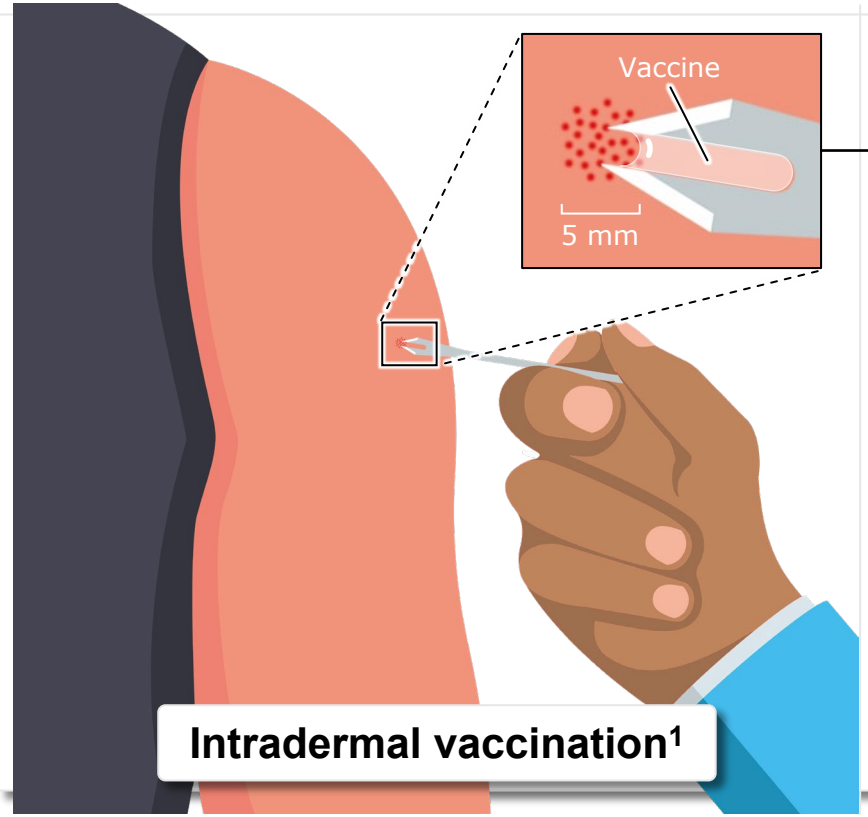
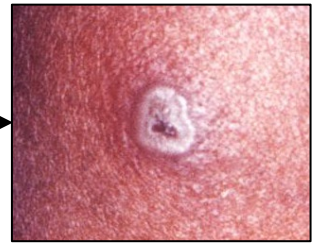
Vaccinia and Horsepox Induce a Skin Reaction Called a "Take" Described by Dr. Edward Jenner





Take[2]

- **Biomarker of protection**
  - Smallpox was eradicated using this marker
  - Revaccination indicated for recipients without "take"
- **Measure of T cell immunity**
  - No need for blood draws or complex laboratory studies
  - No other functional T cell assay is approved or in clinical use for vaccination

*Example of major cutaneous reaction, or "take," resulting from a replication-competent live-virus vaccine with intradermal delivery, indicating successful vaccination[1,2]

[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

Live Virus Recombinant Pox Vaccine (RPV)
Platform Profile

POTENTIALLY LONGER DURABILITY DUE TO POX-ENGINEERED ARCHITECTURE

- Live virus vaccines present unique “danger signals” resulting in strong immune response

PROGRAMMABLE VECTOR DESIGN FOR USE IN DIFFERENT DISEASE MODELS

- Large capacity for expressing inserted genes
- Wide range of clinical applications: pandemic, biodefense, infectious disease, smallpox, oncology

VIRUS-BASED SCIENCE IS WELL ESTABLISHED

- Streamlined development
- Ability to vertically integrate development and manufacturing
- Multi-dose packaging, standard cold-chain products

