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): June 18, 2020

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 7.01. Regulation FD Disclosure.

Arcturus Therapeutics Holdings Inc. (the "Company") has made available a presentation about the Company's business (the "Presentation"), a copy of which is filed as Exhibit 99.1 to this Current Report on Form 8-K (the "Report") and is hereby incorporated by reference.

The furnishing of the Presentation is not an admission as to the materiality of any information therein. The information contained in the Presentation is summary information that should be considered in the context of the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements the Company may make by press release or otherwise from time to time. The Presentation speaks as of the date of this Report. While the Company may elect to update the Presentation in the future to reflect events and circumstances occurring or existing after the date of this Report, the Company specifically disclaims any obligation to do so.

The Presentation contains forward-looking statements, and as a result, investors should not place undue reliance on these forward-looking statements.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this communication and the Presentation are "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. 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 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.

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 this communication and the Presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Arcturus' Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020 and in subsequent filings with, or submissions to, the SEC. Except as otherwise required by law, the Company disclaims 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 June 2020

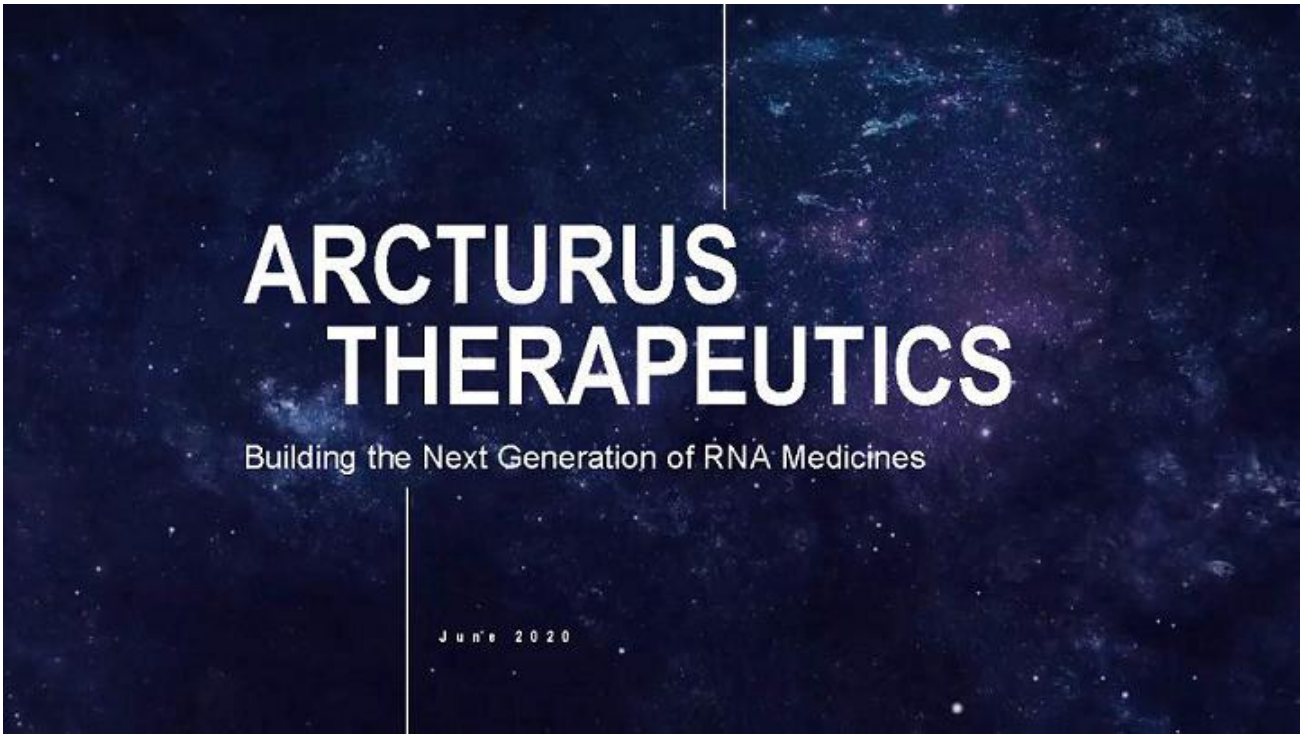
SIGNATURES

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.

Arcturus Therapeutics Holdings Inc.

