

# ARCTURUS THERAPEUTICS

Building the Next Generation of RNA Medicines

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# FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about: expectations regarding our capitalization and resources; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials; our strategy and focus; our efforts to develop a vaccine against COVID-19, the safety, efficacy or reliability of a our COVID-19 vaccine candidate; the development and commercial potential of any of our product candidates; the timing and success of our development efforts; the success of any of our trials and our ability to achieve regulatory approval for any product candidate; the entry into or modification or termination of collaborative agreements and the expected milestones and royalties from such collaborative agreements ; the potential market or clinical or commercial success of the clinical development programs of Arcturus; and any statements other than statements of historical fact, including those related to Arcturus' future cash, market or financial position.

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# Company Highlights



BUILDING INNOVATIVE  
RNA MEDICINES

**Arcturus is a Clinical-Stage mRNA Vaccines and Medicines Company**

## Publicly Traded (Nasdaq: ARCT)

- Headquarters: San Diego, CA
- Number of Employees: 104
- Founded: 2013

## Promising Therapeutic Candidates

- LUNAR-COV19 (COVID-19 Vaccine)
- LUNAR-OTC (Ornithine Transcarbamylase Deficiency)
- LUNAR-CF (Cystic Fibrosis)
- Additional Earlier Stage Programs



**Arcturus Technologies Validated by Multiple Strategic Partners**



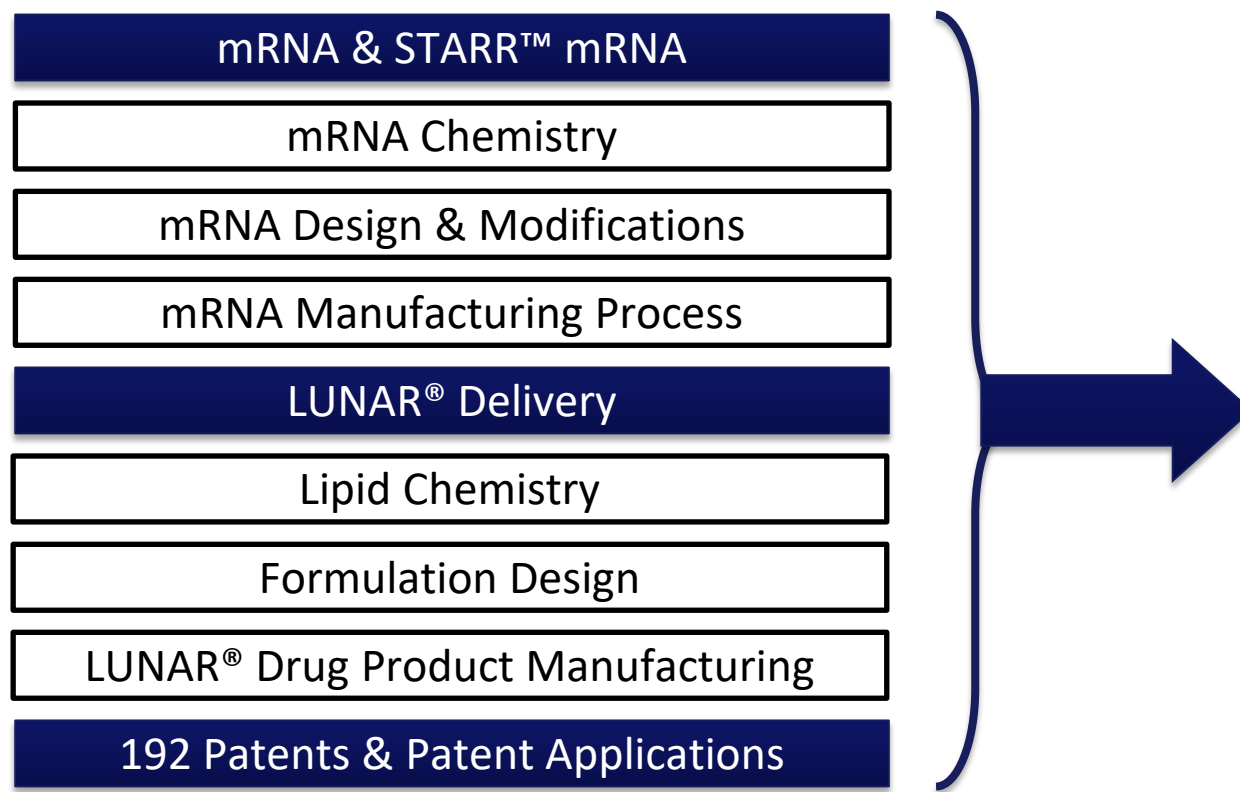


# Proprietary mRNA Technologies Driving Promising Therapeutic Programs

*Broad and Strong Intellectual Property Portfolio*



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Program	Indication
LUNAR-COV19	COVID-19 Vaccine
LUNAR-FLU	Flu Vaccine
LUNAR-OTC	Ornithine Transcarbamylase (OTC) Deficiency
LUNAR-CF	Cystic Fibrosis
LUNAR-CV	Cardiovascular Disease
ADDITIONAL EARLIER STAGE PROGRAMS	

# Arcturus Pipeline of mRNA Medicines







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	Product Name	Indication	Route of Administration	Cell Target	Prevalence Worldwide	Anticipated Milestones
VACCINES	LUNAR-COV19 (ARCT-021)	COVID-19	Intramuscular	Myocytes & Dendritic Cells	Global	Phase 1/2 Initial Data Q4 2020
	LUNAR-FLU	Influenza	Intramuscular	Myocytes & Dendritic Cells	Global	CTA 2021
HEPATIC	LUNAR-OTC (ARCT-810)	Ornithine Transcarbamylase Deficiency	Intravenous	Periportal Hepatocytes	> 10,000	Phase 1 Initial Data Q4 2020
RESPIRATORY	LUNAR-CF	Cystic Fibrosis	Inhaled	Bronchial Epithelial Cells	> 70,000	DC Selection 2020 IND 2021
TARGETED	LUNAR-CV	Cardiovascular Disease	Intravenous	Hepatocytes	~4,000 (HoFH) 3.5 Mill (HeFH)	CTA 2021

**Multiple mRNA Therapeutic Programs in Clinical Development with Milestones in 2020**

# Partnerships Maximize Platform

Program	Partner	Indication
LUNAR-HBV		Hepatitis B Virus (HBV)
LUNAR-NASH		Nonalcoholic Steatohepatitis (NASH)
LUNAR-GSD3		Glycogen Storage Disease Type III
LUNAR-RARE		Undisclosed Rare Disease
LUNAR-RPL	Undisclosed Large Pharma	Vaccines
LUNAR-AH	Undisclosed Animal Health Pharma	Vaccines

**Greater than \$1 Billion in Potential Milestones & Royalties**

ARCTURUS THERAPEUTICS

# LUNAR<sup>®</sup> Delivery Technology

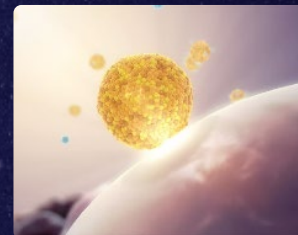
*Biodegradable, highly optimized for each cell type*



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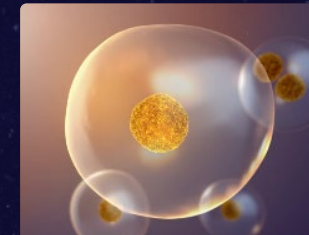


**LUNAR Associates  
with Cell Membrane**



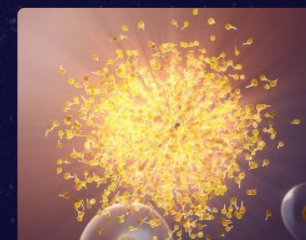
Enters Cell  
Via Endocytosis

**Lipid Particle in  
Endosome**



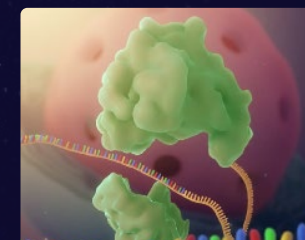
Increased Acidity as  
Endosome Ages

**pH-Mediated  
Disruption**



Rapid Biodegradation  
of Vehicle

**RNA  
in Cytosol**

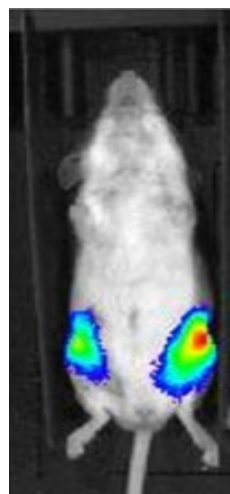


RNA Processing  
and Translation

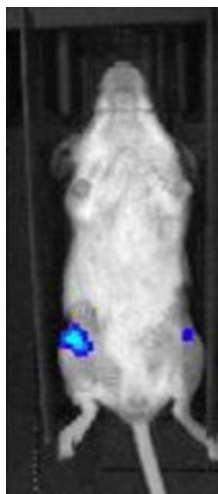
# STARR™ mRNA Superior to Conventional mRNA

*Self-Transcribing and Replicating mRNA (STARR) delivered with LUNAR® provides higher protein expression and potentially longer-lasting duration of protein expression in mouse*

