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): February 17, 2022

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 February 17, 2022, 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 February 17, 2022
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: February 17, 2022

Arcturus Therapeutics Holdings Inc.

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

ARCTURUS® therapeutics

Next Generation RNA Medicines

February 2022

Forward Looking Statements

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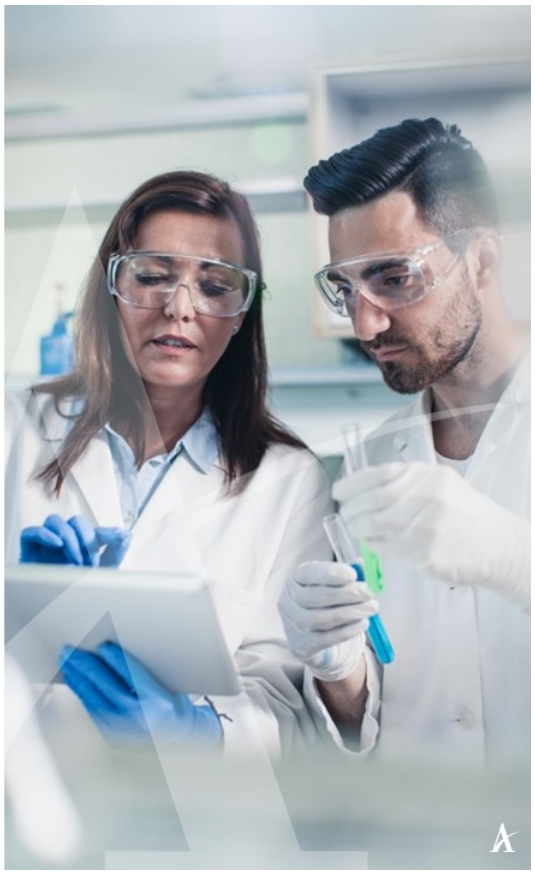
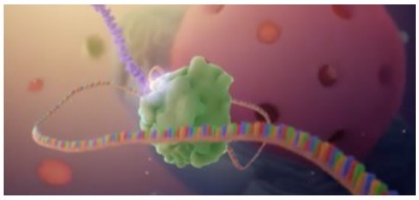


Arcturus Therapeutics



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 (Primary and Booster)*
LUNAR-OTC	*Ornithine Transcarbamylas 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 Primary and Booster 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-154)**	COVID-19 (Targeting VOCs)	Global	Intramuscular	Myocytes & Dendritic Cells	Phase 1/2/3	EUA Filing Commenced Dec 2021 by Vinbiotech; Completion of EUA Submission Q1 2022
	LUNAR-COV19 (ARCT-021)	COVID-19	Global	Intramuscular	Myocytes & Dendritic Cells	Phase 2	Phase 3 Initiation (To be Updated by Global Entity)
	LUNAR-FLU	Influenza	Global	Intramuscular	Myocytes & Dendritic Cells	Preclinical	STARR™ Candidate Selection 2022; CTA 2023
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 Q3 2022

EUA = Emergency Use Authorization; STARR™ = Self-transcribing and replicating RNA, 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

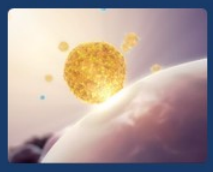
* https://clinicaltrials.gov/ct2/show/NCT04574830

$1B+ in Potential Milestones & Royalties

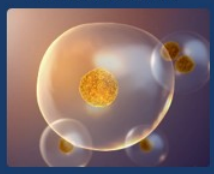
LUNAR® Delivery Technology

Biodegradable, optimized for targeted cell type

LUNAR® interacts with cell membrane

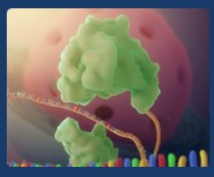


LUNAR® internalized inside endosome



mRNA release

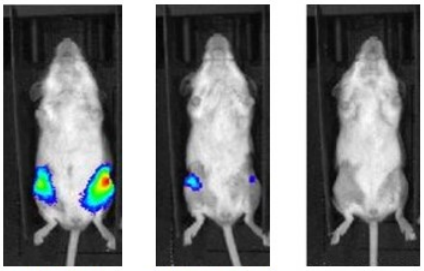
mRNA translated into protein of interest



STARR™ mRNA Expression Superior to Conventional mRNA

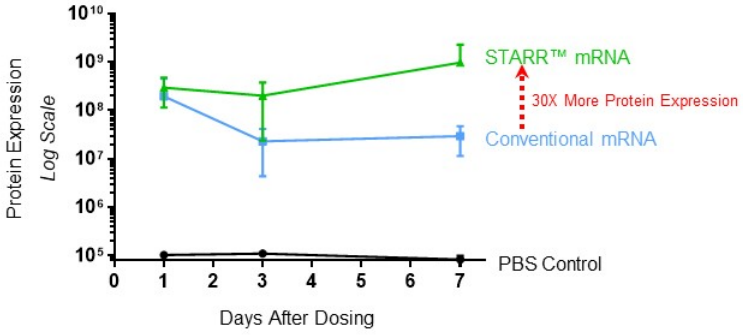
Self-Transcribing and Replicating mRNA (STARR™) delivered with LUNAR® provides increased and longer lasting expression in mouse models

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-154, ARCT-165, ARCT-021)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

LUNAR-COV19

Self-Amplifying (STARR™) mRNA COVID-19 Primary and Booster 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: 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