Date: June 18, 2020

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


ARCTURUS
THERAPEUTICS
Building the Next Generation of RNA Medicines
June 2020

FORWARD LOOKING STATEMENTS

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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: 97
- 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

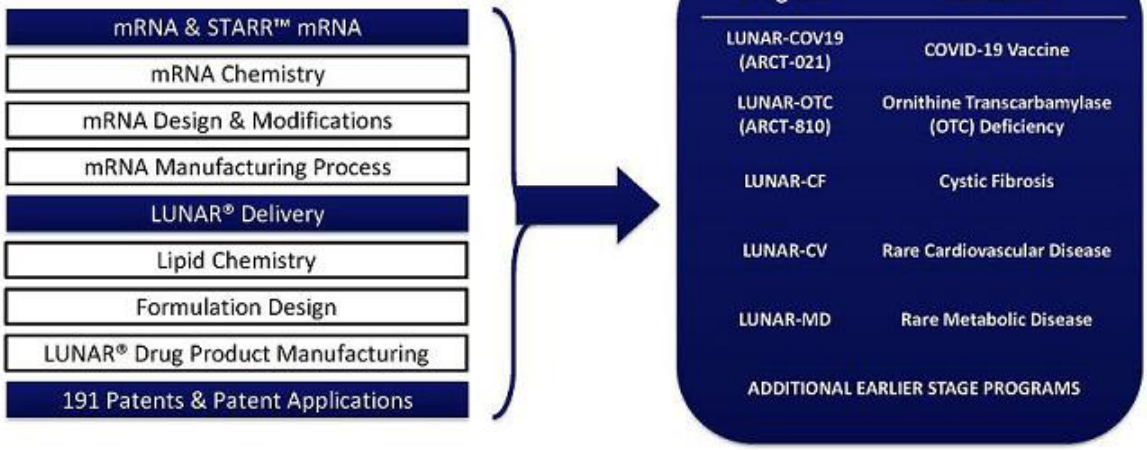
Johnson & Johnson · Takeda · ultragenyx pharmaceutical · Cystic Fibrosis Foundation · DukeNUS Medical School · Catalent

ARCTURUS THERAPEUTICS

Proprietary mRNA Technologies Driving Promising Therapeutic Programs

BUILDING INNOVATIVE RNA MEDICINES

Broad and Strong Intellectual Property Portfolio



Arcturus Pipeline of mRNA Medicines

BUILDING INNOVATIVE RNA MEDICINES

Name	Indication	Route of Administration	Target Organ (Cell Type)	Prevalence Worldwide	Anticipated Milestones
LUNAR-COV19 (ARCT-021)	COVID-19 Vaccine	Intramuscular (i.m.)	Muscle (Myocytes, Dendritic Cells)	Global	Phase 1/2 Initiate Dosing Summer 2020
LUNAR-OTC (ARCT-810)	Ornithine Transcarbamylase (OTC) Deficiency	Intravenous (i.v.)	Liver (Hepatocytes)	> 10,000	Ph1 Data Q4 2020
LUNAR-CF	Cystic Fibrosis	Inhaled Aerosol	Lung (Bronchial Epithelial Cells)	> 70,000	DC Selection 2020 IND 2021
LUNAR-CV	Rare Cardiovascular Disease	Intravenous (i.v.)	Liver (Hepatocytes)	Undisclosed	IND 2021
LUNAR-MD	Rare Metabolic Disease	Intravenous (i.v.)	Liver (Hepatocytes)	Undisclosed	IND 2022

Multiple mRNA Therapeutic Programs with Milestones in 2020

Partnerships Maximize Platform

Program	Partner	Indication
LUNAR-HBV	Johnson & Johnson	Hepatitis B Virus (HBV)
LUNAR-NASH	Takeda	Nonalcoholic Steatohepatitis (NASH)
LUNAR-GSD3	ultragenyx pharmaceutical	Glycogen Storage Disease Type III
LUNAR-RARE	ultragenyx pharmaceutical	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® Delivery Technology

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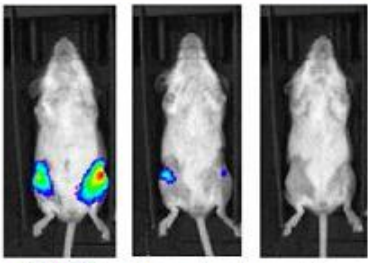
BUILDING INNOVATIVE RNA MEDICINES