**STARR™ Technology**  
**30-Fold Higher Protein Expression**



**STARR™  
Technology**



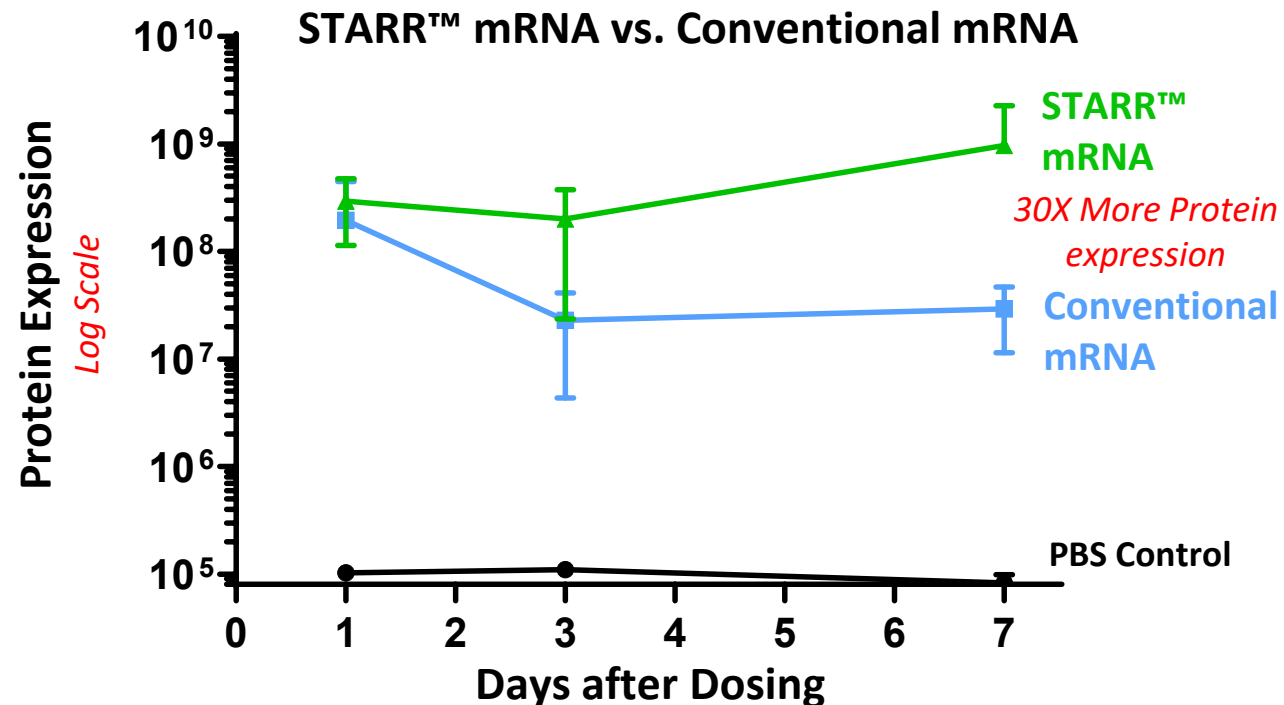
**Conventional  
mRNA**



**PBS  
Control**

## Protein Expression Over 7 days

**STARR™ mRNA vs. Conventional mRNA**



**STARR™ mRNA technology together with LUNAR® delivery may enable single vaccine administration at very low dose**



# **LUNAR-COV19 (ARCT-021)**

## **COVID-19 Vaccine Candidate**

# Arcturus COVID-19 Vaccine Candidate has Significant Advantages



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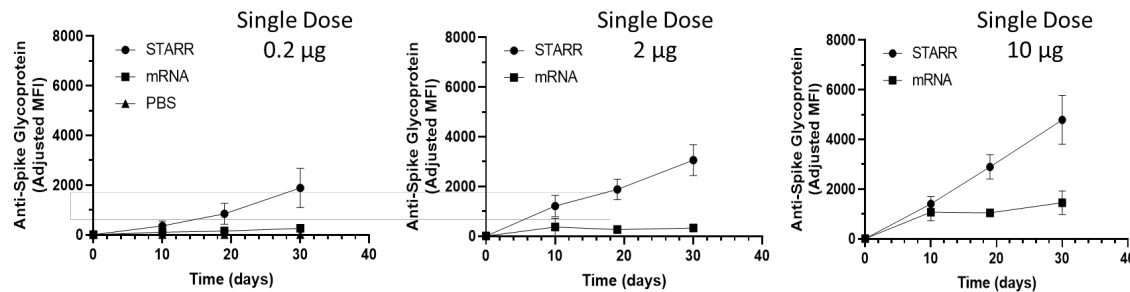
- Duke-NUS Partnership **DukeNUS**  
Medical School
- mRNA Vaccine: Simple, No Adjuvants, No Viruses
- STARR™ mRNA: Produces 30X More Protein than Conventional mRNA
- LUNAR® Technology: Non-viral Delivery System 
- Promising Preclinical Data: Neutralizing Antibodies & Cell-mediated Immunity
- Potential Single-Shot: Simpler Logistics for Vaccinating Large Populations
- Very Low Dose: Enables Rapid Global Scale-up
- Readily Manufactured: Arcturus Processes + Strategic Partnership **Catalent**

# Preclinical Data: Broad and Robust Immune Response

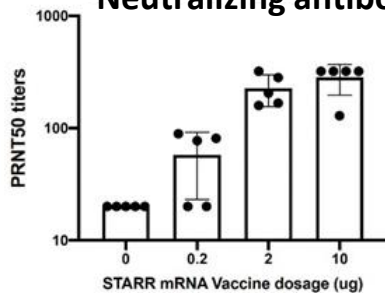


## Humoral Immunity

### STARR™ induces more robust titers compared to conventional mRNA



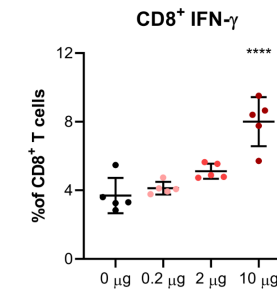
### Neutralizing antibody titers and high seroconversion at low doses



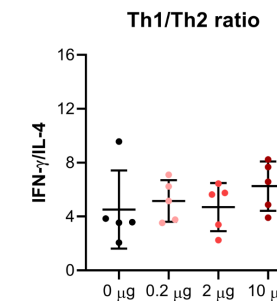
Single Dose (µg)	Seroconversion	Neutralizing Antibody Titers (Geometric Mean)
0.2	80 %	58
2	100 %	218
10	100 %	≥ 320

## Cellular Immunity

### Adaptive Cellular (CD8+ cells)



### Balanced (Th1/Th2) immune response



- Single administration with a very low dose of Arcturus COVID vaccine results in potent immune reaction
- STARR™ mRNA generates neutralizing antibodies (anti-SARS-CoV-2 Spike Glycoprotein IgG) and a cellular T-cell mediated immune response at a much lower dose level compared to conventional mRNA

# Clinical Plan to Rapidly Advance LUNAR-COV19



- **Approved to Proceed with Phase 1/2 Clinical Trial by Singapore Health Sciences Authority (HSA); Human dosing initiated (ref: [clinicaltrials.gov](https://clinicaltrials.gov))**
- **Up to 108 healthy volunteer adults to evaluate safety and immune response**
- **Trial design includes the elderly, and allows for rapid selection of dose to take forward into large registrational studies with lyophilized drug product**
- **With the Company's manufacturing partners, Arcturus is positioned to manufacture millions of doses in 2020 and potentially hundreds of millions of doses annually thereafter**
- **Arcturus retains global rights to LUNAR-COV19**



# **LUNAR-OTC (ARCT-810)**

## **Ornithine Transcarbamylase (OTC) Deficiency**

# OTC Deficiency Market Opportunity



## **Ornithine Transcarbamylase (OTC) Deficiency: The most common urea cycle disorder**

- The urea cycle converts neurotoxic ammonia to water-soluble urea that can be excreted in urine
- Deficiency in OTC causes elevated blood ammonia, which can lead to neurological damage, coma, and death
- 10,000 worldwide prevalence



## **Unmet Medical Need**

- Present standard of care involves a strict diet (low protein, high fluid intake) plus ammonia scavengers (sodium phenylbutyrate)
- Present standard of care does not effectively prevent life-threatening spikes of ammonia
- Severe OTC Deficiency patients are typically referred for liver transplant, currently the only cure



## **LUNAR-OTC Aims to Restore Enzyme Function**

- Expression of OTC enzyme in liver has potential to restore normal urea cycle activity to detoxify ammonia, preventing neurological damage and removing need for liver transplantation