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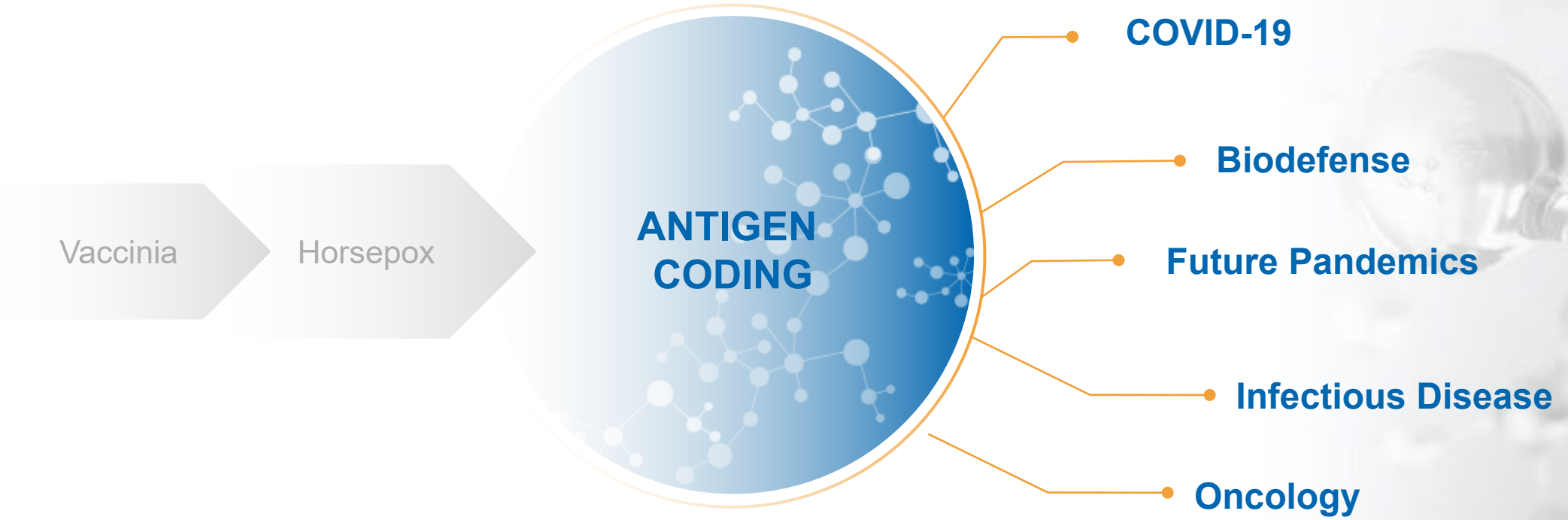
Live Virus Vaccine Platform: Recombinant Pox Vaccine (RPV)
Technology for Emerging Infectious Diseases and Oncolytics



RPV VECTOR BELIEVED SIMILAR TO EDWARD JENNER'S VACCINE[1-3]

Using Proven Science To Address Challenging Disease States, We Have Created A Programmable Technology Platform Aimed At Combating Future Threats To Public Health

INFECTIOUS DISEASE PORTFOLIO

[1]Shrick, L. N Engl J Med 2017; 377:1491-1492. DOI: 10.1056/NEJMc1707600
[2]Esparza, J. Vaccine. 2020 Jun 19; 38(30): 4773–4779. doi: 10.1016/j.vaccine.2020.05.037
[3]Brinkmann, A. Genome Biol. 2020; 21: 286. doi: 10.1186/s13059-020-02202-0

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COVID-19: Entering Endemic Phase in the US

- **Delta and Omicron variant waves are waning in most parts of the US**
  - Leaving a path of morbidity and mortality, including “breakthrough” infection and disease among vaccinated and convalescent

- **U.S. states are rolling back state pandemic restrictions**
  - CDC continues mask recommendation and recently increased the frequency of booster recommendations to every 3 months for individuals with weak immunity[1]
  - California plans to treat COVID as endemic by June, 2022[2]

- **Vaccines: new focus on SARS-CoV-2 variants Omicron and BA.2[3]**
  - Omicron has out-competed the original Wuhan strain, which has become rare
  - Omicron substantially evades *antibody immunity* to earlier variants, but is recognized by *T cell immunity* to earlier variants from vaccination or prior COVID[4]
  - Next generation vaccines are focusing on Omicron and its potential successor, BA.2

