

NanoVac

A Revolutionary Vaccine and Therapeutic
Delivery Platform

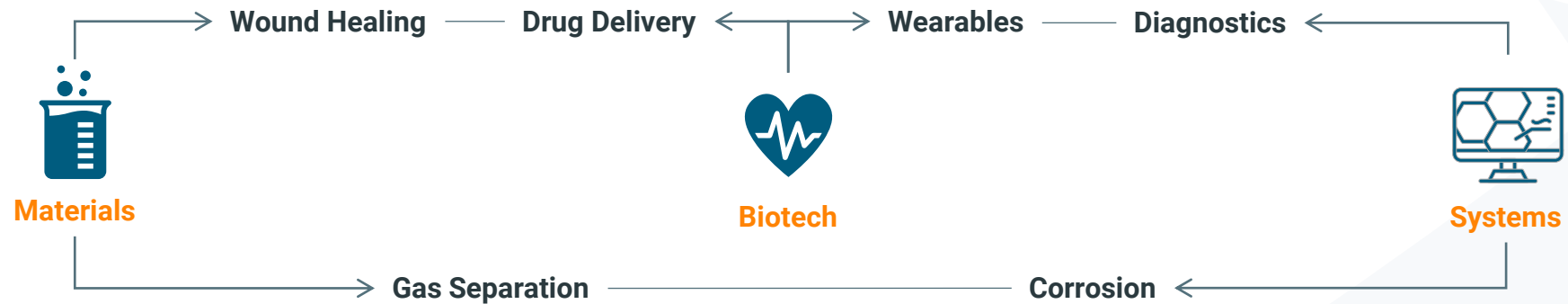
Non-confidential Deck

November 2023

2023 | lunalabs.us

Non-confidential

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

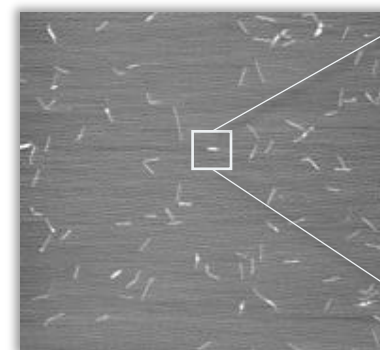
- Leverage more than \$20M/year in non-dilutive contract funding
- De-risk market relevant technologies for subsequent investment to make them market ready
- Increase the productivity of the mission-driven to save time, save money, and save lives

NanoVac is a biomimetic platform designed to optimize delivery of nucleic acids and/or proteins

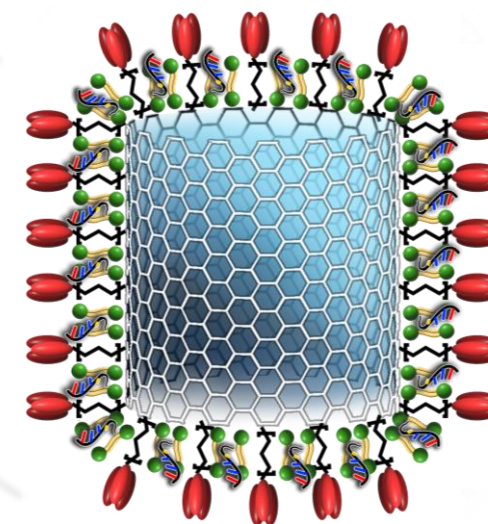
The platform can be specifically engineered for multiple clinical applications

- **Enhances cellular uptake**
- **Stimulates antibody production**
- **Intramuscular, subcutaneous, and intranasal**
- **Enables cold-storage flexibility**
- **Multiple payloads simultaneously**
- **Low-cost and designed to scale**

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



500 nm



NanoVac can deliver diverse and multiple payloads

Successful conjugation and delivery of multiple payloads across a broad size range

	RNA	Proteins / Peptides	DNA
Investigated	<ul style="list-style-type: none"> V1V2 encoding mRNA eGFP encoding mRNA GP140 encoding mRNA GFP saRNA 	<ul style="list-style-type: none"> V1V2 HIV Trimer Luciferase BSA Catalase KLH T-cell targeting small peptide 	<ul style="list-style-type: none"> ssDNA Plasmid dsDNA
Size	mRNA: 300 – 2100 NT (100-600 kDa) saRNA: 8600 NT	1100 Da – 4 MDa	10 NT – 7000 bp
Loading Efficiency	70 – 100%	60 – 99%	75 – 100%
Loading Density (per vehicle)	37 – 236	1 – 470	4 – 526

NanoVac is an innovative delivery platform with unique advantages

LNPs: Inflammatory Reaction to Lipid Nanoparticles

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

LNPs: Narrow Specifications for Cold Storage Conditions

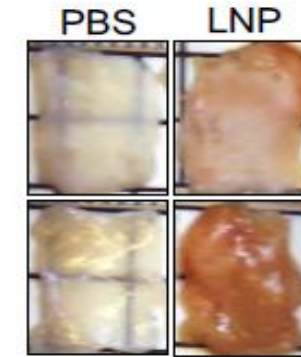
NanoVac imparts greater stability on immobilized antigens and shows less degradation when compared to mRNA alone