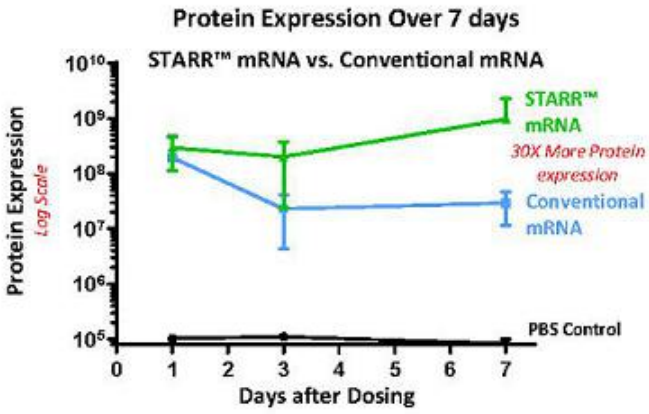
STARR™ mRNA Superior to Conventional mRNA

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

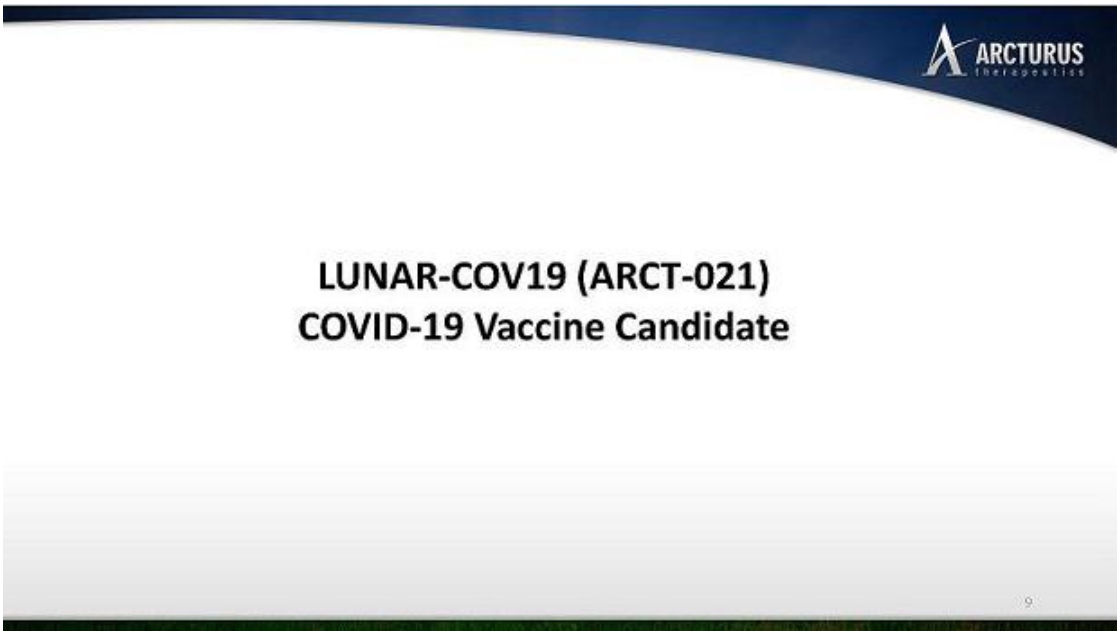
STARR™ Technology
30-Fold Higher Protein Expression



STARR™ Technology | Conventional mRNA | PBS Control



STARR™ mRNA technology together with LUNAR® delivery may enable single vaccine administration at very low dose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LUNAR-COV19 (ARCT-021)
COVID-19 Vaccine Candidate

Arcturus COVID-19 Vaccine Candidate has Significant Advantages

BUILDING INNOVATIVE RNA MEDICINES

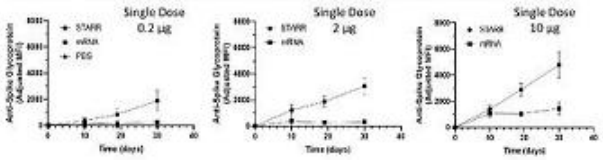
- Duke-NUS Partnership DukeNUS Medical School
- mRNA Vaccine: Simple, No Adjuvants, No Viruses
- STARR™ mRNA: Produces 30X more Protein than Conventional mRNA
- LUNAR® Technology: non-viral Delivery System 
- Promising Preclinical Data: Neutralizing Antibodies & Cell-mediated Immunity
- Potential Single-Shot: 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

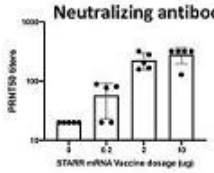
BUILDING INNOVATIVE RNA MEDICINES

Humoral Immunity

STARR™ induces more robust titers compared to conventional mRNA



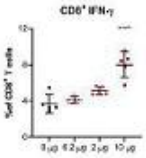
Neutralizing antibody titers and high seroconversion at low doses



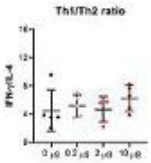
Single Dose (µg)	Seroconversion	Neutralizing Antibody Titers (Geometric Mean)
0.2	60 %	58
2	100 %	258
10	100 %	≥ 320

