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): January 10, 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") plans to discuss the information contained in the presentation attached to this Current Report on Form 8-K as Exhibit 99.1 with third parties in San Francisco, California.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the slides is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the SEC and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the slide titled "Forward-looking Statements" in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description of Exhibit**
99.1	Presentation dated January 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.

Date: January 10, 2020

Arcturus Therapeutics Holdings Inc.

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

ARCTURUS THERAPEUTICS

Building the Next Generation of RNA Medicines

January 2020

FORWARD LOOKING STATEMENTS

This presentation contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about: expectations regarding our capitalization and resources; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials; our strategy and focus; 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; the date that an IND may be filed with the FDA; 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 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, 2018, filed with the SEC on March 18, 2019, and amended on November 7, 2019. 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.

Investment Highlights

BUILDING INNOVATIVE RNA MEDICINES

Arcturus is an mRNA Medicines Drug Development Company Focused on Rare Diseases

LUNAR® Delivery Platform Validated by Multiple Strategic Partners

- More than $1 Billion in potential milestones and royalties

HQ: **San Diego**; Founded: **2013**; Nasdaq: **ARCT**
Outstanding Shares: **15.1M;** Employees: **85;**
Insider Ownership: **33%**

Broad and Strong Intellectual Property Portfolio

- 182 Patents & Patent Applications
- LUNAR® Delivery Technology
- RNA Drug Substance & Drug Product Process Manufacturing

Promising Preclinical Safety Data for LUNAR® Delivery and mRNA Drug Products

2019 Summary

Ultragenyx Collaboration Expanded, $30M

Cystic Fibrosis Foundation Increased Commitment to $15M

Fundraising Completed, $23M from Institutional Investors

Advanced Pipeline

- **LUNAR-OTC:** ARCT-810 Nominated, Received Orphan Drug Designation from FDA, GMP Manufacturing of Drug Product Completed and Released, On-track for Q1-2020 IND
- **LUNAR-CF:** Preclinical Lung Data Collected, CF Foundation Financial Support Received

Expanded Platform to include STARR Technology™

Key Value Drivers → Platform & Pipeline

BUILDING INNOVATIVE RNA MEDICINES

Platform: LUNAR® Delivery, mRNA Drug Substance, and STARR (Self-Transcribing And Replicating RNA) Technology ™

Johnson & Johnson · Takeda · ultragenyx pharmaceutical · SYNTHETIC GENOMICS · CUREVAC the RNA people®

Strategic Partners: More than $1 Billion in Potential Milestones & Royalties

Pipeline: Arcturus mRNA Medicines

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

- OTC Deficiency Market Potential $500M Annual Sales
- Orphan Drug Designation is received from U.S. FDA

LUNAR-CF to treat Cystic Fibrosis (CF)

CYSTIC FIBROSIS FOUNDATION

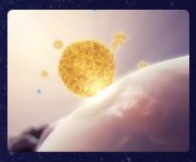
- Class I CF Market Potential $900M Annual Sales

