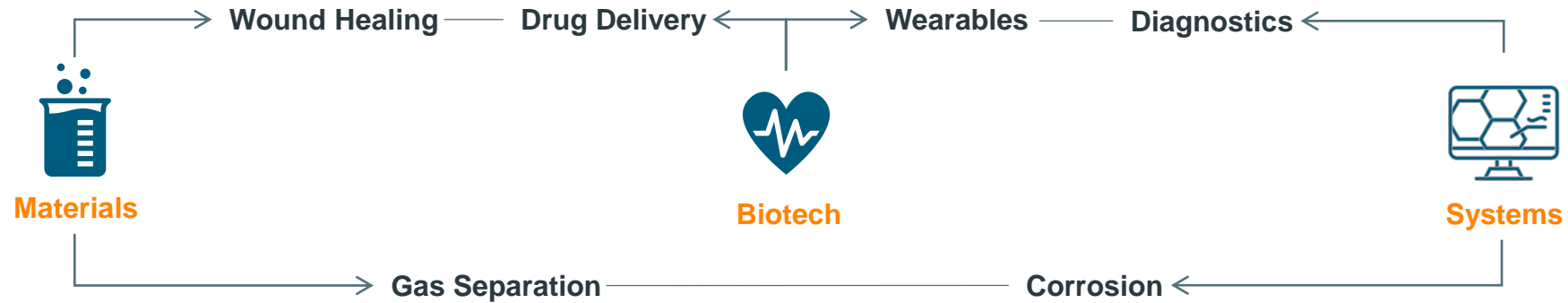


# NanoVac

A Revolutionary Nanotechnology Platform -  
Engineered to Optimize Delivery of Proteins and  
Nucleic-Acid Based Vaccines & Therapeutics

# Luna Labs: A high-throughput innovation engine for hard tech startups



## Who We Are

- A diverse team of 100 scientists, engineers, and business professionals
- 80+ US and international patents and applications in 25+ patent families
- Successful product launches in multiple verticals

## What We Do

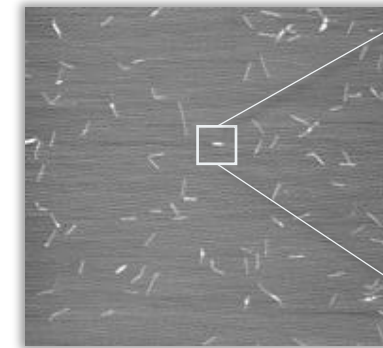
- Leverage more than \$20M/year in non-dilutive contract funding
- De-risk market relevant technologies for subsequent investment to make them market ready
- Increase the productivity of the mission-driven to save time, save money, and save lives

# NanoVac is a Biomimetic Platform Designed to Optimize Delivery of Nucleic-Acid Based Therapies and/or Proteins

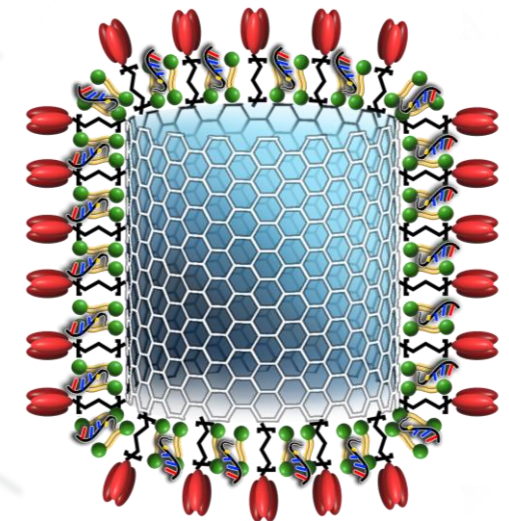
**The platform can be specifically bioengineered for multiple clinical applications including oncology, neurodegenerative disease, cardiology, infectious disease and vaccination**

*US7758889 "Fullerenes in targeted therapies"  
App. No. 63/429,769; 12/2022  
"Surface modified carbon nanotubes and uses thereof"*

- Enhances cellular uptake of mRNA
- Can be engineered to stimulate or avoid specific immunogenic responses
- Intranasal application efficacy demonstrated preclinically and provides IM injection alternative
- Enables cold-storage flexibility and potentially eliminates need for -80°C shelf-life checkpoints
- Can be bioengineered to target multiple cellular engagement points simultaneously
- Ready to scale rapidly and cost effectively



500 nm



## NanoVac Can Simultaneously Deliver Diverse and Multiple Payloads

Successful demonstration of conjugation and delivery of mRNA, DNA, peptides and proteins

mRNA	Protein / Small Molecule	DNA
<ul style="list-style-type: none"><li>• V1V2 encoding mRNA</li><li>• eGFP encoding mRNA</li></ul>	<ul style="list-style-type: none"><li>• V1V2</li><li>• HIV Trimer</li><li>• Luciferase</li><li>• BSA</li><li>• Catalase</li><li>• KLH</li></ul>	<ul style="list-style-type: none"><li>• ssDNA</li><li>• Plasmid</li></ul>
717 – 783 NT (221-280 kDa)	21 kDa – 4 MDa	10NT – 6879bp
70 – 100% loading efficiency	60 – 99% loading efficiency	75 – 100%
37 – 236 per vehicle	1 – 470 per vehicle	4 – 526 per vehicle