LNPs: Lacks Compatibility with Some Admin Methods

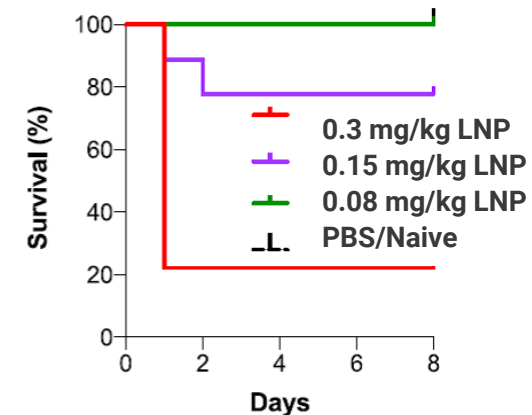
NanoVac has demonstrated feasibility for intranasal administration

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

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



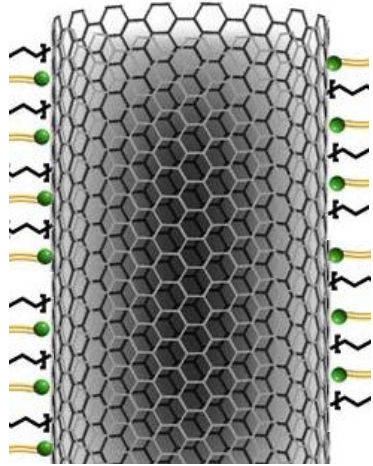
Administration of LNPs induces robust and visible inflammation in lung tissue as compared to phosphate buffered saline (PBS)



At even moderate doses in rats, deaths were observed

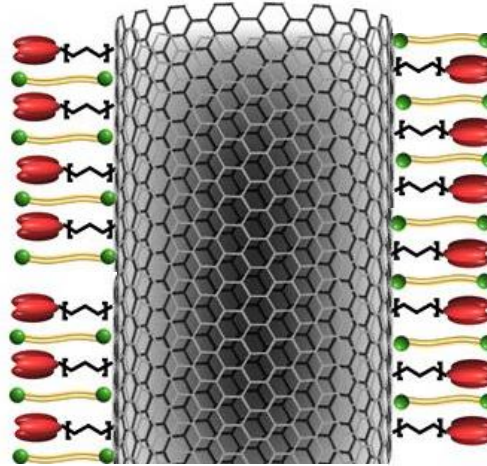
Ndeupen et al., iScience 24, 2021

NanoVac can be customized by delivery method or payload



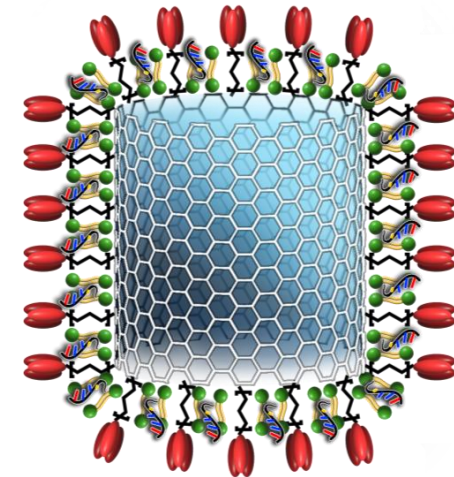
NanoVac Vehicle

- Mimics virus size
- Biodegradable
 - Supports biocompatibility and circulation



NanoVac Payload

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

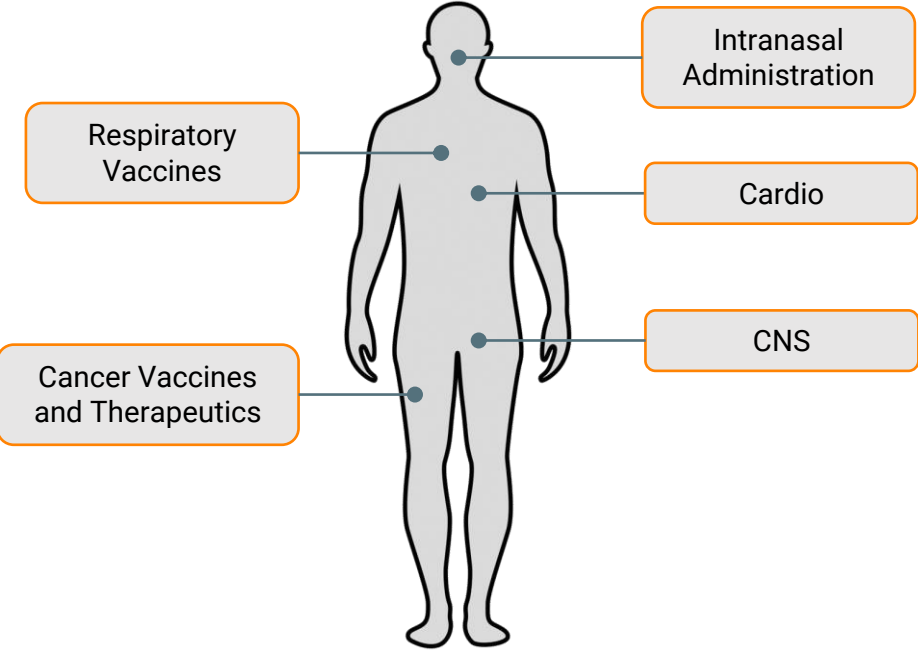


NanoVac V1V2

- 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 and infectious disease 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