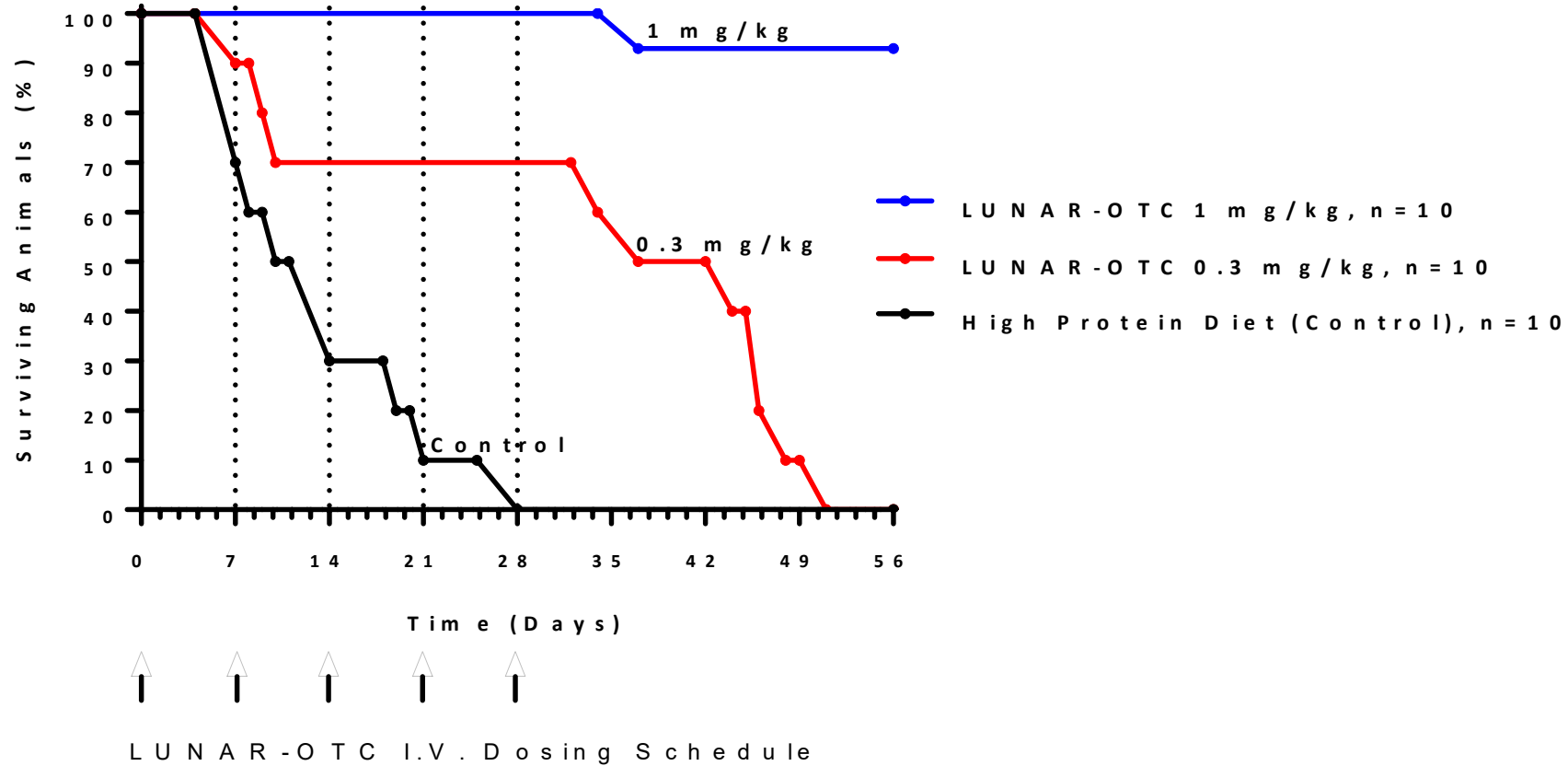
# LUNAR-OTC

Disease Normalization Following Single and Repeat Dosing in OTC Mouse Model



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## Survival of OTC-deficient Mice on High Protein Diet - Weekly LUNAR-OTC Treatment

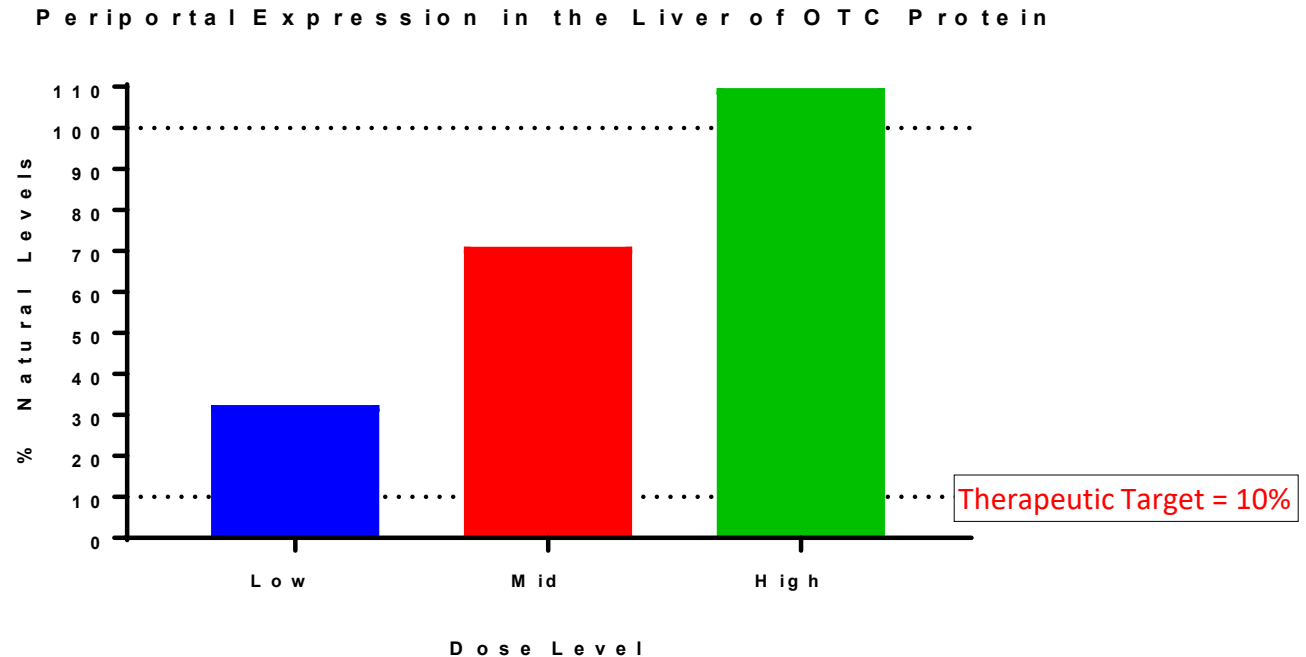


# LUNAR-OTC



Exceeds Therapeutic Target of 10% Enzyme Replacement at all Doses in OTC-Deficient Mouse Model

- OTCD impacts ureagenesis (ammonia detoxification)
- The main site of ureagenesis is the periportal region of the liver\*
- Establishing 10% of natural enzyme levels is expected to be therapeutically significant



\*Li, L. et al. PGC-1 $\alpha$  Promotes Ureagenesis in Mouse Periportal Hepatocytes through SIRT3 and SIRT5 in Response to Glucagon. *Scientific Reports*. 6:24156 | DOI: 10.1038/srep24156, April 2016

\*Lamers, W.H., Hakvoort, T.B.M., and Köhler, E.S. 'Molecular Pathology of Liver Diseases' in Monga S.P.S. (ed.), *MOLECULAR PATHOLOGY LIBRARY SERIES*, Springer Publishing, New York, pp. 125-132 | DOI: 10.1007/978-1-4419-7107-4

**LUNAR-OTC treatment increases OTC expression in mouse periportal hepatocytes (main site of ureagenesis)**



# ARCT-810 Phase 1/1b Study Ongoing

## Two Single Ascending Dose Studies

- New Zealand Phase 1 clinical trial began in early June in up to 30 healthy volunteers
  - 3 of 5 cohorts dosed
  - No significant AEs, lab value abnormalities or infusion related reactions despite no steroid premedication
  - On track to complete Q4 2020
- U.S. Phase 1b clinical trial in up to 12 stable OTC-deficient patients
  - Patient study – up to 3 dose levels
  - All doses are within the anticipated range for therapeutic biological effect
  - On track to dose by Q4 2020
  - Timing of initial data dependent on COVID19 status

**Primary Goal:** Identify safest doses to take forward into multiple dose clinical trials

**Primary Endpoints:** Safety and tolerability

**Exploratory Endpoints:** Biomarkers include ureagenesis, plasma ammonia levels, plasma OTC enzyme activity, and urine orotic acid levels

# **LUNAR-CF**

## **Cystic Fibrosis**

# Cystic Fibrosis Market Opportunity



## **Cystic Fibrosis: The most common rare disease in the United States**

- Caused by genetic mutations in the CFTR gene, resulting in aberrant flux of ions in and out of cells, causing thick mucus buildup in lung airways
- Chronic airway obstruction leads to infection and inflammation, which causes permanent tissue scarring and respiratory failure
- 70,000 worldwide prevalence



## **Unmet Medical Need**

- No CFTR functional corrector is approved for treatment of all patients
- Present standard of care does not effectively prevent long-term effects of mucus accumulation. CF patients with late-stage loss of respiratory function require lung transplant



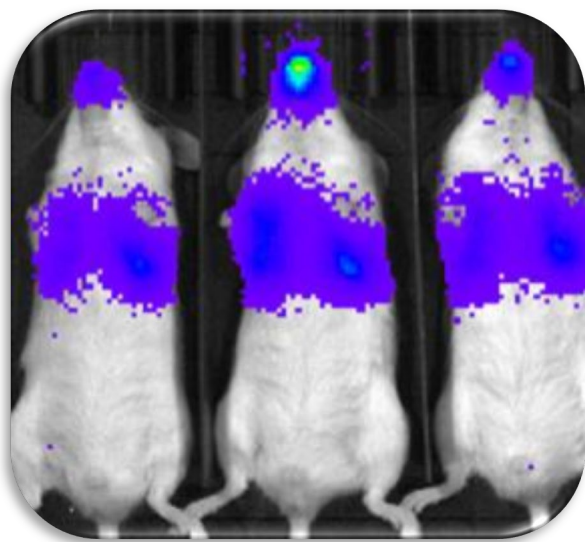
## **LUNAR-CF Aims to Restore CFTR Function**

- An mRNA replacement therapy has the potential to deliver a new copy of CFTR into the lungs of CF patients, independent of any genotype
- A functional CFTR protein can restore chloride channel efflux in the airways, reducing mucus accumulation, tissue scarring and minimizing the progressive respiratory dysfunction observed in CF patients