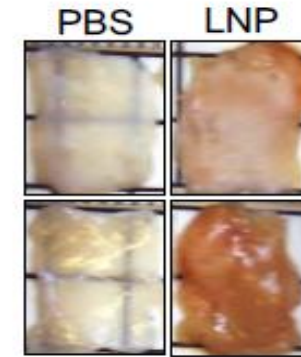
# The Problem: The Lipid Nanoparticle Delivery Platform Poses Serious Challenges Not Yet Resolved for mRNA Based Therapeutics

**Inflammatory Reaction to Lipid Nanoparticles**

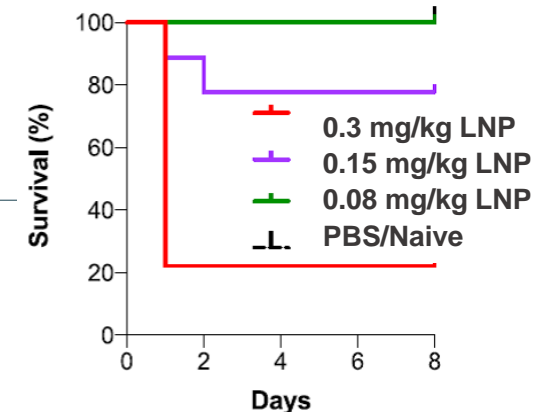
**Narrow Specifications for Cold Storage Conditions**

**Lack of Compatibility with Some Administration Methods**

**Can be Toxic via Intranasal Administration (0.3mg/kg)**



Administration of LNPs induces robust and visible inflammation in lung tissue as compared to phosphate buffered saline (PBS)



At even moderate doses in rats, deaths were observed

*Ndeupen et al., iScience 24, 2021*

# The Solution: Develop a Therapeutic Delivery Platform Which Addresses Current Challenges Posed by LNPs

## Inflammatory Reaction to Lipid Nanoparticles

NanoVac design allows a reduction of the lipid to mRNA ratio from 20:1 to 1:1

## Narrow Specifications for Cold Storage Conditions

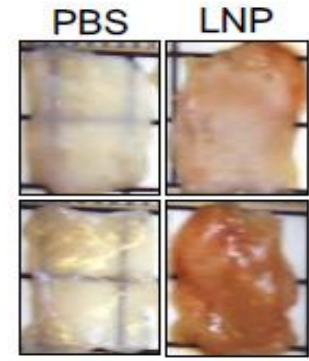
NanoVac imparts greater stability on immobilized molecules and shows less degradation when compared to mRNA alone

## Lack of Compatibility with Some Administration Methods

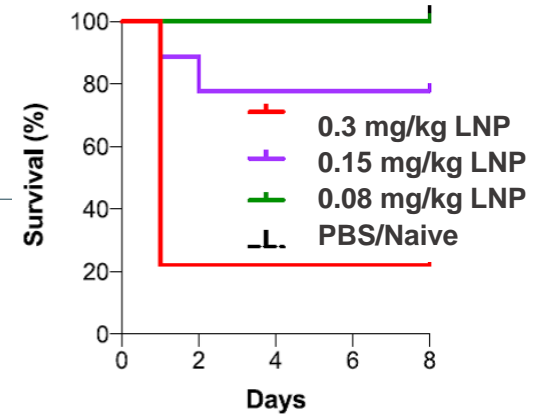
NanoVac has demonstrated feasibility for intranasal administration

## Can be Toxic at Low Doses via Intranasal (0.3mg/kg)

NanoVac has demonstrated no adverse effects at up to 20 mg/kg



Administration of LNPs induces robust and visible inflammation in lung tissue as compared to phosphate buffered saline (PBS)



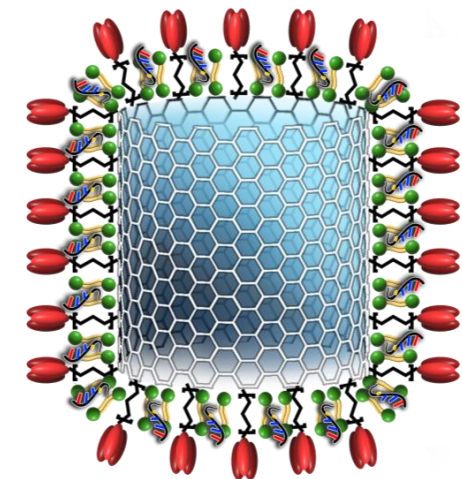
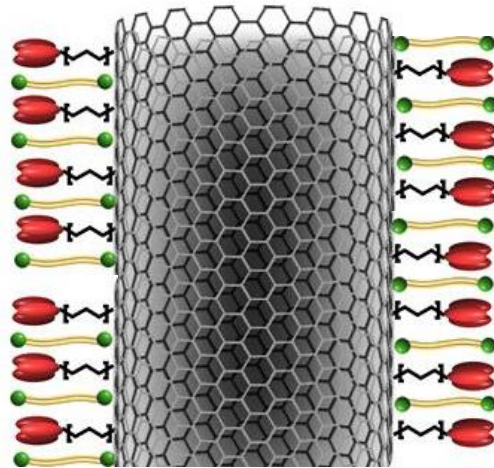
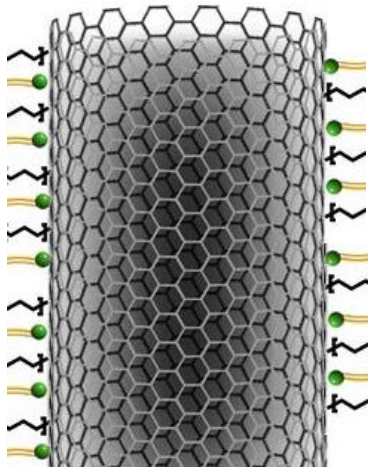
At even moderate doses in rats, deaths were observed