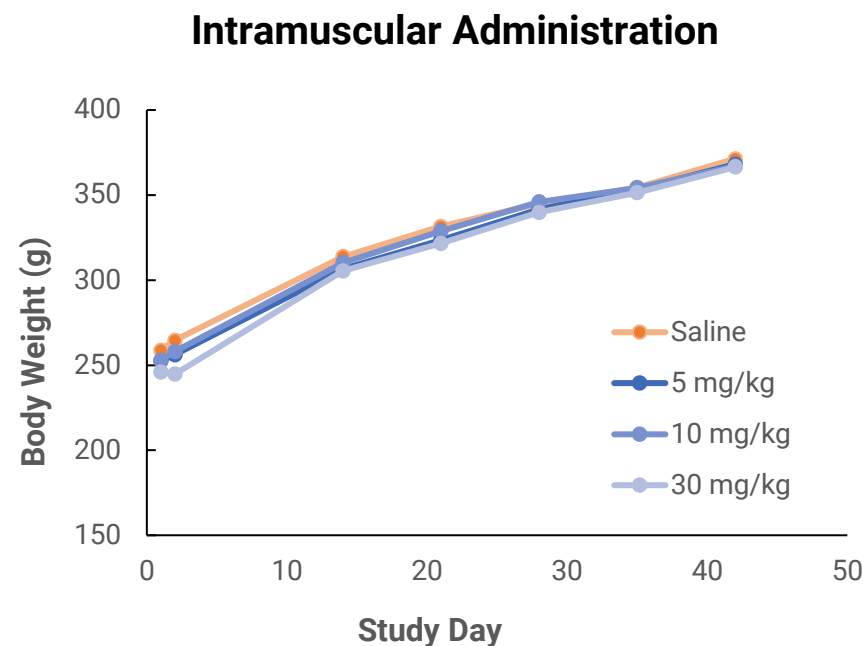
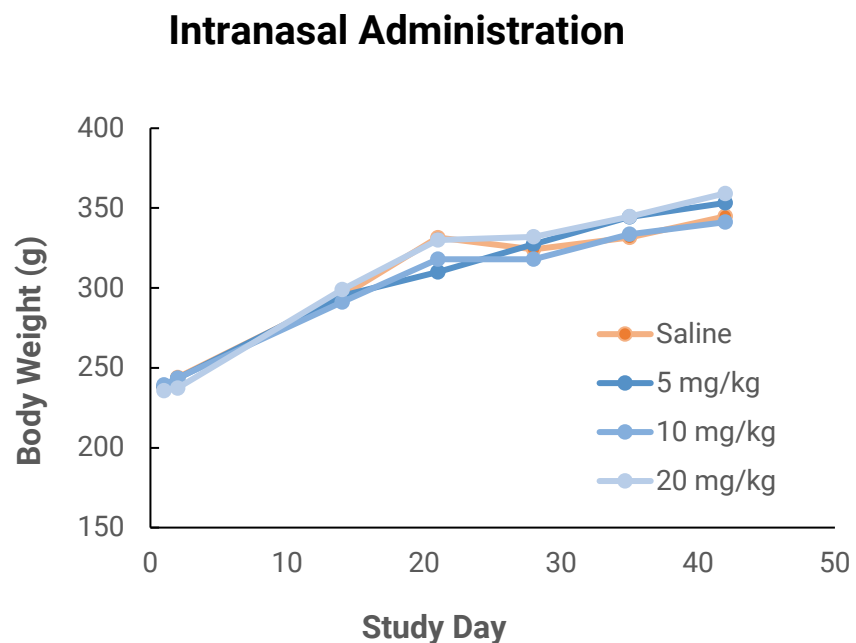
“The battle really is about [which company] is going to be, in the future, the go-to source that other companies may have to license from.”

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

Robbins, R and Gross, J. New York Times, 8/26/2022.

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)

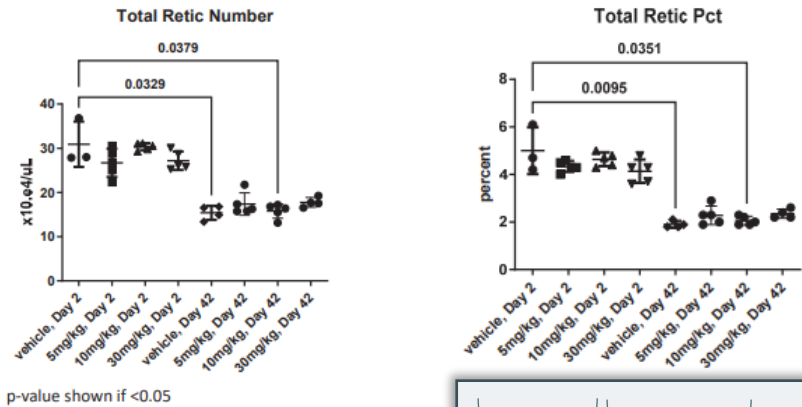


The NanoVac Vehicle causes no adverse effects at up to 20 mg/kg (IN) or 30 mg/kg (IM) dosing