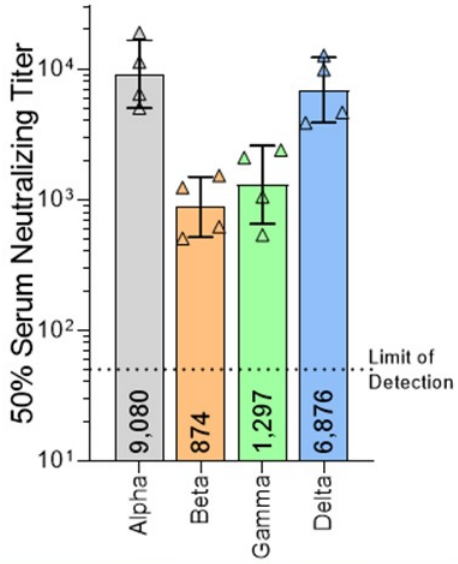
- LUNAR-COV19 (ARCT-154, ARCT-165)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

LUNAR-COV19

ARCT-154, ARCT-165

Self-Amplifying (STARR™) mRNA COVID-19
Primary and Booster Vaccine Candidates Targeting

Preclinical Data: ARCT-154 – Neutralizing Antibody Titers in Non-Human Primates



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

Clinical Trial Update: ARCT-154 and ARCT-165

ARCT-154 - 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

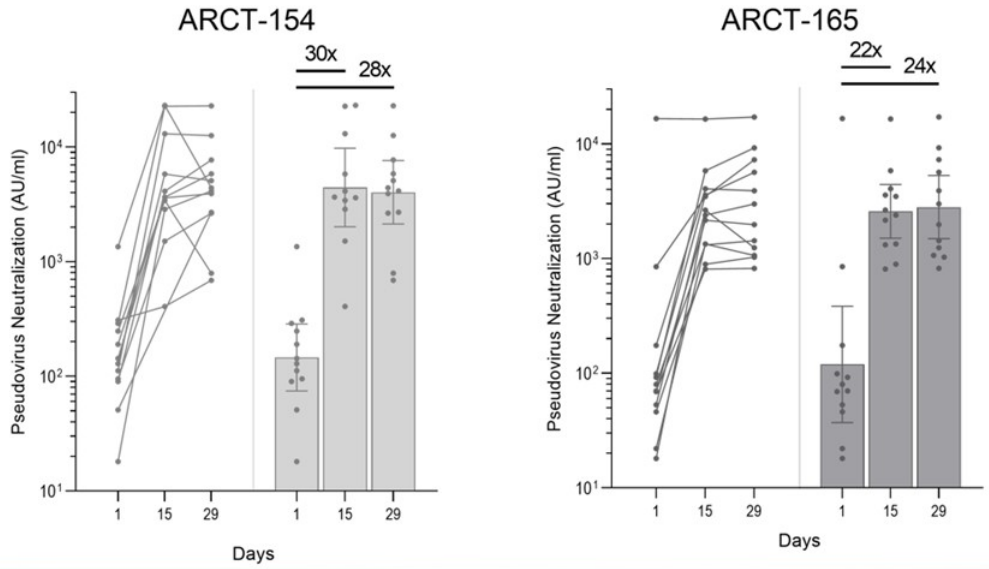
- Participants in Phase 1/2/3a/3b receive two doses of ARCT-154 (5 mcg) or placebo separated by 28 days.
- Placebo participants in Phase 1/2/3a/3b receive ARCT-154 (5 mcg) at two months after second dose
- Participants in Phase 3c receive two doses of ARCT-154 (5 mcg) or AstraZeneca COVID-19 vaccine separated by 28 days
- Emergency Use Authorization (EUA) filing commenced in December 2021; completion anticipated in Q1 2022

Phase 1/2 Booster Clinical Trial in Singapore and U.S. Evaluating ARCT-021, ARCT-154, and ARCT-165

Two Cohorts (n = 72)

- Cohort A: Primary vaccination evaluation; enrollment ongoing
- Cohort B: Evaluation of Arcturus vaccine candidates as booster following initial vaccination with Comirnaty®
  - Data shows encouraging neutralizing antibody activity against variants of concern (including Omicron, Delta, and Beta)

Phase 1/2 Booster Clinical Trial Data – Neutralizing Antibodies Against D614G in Validated Pseudovirus Microneutralization Assay