Ndeupen et al., iScience 24, 2021



# NanoVac is a Therapeutic Delivery Platform with Agnostic Potential in Surface Chemistry Modification

## Example 1: Target a challenging virus like HIV-1 using an mRNA and protein engagement model



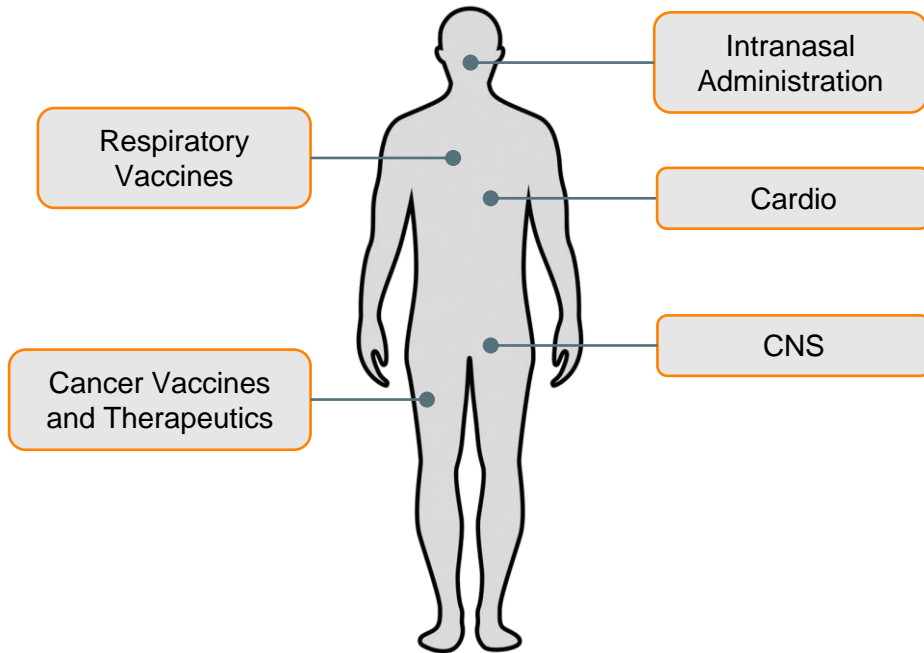
- **NanoVac Vehicle**
- Mimics virus size
- Biodegradable
- Supports biocompatibility and circulation

- **NanoVac Vaccine**
- Can be immobilized with proteins, mRNA, or both
- Allows control of antigen density and epitope presentation

- **NanoVac V1V2**
- Current development for HIV-1 vaccination
- Both mRNA and V1V2 protein subunits delivered

# Potential for NanoVac to be Integrated for a Wide Range of Therapeutic Targets

NanoVac is a Breakthrough mRNA and/or Protein Delivery Platform



## Potential Markets

### Respiratory Vaccines, Mucosal Delivery, Cancer Therapeutics

**\$570M** global HIV Vaccines market by 2027

**\$128B** mRNA product market size by 2030, growing at 13% CAGR

**180+** mRNA-based pipeline agents, 80% in preclinical stage

**\$47B** mRNA cancer vaccine and therapeutic market

**45** mRNA cancer vaccine or therapeutic targets in pre-clinical R&D stage

Sources: Precedence Research, Verified Market Research, Vantage Market Research

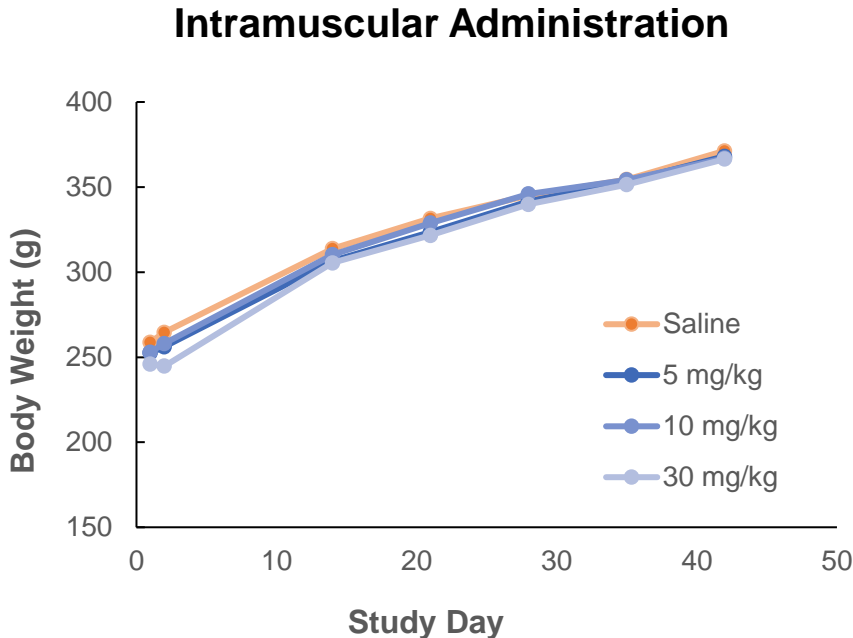
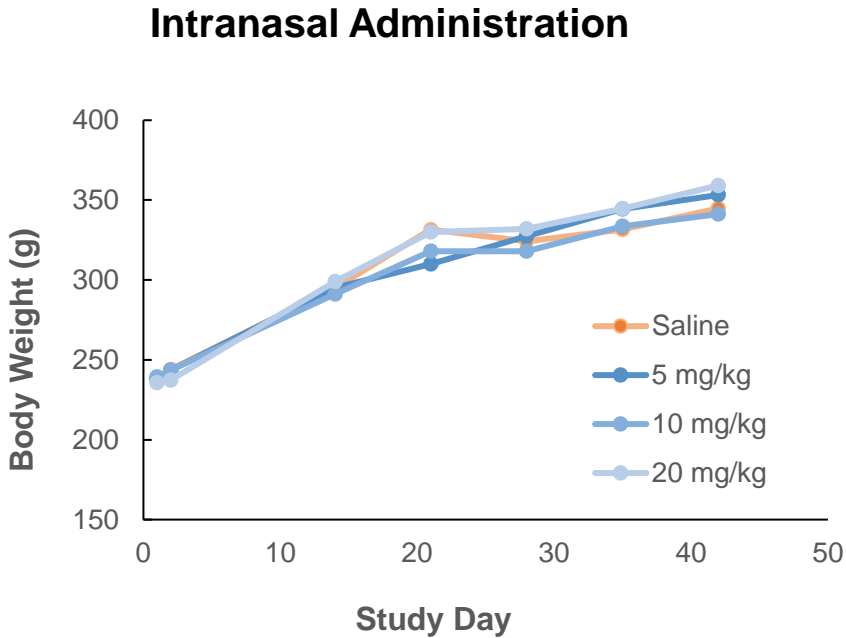
**“The battle really is about [which company] is going to be, in the future, the go-to source that other companies may have to license from.”**

