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 16, 2021

ARCTURUS THERAPEUTICS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38942**	**32-0595345**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10628 Science Center Drive, Suite 250
San Diego, California 92121
(Address of principal executive offices)

Registrant's telephone number, including area code: (858) 900-2660

(Former name or former address, if changed since last report)

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:

☐ 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, par value $0.001 per share	**ARCT**	**The Nasdaq Stock Market LLC**

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 8.01. Other Events.

Corporate Presentation

On November 16, 2021, the Company posted an updated corporate presentation on its website. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Cautionary Note Regarding Forward-Looking Statements

The 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: our strategy, future operations, collaborations, the likelihood of success (including safety and efficacy) and promise of our pipeline, the planned initiation, design or completion of clinical trials, anticipated sponsorship and/or funding of clinical trials of our candidates, the likelihood that we will obtain clearance from regulatory authorities to proceed with planned clinical trials, the ability to enroll subjects in clinical trials, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood that clinical data will be sufficient for regulatory approval or completed in time to submit an application for regulatory approval within a particular timeframe, the anticipated timing for regulatory submissions, the timing of, and expectations for, any results of any preclinical or clinical studies or regulatory approvals, the potential administration regimen or dosage, or ability to administer multiple doses of, any of our drug candidates, our manufacturing methods and technologies (including purification, lyophilization and stability of our products), the likelihood that a patent will issue from any patent application, our current cash position and adequacy of our capital to support future operations, and any statements other than statements of historical fact.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions (including the negative thereof) intended to identify forward looking statements. Arcturus may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in any forward-looking statements such as the foregoing, and you should not place undue reliance on such forward-looking statements. The forward-looking statements contained or implied in the presentation are subject to other risks and uncertainties, including those discussed under the heading “Risk Factors” in Arcturus’ most recent Annual Report on Form 10-K with the SEC and in other filings that Arcturus makes with the SEC. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Presentation dated November 16, 2021
104	Cover Page to this Current Report on Form 8-K in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 16, 2021

Arcturus Therapeutics Holdings Inc.

By: /s/ Joseph E. Payne
Name: Joseph E. Payne
Title: Chief Executive Officer

ARCTURUS® therapeutics

Next Generation RNA Medicines

November 2021

FORWARD LOOKING STATEMENTS

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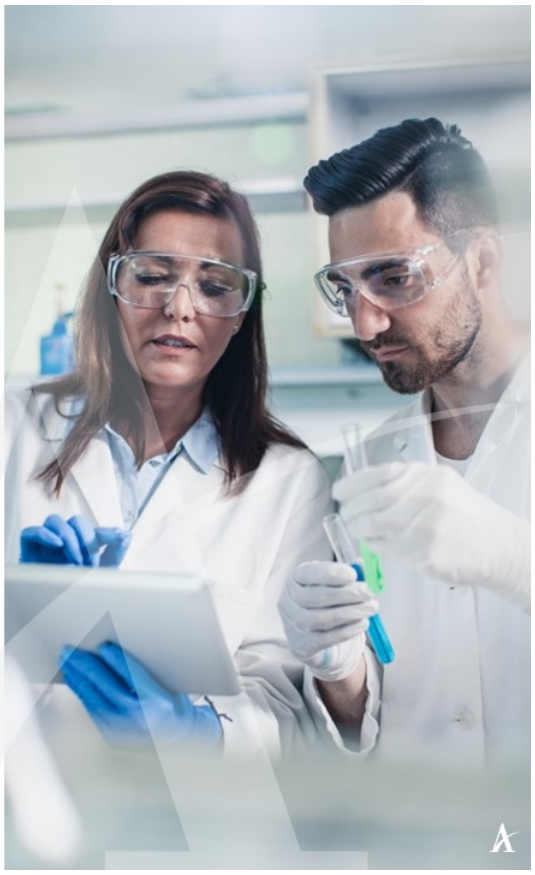
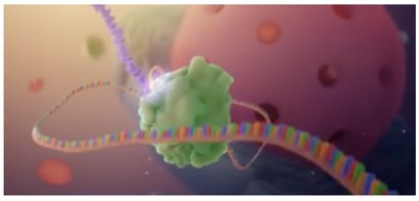
In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof) intended to identify forward looking statements. Arcturus may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in any forward-looking statements such as the foregoing, and you should not place undue reliance on such forward-looking statements. The forward-looking statements contained or implied in this presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Arcturus' most recent Annual Report on Form 10-K with the SEC and in other filings that Arcturus makes with the SEC. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.



Arcturus Therapeutics



Clinical-Stage mRNA Vaccines and Medicines Company

Publicly Traded (Nasdaq: ARCT)

HQ: San Diego, CA
Founded 2013
160+ Employees

Therapeutic Candidates

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

Multiple Strategic Partners

Johnson & Johnson | Cystic Fibrosis Foundation | DukeNUS Medical School | Takeda | ultragenyx pharmaceutical

Proprietary mRNA Technologies Driving Therapeutic Programs

Broad intellectual property portfolio

mRNA & STARR™ mRNA

mRNA Chemistry

mRNA Design & Modifications

mRNA Manufacturing Process

LUNAR® Delivery

Lipid Chemistry

Formulation Design

LUNAR® Drug Product Manufacturing

230+ Patents & Patent Applications

Program	Indication
LUNAR-COV19	COVID-19 Vaccine
LUNAR-FLU	Flu Vaccine
LUNAR-OTC	Ornithine Transcarbamylase (OTC) Deficiency
LUNAR-CF	Cystic Fibrosis