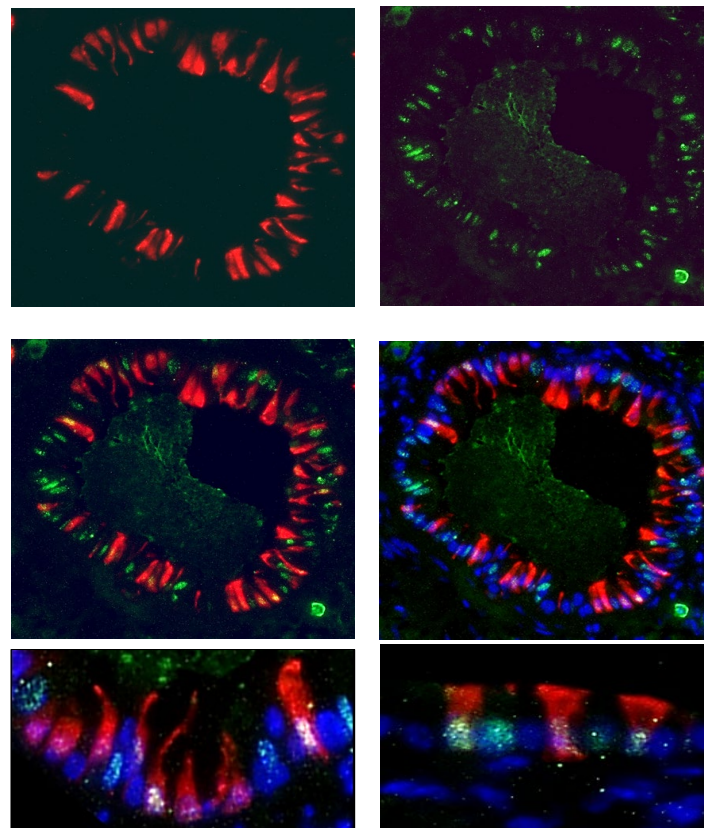
# Delivery of LUNAR<sup>®</sup>-mRNA to Rodent Airways

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Nebulization: Upper/Lower Airways

LUNAR<sup>®</sup> + Luciferase mRNALUNAR<sup>®</sup> Targets Mice Epithelial Airways (**TdTomato**),  
Including Ciliated Cells (**TdTomato**/**FoxJ1**)

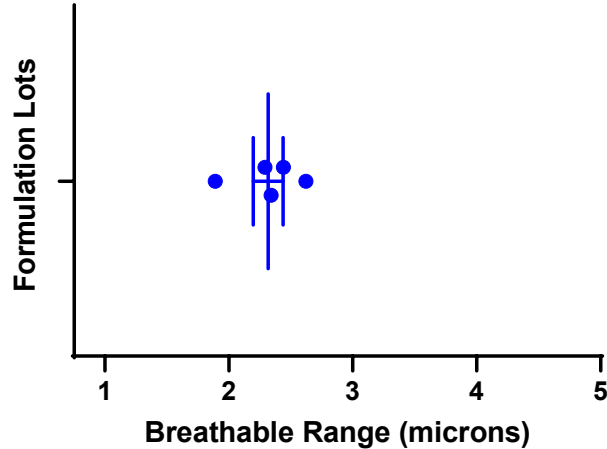
TdTomato / FoxJ1 / Dapi

Efficient delivery of LUNAR<sup>®</sup>-mRNA formulations in rodent airways



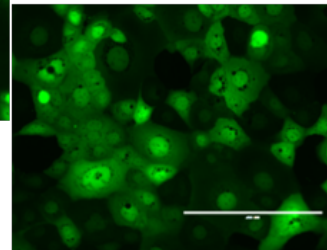
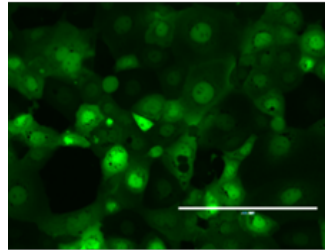
# LUNAR<sup>®</sup>, an aerosolized delivery platform for lung

Aerosolized LUNAR<sup>®</sup>  
Particles are Breathable



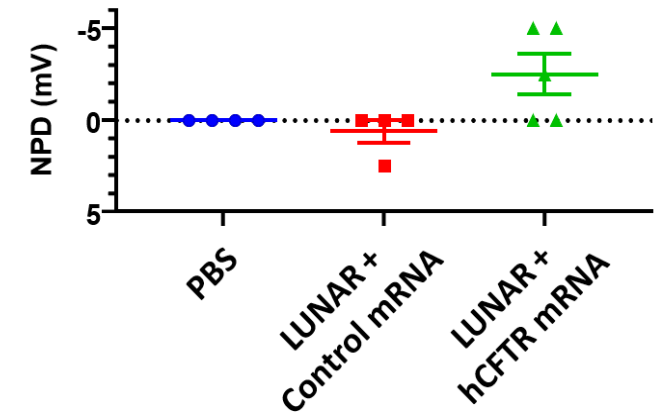
Aerosolized LUNAR<sup>®</sup>-mRNA (EGFP)  
maintains activity

Pre-Nebulization



Post-Nebulization

LUNAR<sup>®</sup>-mRNA (hCFTR) is biologically  
active *in vivo* (NPD, Mouse)



Aerosolized LUNAR<sup>®</sup> droplets are in the optimal breathable range (1-5 microns)

Aerosolized LUNAR<sup>®</sup> maintains activity as measured by EGFP protein expression & Nasal Potential Difference (NPD)

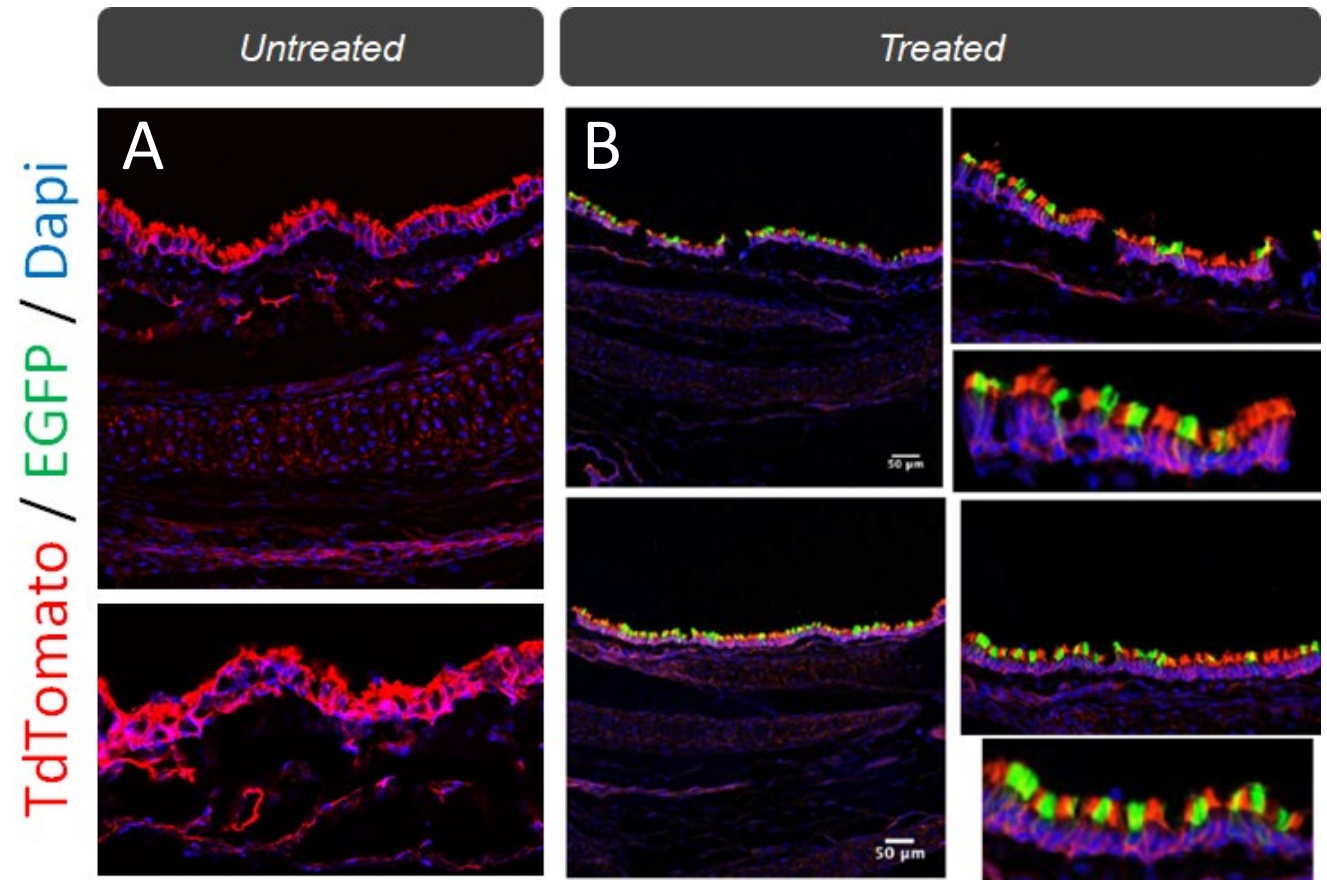
# Delivery of LUNAR<sup>®</sup>-mRNA into Epithelial Airways in Ferret

*EGFP conversion in tracheal epithelial airways observed in the ROSA26TG Ferret model*



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- Ferrets are an excellent species for modeling certain human lung diseases\*
- Novel LUNAR<sup>®</sup> formulations of CRE mRNA were tested in a transgenic ROSA26TG ferret model
- Activation of EGFP expression indicates that LUNAR<sup>®</sup> targets epithelial airways
- Anticipated next steps: Development Candidate Selection 2020 & IND Filing 2021



In collaboration with John Engelhardt

**LUNAR<sup>®</sup> effectively delivered mRNA to the tracheal epithelial airways in a Ferret model**

## **LUNAR-CV**

**Targeted** Messenger RNA Therapeutic  
Cardiovascular Disease; LDL-Cholesterol Reduction

# HoFH Market Opportunity



## **Homozygous Familial Hypercholesterolemia (HoFH):**

- Severely elevated LDL Cholesterol (LDL-C) levels increases risk for cardiovascular disease
- In ~90% of HoFH patients, the LDL receptor (LDL-R) is deficient or absent that leads to low or no LDL-C uptake and subsequent degradation in the liver
- ~4000 HoFH patients and 3.5 million heterozygous FH (HeFH) patients in G7