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 Development Plan to Rapidly Advance LUNAR-COV19

- Initiate Phase 1/2 dosing this summer 2020
- Enroll up to 108 healthy volunteer adults, including the elderly, to evaluate safety and immune response
- Trial design allows us to potentially rapidly select dose to take forward to large registrational studies
- Based on anticipated single, low dose vaccine and Catalent partnership, Arcturus could potentially manufacture hundreds of millions of doses in 2021
- Arcturus retains global rights to LUNAR-COV19

LUNAR-OTC (ARCT-810)
Ornithine Transcarbamylase (OTC) Deficiency

OTC Deficiency Market Opportunity

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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

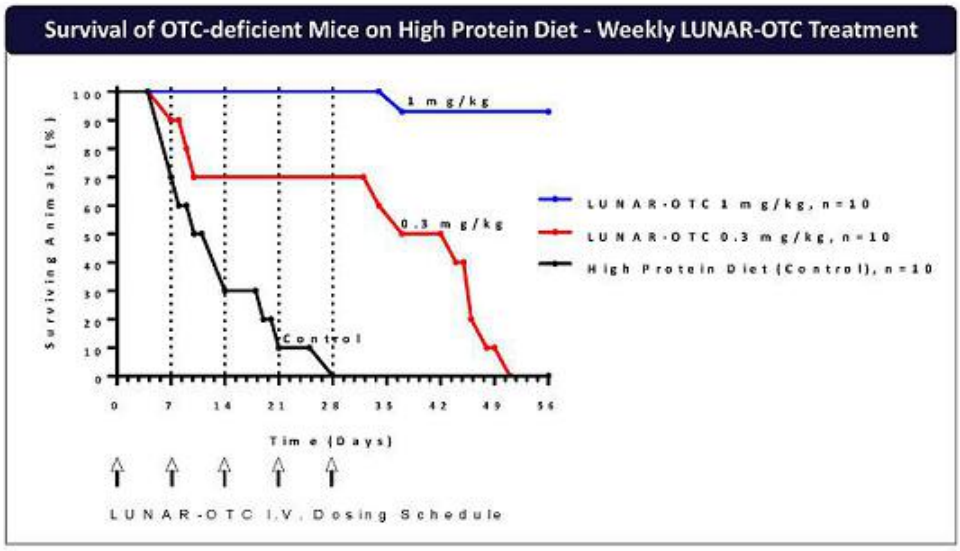
- Present standard of care involves a strict diet (low protein, high fluid intake) plus ammonia scavengers (sodium phenylbutyrate)
- Present standard of care does not effectively prevent life-threatening spikes of ammonia
- Severe OTC Deficiency patients are typically referred for liver transplant, currently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



ARCTURUS THERAPEUTICS

LUNAR-OTC

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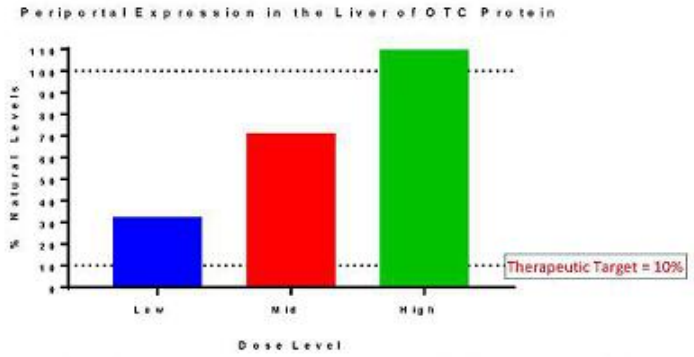
Exceeds Therapeutic Target of 10% Enzyme Replacement at all Doses in OTC-Deficient Mouse Model

- 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-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., Hekvoort, T.S.N., and Kohler, 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 Dose Studies

- New Zealand Phase 1 clinical trial underway, up to 30 healthy volunteers – Clinical Trial Application (CTA) approved
- U.S. Phase 1b clinical trial in up to 12 stable OTC-deficient patients – IND allowed to proceed