[1]Achenbach, J. “Americans are tired of the pandemic. But disease experts preach caution - and endure a ‘kill the messenger moment’. *Washington Post* Feb 17, 2022. (www.washingtonpost.com/health/2022/02/17/mask-mandates-opposition/)
[2]Beachum L and Suliman A, “California unveils plan to become first state to treat coronavirus as ‘endemic’ risk.” *Washington Post* Feb 18, 2022. (www.washingtonpost.com/nation/2022/02/18/california-covid-newsom-endemic-smarter-plan/)
[3]Bernstein L. “There’s a new version of omicron but so far it doesn’t appear to be more dangerous.” *Washington Post* Jan 24, 2022 (www.washingtonpost.com/health/2022/01/24/covid-omicron-ba2/)
[4] Keeton R et al., “T cell responses to SARS-CoV02 spike cross-recognize omicron.” *Nature Jan 31, 2022*. (www.nature.com/articles/s41586-022-04460-3)

COVID-19: The Missing Pieces

- **Vaccines: early vaccines slowed pandemic, but are showing limitations**
  - Short term protection – requirement for boosters with mRNA vaccines;
  - Increasing focus on preventing hospitalization and death

- **Anti-viral drugs: Veklury® (remdesivir), Paxlovid™ (nirmatrelvir[1]), and Lagevrio® (molnupiravir) are available**
  - Pfizer's Paxlovid looks promising; Merck's Lagevrio did not show benefit in 2nd cohort[2]

- **Anti-SARS-CoV-2 monoclonal antibodies: increasing adoption; concern about variants**
  - Of the original EUA mAbs, only Vir/GSK's XEVURDY® (sotrovimab) was considered active against the omicron variant of SARS-CoV-2 but is not considered active against BA.2 and is not longer distributed in 8 US states[3]
  - Lilly's bebtelovimab, active against omicron, recently received EUA for treatment of mild or moderate COVID[4]
- **Tests: unmet need to determine COVID immunity[3]**
- **Long COVID: no approved treatment for 'Long Covid'**

[1]PAXLOVID™ (nirmatrelvir plus ritonavir)
[2]Merck Says Its Covid Pill Is Less Effective in a Final Analysis - The New York Times (nytimes.com)
[3]Brennan, Z. *Endpoints*, March 28, 2022 US halts use of GSK/Vir monoclonal in 8 states as FDA says it can't defeat new Omicron subvariant. endpts.com/us-halts-use-of-gsk-vir-monoclonal-in-8-states-as-fda-says-it-cant-defeat-new-omicron-subvariant/
[4]Redfield R and Siegel S. "A test to determine COVID immunity could reshape US policy." The Hill. Feb 17, 2022: (https://thehill.com/opinion/healthcare/594522-a-test-to-determine-covid-immunity-could-reshape-us-policy?)

COVID-19 Vaccines: Where We Are Today

Durability of protection

- mRNA vaccinated people lose protection, starting at 4-6 months[1]
- High rates of “breakthrough” COVID during Delta and Omicron waves
- Booster vaccinations with mRNA vaccines recommended at 4-6 months

Effect on forward transmission (spread of infection to others)

- Concerns about whether vaccinated people can be infectious to others

Detecting vaccine failure

- Need a strategy for identifying individuals at risk after vaccination

No recognized, clinical applicable biomarker of vaccine protection

- Best proxy is neutralizing antibodies, which are hard to measure

Current and future variants (e.g., Delta, Omicron variants)

- Less protection from existing vaccines
- Unknown effectiveness for future variants

[1]www.cdc.gov/media/releases/2021/s0818-covid-19-booster-shots.html

COVID-19 Vaccines: Where Do We Go From Here?

mRNA vaccines have slowed pandemic, but may not be a long-term solution

- Vaccinated people lost protection and showed high rates of “breakthrough” COVID during Delta and Omicron waves
- COVID is becoming endemic in the US; vaccination of entire world every 6 months not practical

Operation Warp Speed (OWS) identified 4 types of vaccines:

1. RNA/DNA – Pfizer[1] and Moderna[2] are fully approved by the FDA
2. Subunit – NovaVax submitted EUA; Sanofi/GSK have announced data showing protection from hospitalization and death
3. Non-replicating – J&J has EUA; AstraZeneca widely used ex-US
4. Live Virus Vaccines – none were ultimately adopted by OWS