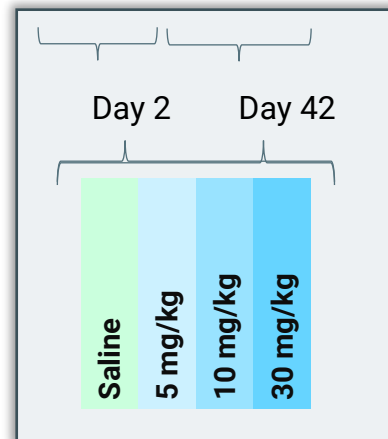
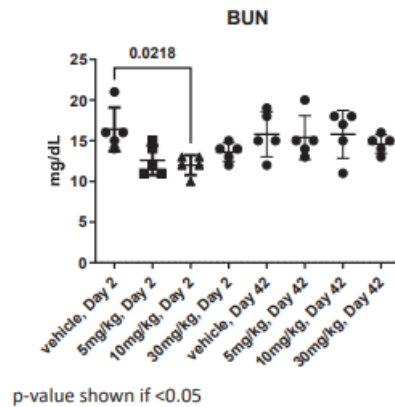
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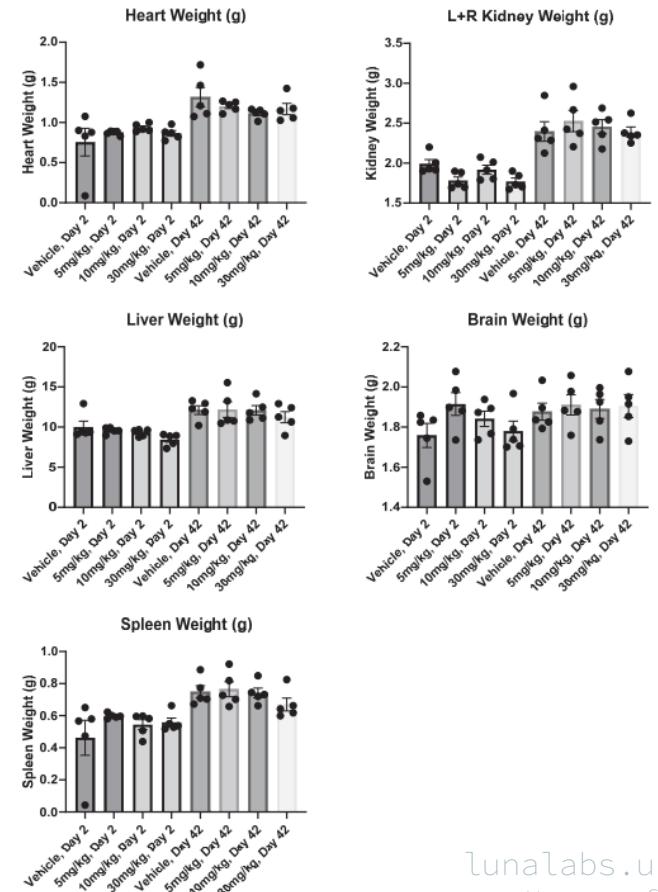
**Hematology
(Reticulocyte Analysis)**