– Ameet Sarpatwari, Pharma Policy & Law, Harvard University, discussing mRNA intellectual property space



# The NanoVac Vehicle is Well-Tolerated Following Both Intranasal and Intramuscular Administration in Rats

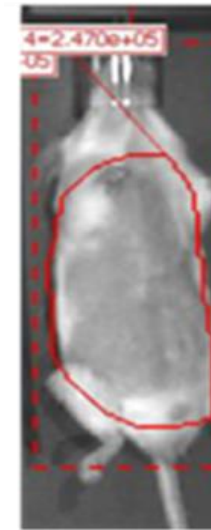
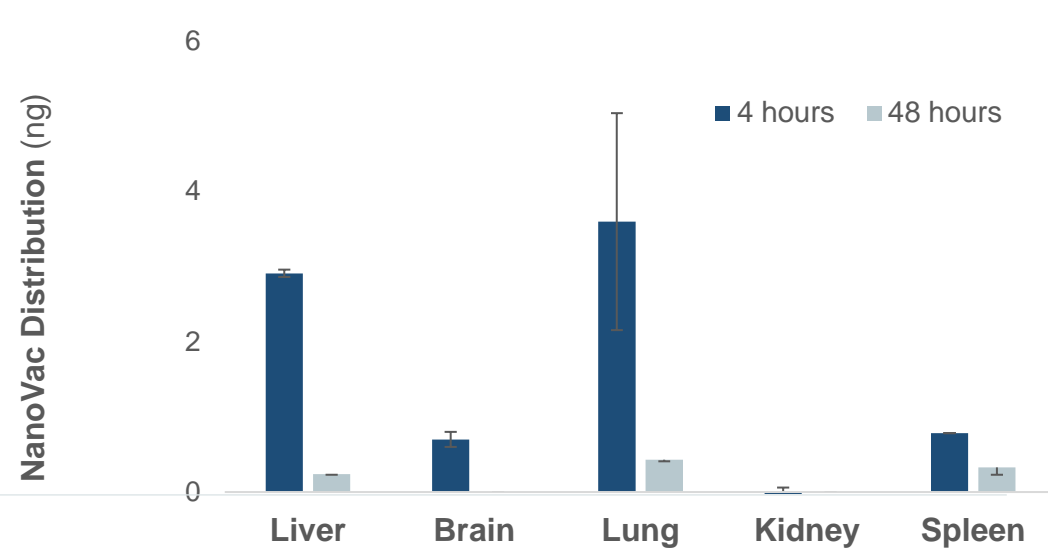
**No adverse effects observed in body weight, organ weight, hematology (Retic), or biochemistry (BUN)**



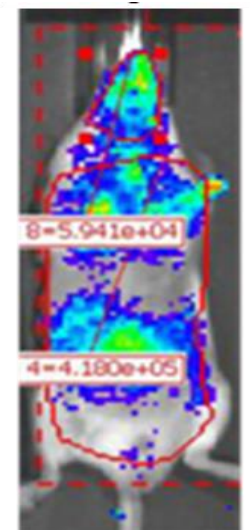
**The NanoVac Vehicle causes no adverse effects at up to 30 mg/kg dosing**