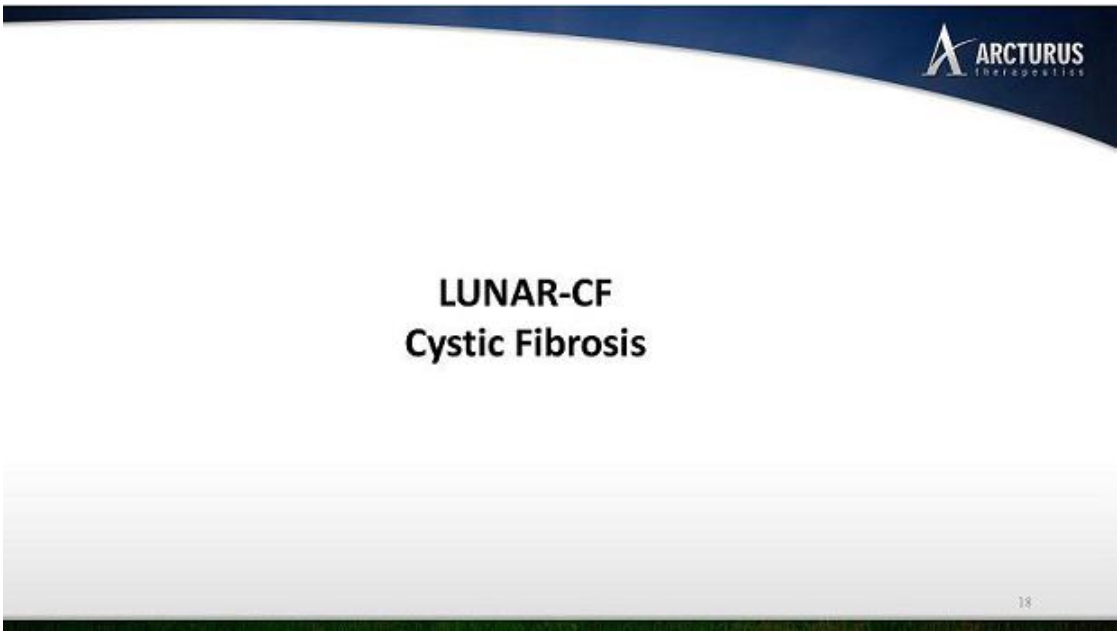
Primary Goal: Identify safest doses to take forward into multiple dose clinical trials
Primary Endpoints: Safety and tolerability
Exploratory Endpoints: Biomarkers ureagenesis, plasma ammonia levels and OTC enzyme activity, urine orotic acid levels

Dosing

- Single ascending dose (SAD) studies; randomized, placebo controlled and blinded
- Healthy volunteer study – up to 5 dose levels; Patient study – up to 3 dose levels
- All doses are within the anticipated range for therapeutic biological effect

Timing of Human Data

- Phase 1 healthy volunteer study has initiated; targeted to complete in Q4 2020
- Phase 1b patient study initiation dependent on COVID19 status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LUNAR-CF
Cystic Fibrosis
18

Cystic Fibrosis Market Opportunity

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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®-mRNA to Rodent Airways

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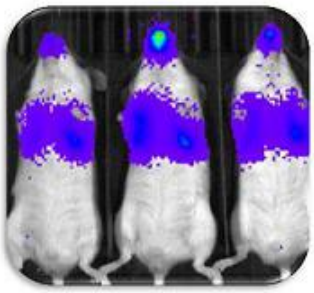
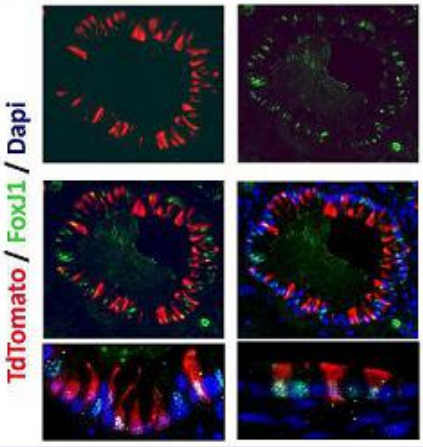
Nebulization: Upper/Lower Airways



LUNAR® + Luciferase mRNA

LUNAR® Targets Mice Epithelial Airways (TdTomato), Including Ciliated Cells (TdTomato/FoxJ1)



Efficient delivery of LUNAR®-mRNA formulations in rodent airways

LUNAR®, an aerosolized delivery platform for lung

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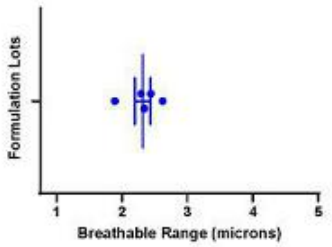
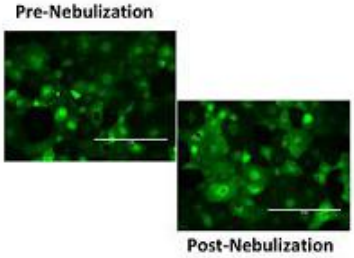
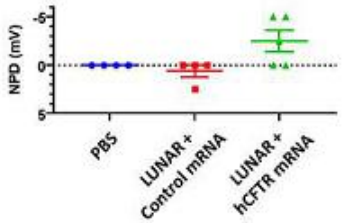
Aerosolized LUNAR® Particles are Breathable