**Clinical Chemistry
(Blood Urea Nitrogen)**



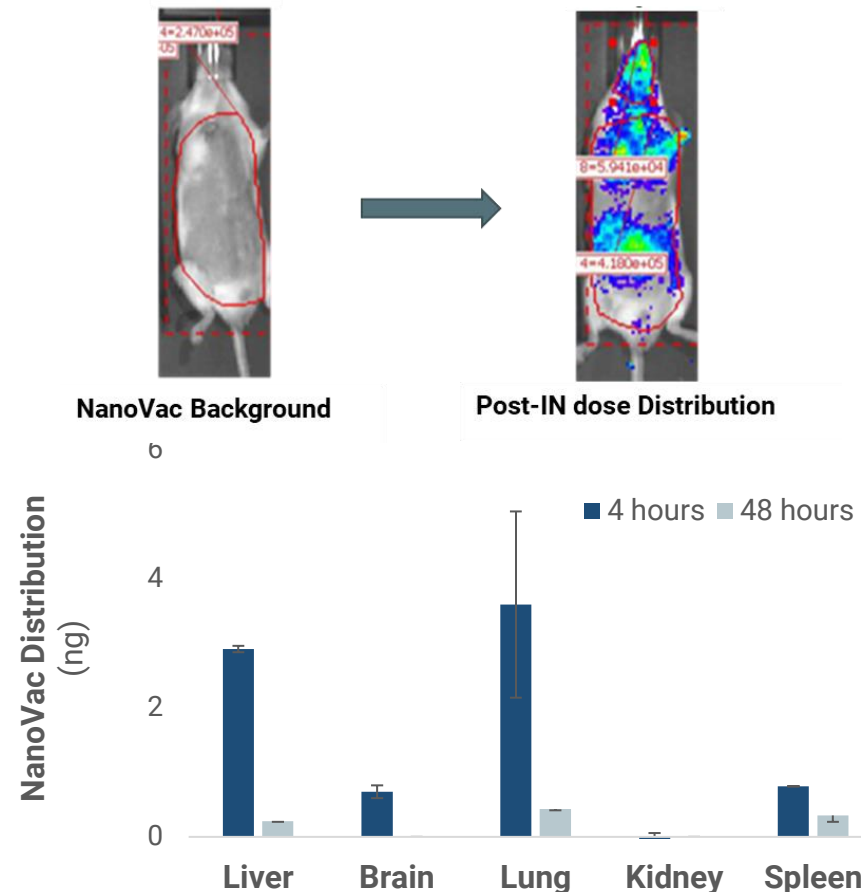
Organ Weight



The NanoVac vehicle is rapidly cleared following intranasal administration

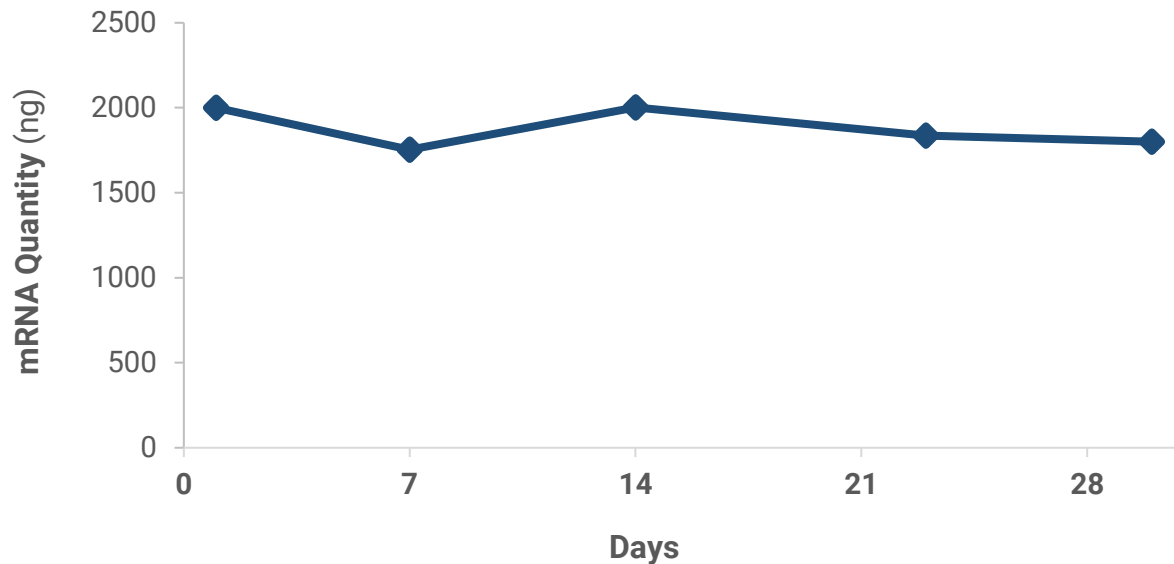
Biodistribution studies using LcL-labeled NanoVac vehicle demonstrates rapid clearance after intranasal administration.

- Dose volume 1 mL/kg; 5 mg vehicle, 0.3 mg LcL per kg dose.
- Clearance from organs was rapid
 - NanoVac Vehicle was broadly distributed throughout tissue at 4 hours with near clearance observed at 48 hours
- Cardiac perfusion was not performed prior to imaging
- Minor inflammation at the site of administration and local sequestration observed
- Ongoing work to perform biodistribution studies with radiolabeled vehicles

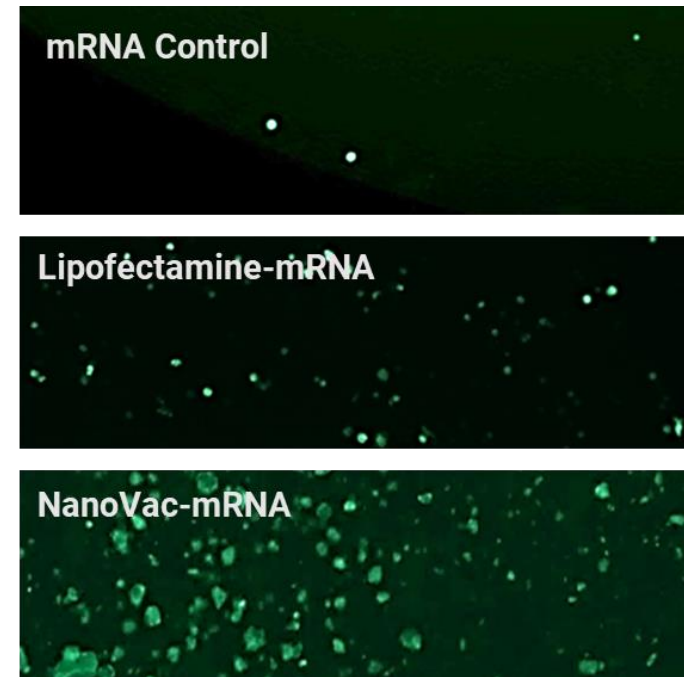


The NanoVac vaccine platform stabilizes mRNA and enhances uptake and translation

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. Provides storage over months-long periods using only refrigeration.



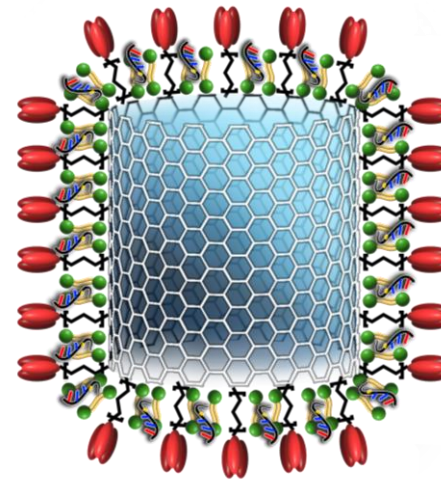
Cellular transfection studies show enhanced cell uptake with NanoVac platform delivery.