# The NanoVac Vehicle is Safely and Rapidly Cleared Within 48 Hours in a Preclinical Model

## Biodistribution studies using LcL-labeled NanoVac vehicle demonstrate rapid tissue clearance



NanoVac Background

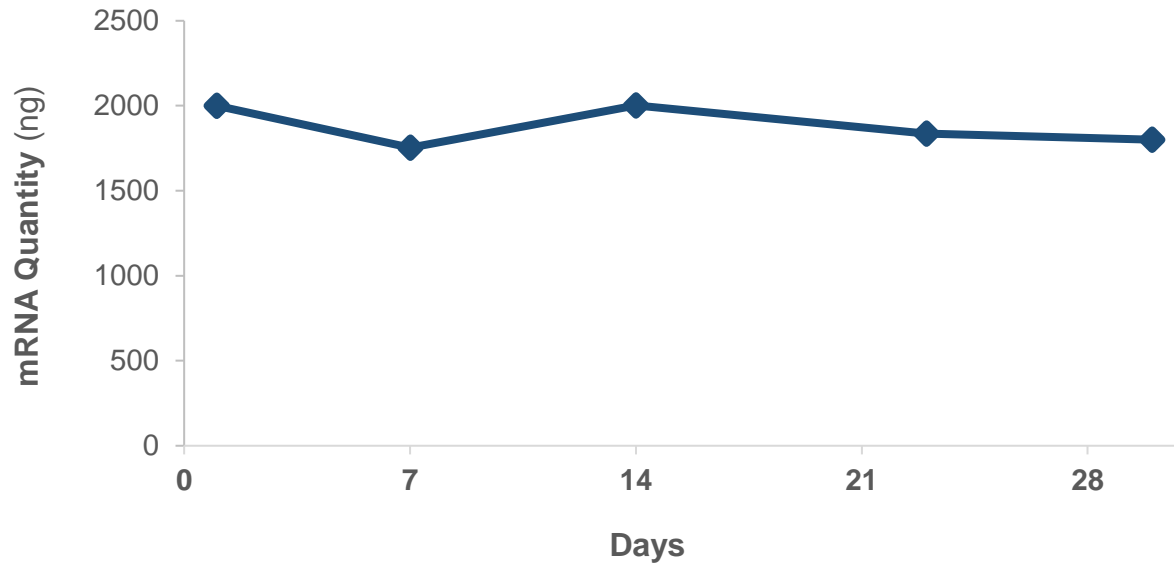


Post-IN dose Distribution

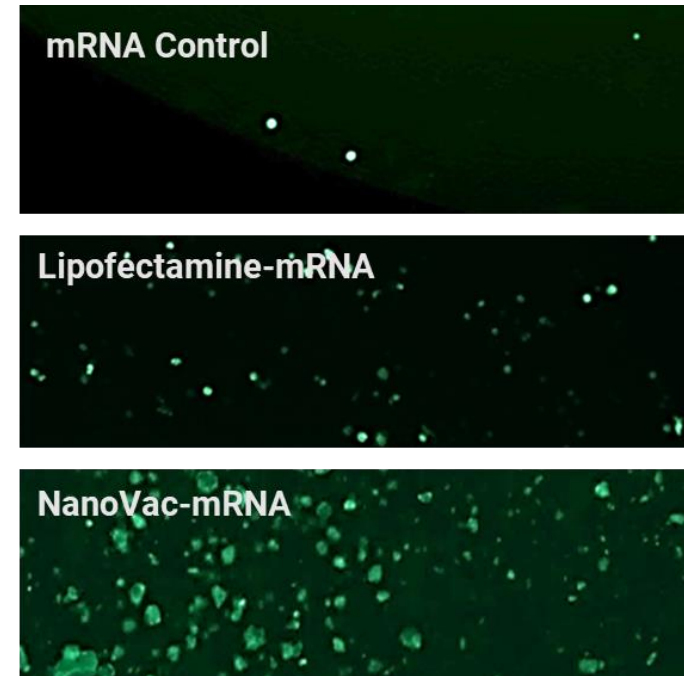
- **Clearance from organs was rapid**
  - NanoVac Vehicle was broadly distributed throughout tissue
  - Observed clearance from organs within 48 hours
- **Limited adverse effects were observed**
  - Minor inflammation at site of administration and local sequestration consistent with tissue response

# The NanoVac Vaccine Platform Stabilizes mRNA and Enhances Translation as compared to standards

**mRNA remains stable with NanoVac over a 30 day period under refrigeration, and demonstrates significantly enhanced transfection and mRNA translation in THP-1 cells**



**mRNA immobilized on the NanoVac Vehicle was stable and undegraded over 30 days of refrigerated (4 °C) storage. This enables flexibility and options for cold chain transport and penetration into diverse markets where certamost.**



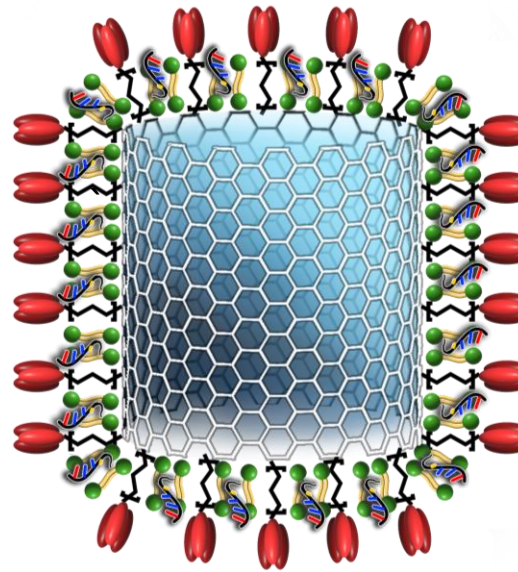
**Cellular transfection studies show enhanced cell uptake with NanoVac platform delivery.**