Additional earlier stage programs

Pipeline of mRNA Therapeutic Candidates

Multiple mRNA therapeutic and vaccine programs in clinical development

Franchise	Candidate	Indication	Prevalence	Route of Administration	Cell Target	Stage	Anticipated Milestones
Vaccines	**LUNAR-COV19 (ARCT-021)**	COVID-19	Global	Intramuscular	Myocytes & Dendritic Cells	Phase 2	Ph 3 Initiation (Global Entity)
	LUNAR-COV19 (ARCT-154)	COVID-19 (Targeting VOCs)	Global	Intramuscular	Myocytes & Dendritic Cells	Phase 1/2/3	EUA Filing by Vinbiotech December 2021
	LUNAR-FLU	Influenza	Global	Intramuscular	Myocytes & Dendritic Cells	Preclinical	CTA H2 2022
Hepatic	**LUNAR-OTC (ARCT-810)**	Ornithine Transcarbamylase Deficiency	> 10,000	Intravenous	Periportal Hepatocytes	Phase 2	Interim Data H2 2022
Respiratory	**LUNAR-CF (ARCT-032)**	Cystic Fibrosis	85,000-100,000	Inhaled	Bronchial Epithelial Cells	Preclinical	CTA H1 2022

EUA = Emergency Use Authorization; CTA = Clinical Trial Application; IND = Investigational New Drug Application; VOC = Variant of Concern

Licensed Platforms

Program	Partner	Indication	Stage
LUNAR-GSDIII	ultragenyx pharmaceutical	Glycogen Storage Disease Type III	Phase 1/2 *
LUNAR-RARE	ultragenyx pharmaceutical	Undisclosed Rare Disease	Preclinical
LUNAR-HBV	Johnson & Johnson	Hepatitis B Virus (HBV)	Preclinical
LUNAR-NASH	Takeda	Nonalcoholic Steatohepatitis (NASH)	Preclinical

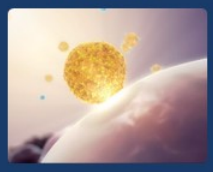
* https://clinicaltrials.gov/ct2/show/NCT04574830

$1B+ in Potential Milestones & Royalties

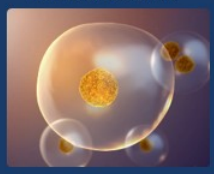
LUNAR® Delivery Technology

Biodegradable, optimized for targeted cell type

LUNAR® binds to cell membrane

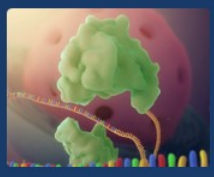


LUNAR® internalized inside endosome



mRNA release

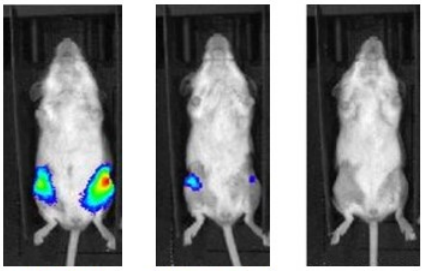
mRNA translated into protein of interest



STARR™ mRNA Expression Superior to Conventional mRNA

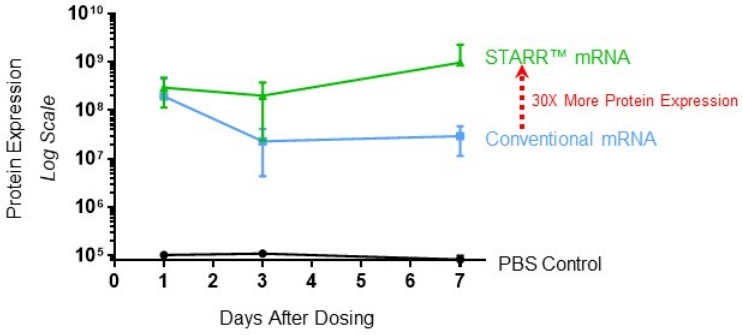
Self-Transcribing and Replicating mRNA (STARR™) delivered with LUNAR® provides increased and longer lasting expression in mouse models

STARR™ Technology
30-Fold Higher Protein Expression



STARR™ mRNA | Conventional mRNA | PBS Control

Protein Expression Over 7 days
STARR™ mRNA vs. Conventional mRNA



Single dose of STARR™ mRNA technology with LUNAR® delivery provided enhanced protein expression *in vivo* (mouse)

- LUNAR-COV19 (ARCT-021 and ARCT-154)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

LUNAR-COV19
(ARCT-021 and ARCT-154)

STARR™ COVID-19 Vaccine Candidates

Arcturus COVID-19 Vaccine Candidates have a Differentiated Profile

mRNA Vaccine - No Adjuvants, No Viral Vector Used, Readily Updatable as New Variants Arise

Self-Amplifying (STARR™) mRNA and LUNAR® Non-viral Delivery Technology

Clinical Data Demonstrate Humoral and Cellular Immunogenicity, and Tolerability

Low Dose Enables Rapid Global Scale-up

Global Manufacturing Footprint

Lyophilized Formulation: No Need for Storage at Ultra-cold Temps, Improved Supply Chain & Distribution Benefits

Global Manufacturing Footprint

Global manufacturing partners include Aldevron, Catalent, Recipharm, Polymun Scientific, ARCALIS, and Vingroup
Manufactured GMP finished doses of lyophilized vaccines for stockpiling purposes
Global capability to produce millions of doses

- LUNAR-COV19 (ARCT-021)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

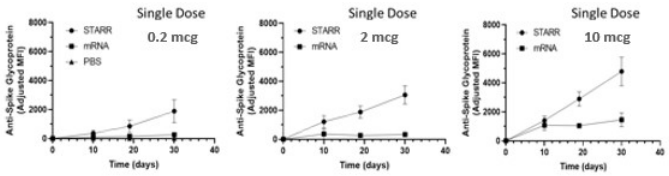
LUNAR-COV19 (ARCT-021)