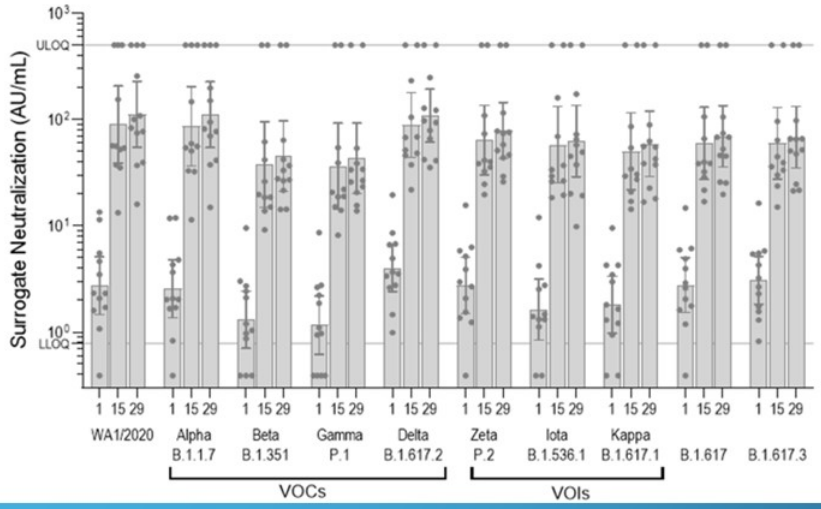


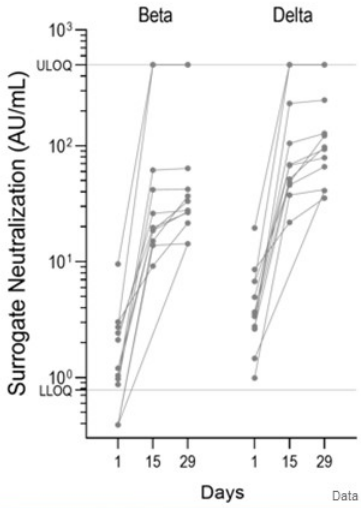
Data from PPD Laboratories, USA

Boosting with ARCT-154 (n = 12) increased geometric mean neutralizing antibody concentration against D614G **28-fold**

Boosting with ARCT-165 (n = 12) increased geometric mean neutralizing antibody concentration **24-fold**

Phase 1/2 Booster Clinical Trial Data – Broad Neutralization Activity Against Variants of Concern upon Boosting with ARCT-154 (5 mcg) in Exploratory Surrogate Virus Neutralization Assay

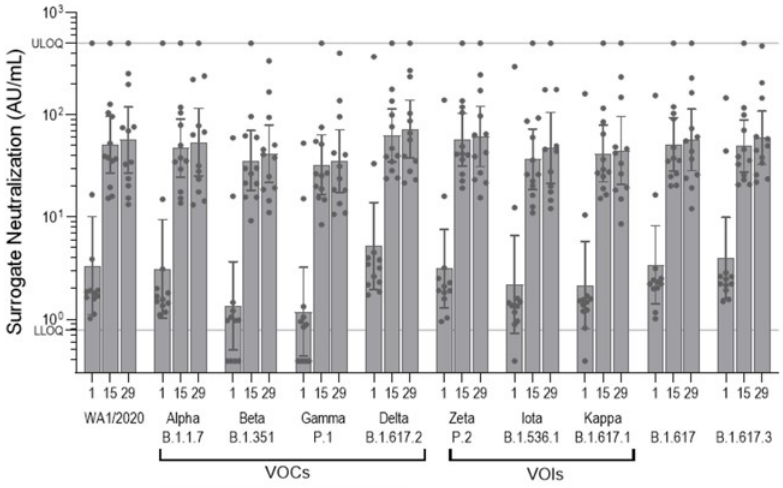


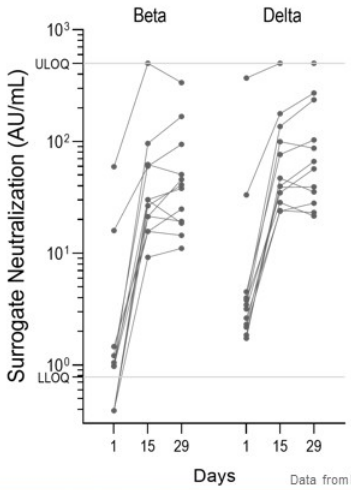


Data from PPD Laboratories, USA

Boosting with ARCT-154 (n = 12) increased geometric mean neutralizing antibody concentrations against a broad range of Variants of Concern (VoCs) and Variants of Interest (VoIs), including Delta and Beta

Booster Clinical Trial Data – Broad Neutralization Activity Against Variants of Concern upon Boosting with ARCT-165 (5 mcg) in Exploratory Surrogate Virus Neutralization Assay

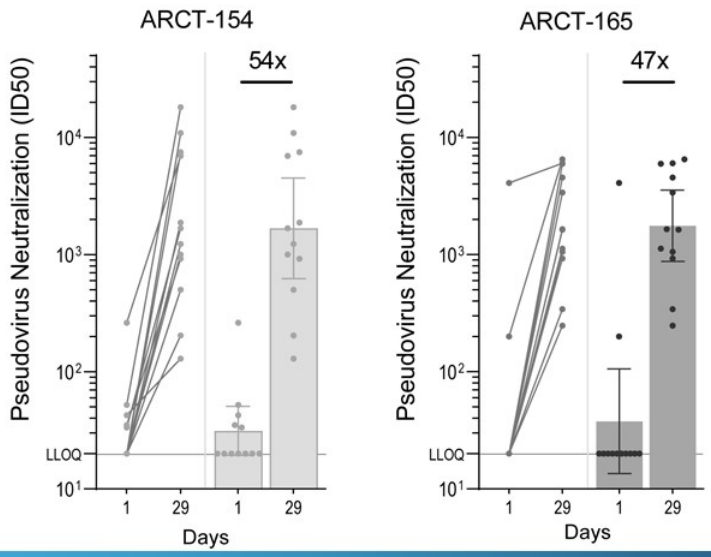




Data from PPD Laboratories, USA

Boosting with ARCT-165 (n = 12) increased geometric mean neutralizing antibody concentrations against a broad range of Variants of Concern (VoCs) and Variants of Interest (VoIs), including Delta and Beta

Phase 1/2 Booster Clinical Trial Data – Neutralizing Antibodies Against Omicron in Exploratory Microneutralization Assay



Data from Penny Moore Lab, South Africa

Boosting with ARCT-154 (n = 12) increased geometric mean neutralizing antibody titers against Omicron **54-fold**

Boosting with ARCT-165 (n = 12) increased geometric mean neutralizing antibody titers **47-fold**