## **Unmet Medical Need**

- Current cholesterol-lowering medications do not sufficiently lower LDL levels in HoFH
- Most individuals with HoFH experience severe coronary artery disease by their mid-20s and apheresis is recommended by 5 years-old
- High rate of coronary bypass surgery or death by the teenage years in HoFH



## **LUNAR-CV Aims to lower LDL-Cholesterol to Normal Levels**

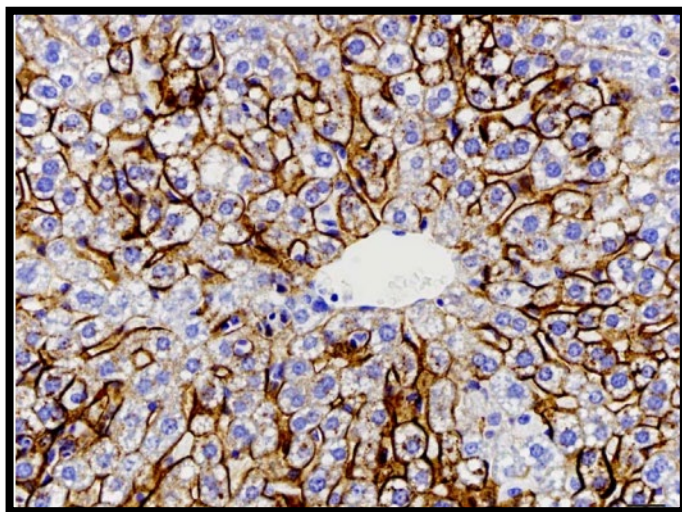
- Restoration of LDL-Receptor function with mRNA therapy in the liver has potential to lower plasma LDL-Cholesterol levels, preventing cardiovascular disease, removing need for apheresis
- Potential to treat HeFH patients who do not respond effectively to existing therapies



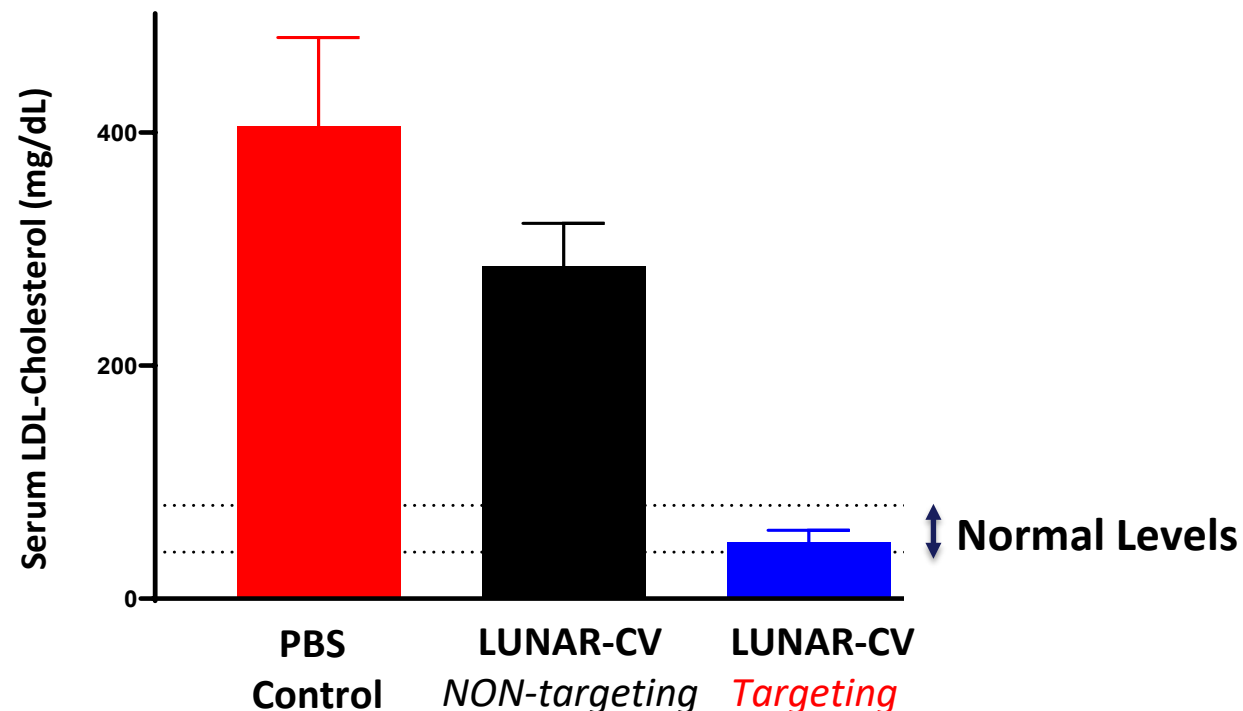
# LUNAR-CV, Targeted mRNA Therapeutic

*Targets Hepatocytes in LDL Receptor Knock-out Mouse Model*

*Result: LDL-Cholesterol is bound and cleared from the plasma*



*in vivo* Proof-of-Concept:  
Hepatocytes Expressing LDL Receptors in  
LDL-R KO Mouse Model



**LUNAR-CV Utilizes Arcturus Targeting LUNAR<sup>®</sup> Delivery Technology**  
**LUNAR-CV Treatment Results in LDL-Cholesterol Levels Being Restored to Normal**

# Moving Forward

# Anticipated Milestones and Cash Position



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## LUNAR-COV19 (ARCT-021)

Phase 1/2 Initial Data	Q4 2020
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## LUNAR-FLU

Clinical Trial Application Filing	2021
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## LUNAR-OTC (ARCT-810)

Phase 1 Initial Results	Q4 2020
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## LUNAR-CF

Development Candidate Selection	2020
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IND Application Filing	2021
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## LUNAR-CV

Clinical Trial Application Filing	2021
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## Cash Position

\$136.1 million as of June 30, 2020

\$186.3 million added in Q3 2020 from Public Offering

**Sufficient to support operations for more than two years**

## Management Team



Joseph E. Payne, MSc  
President & CEO



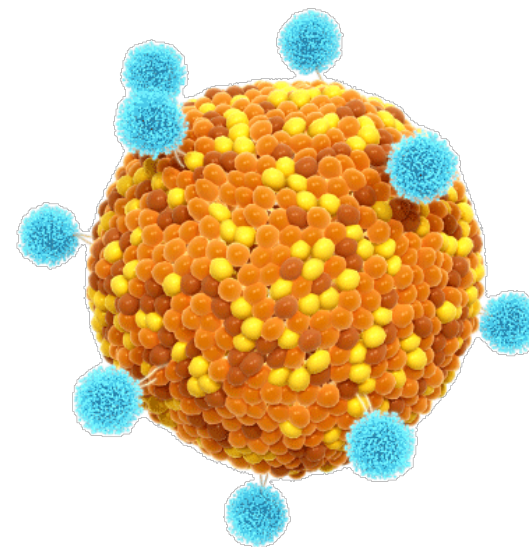
Pad Chivukula, Ph.D.  
CSO & COO



Andrew Sassine, MBA  
CFO



Steve Hughes, M.D.  
Chief Development Officer



## Board of Directors



Peter Farrell, Ph.D.  
Chairman of the Board



Karah Parschauer, JD  
Director of the Board



Edward W. Holmes, M.D.  
Director of the Board



James Barlow, MA  
Director of the Board



Magda Marquet, Ph.D.  
Director of the Board



Joseph E. Payne, MSc  
Director of the Board  
President & CEO



Andrew Sassine, MBA  
Director of the Board, CFO



Emil D. Kakkis, M.D., Ph.D.  
Board Advisor







# Appendix



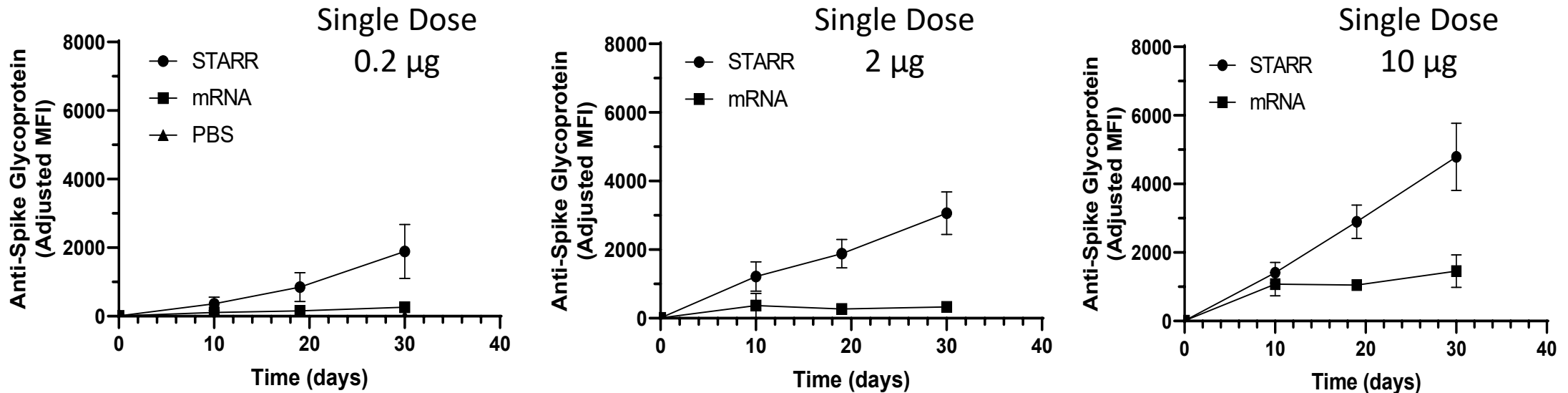
# LUNAR-COV19 Preclinical Seroconversion Data