STARR™ COVID-19 mRNA Vaccine Candidate

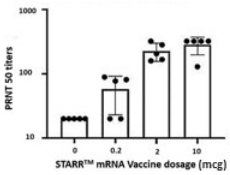
Preclinical data: Robust Immune Response in Mouse Models

Humoral immunity

STARR™ induces more robust titers compared to conventional mRNA



Neutralizing antibody titers and high seroconversion at low doses

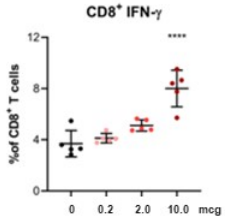


Single Dose (mcg)	Seroconversion	Neutralizing Antibody Titers (Geometric Mean)
0.2	80 %	58
2	100 %	218
10	100 %	≥ 320

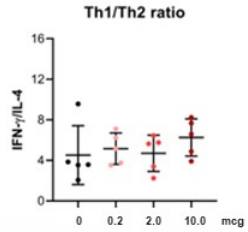
Cellular immunity

7 Days Post Single Dose

Adaptive Cellular Response (CD8+ cells)



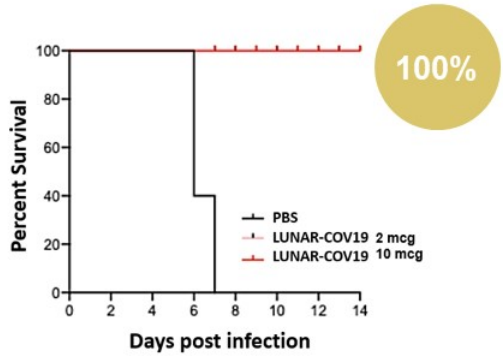
Balanced Th1/Th2 Immune Response (CD4+ cells)



- 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

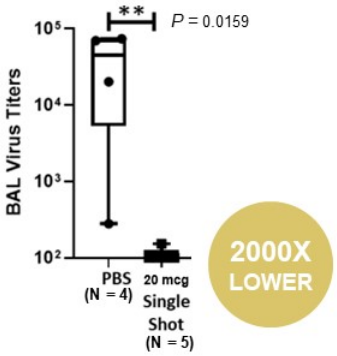
ARCT-021 in Challenge Models

Mouse model (transgenic human ACE2)



ARCT-021 significantly effective in a virus challenge study in the human ACE2 transgenic mouse model; single dose provided complete protection from SARS-CoV-2 infection and death, compared to control mice which experienced 100% mortality

Primate model (macaque)



7 Days After SARS-CoV-2 Virus Challenge

- Lung viral titers exceeded 13,100 (median) in non-vaccinated primates (PBS)
- Lung viral titers = 6.5 (median); more than 2000X lower in primates administered a single shot of ARCT-021

Single administration of ARCT-021 significantly effective in primate model (macaque); vaccinated macaques show substantial (3.30 log lower) reductions in median lung viral titers

ARCT-021 Clinical Trials

Phase 1/2 Clinical Trial

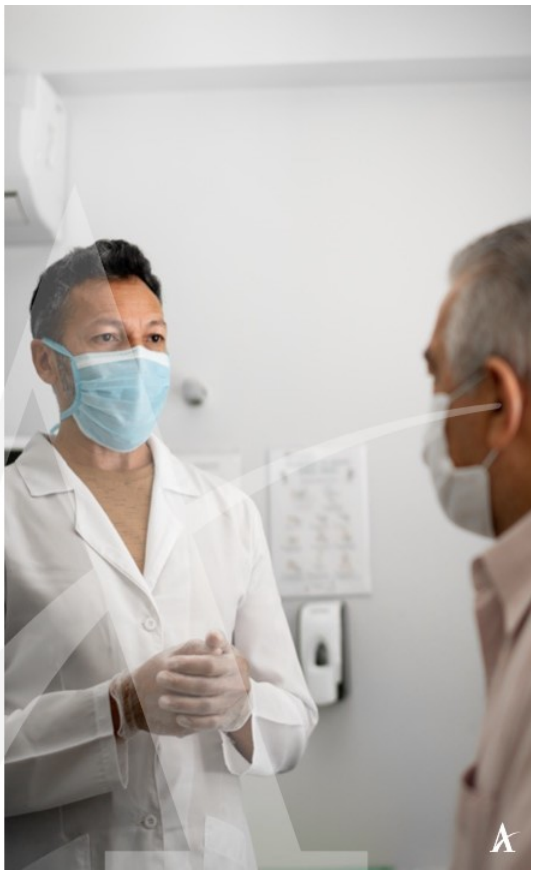
- Completed dosing all subjects (n=106), including older adults
- High seroconversion rates for IgG binding antibodies, and Th1 dominant CD4+ immune responses, neutralizing antibodies (PRNT50) Geometric Mean Titer (GMT) levels in the range of titers observed in convalescent serum
- Favorable safety and tolerability; no subjects withdrawn from dosing

Phase 2 Clinical Trial Ongoing

- Fully enrolled with 579 participants dosed across USA and Singapore
- Two dose levels evaluated: 5 mcg and 7.5 mcg
- Two interim analysis conducted; DSMB recommended to proceed with no modifications to protocol
- >90% seroconversion after single 5 mcg dose for IgG antibodies binding SARS-CoV-2 spike protein
- Booster vaccination with ARCT-021, -154, and -165 also being evaluated

Phase 3 Clinical Trial Initiation Anticipated

- Global entity to sponsor and fund
- Multinational study
- Placebo-controlled
- To enroll tens of thousands of participants
- 5 mcg, single injection regimen