ARCTURUS THERAPEUTICS

LUNAR® Delivery Technology

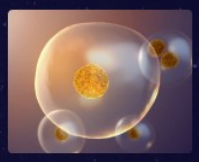
BUILDING INNOVATIVE RNA MEDICINES

LUNAR Associates with Cell Membrane



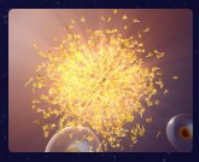
Enters Cell Via Endocytosis

Lipid Particle in Endosome



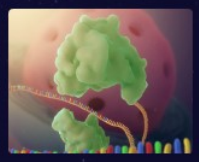
Increased Acidity as Endosome Ages

pH-Mediated Disruption



Rapid Biodegradation of Vehicle

RNA in Cytosol



RNA Processing and Translation

Arcturus Platform: Enabling Genetic Medicines

BUILDING INNOVATIVE RNA MEDICINES

Program	Partner	Indication	Arcturus Chemistry	Arcturus Delivery	Program Status
LUNAR-GSD3	ultragenyx pharmaceutical	Glycogen Storage Disease Type III	mRNA	LUNAR® Hepatocytes	Target IND 2020+
LUNAR-RARE	ultragenyx pharmaceutical	Undisclosed Rare Disease	mRNA	LUNAR® Hepatocytes	Preclinical
LUNAR-HBV	Johnson & Johnson	Hepatitis B	RNA	LUNAR® Hepatocytes	Preclinical
LUNAR-NASH	Takeda	NASH	RNA	LUNAR® Stellate Cells	Preclinical
LUNAR-RPL	Large Pharma	Infectious Disease Prophylactic Vaccines	SGI's Replicon RNA	LUNAR®	Preclinical
LUNAR-AH	Large Animal Health Pharma	Infectious Disease Prophylactic Vaccines	SGI's Replicon RNA	LUNAR®	Preclinical

- Greater than $1 Billion in Potential Milestones & Royalties
- Enabling Different Types of RNA – Messenger RNA, Gene Editing RNA, Replicon RNA
- Multiple Cell Types Targeted
- LUNAR-GSD3 (UX053) partnered with Ultragenyx – IND Target 2020+

Arcturus Pipeline of mRNA Medicines

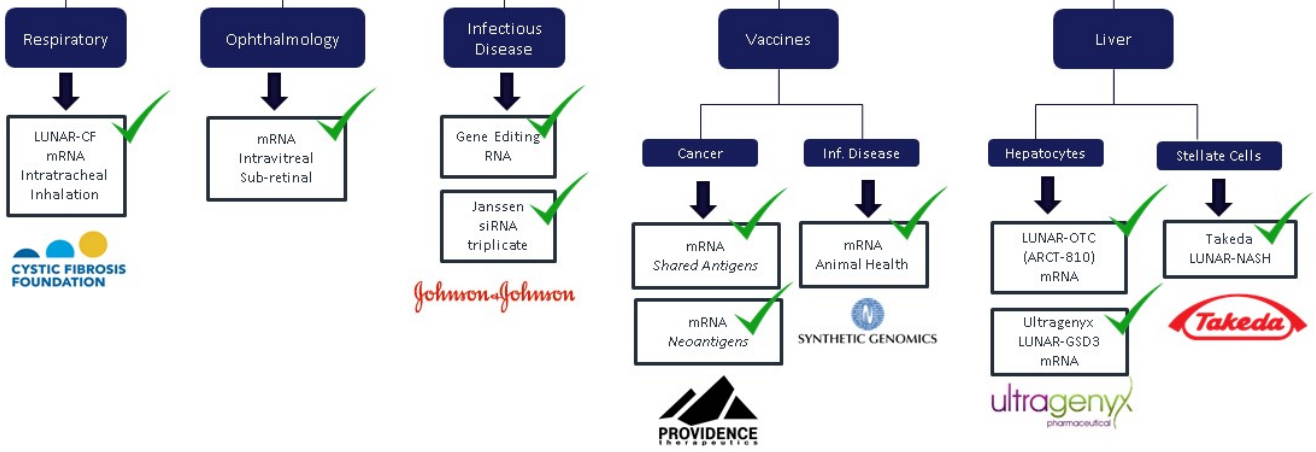
BUILDING INNOVATIVE RNA MEDICINES

Name	Indication	Expected IND Date	Route of Administration	Target Organ	Target Cells	Prevalence Worldwide
LUNAR-OTC (ARCT-810)	Ornithine Transcarbamylase (OTC) Deficiency	Q1 2020	Intravenous (i.v.)	Liver	Hepatocytes	> 10,000
LUNAR-CF	Cystic Fibrosis	2021	Nebulized Aerosol	Lung	Bronchial Epithelial Cells	> 70,000
LUNAR-CV	Rare Cardiovascular Disease	Preclinical	Intravenous (i.v.)	Liver	Hepatocytes	Undisclosed
LUNAR-MD	Rare Metabolic Disease	Preclinical	Intravenous (i.v.)	Liver	Hepatocytes	Undisclosed

- Pipeline programs focus on messenger RNA (mRNA) drug products for rare diseases
- LUNAR-OTC (ARCT-810, intravenous mRNA medicine): IND Filing Target Q1 2020
- LUNAR-CF is funded by the Cystic Fibrosis (CF) Foundation: IND Filing Target 2021
- LUNAR-CV and LUNAR-MD are preclinical programs