- LUNAR-COV19 (ARCT-154, ARCT-165, ARCT-021)
- LUNAR-OTC (ARCT-810)
- LUNAR-CF (ARCT-032)

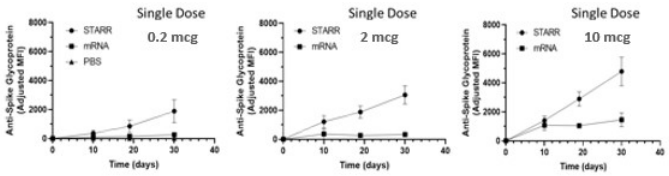
LUNAR-COV19
ARCT-021

STARR™ COVID-19 mRNA Vaccine Candidate

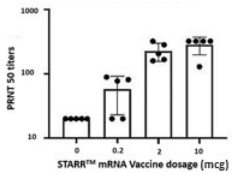
STARR™ Preclinical Data Using Ancestral/Wuhan Strain – Robust Immune Response in Mouse Models

Humoral immunity

STARR™ induces more robust titers compared to conventional mRNA



Neutralizing antibody titers and high seroconversion at low doses

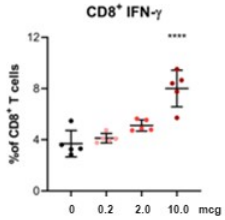


Single Dose (mcg)	Seroconversion	Neutralizing Antibody Titers (Geometric Mean)
0.2	80 %	58
2	100 %	218
10	100 %	≥ 320

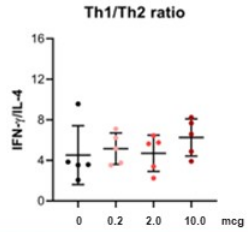
Cellular immunity

7 Days Post Single Dose

Adaptive Cellular Response (CD8+ cells)



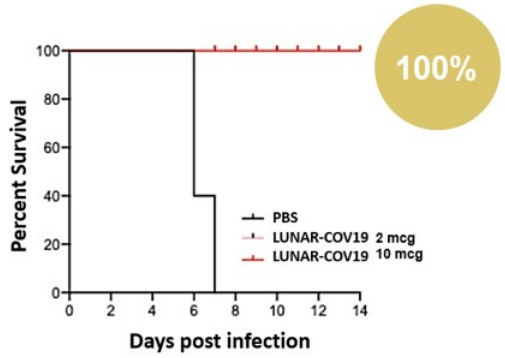
Balanced Th1/Th2 Immune Response (CD4+ cells)



- Single administration with a very low dose of Arcturus COVID vaccine resulted in potent immune reaction against ancestral/Wuhan strain
- STARR™ mRNA generate 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

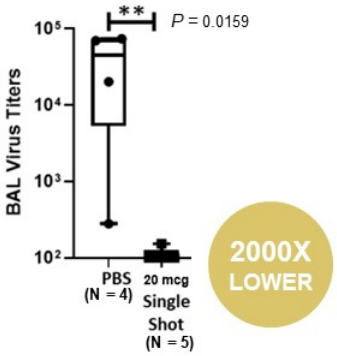
ARCT-021 Activity Against Ancestral/Wuhan Strain in Challenge Models

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) against SARS-Cov-2; vaccinated macaques show substantial (3.30 log lower) reductions in median lung viral titers

ARCT-021 Clinical Trials

Phase 1/2 Clinical Trial

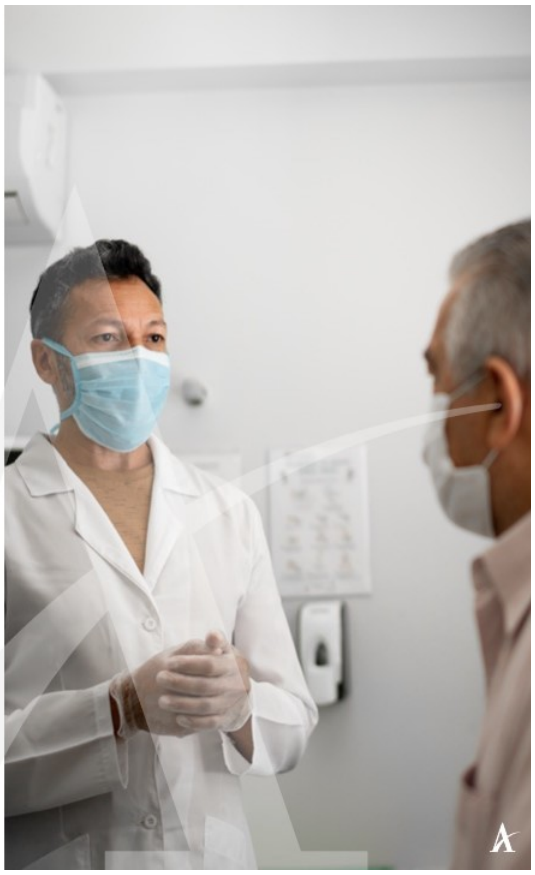
- Completed dosing all subjects (n=106), including older adults
- High seroconversion rates for IgG binding antibodies, and Th1 dominant CD4+ immune responses, neutralizing antibodies (PRNT50) Geometric Mean Titer (GMT) levels in the range of titers observed in convalescent serum
- Favorable safety and 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, ARCT-165, 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