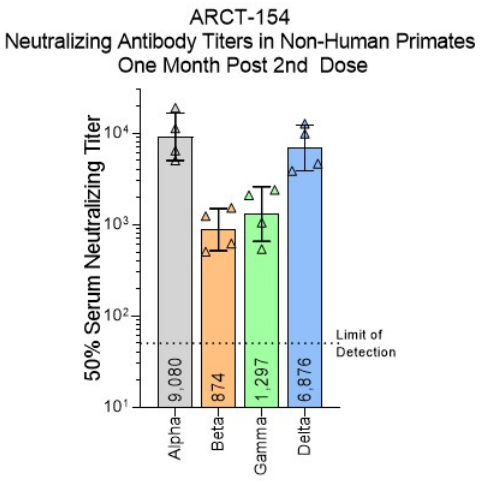
Comirnaty® is a trademark of BioNTech

- LUNAR-COV19 (ARCT-154)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

LUNAR-COV19 (ARCT-154)

STARR™ COVID-19 mRNA Vaccine Candidate Targeting Variants of Concern

ARCT-154 Preclinical Data and Clinical Trial Update



Non-Human primate (NHP) data collected one month after second dose of 7.5 mcg; Analysis of NHP serum was performed using non-replicating vesicular stomatitis virus pseudo-typed with the spike protein of the SARS-CoV-2 variants of concern indicated. Titers (geometric mean) were determined by calculating the dilution that resulted in 50% inhibition of cells expressing GFP encoded by the pseudovirus, a surrogate of virus infection. Error bars indicate geometric standard deviation.

Phase 1/2/3 Clinical Trial in Vietnam

- Phases 1/2/3 sponsored & funded by Vinbiotech
- Randomized, observer-blind, placebo-controlled design
- Enrollment completed with over 19,000 participants

Phase	n	Cohorts	Evaluation
1, 2, 3a	100, 300, 600	3:1 ARCT-154 : Placebo	Safety and Immunogenicity
3b	>16,000	1:1 ARCT-154 : Placebo	Safety and Immunogenicity
3c	~2,000	1:1 ARCT-154 : AstraZeneca COVID-19 Vaccine	Head-to-head comparison of immunogenicity non-inferiority

- Participants in Phase 1/2/3a/3b receive two doses of ARCT-154 (5 mcg) or placebo separated by 28 days.
- Placebo participants in Phase 1/2/3a/3b receive ARCT-154 at two months after second dose
- Participants in Phase 3c receive two doses of ARCT-154 (5 mcg) or AstraZeneca COVID-19 vaccine separated by 28 days
- Emergency Use Authorization (EUA) filing in Vietnam anticipated in December 2021

Phase 1/2 Clinical Trial in Singapore and US

- Two Cohorts (n = 72)
  - Primary vaccination evaluation; enrollment ongoing
  - Booster evaluation following initial vaccination with Comirnaty®; enrollment completed
    - Initial data anticipated in first quarter of 2022

- LUNAR-COV19 (ARCT-021)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

LUNAR-OTC (ARCT-810)

Ornithine Transcarbamylase (OTC) Deficiency

Ornithine Transcarbamylase (OTC) Deficiency

ARCT-810 market opportunity

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

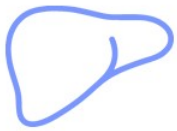
10,000 worldwide prevalence

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



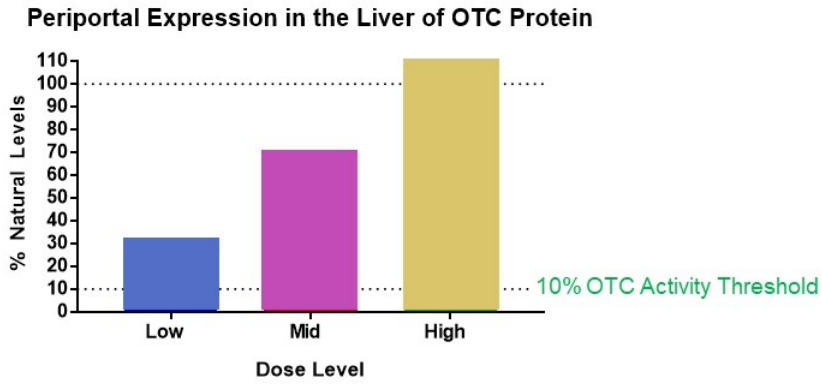
LUNAR-OTC Aims to Restore Enzyme Function

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

Exceeds target of 10% enzyme replacement at low, medium, and high doses in OTC-deficient mouse model

- OTCD impacts ureagenesis (ammonia detoxification)
- The main site of ureagenesis is the periportal region of the liver*



*Li, L. et al. PGC-1α 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 Clinical Update

Phase 1 **Clinical Trial in Health Volunteers Completed**

Phase 1b **Clinical Trial in OTC-Deficiency Adults Ongoing**

Phase 2 **Clinical Trial in OTC-Deficient Adolescents and Adults Approved to Proceed**

Randomized, double-blind, placebo-controlled, nested single and multiple ascending dose

Enroll up to 24 subjects across two dose cohorts

- *Primary Endpoints* Safety and tolerability
- *Secondary Endpoints* Pharmacokinetics and pharmacodynamic measures (ureagenesis assay, 24-hr ammonia profile)
- *Exploratory Endpoints* Biomarkers include plasma amino acids, plasma OTC enzyme activity, and urine orotic acid levels

Interim Phase 2 data anticipated in H2 2022 in a subset of participants

- LUNAR-COV19 (ARCT-021)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

LUNAR-CF (ARCT-032)

Cystic Fibrosis

Cystic Fibrosis

ARCT-032 Market Opportunity

Cystic Fibrosis

85,000-100,000 worldwide prevalence

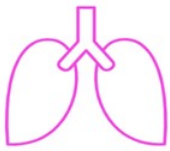
Caused by genetic mutations in the CFTR gene, resulting in aberrant flux of ions in and out of cells, causing thick mucus buildup in lung airways