BUILDING INNOVATIVE RNA MEDICINES

LUNAR® Platform Preclinical Proof-of-Concept Demonstrated



LUNAR® Platform Preclinical Proof-of-Concept Demonstrated in Hepatocytes, Liver Stellate Cells, Bronchial Epithelial Cells (Lung), Photoreceptors (Eye), Infectious Diseases, Cancer Vaccines

OTC Deficiency Market Opportunity

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

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

Unmet Medical Need

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

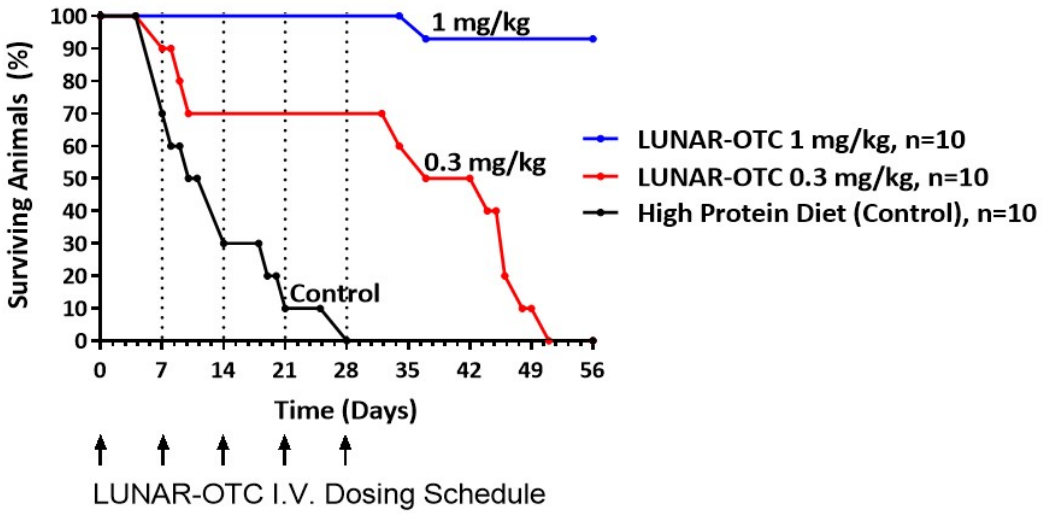
LUNAR-OTC Aims to Restore Enzyme Function

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

LUNAR®-OTC

Disease Normalization Following Single and Repeat Dosing in OTC Mouse Model

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

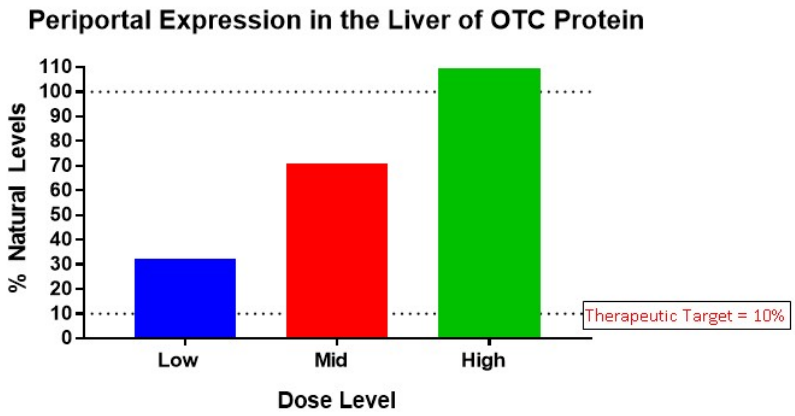


LUNAR-OTC

BUILDING INNOVATIVE RNA MEDICINES

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



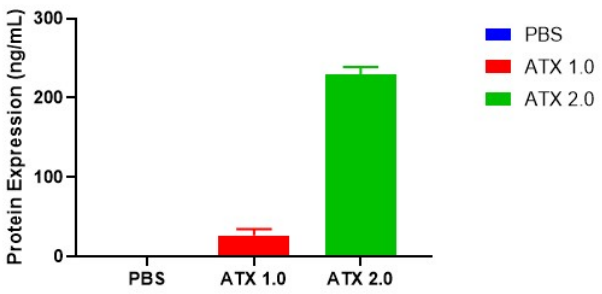
*Li, L. et al. PGC-1α Promotes Ureagenesis in Mouse Periportal Hepatocytes through SIRT3 and SIRT5 in Response to Glucagon. Scientific Reports. 6:24156 | DOI: 10.1038/srep24156, April 2016
*Lamers, W.H., Hakvoort, T.B.M., and Köhler, E.S. 'Molecular Pathology of Liver Diseases' in Monga S.P.S. (ed.), *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)