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)

Delivery of LUNAR®-mRNA into Epithelial Airways in Ferret

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

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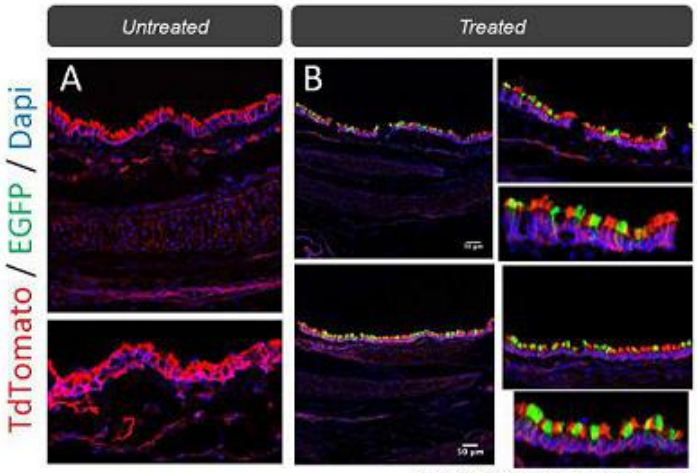
- **Ferrets are an excellent species for modeling certain human lung diseases***
- **Novel LUNAR® formulations of CRE mRNA were tested in a transgenic ROSA26TG ferret model**
- **Activation of EGFP expression indicates that LUNAR® targets epithelial airways**
- **Anticipated next steps: Development Candidate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



In collaboration with John Engelhardt

LUNAR® effectively delivered mRNA to the tracheal epithelial airways in a Ferret model

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

Moving Forward

Anticipated Milestones and Cash Position

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LUNAR-COV19 (ARCT-021)	
Phase 1/2 Initiation	**Summer 2020**
Initial Clinical Data	**Q3/Q4 2020**

LUNAR-OTC (ARCT-810)	
Phase 1 Data	**Q4 2020**

LUNAR-CF	
Development Candidate Selection	**2020**
IND Application Filing	**2021**

Cash Position
$59.5 million as of March 31, 2020
$75.5 million added in Q2 2020 from Secondary Offering
$9.6 million added in Q2 2020 for Ultragenyx Option
$4.9 million added from COVID-19 vaccine contract
Sufficient to support operations for more than two years

BUILDING INNOVATIVE RNA MEDICINES

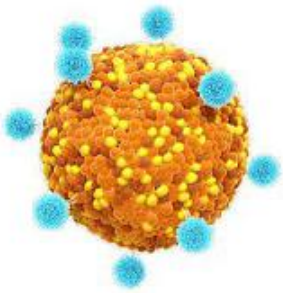
Management Team

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

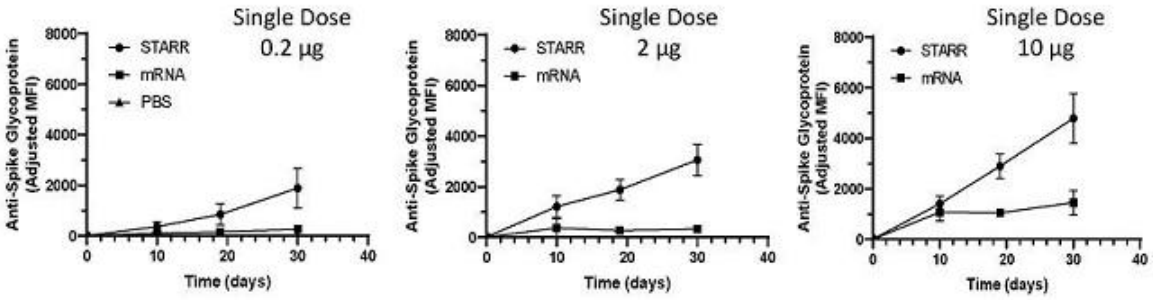
Andrew Sassine, MBA
Director of the Board, CFO