Chronic airway obstruction leads to infection and inflammation, which causes permanent tissue scarring and respiratory failure

Unmet Medical Need

CFTR functional modulators are not 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



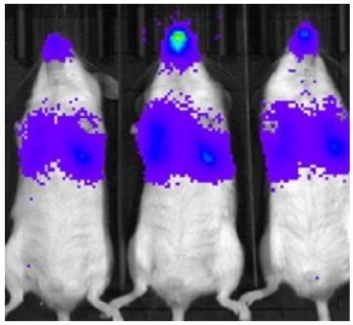
LUNAR-CF Aims to Restore CFTR Function

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

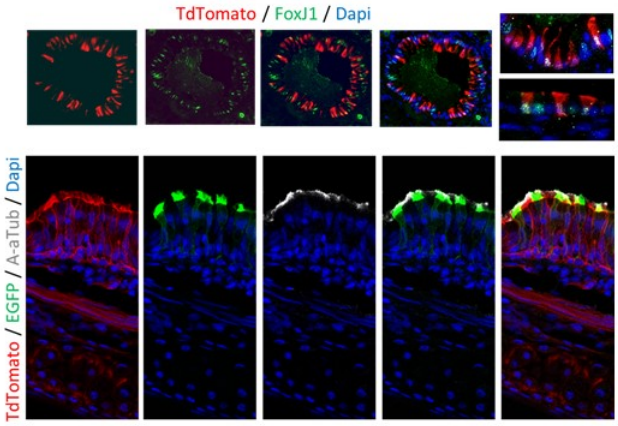
Delivery of LUNAR®-mRNA into Rodent and Non-Rodent Airways

Nebulization: upper/lower airways



LUNAR® + Luciferase mRNA

LUNAR® targets mice epithelial cells in rodents and nonrodents

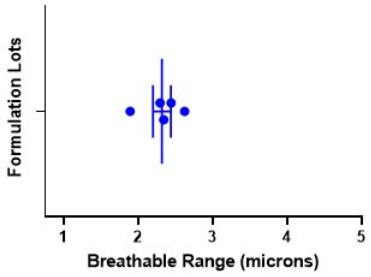


Ciliated cells (FoxJ1 in rodent/top, Acetylated alpha-tubulin in nonrodent/bottom)

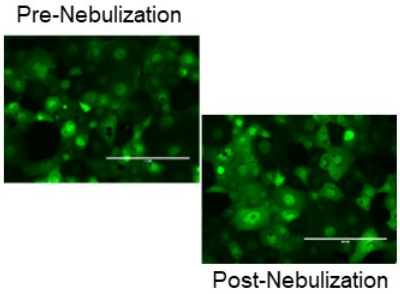
Efficient delivery of LUNAR®-mRNA formulations into rodent and non-rodent airways

Aerosolized LUNAR® Delivery Platform for Lung

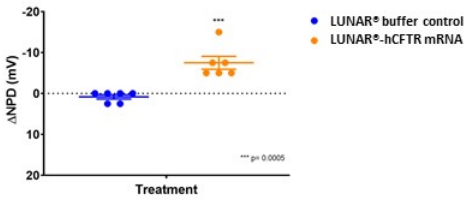
Aerosolized LUNAR® particles are breathable



Aerosolized LUNAR® mRNA (eGFP) maintains activity

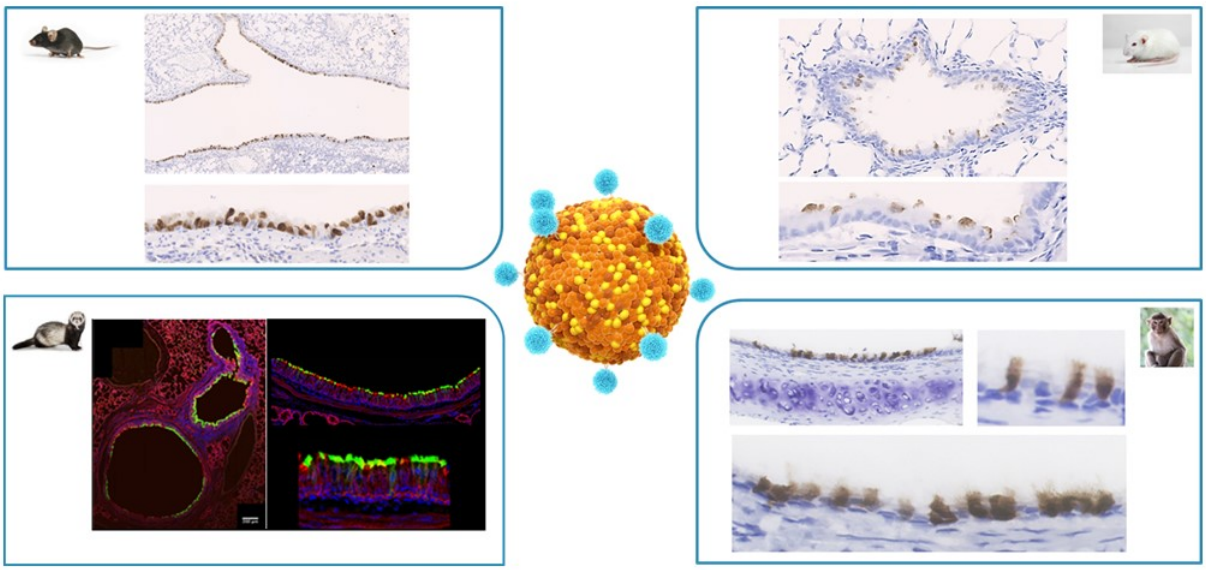


LUNAR® mRNA (hCFTR) is biologically active *in vivo* (NPD, mouse)