## Seroconversion Rate (% of Animals) – STARR™ mRNA vs. Conventional mRNA

Single Dose (µg)	LUNAR® Delivery			
	STARR™ mRNA (%)		Conventional mRNA (%)	
	Day 10	Day 19	Day 10	Day 19
0.2	40	60	20	20
<b>2</b>	80	<b>100</b>	20	0
10	100	100	40	80

**100% of mouse seroconverted by day 19 at a single low dose (2 µg)**

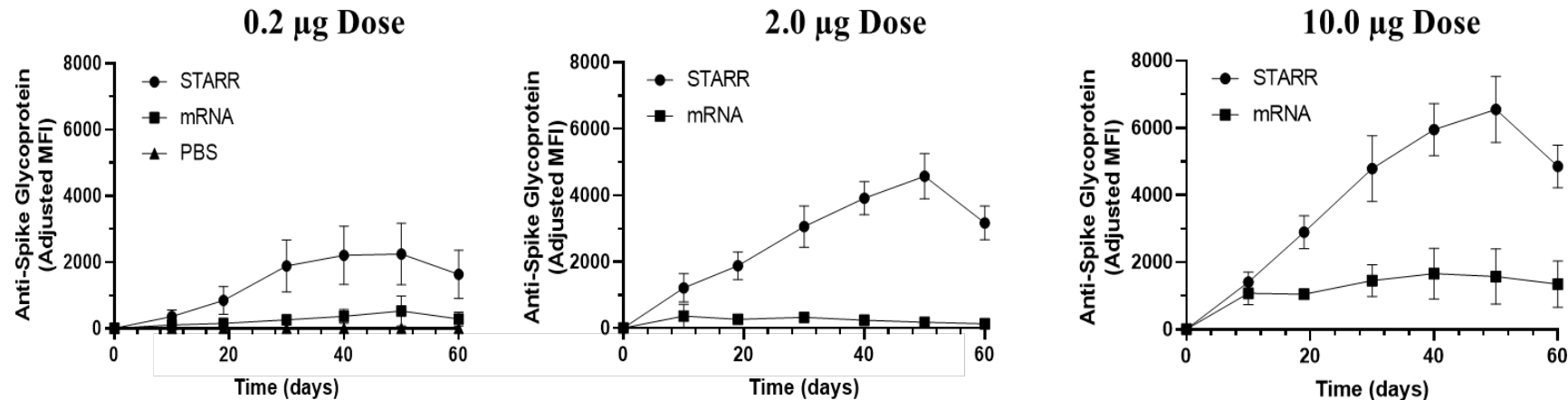
# Higher and More Robust Antibody Titters



- **Higher titers** (anti-SARS-CoV-2 Spike Glycoprotein IgG) elicited by STARR™ mRNA
- **Titers continue to increase** with STARR™ mRNA; plateau is reached with conventional mRNA
- Dose dependent increase in IgG titers

# Anti-Spike Protein Levels Continue to Increase Over 50 Days

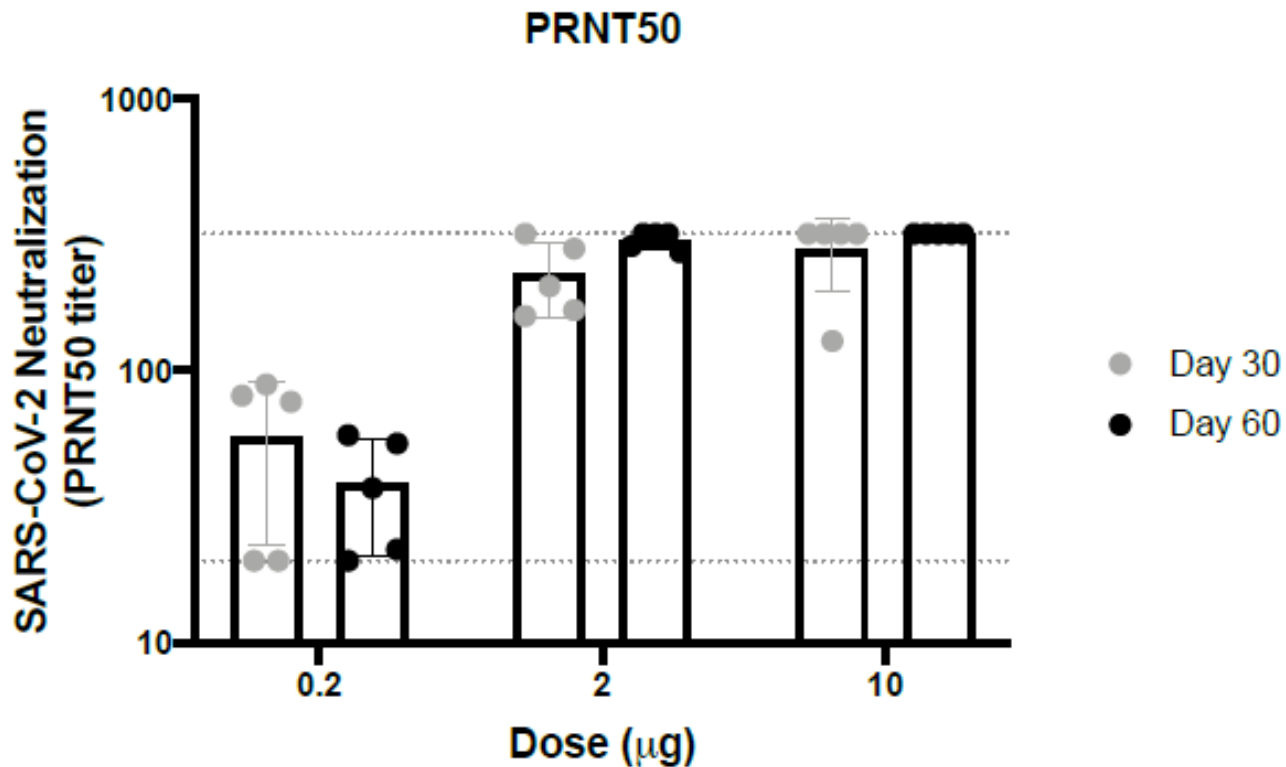
## Single Administration of LUNAR-COV19



- **Higher titers** (anti-SARS-CoV-2 Spike Glycoprotein IgG) elicited by STARR™ mRNA
- **Titers continue to increase over 50 days** with STARR™ mRNA; plateau reached with conventional mRNA
- Dose dependent increase in IgG titers; Luminex bead assay, 1/2000 serum dilution

# Neutralizing Antibodies Continue to Increase After 60 Days

*Single Administration (small dose, 2ug) of LUNAR-COV19*

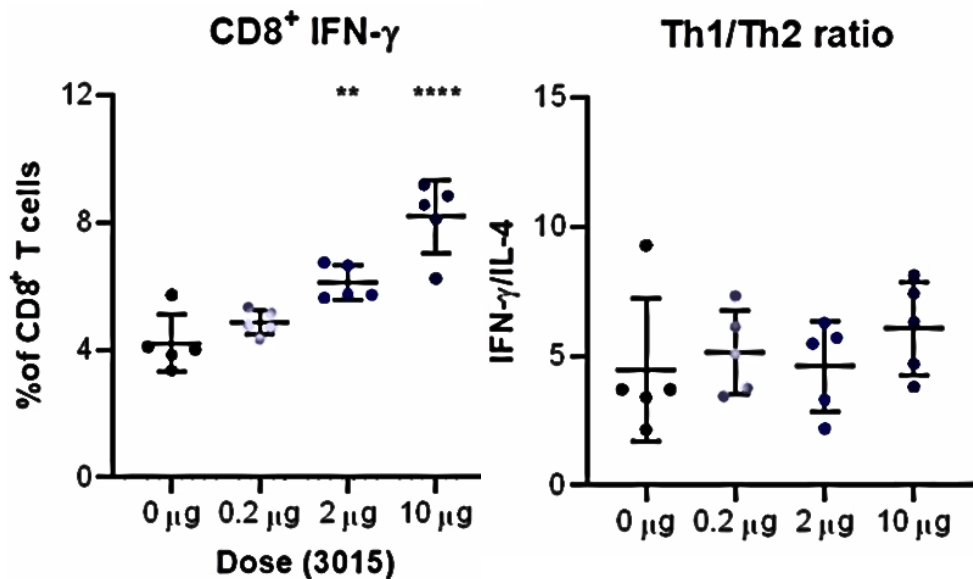


## Virus neutralization assay:

Serum dilutions are incubated with SARS-CoV-2 virus, then added to cells. The cells die forming plaques, which are counted. The serum dilution that reduces the number of plaques by 50% is recorded (PRNT50). Maximum serum dilution tested was 1/320

**After single dose (2 ug) of LUNAR-COV19, neutralizing antibodies continue to increase for 60 days (>300 titer)**

# Arcturus Vaccine elicits a Balanced Cell Mediated Immune Response



RNA Dose (μg)	% IFN-g + CD8 <sup>+</sup> T Cells	CD4+ Th1/Th2 (IFN-g/IL4)
0.0	4.0	4.6
0.2	4.5	5.3
2.0	6.0	5.0
10.0	8.0	6.0

## Results Summary

- RNA dose dependent increase in IFN-g positive CD8<sup>+</sup> T-cells
- Th1 biased CD4<sup>+</sup> response and lack of change in Th1/Th2 ratio with increased RNA dose indicate balanced cell mediated immune response