NanoVac V1V2 is being implemented in HIV-1 vaccination... and has the potential for many other indications

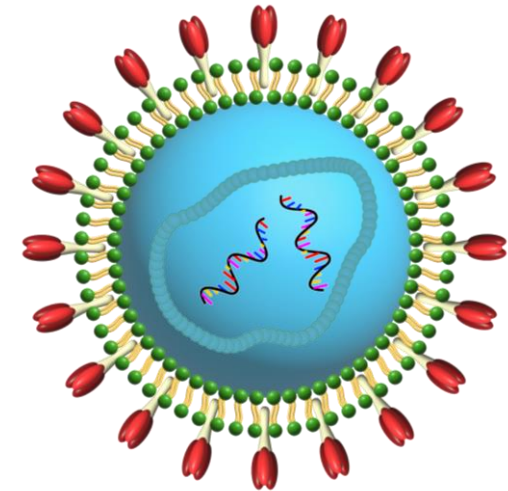
Can be engineered to mimic size, shape, and antigen presentation of virion

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.

- 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



**NanoVac V1V2
Designed to Mimic
Virion Structure**

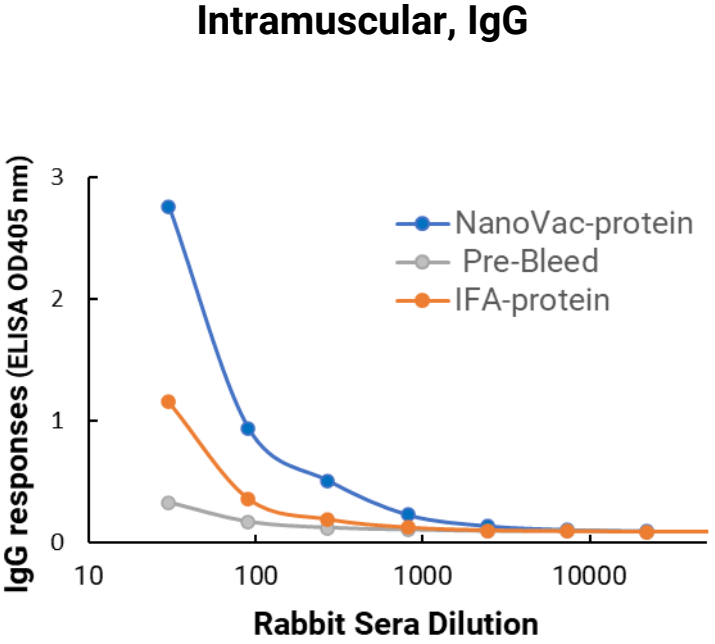
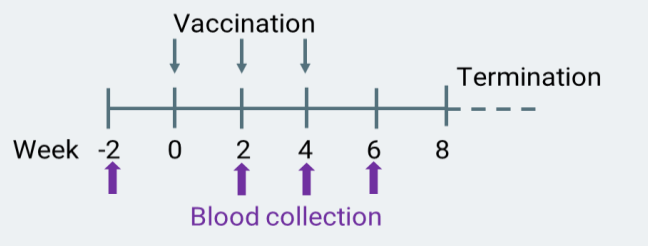


HIV-1 Virion

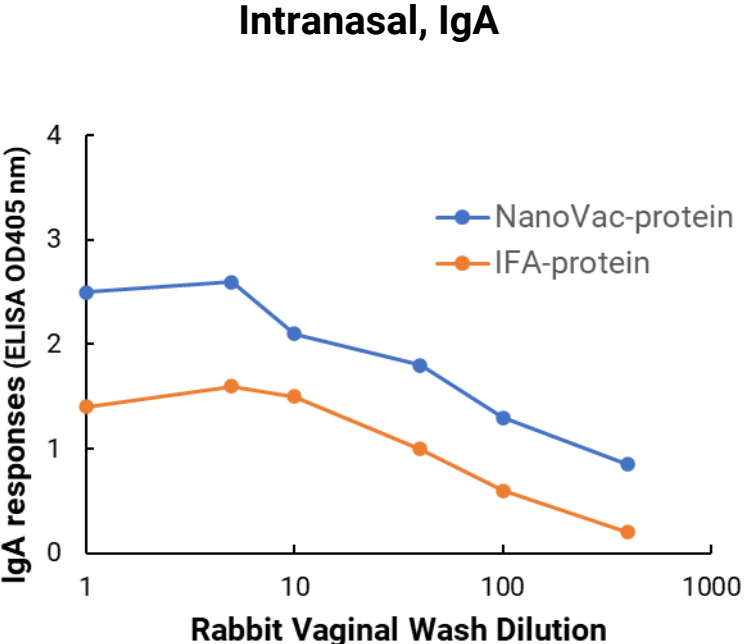
NanoVac V1V2 protein vaccine demonstrates enhanced and accelerated immune response via IM/IN delivery in rabbits