- Aerosolized LUNAR® droplets are in the optimal breathable range (1-5 microns)
- Aerosolized LUNAR® maintains activity as measured by eGFP protein expression & Nasal Potential Difference (NPD)

LUNAR®-mRNA Delivery to Airways Epithelium

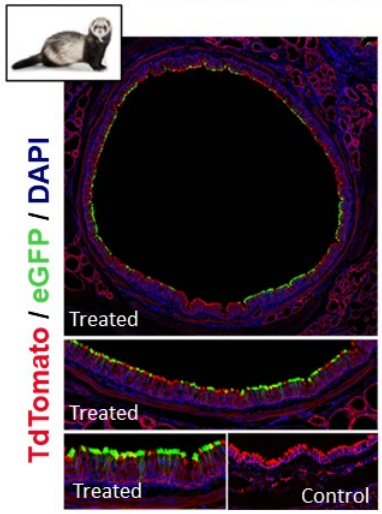


LUNAR® airway delivery is maintained across species (rodent and nonrodents)

Delivery of LUNAR®-mRNA to Airway Epithelium in a Ferret Model

eGFP conversion in tracheal epithelial airways observed in the ROSA26TG ferret model

- Ferrets are a reliable species for modeling certain human lung diseases*
- Novel LUNAR® formulations of Cre mRNA were tested in a transgenic ROSA26TG ferret model
- Activation of eGFP expression indicates that LUNAR® targets epithelial cells in ferret airways



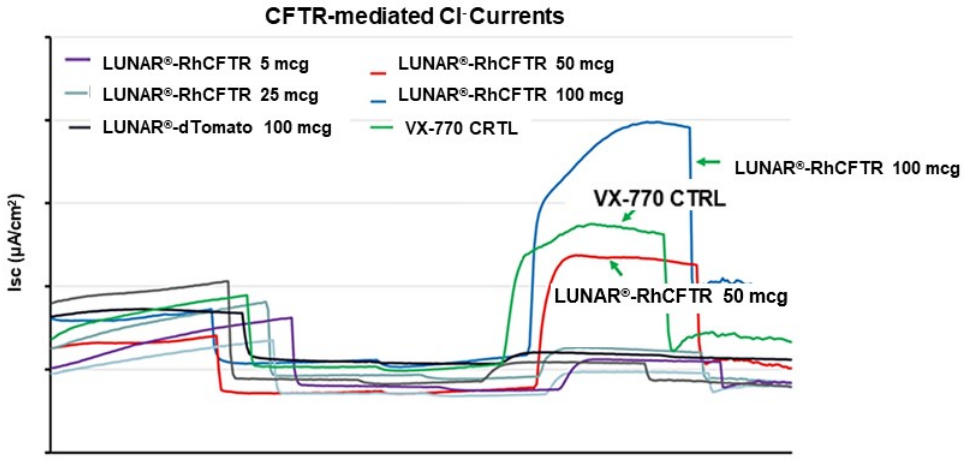
In collaboration with John Engelhardt, *University of Iowa*

*Yu, M., Sun, X., Tyler, S.R. *et al.* Highly Efficient Transgenesis in Ferrets. *Sci Rep* 9, 1971 (2019)

LUNAR® effectively delivered mRNA to airway epithelium in a ferret model

Functional Restoration of Chloride Current with LUNAR®-hCFTR

CFTR-deficient (G551D) Ferret Bronchial Epithelial Cells



Dose-dependent restoration of chloride activity in ferret bronchial epithelial cells carrying a G551D mutation

LUNAR®-hCFTR mRNA effectively restored chloride activity in CFTR-deficient ferret bronchial epithelial cells

ARCTURUS® therapeutics

Moving Forward

Anticipated Near-Term Milestones

ARCT-021 (COVID vaccine candidate)	
Phase 3 Initiation	Under Discussion with Global Entity
ARCT-154 (COVID vaccine candidate targeting VOCs)	
EUA Filing in Vietnam	December 2021
ARCT-810 (LUNAR-OTC)	
Interim Phase 2 Data	H2 2022
ARCT-032 (LUNAR-CF)	
Clinical Trial Application	H1 2022
LUNAR-FLU	
Clinical Trial Application	H2 2022

Team Arcturus

Management Team

Joseph E. Payne, MSc
President & CEO

Pad Chivukula, Ph.D.
CSO & COO

Andrew Sassine, MBA
CFO

Steve Hughes, M.D.
Chief Medical Officer

Lance Kurata, J.D.
Chief Legal Officer

Dushyant Varshney, Ph.D.
CTO

Nirdosh Jagota, Ph.D.
Chief Regulatory Officer

Board of Directors

Peter Farrell, Ph.D.
Chairman 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

Team Arcturus

Scientific Advisory Board

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CEO of Virtus Consultants, former Governor of Kansas. Appointments at Georgetown, Kansas School of Medicine, Uniformed Services University for Health Sciences, International Medical Corps

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Professor and Deputy Director of the Emerging Infectious Diseases Programme at the Duke-NUS Medical School

Frederick G. Hayden, M.D., FACP

Professor Emeritus of Clinical Virology and Medicine at Virginia University School of Medicine

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Robert T. Schooley, M.D.

Distinguished Professor of Medicine and Sr. Director of International Initiatives at the University of California San Diego

Jonathan Smith, Ph.D.

Chief Scientific Officer at VLP Therapeutics

Michael Hodges, M.D., BSc.

Biotechnology Scientific Advisor

Drew Weissman, M.D., Ph.D.