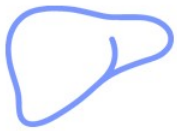
10,000 worldwide prevalence

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



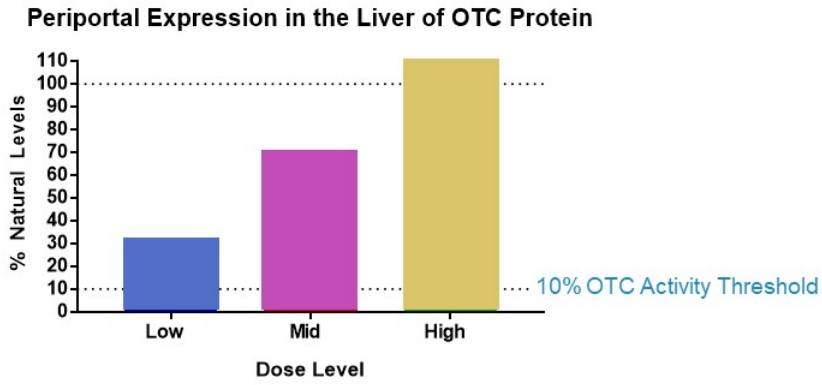
LUNAR-OTC Aims to Restore Enzyme Function

Expression of OTC enzyme in liver has potential to restore 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

- Single doses of ARCT-810 (OTC mRNA) up to 0.4 mg/kg found to be generally safe and well tolerated
- All doses tested were in the expected therapeutic range

Phase 1b Clinical Trial in OTC-Deficiency Adults Ongoing

- Multiple sites activated or in start-up
- Anticipate completion of first dose cohort in 2Q 2022

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; Approved to proceed in multiple European countries

- 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

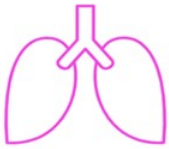
Caused by genetic mutations in the CFTR gene, resulting in aberrant flux of ions in and out of cells, causing thick mucus buildup in lung airways

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

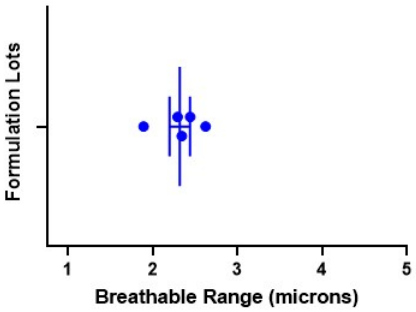
An mRNA replacement therapy has the potential to deliver a new copy of CFTR into the lungs of CF patients, independent of any genotype

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

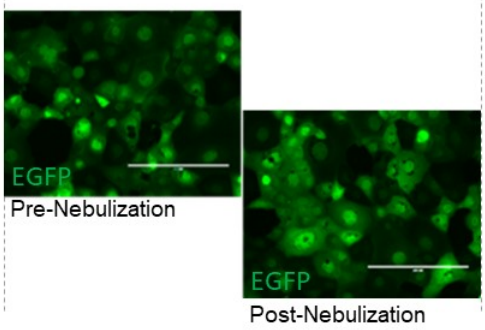
CTA filing for First-in-Human study planned Q3 2022

Aerosolized LUNAR® Delivery Platform for Lung

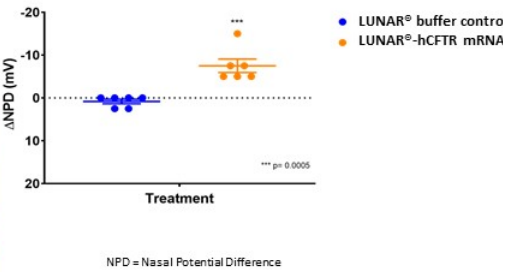
Aerosolized LUNAR® particles are in the respirable size range



Expression is preserved after aerosolization of LUNAR®-mRNA



ARCT-032 is biologically active *in vivo* (mouse)

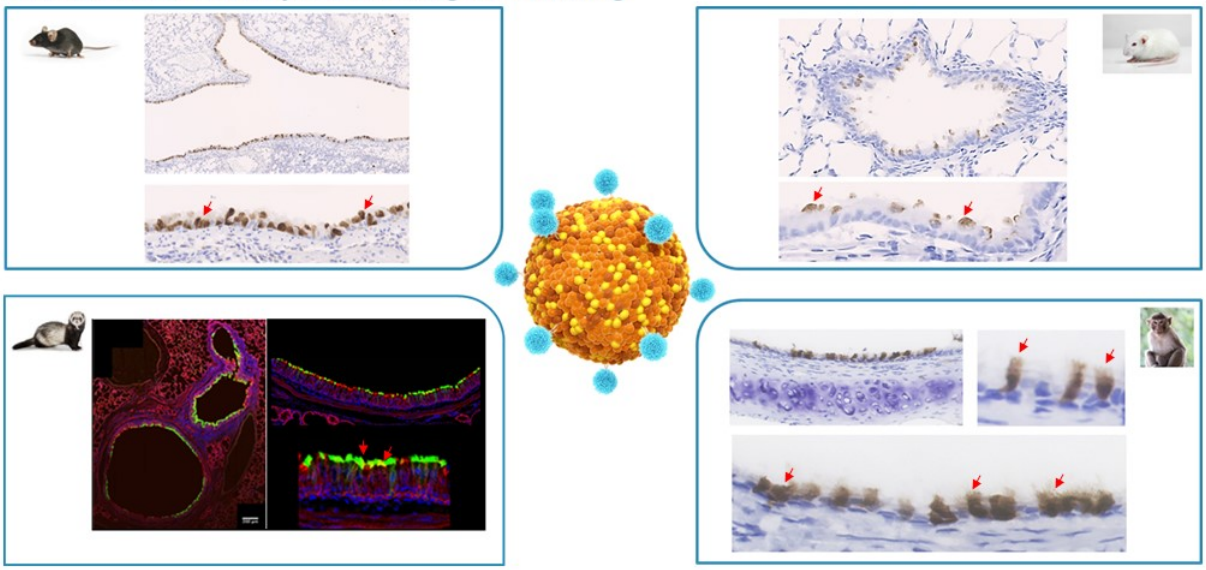


NPD = Nasal Potential Difference

- Aerosolized LUNAR®-mRNA is within the appropriate droplet size and maintains expression
- ARCT-032 improves CFTR activity in CF mouse model