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


ARCTURUS26
therapeutics

Appendix

Higher and More Robust Antibody Titers



- **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

LUNAR-COV19 Positive Preclinical Data

Arcturus COVID-19 vaccine to begin human dosing this Summer

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

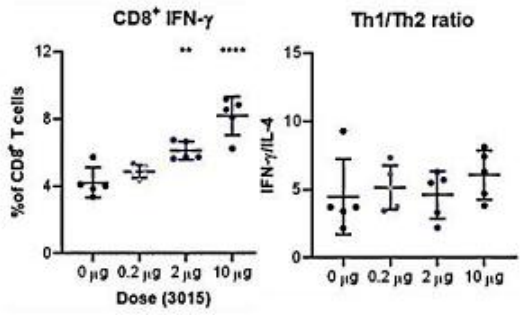
Single Dose (µg)*	LUNAR® Delivery			
	STARR™ mRNA (%)		Conventional mRNA (%)	
	Day 10	Day 19	Day 10	Day 19
0.2	40	60	20	20
2	80	**100**	20	0
10	100	100	40	80

*One microgram (µg) is 1 billionth of a kilogram (i.e. 1 Kg STARR™ mRNA contains 500 million doses at 2 µg /dose)

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

Arcturus Vaccine elicits a Balanced Cell Mediated Immune Response

BUILDING INNOVATIVE RNA MEDICINES



RNA Dose (μg)	% IFN-g + CD8+ 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+ T-cells
- Th1 biased CD4+ response and lack of change in Th1/Th2 ratio with increased RNA dose indicate balanced cell mediated immune response

LUNAR-COV19 Data Summary

BUILDING INNOVATIVE RNA MEDICINES

- 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 $CD8^+$ 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 THERAPEUTICS

Arcturus Safety Profile

BUILDING INNOVATIVE RNA MEDICINES

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)**

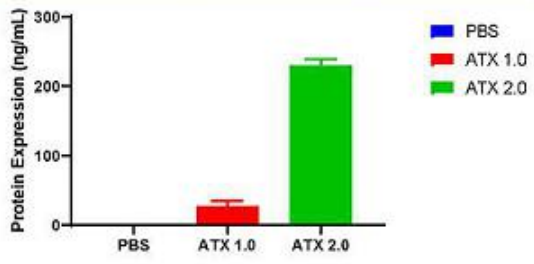
Arcturus mRNA chemistry shows promising efficacy and tolerability data

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

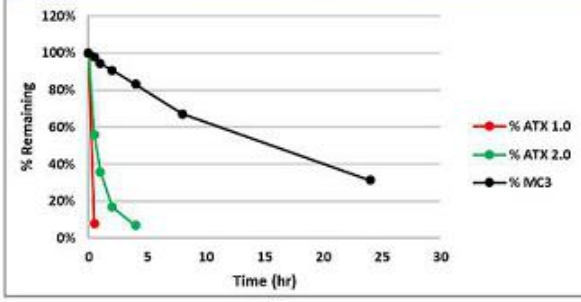
ATX Lipids are Effective and Biodegradable

BUILDING INNOVATIVE RNA MEDICINES

Protein Expression (*in vivo*)

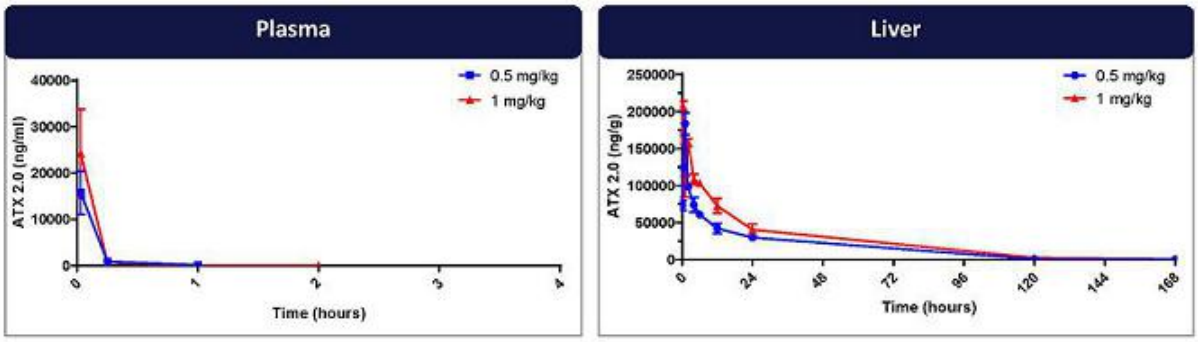


Esterase Catalyzed Degradation (*in vitro*)