Professor of Medicine at the Perelman School of Medicine

ARCTURUS® therapeutics

Appendix

LUNAR-COV19 Seroconversion Data (Preclinical)

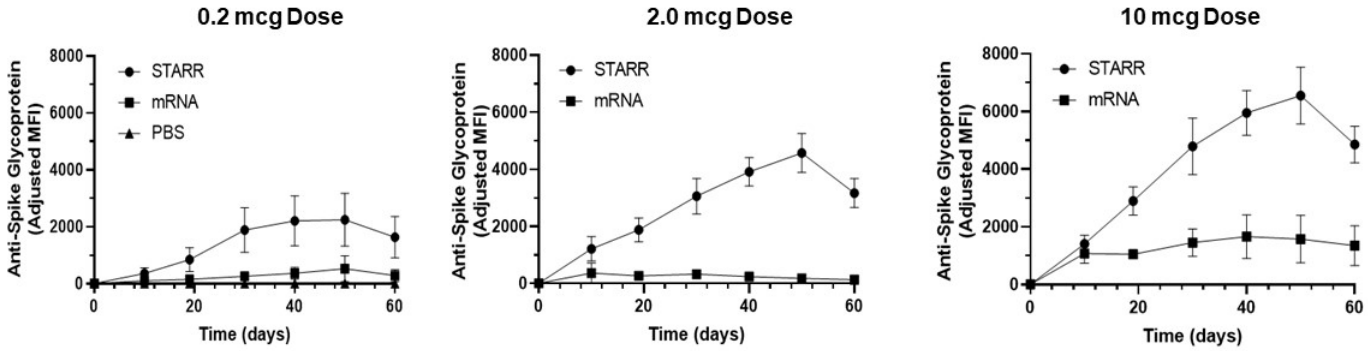
Seroconversion rate (% of Animals) – STARR™ mRNA vs. conventional mRNA

Single Dose (mcg)	LUNAR® Delivery			
	STARR™ mRNA (%)		Conventional mRNA (%)	
	Day 10	Day 19	Day 10	Day 19
0.2	40	60	20	20
2	80	**100**	20	0
10	100	100	40	80

100% of mice seroconverted by day 19 at a single low dose (2 mcg)

Preclinical Data: Anti-Spike Protein Levels Continue to Increase Up to 50 Days

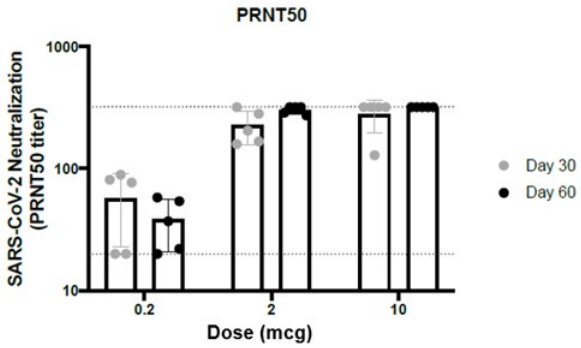
Single administration of LUNAR-COV19 (mouse)



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

Preclinical Data: Neutralizing Antibodies Continue to Increase for 60 Days

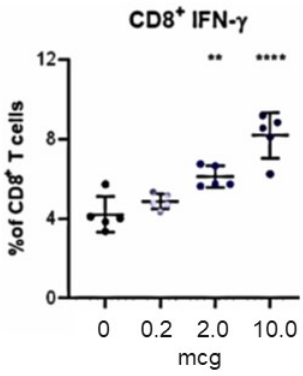
Single administration (small dose, 2 mcg) of LUNAR-COV19 (mouse)

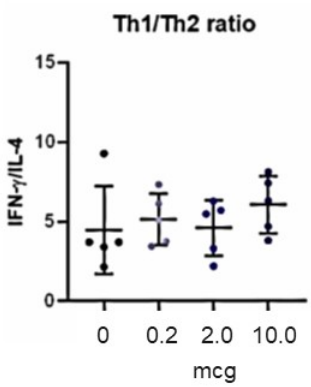


Virus neutralization assay:
Serum dilutions are incubated with SARS-CoV-2 virus, then added to cells. The cells die forming plaques, which are counted. The serum dilution that reduces the number of plaques by 50% is recorded (PRNT50). Maximum serum dilution tested was 1/320

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

Preclinical Data: Arcturus Vaccine Elicits a Balanced Cell-Mediated Immune Response in Mouse Model



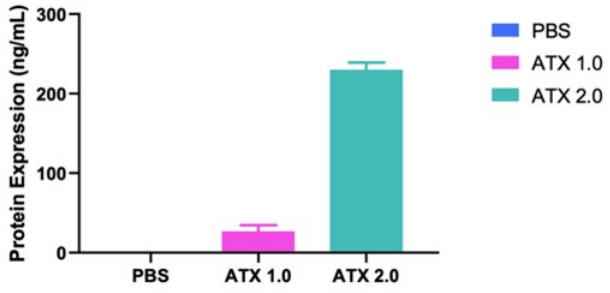


RNA Dose (mcg)	% IFN-γ+ CD8+ T Cells	CD4+ Th1/Th2 (IFN-γ/IL4)
0	4.0	4.6
0.2	4.5	5.3
2.0	6.0	5.0
10.0	8.0	6.0

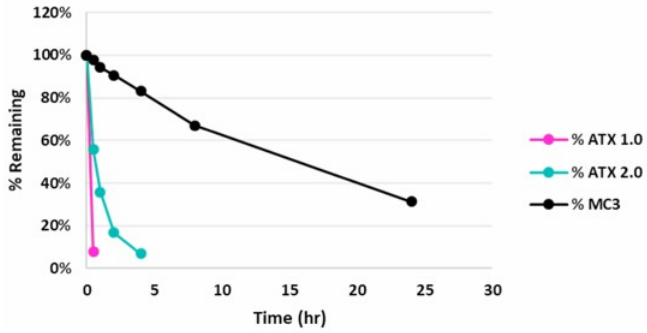
- RNA dose dependent increase in IFN-γ positive CD8+ T-cells
- Th1 biased CD4+ response and stable Th1/Th2 ratio with increased RNA dose indicate balanced cell mediated immune response