LUNAR®-mRNA Delivery to Airways Epithelium

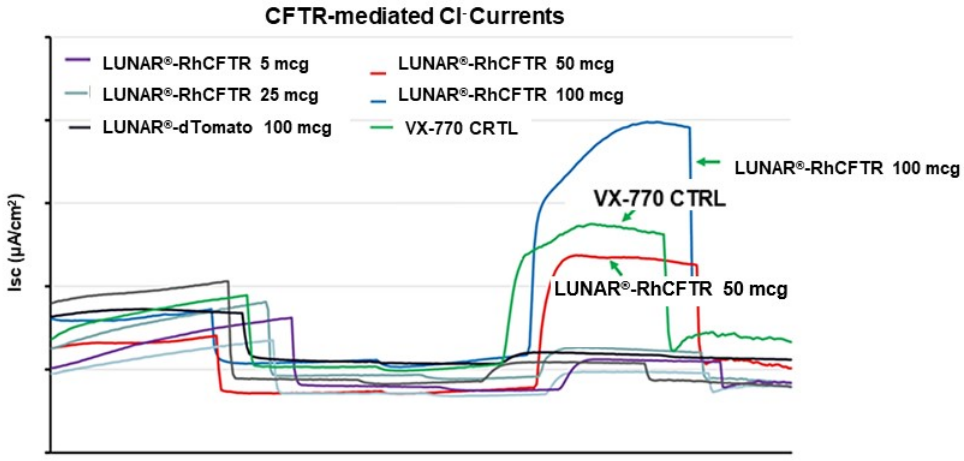
Transduction demonstrated by brown and green staining



LUNAR® delivery is maintained across rodent and nonrodents species

Functional Restoration of Chloride Current with ARCT-032

CFTR-deficient (G551D) Ferret Bronchial Epithelial Cells



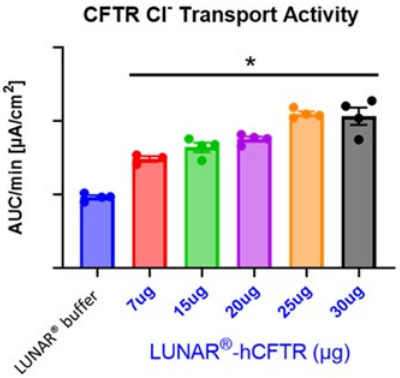
Dose-dependent restoration of chloride activity in ferret bronchial epithelial cells carrying a G551D mutation

Dose-dependent restoration of chloride activity with ARCT-032

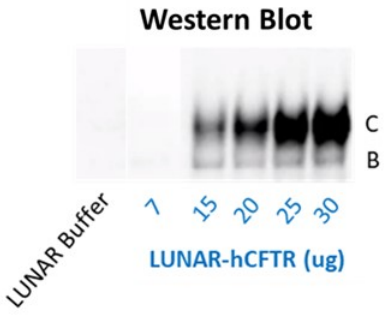
Activity comparable to VX-770 (ivacaftor) in G551D gating-mutation cells

Restoration of CFTR Expression and Function in Human bronchial epithelial cells with F508del mutation

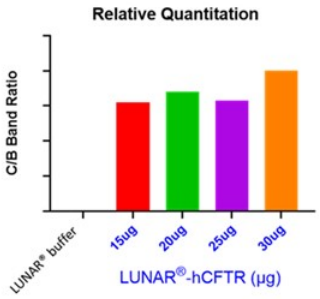
ARCT-032 restored chloride activity in ALI culture of HBE cells carrying a F508del$^{+/+}$ mutation



High levels of mature CFTR protein were generated in F508del$^{+/+}$ HBE cells transduced with ARCT-032



Increased C/B band ratio in F508del$^{+/+}$ HBE cells transduced with ARCT-032



ARCT-032 resulted in a dose-dependent restoration of chloride activity and generation of high levels of mature C-Band CFTR in F508del$^{+/+}$ human bronchial epithelial cells

ARCTURUS® therapeutics

Moving Forward

Anticipated Near-Term Milestones

ARCT-154 (COVID vaccine candidate targeting VOCs)	
EUA Filing in Vietnam	Completion of Submission Q1 2022
ARCT-154 (COVID vaccine candidate targeting VOCs)	
Clarity on Regulatory Path for Booster Indication	Q1 2022
ARCT-021 (COVID vaccine candidate)	
Phase 3 Initiation	To be Updated by Global Entity
ARCT-810 (LUNAR-OTC)	
Interim Phase 2 Data	H2 2022
ARCT-032 (LUNAR-CF)	
Clinical Trial Application	Q3 2022
LUNAR-FLU	
Clinical Trial Application	STARR™ Candidate Selection 2022; CTA 2023