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

- 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



Results above for IgG obtained on 3rd bleed, prior to third dose

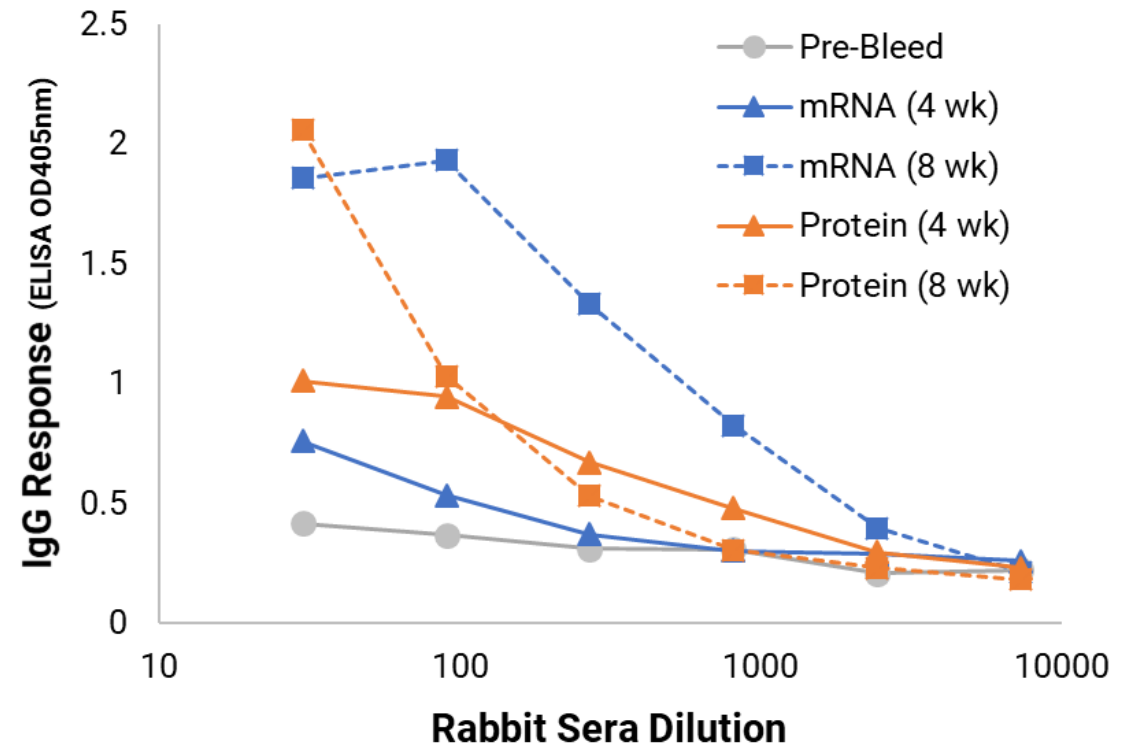
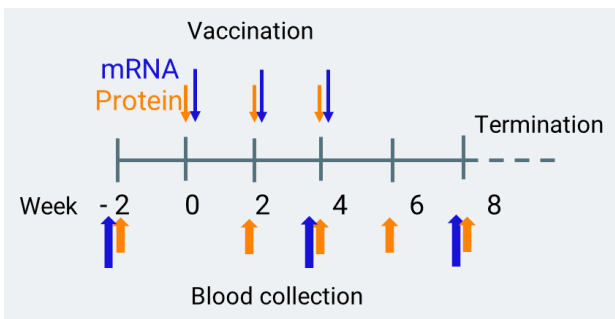


Results above for IgA obtained at Week 6 after 3 doses

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

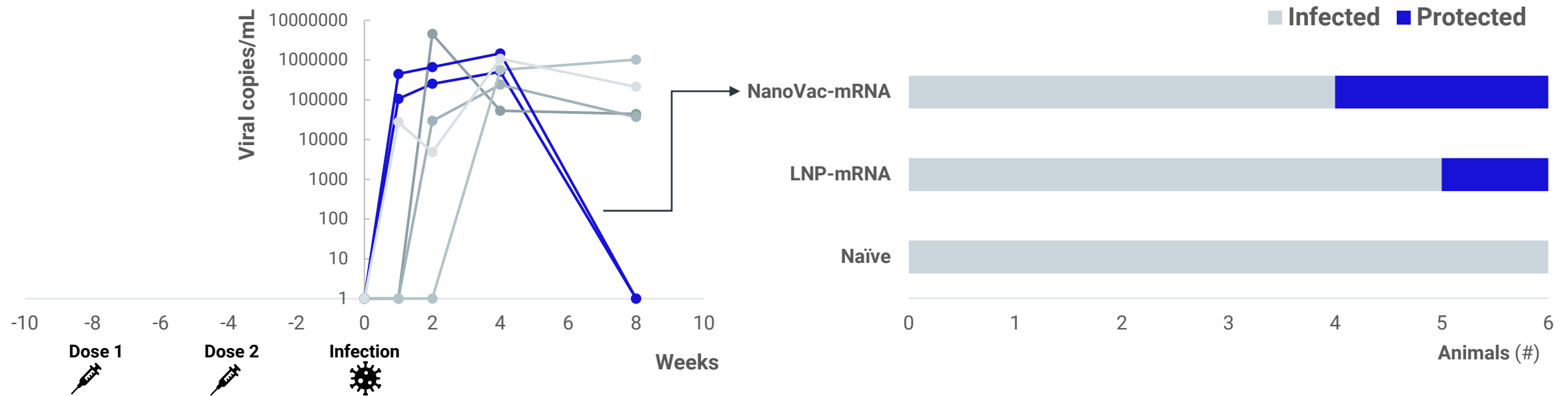
- NanoVac V1V2 utilizing glycoprotein presentation stimulates an earlier immune response (**orange**)
- NanoVac V1V2 using mRNA-based protein production shows enhancement and preservation of a longer lasting response (**blue**)