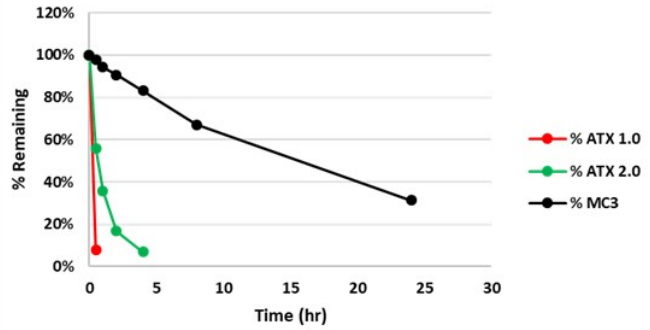
ATX Lipids are Effective and Degrade Rapidly

BUILDING INNOVATIVE RNA MEDICINES

Protein Expression (*in vivo*)



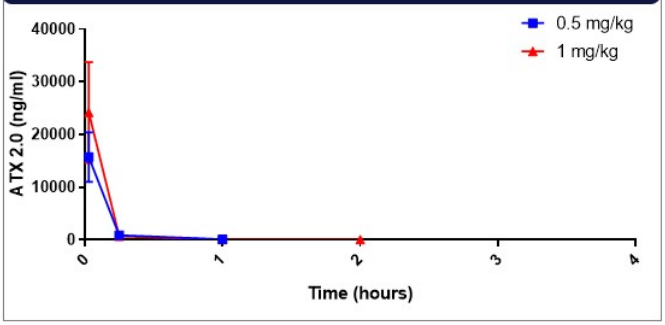
Esterase Catalyzed Degradation (*in vitro*)



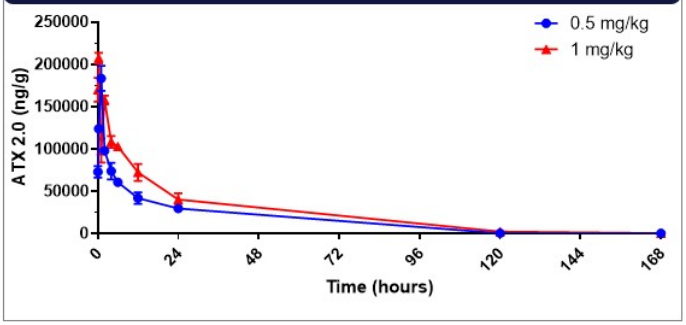
Next Generation ATX Lipids Retain Degradability & Improve Delivery Efficiency

ATX 2.0 Lipid Rapidly Clears *in vivo*

Plasma



Liver



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

ARCTURUS THERAPEUTICS

Arcturus Safety Profile

BUILDING INNOVATIVE RNA MEDICINES

External Validation

- Multiple strategic partnerships over many years confirms the positive 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

Cystic Fibrosis Market Opportunity

BUILDING INNOVATIVE RNA MEDICINES

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

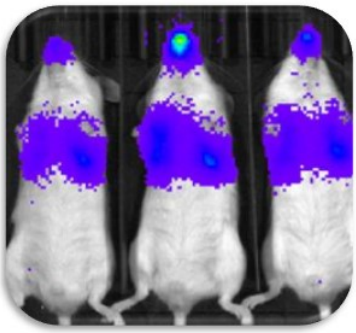
LUNAR-CF Aims to Restore CFTR Function

- 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

LUNAR® Delivery of mRNA to Lung (Mouse)