## NanoVac V1V2 is Being Implemented in HIV-1 Vaccination... and has the Potential for Many Other Indications

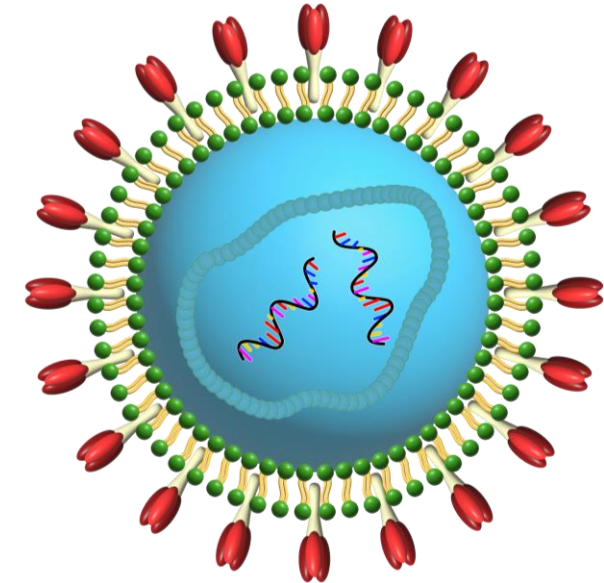
**Can be engineered to mimic size, shape, and antigen presentation of virion**

- Mimics HIV-1 virion size and density of its V1V2 antigen presentation
- Optimizes presentation of V1V2 antigens enhancing cellular uptake
- Stimulates systemic and long-term immune responses
- Produced in three variations: protein V1V2, mRNA V1V2, protein + mRNA

Y. Xu, C.K. Tison, T. Ferguson, et al. "Mucosal Delivery of HIV-1 Glycoprotein Vaccine Candidate Enabled by Short Carbon Nanotubes." Particle and Particle Systems Characterization. 2022.



**NV-V1V2 Designed to Mimic Virion Structure**



**HIV-1 Virion**

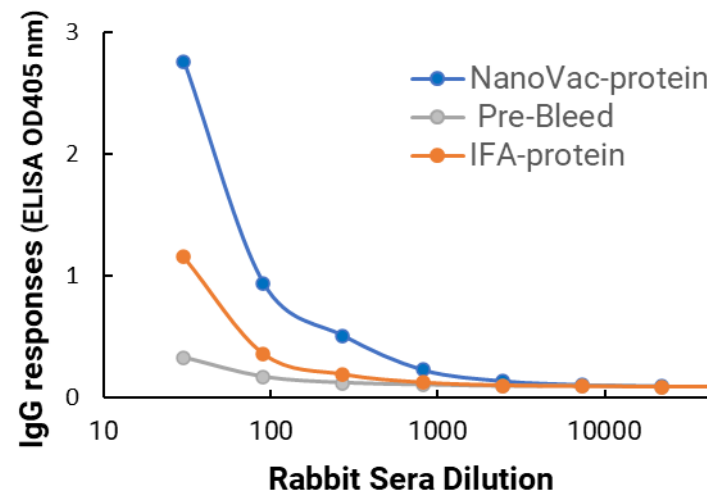


# NanoVac V1V2 Protein Vaccine Demonstrates an Enhanced and Accelerated Immune Response for both IM and IN Delivery

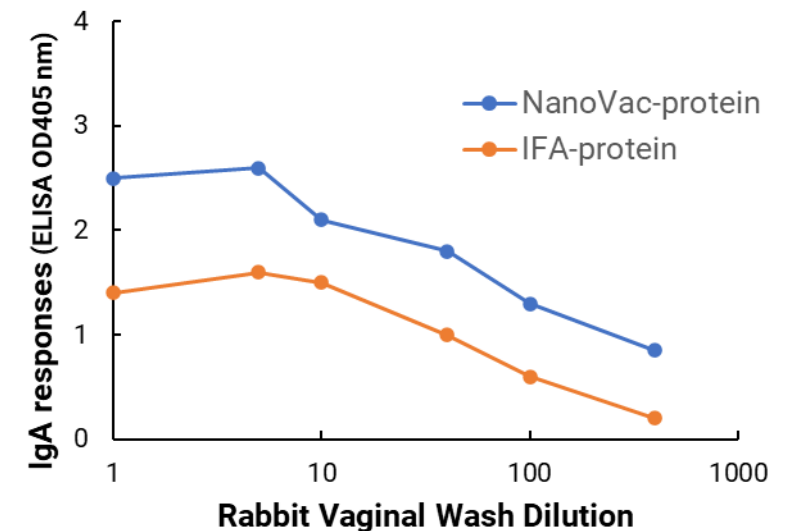
Compared to standard adjuvants, the protein-based NV-V1V2 resulted in accelerated and increased immune response via intramuscular (IM) and intranasal (IN) administration

- IM and IN administration of NanoVac accelerated the generation of an enhanced systemic immune response (IgG) after the second dose, **two weeks earlier** than the antigen with IFA
- NanoVac delivery **doubled the titer of mucosal antibody IgA** in vaginal washes as compared to V1V2 immunogen adjuvanted with IFA after IN administration