NanoVac mRNA V1V2 was more effective at vaccinating against HIV-1 compared to standard LNP-based mRNA delivery

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

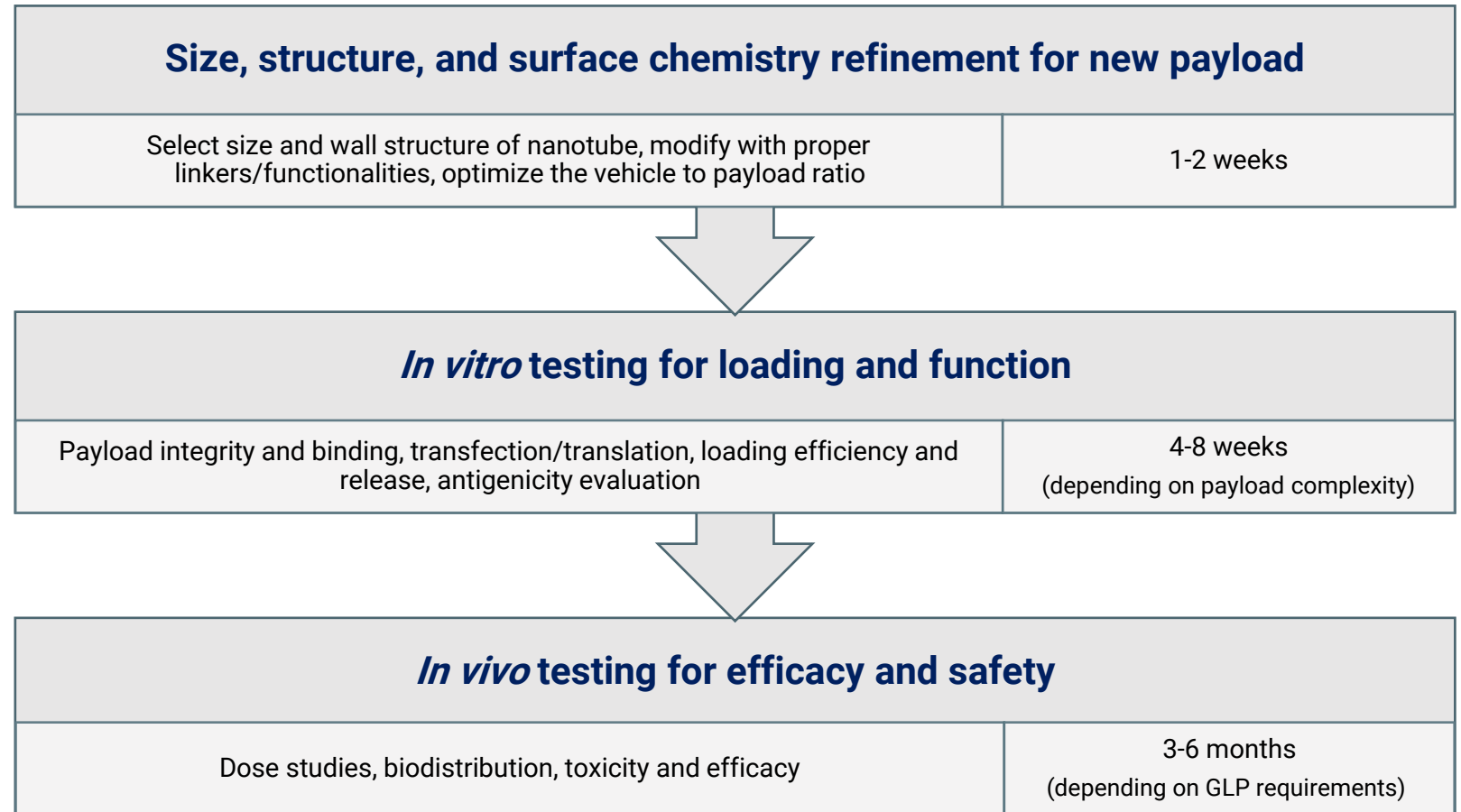
- Humanized mice were IM administered **NanoVac-mRNA** or MC3 **Lipid NP-mRNA**
- **33% protection rate** demonstrated with NanoVac-mRNA after clearance of viral load



NanoVac proof-of-concept development timeline & activities

The NanoVac vehicle can rapidly pivot for delivery of new payloads, with only weeks required to optimize and characterize loading

- New protein or mRNA payloads for indications of interest
- Payload classes could be expanded for novel uses
- Adaptable to targeted delivery
- Formulation can be modified for intramuscular, subcutaneous, or intranasal administration routes



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, School of Medicine, Immunology & Microbiology



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 NAMS
Clinical: Michigan State University and Charles River Labs



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