# LUNAR-COV19 Data Summary

- Very low dose: Strong neutralizing antibody response with just a single dose of 0.2 – 10 µg STARR™ RNA
- Strong humoral response continuous increase in neutralizing antibodies beyond Day 30
- Strong T-cell response: dose responsive increase in IFN-g positive CD8<sup>+</sup> T-cells
- Potential single shot simplifies vaccination campaigns
- Safety: balanced cellular immune response – favorable profile to mitigate against immune pathology and Vaccine Induced Enhancement
- Superior immunogenic profile of STARR™ compared to conventional mRNA
- Adjuvant-free, Preservative-free, Antibiotic-free reduces public concerns

**Arcturus LUNAR-COV19 is a promising COVID-19 vaccine**



# Arcturus Safety Profile

## External Validation

- Multiple strategic partnerships over many years confirms the positive potential safety profile of Arcturus LUNAR® and mRNA

## Arcturus is committed to developing safe mRNA products

- 15 studies over several years with strategic partners

## Top Safety Concern for RNA Medicines is Delivery

### Arcturus LUNAR® Delivery Technology is well tolerated in non-human primates (NHPs)

- ✓ @ 15 mg/kg single dose of non-coding siRNA
- ✓ @ 3 mg/kg x eight (8) weekly doses of non-coding siRNA (total of 24 mg/kg over 2 months)

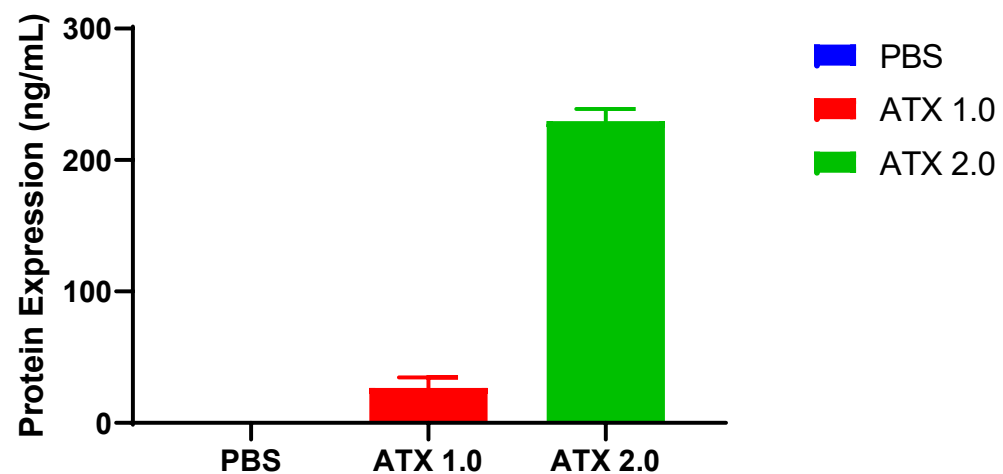
## Arcturus mRNA chemistry shows promising efficacy and tolerability data

- Efficacy of OTC mRNA in mouse model @ 0.1 – 1 mg/kg

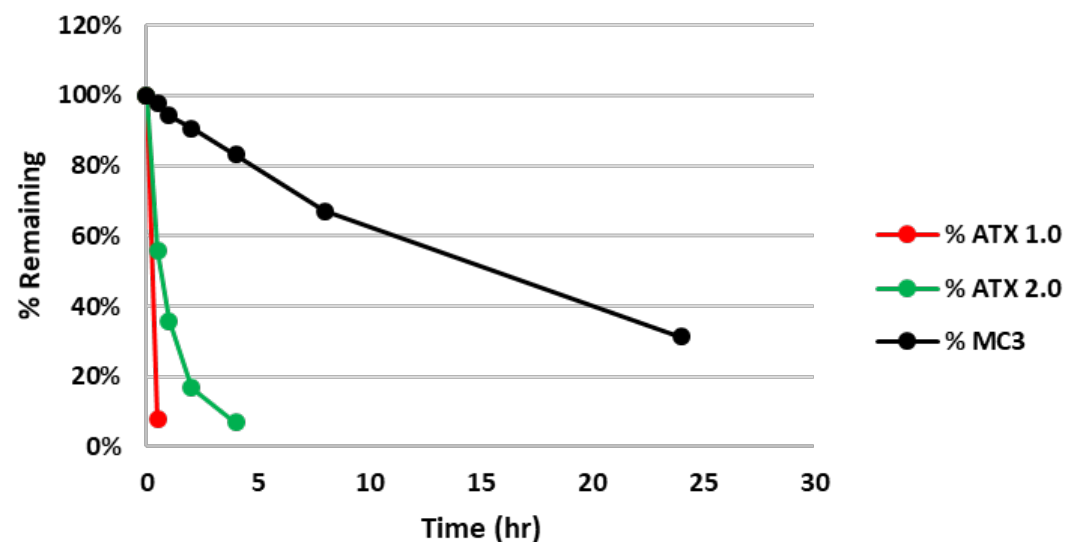
# ATX Lipids are Effective and Biodegradable

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## Protein Expression (*in vivo*)



## Esterase Catalyzed Degradation (*in vitro*)

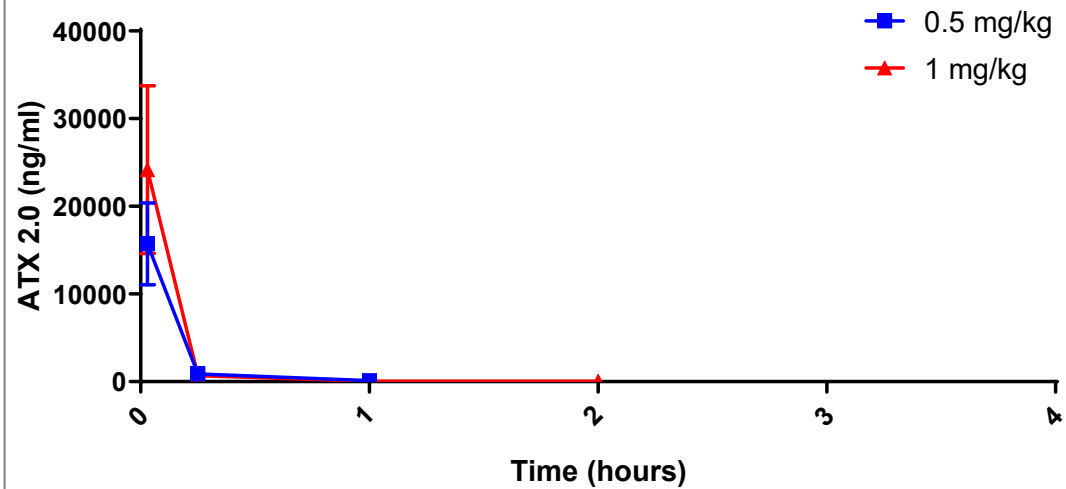


Next Generation ATX Lipids Retain Degradability & Improve Delivery Efficiency

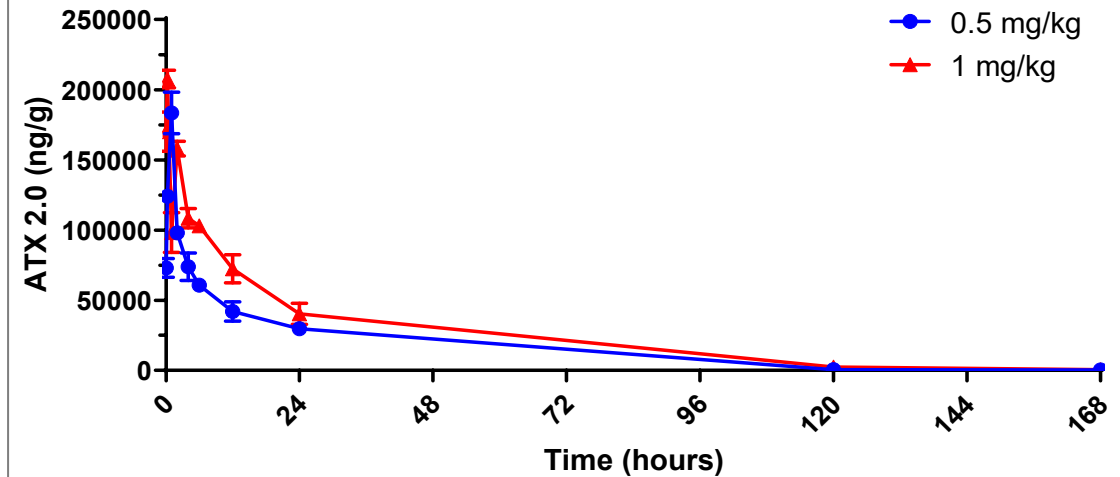
# ATX 2.0 Lipid is Biodegradable and Clears *in vivo*



## Plasma



## Liver



- ATX Lipid (the major component in LUNAR® technology) is degraded *in vivo*
- ATX 2.0 Lipid Half-Life in the Liver is Approximately 20 hours

# Drug Substance: mRNA Design

BUILDING INNOVATIVE  
RNA MEDICINES**Arcturus' proprietary mRNA optimization platform****Sustained hEPO activity in NHPs upon repeat dosing**