Intramuscular, IgG



Intranasal, IgA

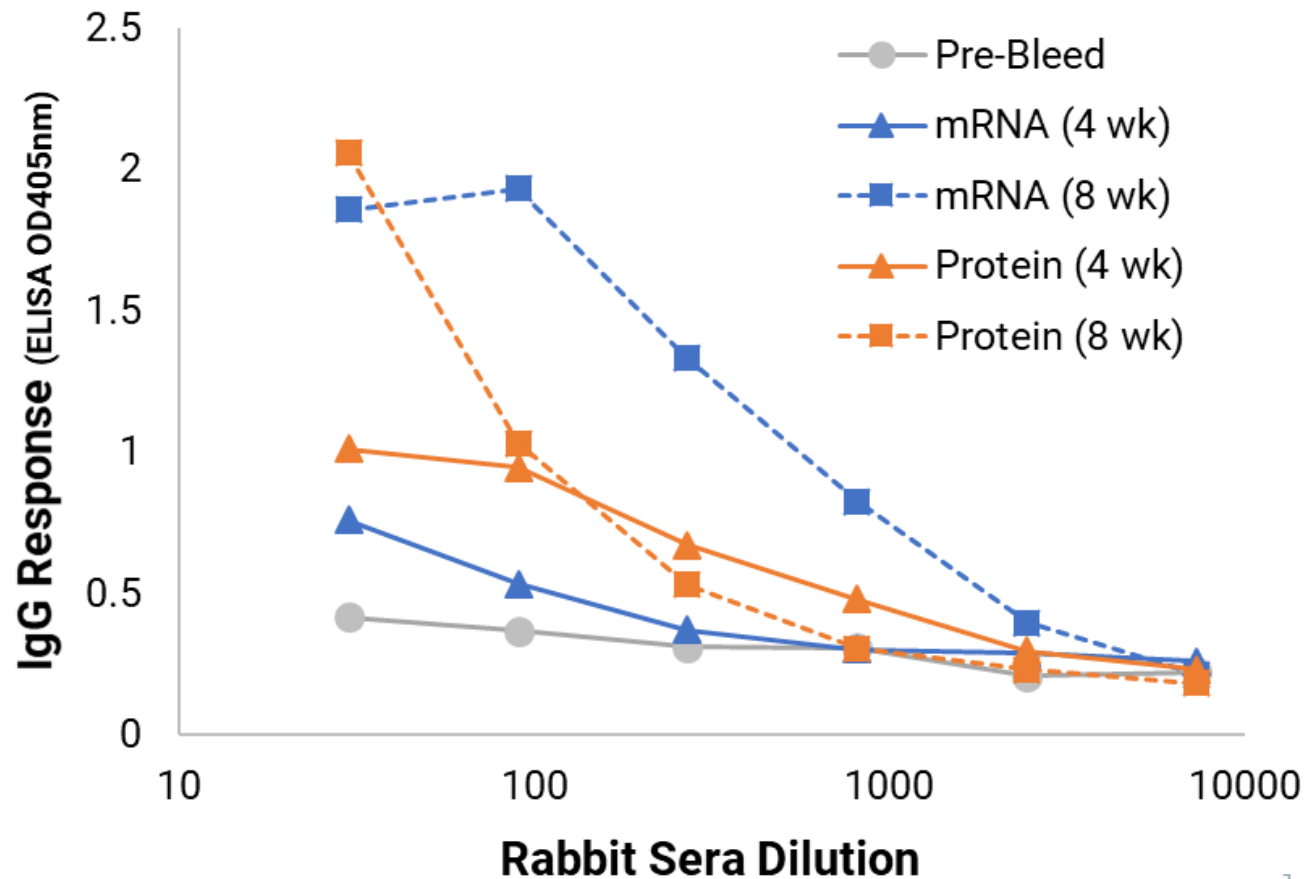




# NanoVac is a Successful Delivery Platform for both mRNA and Proteins in a Preclinical Rabbit Model of HIV-1

## Proof-of-concept data demonstrates feasibility for HIV-1 Vaccination and other mRNA-based therapeutics

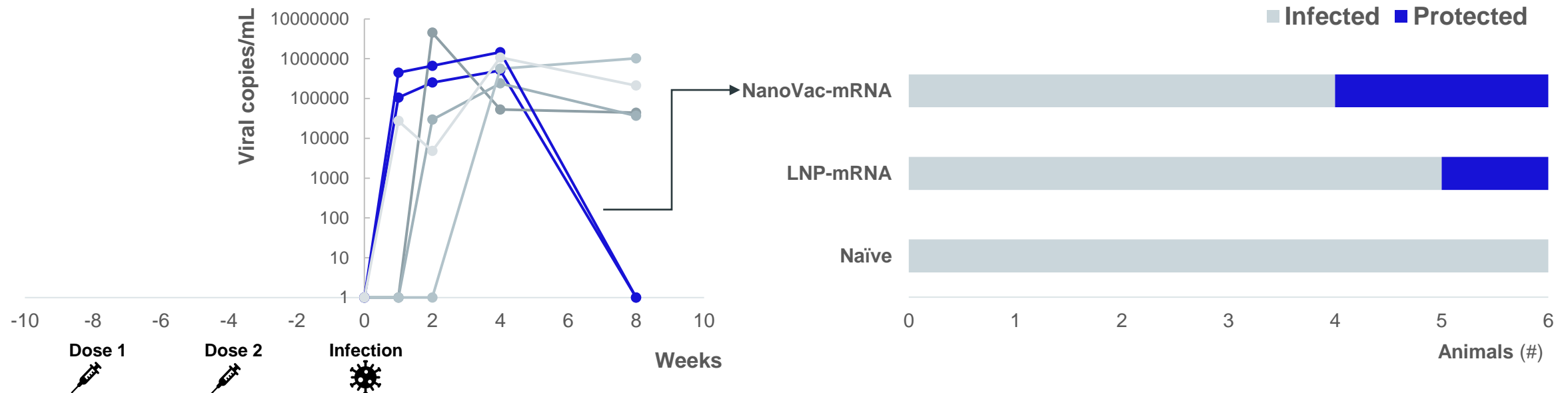
- NV-V1V2 utilizing glycoprotein presentation stimulates an earlier immune response (**orange**)
- NV-V1V2 using mRNA-based protein production shows enhancement and preservation of a longer lasting response (**blue**)