Team Arcturus

Management Team

Joseph E. Payne, MSc
President & CEO

Pad Chivukula, Ph.D.
CSO & COO

Andrew Sassine, MBA
CFO

Lance Kurata, J.D.
Chief Legal Officer

Dushyant Varshney, Ph.D.
CTO

Kelly Lindert, M.D.
CDO, Vaccines

Steve Hughes, M.D.
Strategic Clinical Advisor

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Peter Farrell, Ph.D.
Chairman of the Board

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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

Jing L. Marantz, M.D., Ph.D., MBA
Director of the Board

Team Arcturus

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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

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Chief Scientific Officer at VLP Therapeutics

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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 against Ancestral/Wuhan Strain (Preclinical)

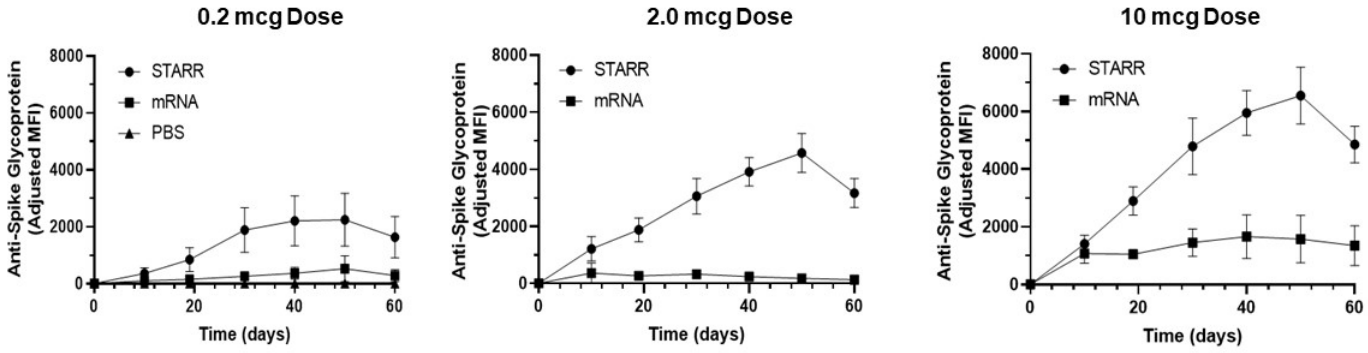
Seroconversion rate (% of Animals) – STARR™ mRNA vs. conventional mRNA

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

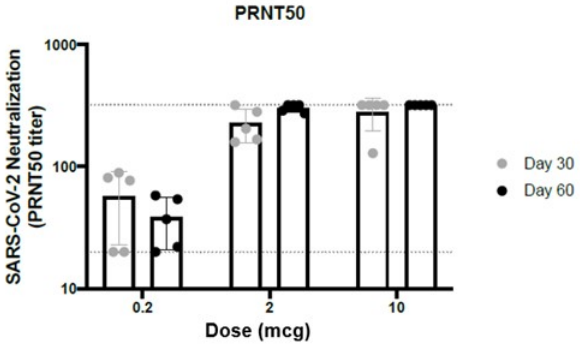
Single administration of LUNAR-COV19 ancestral/Wuhan strain spike protein mRNA in conventional mRNA or STARR™ format (in mice)



- 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

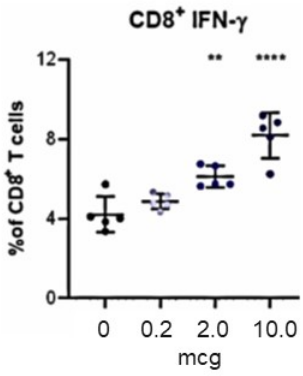
Single administration (small dose, 2 mcg) of LUNAR-COV19 ancestral/Wuhan strain spike protein (mouse)

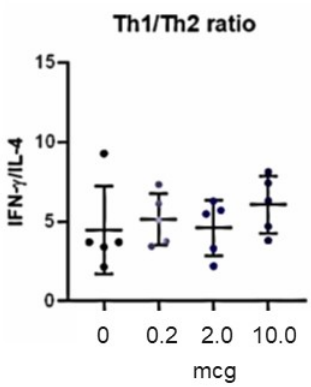


Virus neutralization assay:
Serum dilutions are incubated with SARS-CoV-2 virus, then added to cells. The cells die forming plaques, which are counted. The serum dilution that reduces the number of plaques by 50% is recorded (PRNT50). Maximum serum dilution tested was 1/320

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

Preclinical Data: Arcturus Vaccine Elicits a Dose-Dependent Cell-Mediated Immune Response against Ancestral/Wuhan strain in Mouse Model



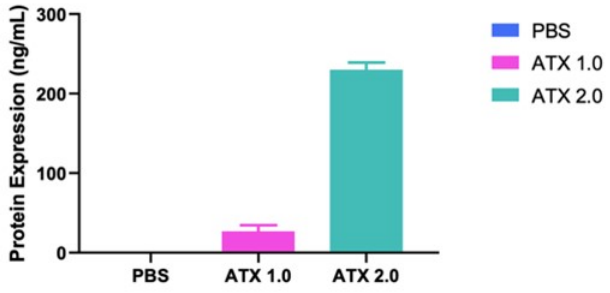


RNA Dose (mcg)	% IFN-γ+ CD8+ T Cells	CD4+ Th1/Th2 (IFN-γ/IL4)
0	4.0	4.6
0.2	4.5	5.3
2.0	6.0	5.0
10.0	8.0	6.0