ATX Lipids Facilitate Delivery and are Biodegradable

Protein Expression (*in vivo*)



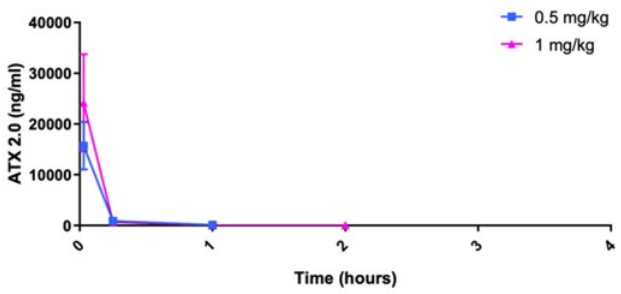
Esterase Catalyzed Degradation (*in vitro*)



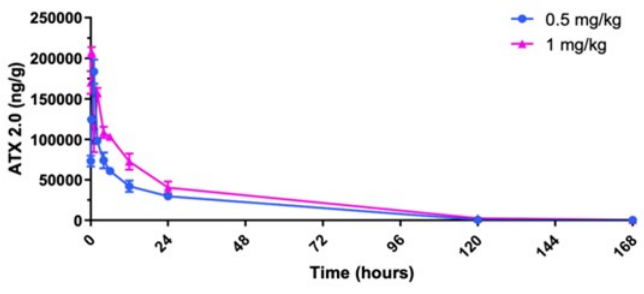
Next generation ATX lipids retain degradability and improve delivery efficiency

ATX 2.0 Lipid is Biodegradable and Exhibits a Favorable PK/PD Profile

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

Key Existing Country Relationships

Singapore

Research Partnership with Duke-NUS Medical School

Financial Support from the Economic Development Board of Singapore

- $10 M Grant for Research and Preclinical Work
- $6.7 M Grant for Phase 1/2 Clinical Trial
- Executed Manufacturing Support Agreement
- for $46.6 Million Non-Recourse Loan
- Up to $175 Million in vaccine purchases

Vietnam

Collaboration with Vingroup to Establish Manufacturing Facility

- $40 million upfront payment and potential royalties based on vaccines produced

Israel

Supply Agreement with Israel Ministry of Health

- Announced August 18, 2020
- $12.5 M Initial Reserve Payment was paid in October 2020

Drug Substance: mRNA Design

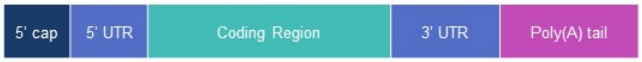
Arcturus' proprietary mRNA optimization platform

Optimize

- mRNA sequence
- Chemistry
- Process

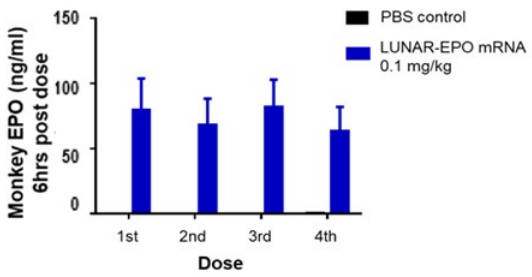
Improve

- Protein Expression
- Duration
- Functional Activity



Sustained hEPO activity in NHPs upon repeat dosing

Weekly Dosing in Non-Human Primates (NHPs)

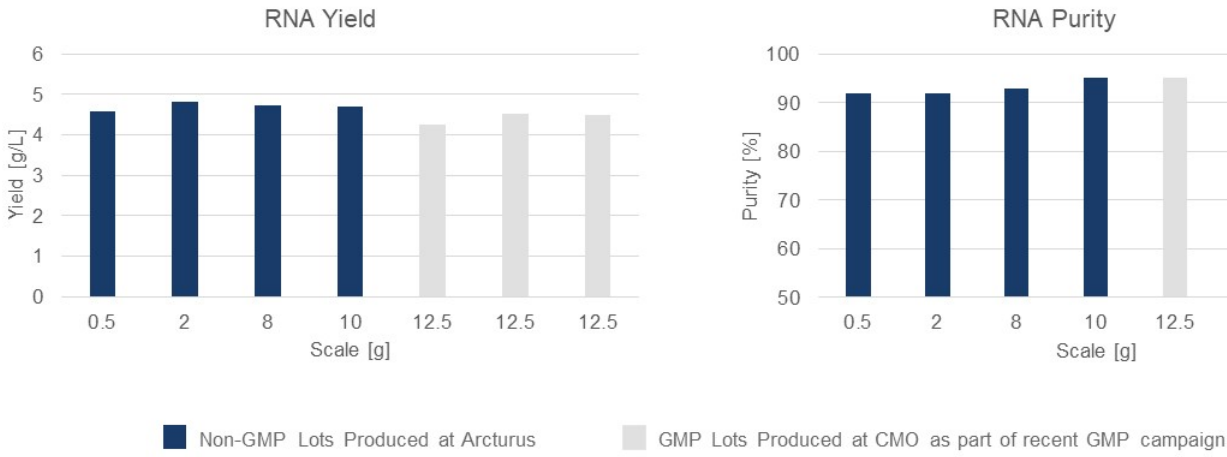


Proprietary mRNA optimization platform demonstrates sustained activity upon repeat dosing in NHPs

Drug Substance (mRNA) Manufacturing

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	Access Large Patient Populations
Adaptable	Can Utilize a Variety of Modifications

Drug Substance (mRNA) Manufacturing



Several successful GMP campaigns; acceptable quality and yield