# NanoVac mRNA V1V2 was More Effective at Vaccinating against HIV-1 compared to standard Lipid NP-mRNA Delivery

In a humanized mouse model, 2 of 6 NV-V1V2 animals challenged with HIV-1 cleared infection vs. 1 of 6 of animals in the LNP control group

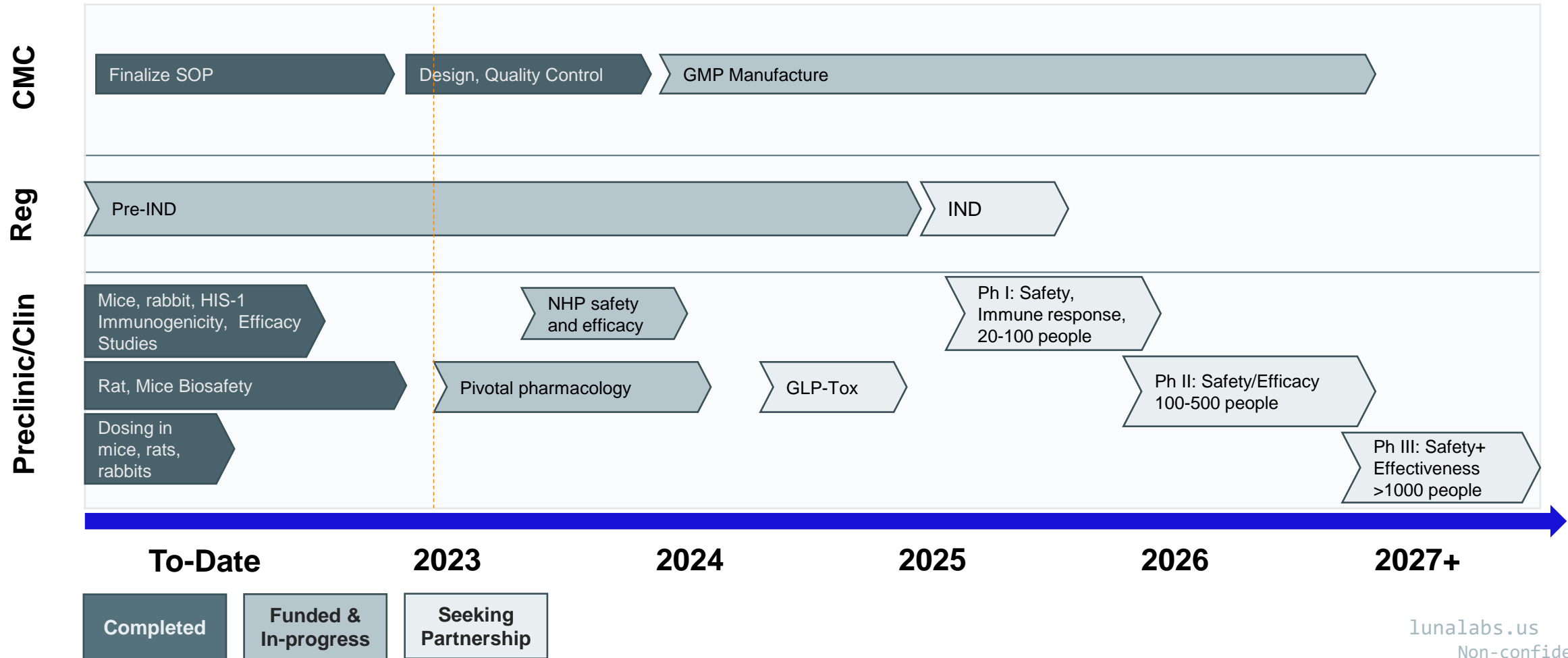
- Humanized mice were IM administered **NanoVac-mRNA** or **Lipid NP-mRNA**
- **33% protection rate** demonstrated with NanoVac-mRNA after clearance of viral load



# NanoVac Development Timeline & Activities

The NanoVac vehicle is ready for GMP manufacture, GLP-Tox, and transition to the clinic. Rapidly pivots to new vaccine or therapeutic targets

- US7758889 protection through 2027
- App. No. 63/429,769 "Surface modified carbon nanotubes and uses thereof" protection through ~ 2042



## NanoVac is Backed by an Experienced and Innovative Team



### **James Garrett, PhD, MBA – CEO**

- 20+ years in corporate guidance of product development
- PhD, Penn State University, Chemistry
- MBA, William & Mary



### **Tammy Ferguson, PhD – Immunology Lead, Luna Labs**

- 20+ years in immune-biology and molecular biology
- PhD, Virginia Commonwealth University, Biology



### **Chris Tison, PhD – Director of Biotechnology**

- 10+ years managing biotech R&D
- PhD, Georgia Tech, Materials Science & Engineering, Biomaterials



### **Moriya Tsuji, PhD, MD - Professor of Medicine at Columbia University**

- Aaron Diamond Aids Research Center
- 35+ years immunology, vaccinology and infectious diseases using HIS mouse models



### **Yang Xu, PhD – Principal Investigator and Pharma Team Lead**

- 15+ years managing vaccine development pipelines.
- PhD, Nanjing University, Chemistry



### **Xiangpeng Kong, PhD – Professor of Molecular Pharmacology at NYU**

- 30+ years in structural biology, structure-based immunogen design
- HIV/AIDS vaccine discovery, biophysics, and pharmacology

**Legal:** Sean Liu and Bryan Davidson, Nixon & Vanderhye  
**Regulatory:** NSF Health Sciences and NAMSA  
**Clinical:** Michigan State University and Charles River Labs



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