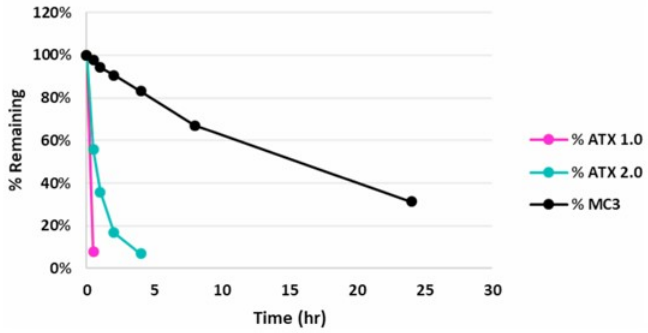
- RNA dose-dependent increase in IFN-γ positive CD8+ T-cells
- Th1 biased CD4+ response and stable Th1/Th2 ratio with increased RNA dose indicate balanced cell mediated immune response

ATX Lipids Facilitate Delivery and are Biodegradable

Protein Expression (*in vivo*)



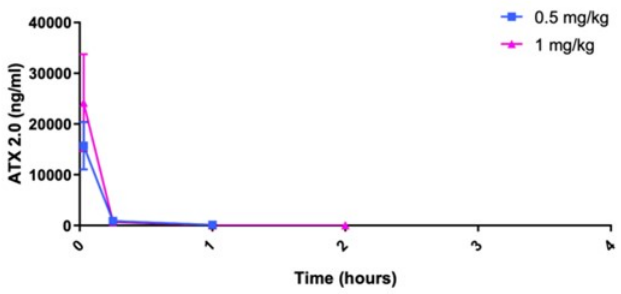
Esterase Catalyzed Degradation (*in vitro*)



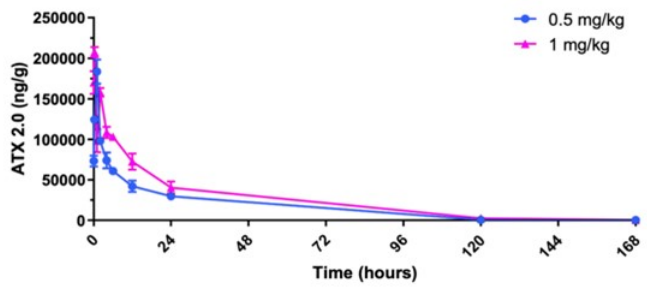
Next generation ATX lipids retain degradability and improve delivery efficiency

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

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

Vietnam

Collaboration with Vingroup

- Fully Sponsored Phase 1/2/3 Trial of ARCT-154
- Establish Hanoi Manufacturing Facility (Up to 200M doses/year)
- $40M 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

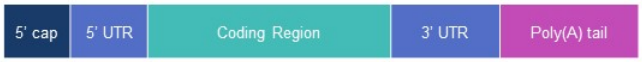
Arcturus' proprietary mRNA optimization platform

Optimize

- mRNA sequence
- Chemistry
- Process

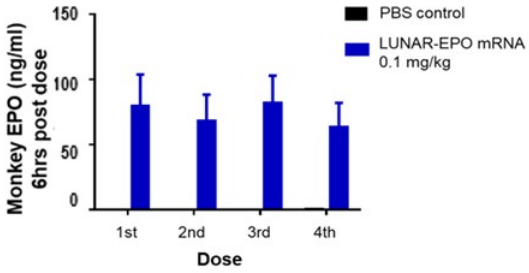
Improve

- Protein Expression
- Duration
- Functional Activity



Sustained hEPO activity in NHPs upon repeat dosing

Weekly Dosing in Non-Human Primates (NHPs)

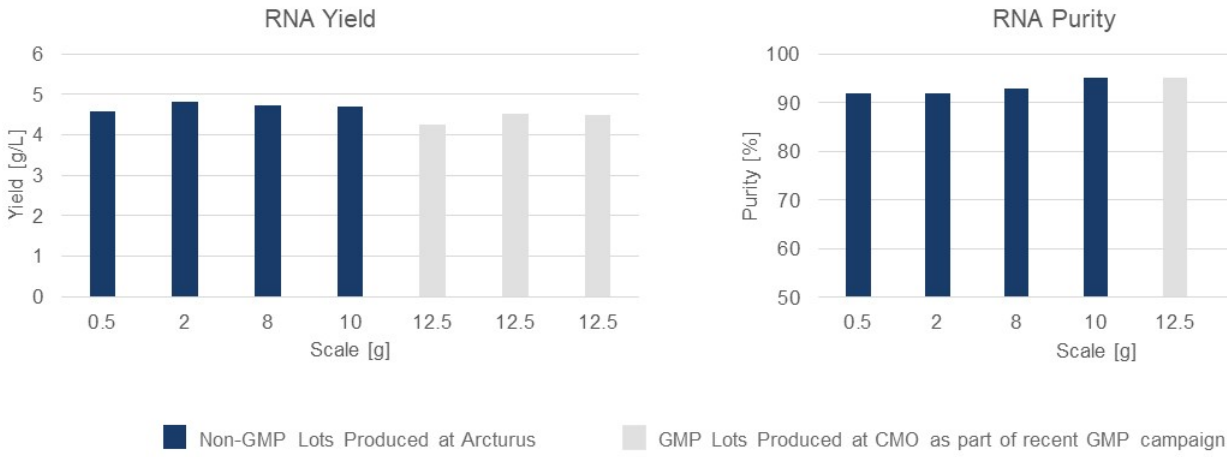


Proprietary mRNA optimization platform demonstrates sustained activity upon repeat dosing in NHPs

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