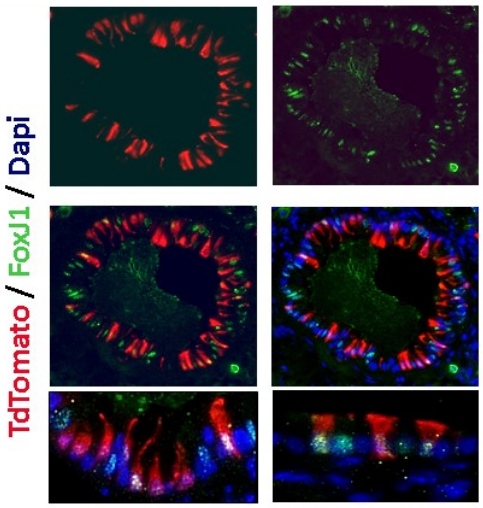
BUILDING INNOVATIVE RNA MEDICINES

Nebulization



LUNAR® + Luciferase mRNA

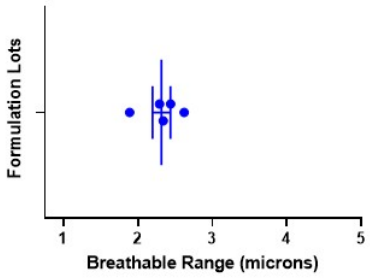
LUNAR® Delivery of mRNA into Bronchial Epithelial Cells (BECs)



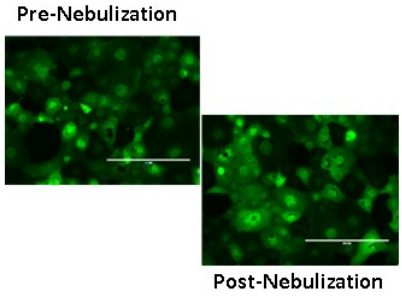
Functional Nebulized Delivery of LUNAR®+ mRNA into Lung Epithelial Cells

Aerosolized LUNAR®

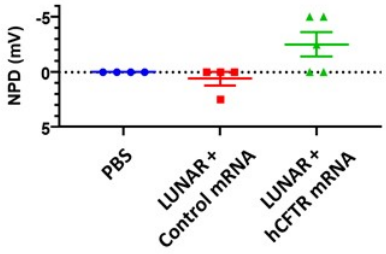
Aerosolized LUNAR® Particles are Breathable



Aerosolized LUNAR® -mRNA (GFP) maintains activity



Aerosolized LUNAR®-CF is functional *in vivo* (mouse)



Aerosolized LUNAR® Droplets are in the Optimal Breathable Range (2-3 microns)
Aerosolized LUNAR® Maintains Function as Measured by GFP Protein Expression & Nasal Potential Difference (NPD)

Drug Substance: mRNA Design

BUILDING INNOVATIVE RNA MEDICINES

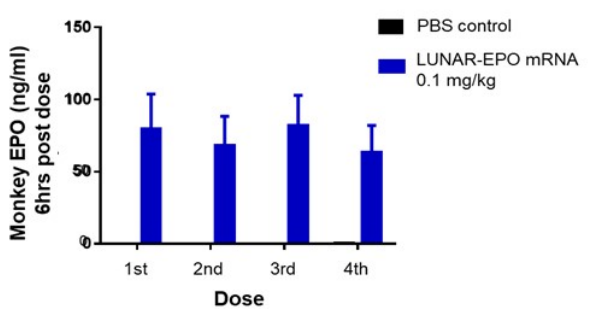
Arcturus' proprietary mRNA optimization platform