Live Virus Vaccines

- Merck was developing two programs: VSV and Measles, but they were not included in OWS and were abandoned in January 2021[3]

[1]COMIRNATY is the brand name for the Pfizer-BioNTech COVID-19 vaccine
[2]https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine
[3]https://www.merck.com/news/merck-discontinues-development-of-sars-cov-2-covid-19-vaccine-candidates-continues-development-of-two-investigational-therapeutic-candidates/

TNX-1850*: COVID-19 Vaccine
Live Virus Platform Development Program

APPLICATION OF LIVE VIRUS PLATFORM

- First version TNX-1800 encodes spike protein from SARS-CoV-2, Wuhan strain
- Planned new version TNX-1850 encodes spike protein from SARS-CoV-2 BA.2 strain[1]

ANIMAL TESTING OF TNX-1800 WITH SOUTHERN RESEARCH INSTITUTE

- Non-human primate immune response: positive results reported in 4Q 2020
- Non-human primate CoV-2 challenge testing: positive data reported in 1Q 2021

DEVELOPED IN COLLABORATION WITH UNIVERSITY OF ALBERTA

- Proprietary synthetic biology approach and vector system

Patents Filed

DEVELOPMENT PROGRAM

Market Entry: COVID-19 Vaccine

Additional Indications: Future Pandemic, Infectious Disease, Smallpox, Cancer

Status: Preclinical

Next Steps: Developing TNX-1850 (BA.2) version; initiate Phase 1 Trial, 2H 2023

*TNX-1850 is in the pre-IND stage of development and has not been approved for any indication.

[1]Brennan, Z. *Endpoints* March 2, 2022 (https://endpts.com/weaker-omicron-variant-is-great-news-for-the-world-but-bad-news-for-covid-related-clinical-trials/)

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Live Virus Platform: What Makes TNX-1850 Different from mRNA Vaccines

CRITERIA	mRNA VACCINES	TNX-1850
Number of shots	Two	One
Duration	6 months	Years / decades
Boosters	Recommended	Likely not required
Protection from variants	Decreased	Expected
Forward transmission	Unknown for variants	Likely prevents
Biomarker	None	Yes – “Take”
Manufacturing	Complex	Conventional
Glass-sparing packaging	No	Yes
Shipping and storage	Cold chain	Standard refrigeration
Protection from smallpox	No	Yes

** Characterizations of TNX-1850 shown in table represent expectations.*

Live Virus RPV Platform & COVID-19 Vaccine
Internal Development & Manufacturing Capabilities

Infectious Disease R&D Center (RDC) – Frederick, MD

- Function: Accelerated development of vaccines and antiviral drugs against COVID-19, its variants and other infectious diseases
- Description: ~48,000 square feet; BSL-2 with some areas designated BSL-3
- Status: Operational; acquisition completed on October 1st, 2021

Advanced Development Center (ADC) – North Dartmouth, MA

- Function: Development and clinical scale manufacturing of live-virus vaccines to support Phase 1 and Phase 2 trials
- Description: ~45,000 square feet, BSL-2
- Status: Partially operational as of 2Q 2022

Commercial Manufacturing Center (CMC) – Hamilton, MT

- Function: Phase 3 and Commercial scale manufacturing of live-virus vaccines
- Description: ~44 acre green field site, planned BSL-2
- Status: Planning for site enabling work in 2022

Architectural Rendering

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American Pandemic Preparedness Plan (AP3)

- **"Platforms" – Foundation of Pandemic Response**
  - Key element of AP3 from White House Office of Science and Technology Policy or OSTP[1,2]
    - 100 days to human trials
    - Technologies that do not require sterile injection

- **TNX-801/TNX-1850 (live virus RPV) platform addresses OSTP requirements[1,2]**
  - Our goal is to be able to test new live virus vaccines against novel pathogens within the 100 days of obtaining sequence
    - RDC is equipped to make new vaccines
    - ADC will be equipped to make clinical trial material
    - CMC is planned to make commercial scale material

[1] Sept 3, 2021 (https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf)
[2] Sept 3, 2021 (https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/)

THANK YOU