Next Generation ATX Lipids Retain Degradability & Improve Delivery Efficiency

ATX 2.0 Lipid is Biodegradable and Clears *in vivo*



- 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

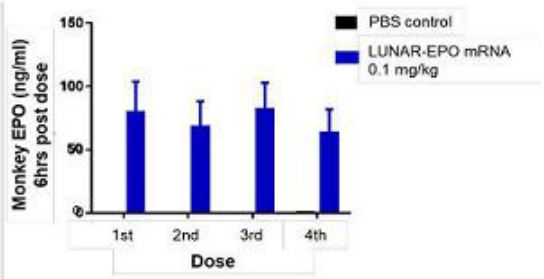
Optimize
mRNA sequence
Chemistry
Process

⇨

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

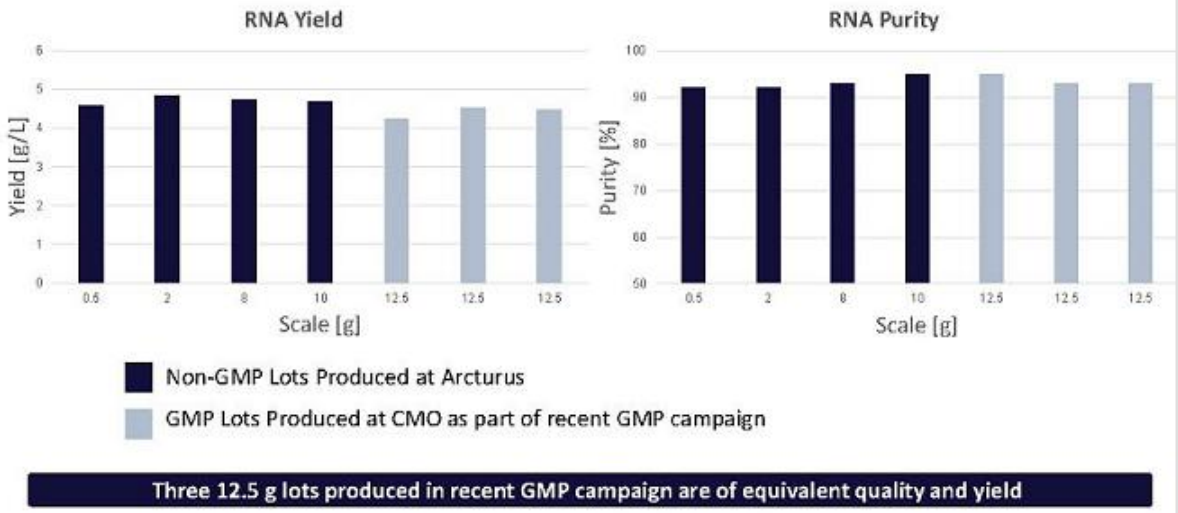
BUILDING INNOVATIVE RNA MEDICINES

DNA Template Production → IVT and Capping Reaction → Purification Process → Buffer Exchange & Concentration

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

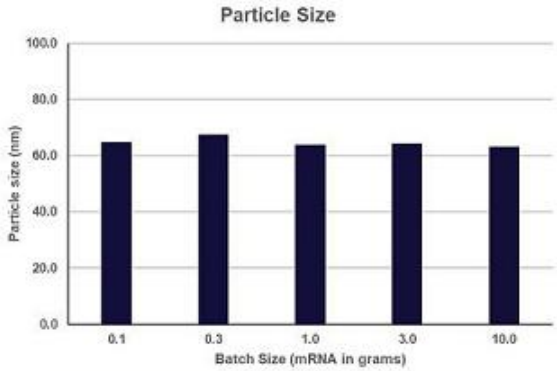
Drug Substance (mRNA) Manufacturing

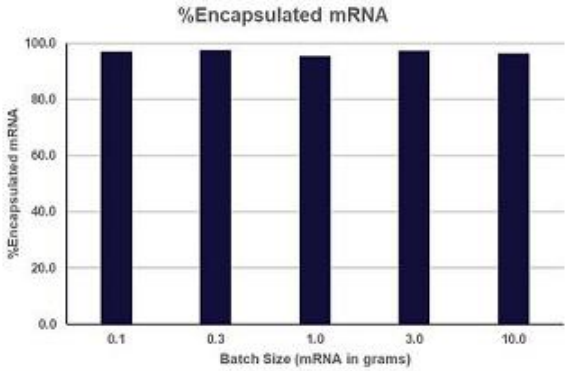


Three 12.5 g lots produced in recent GMP campaign are of equivalent quality and yield

Drug Product (LUNAR® + mRNA) Manufacturing

BUILDING INNOVATIVE RNA MEDICINES





- Manufacturing of Drug Product Demonstrated up to Multigram Scale with Yields ≥ 85%
- GMP Batch of LUNAR®-OTC (ARCT-810) Drug Product Manufactured and Released