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

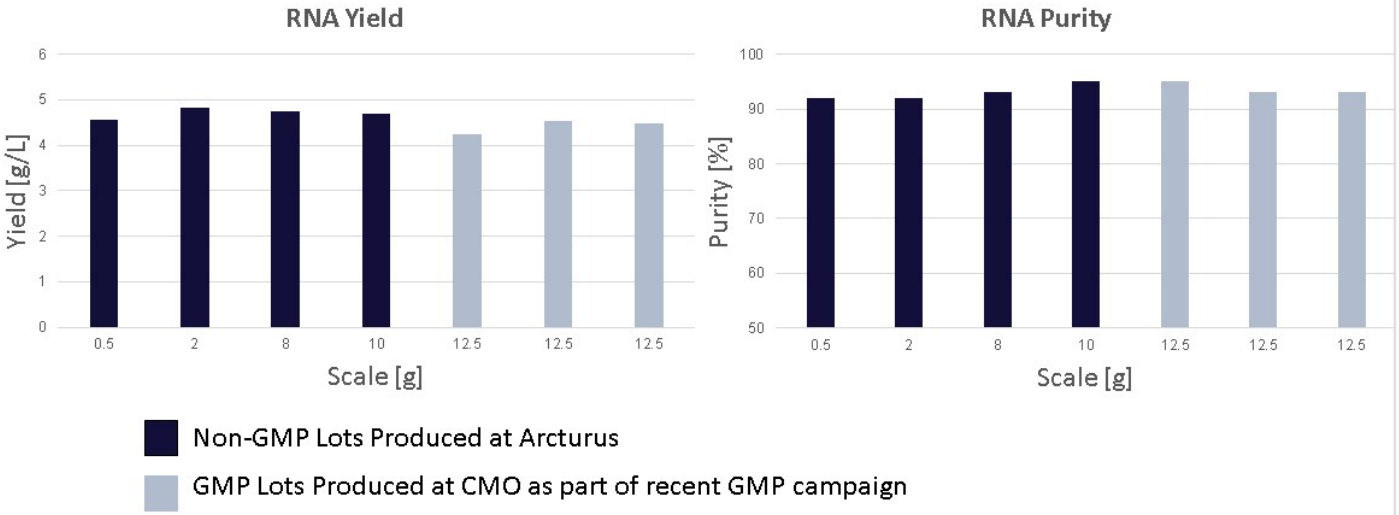
BUILDING INNOVATIVE RNA MEDICINES

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

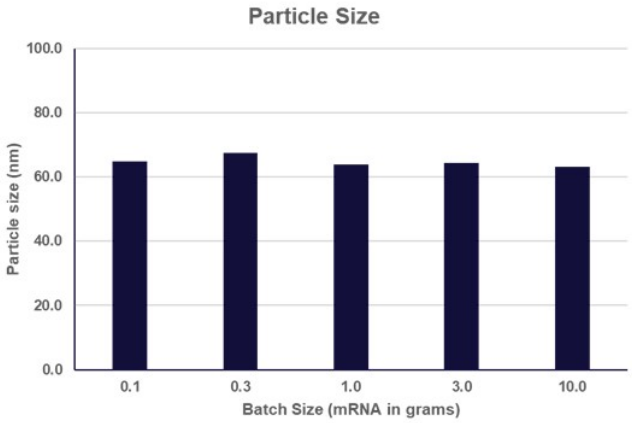
Arcturus Internal non-GMP mRNA Production Capabilities: Up to 30 g in Less Than One Week

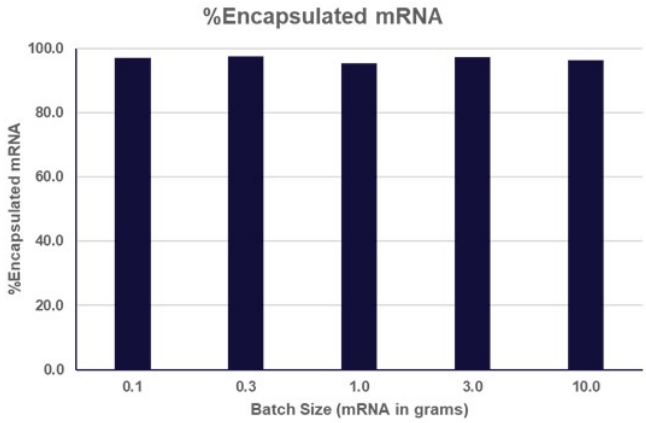
Drug Substance (mRNA) Manufacturing



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

Drug Product (LUNAR® + mRNA) Manufacturing





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

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

ResMed · ultragenyx pharmaceutical · Sanford Consortium for Regenerative Medicine · Allergan · ALTHEA · MERCK · Fidelity Investments · ultragenyx pharmaceutical

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

MERCK Nitto Fidelity INVESTMENTS IONIS PHARMACEUTICALS


ARCTURUS
therapeutics