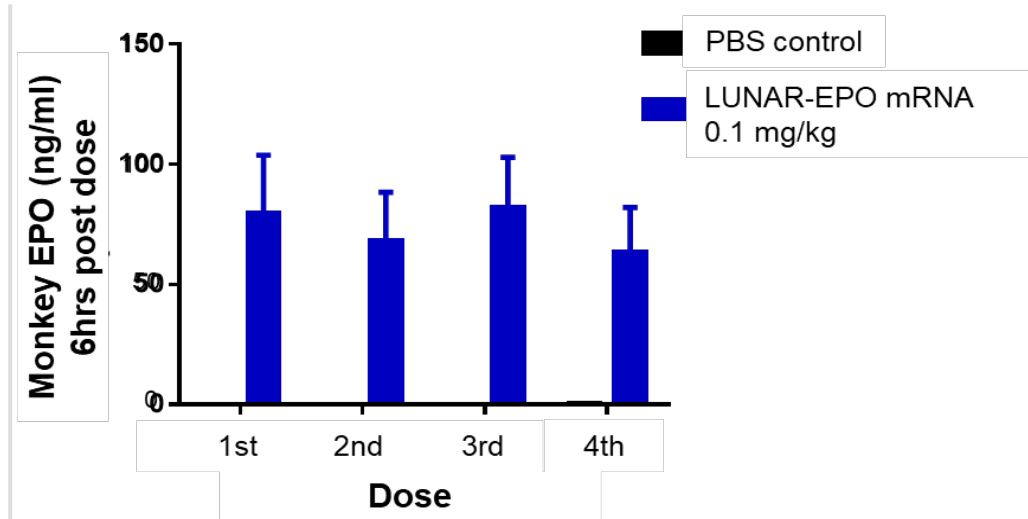
Optimize  
mRNA sequence  
Chemistry  
Process



Improve  
Protein Expression  
Duration  
Functional Activity



## Weekly Dosing in Non-Human Primates (NHPs)

**Proprietary mRNA Optimization Platform Demonstrates Sustained Activity Upon Repeat Dosing in NHPs**

# Drug Substance (mRNA) Manufacturing

BUILDING INNOVATIVE  
RNA MEDICINES

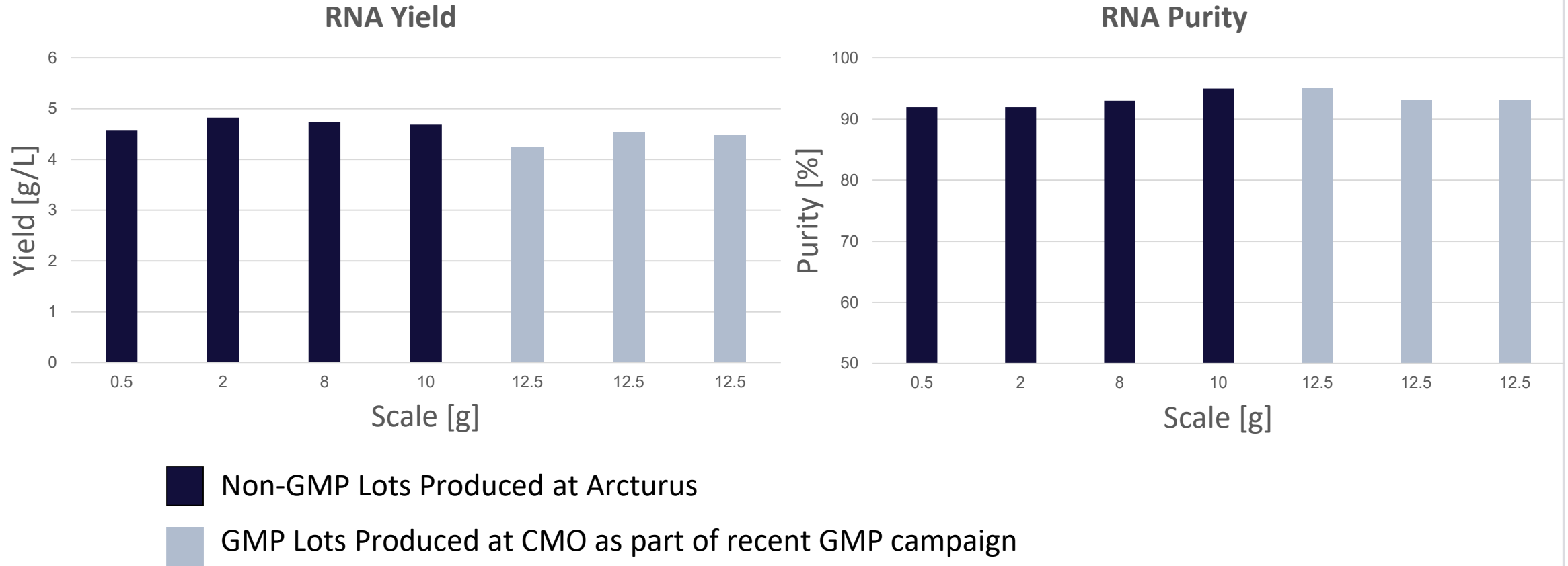
Features	Benefits
Optimized IVT Method	Reduced Cost; Higher Purity
Improved Capping Reaction	Reduced Cost of Goods
Proprietary Purification Process	Higher Purity in a Shorter Time
Efficient	Entire Process Less Than One Week
Scalable to > 1Kg	Access Large Patient Populations
Adaptable	Can Utilize a Variety of Modifications

**Arcturus Internal non-GMP mRNA Production Capabilities: Up to 30 g in Less Than One Week**

# Drug Substance (mRNA) Manufacturing



BUILDING INNOVATIVE  
RNA MEDICINES



Three 12.5 g lots produced in recent GMP campaign are of equivalent quality and yield

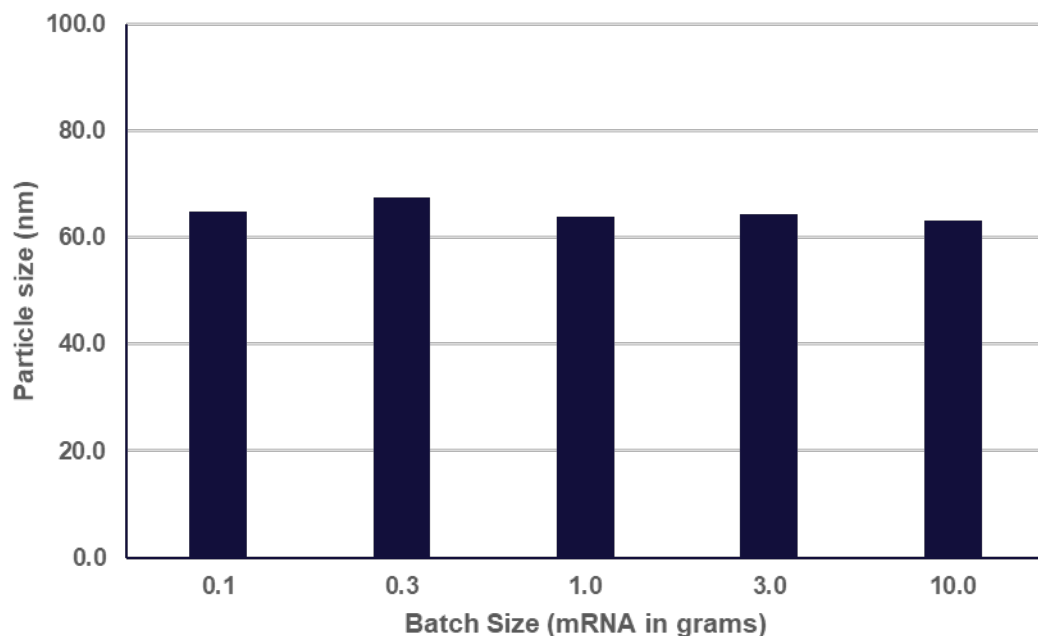


# Drug Product (LUNAR<sup>®</sup> + mRNA) Manufacturing

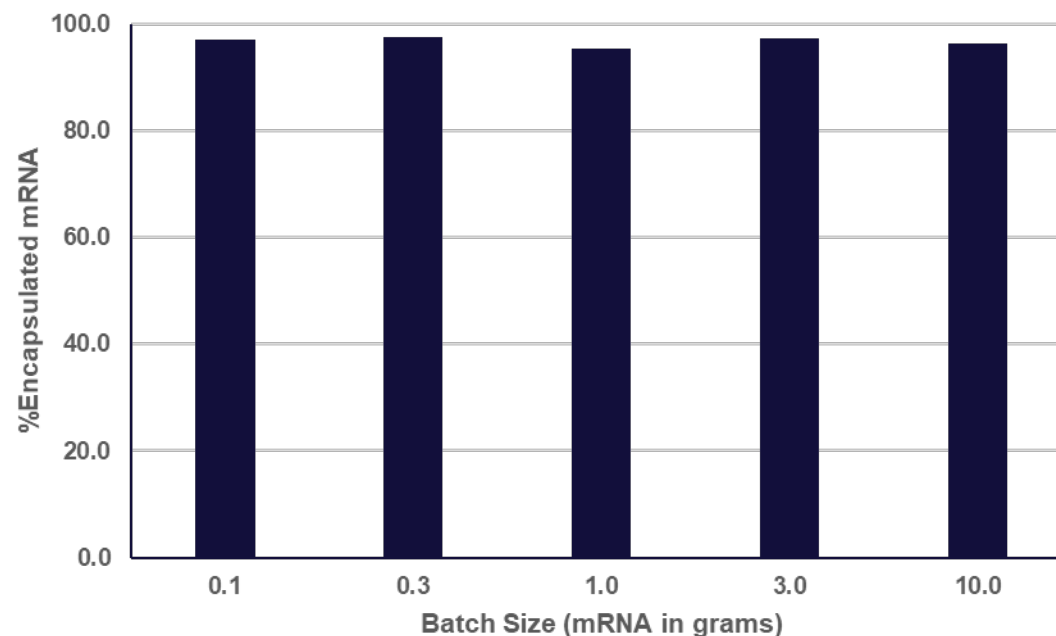


BUILDING INNOVATIVE  
RNA MEDICINES

Particle Size



%Encapsulated mRNA



- Manufacturing of Drug Product Demonstrated up to Multigram Scale with Yields  $\geq 85\%$
- GMP Batch of LUNAR<sup>®</sup>-OTC (ARCT-810) Drug Product Manufactured and Released