UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 7, 2019

ARCTURUS THERAPEUTICS HOLDINGS INC.
(Exact name of registrant as specified in its charter)

Delaware	001-38942	46-1981974
(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

Arcturus Therapeutics Ltd.
(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))

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. ☐

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**

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" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements about: expectations regarding our capitalization, strategy, future operations, collaborations or 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, modification or termination of collaborative agreements; the date that an IND may be filed with the FDA; the potential market or success for the clinical development programs of the Company; the likelihood of success of the Company's technology or potential development of any of the Company's products, preclinical or clinical development programs; the expected employment of key personnel; the yield of preventative and therapeutic treatments or commercial or therapeutic success of the Company's products or programs, including those for the treatment of cystic fibrosis; or any statements other than statements of historical fact, including those related to the Company's future cash, market or financial position. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time. Forward-looking statements speak only as of the date they are made and the Company assumes no duty to update forward-looking statements, except as required by law.

In addition to factors previously disclosed in the Company's reports filed with the SEC and those identified elsewhere in this communication, the following factors, among others, could cause actual results to differ materially from forward-looking statements and historical performance: the availability and access, in general, of funds to fund operations and necessary capital expenditures, the strength of our intellectual property portfolio, the expected safety profiles of our product candidates, the proof of concept of our product candidates, the target opportunities for certain of our product candidates, our expected dates of submission of one or more Investigational New Drug Applications to the FDA, market opportunities with respect to certain diseases connected with our product candidates, manufacturing and formulation capabilities of the Company or our manufacturing partners with respect to our product candidates, as well as our management's response to the preceding factors. The foregoing factors are in addition to the other factors set forth in the Company's reports on Form 10-K, Form 8-K, and other documents on file with the SEC.

Other risks and uncertainties are more fully described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 18, 2019, and in other filings that the Company makes and will make with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The statements made in this Current Report on Form 8-K and the exhibit(s) attached hereto speak only as of the date stated herein, and subsequent events and developments may cause the Company's expectations and beliefs to change. While the Company may elect to update these forward-looking statements publicly at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date stated herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Presentation of Arcturus Therapeutics Holdings Inc., dated November 2019

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: November 7, 2019

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

Exhibit 99.1

ARCTURUS THERAPEUTICS

Building the Next Generation of RNA Medicines

November 2019

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 press 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 in subsequent filings with, or submissions to, the SEC. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

ARCTURUS THERAPEUTICS

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

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

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

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

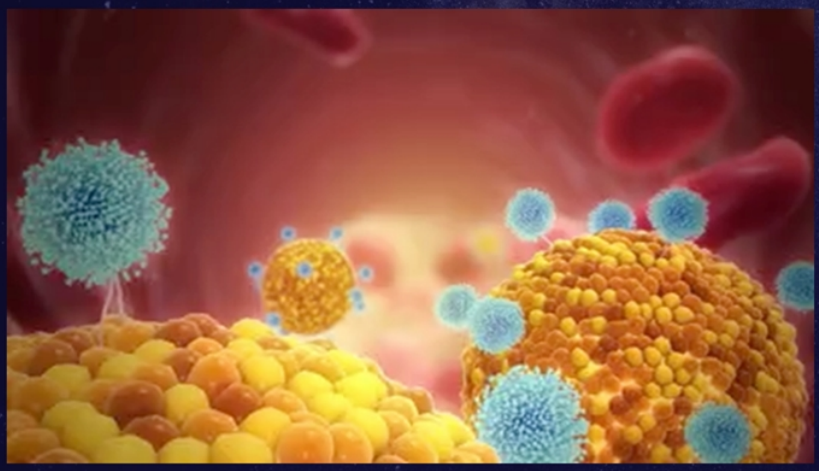
LUNAR-OTC (ARCT-810) to treat Ornithine Transcarbamylase (OTC) Deficiency
- OTC Deficiency market potential $500M annual sales
- Orphan Drug Designation is received from U.S. FDA

LUNAR-CF to treat Cystic Fibrosis (CF); Funded by the CYSTIC FIBROSIS FOUNDATION
- Class I CF market potential $900M annual sales

ARCTURUS THERAPEUTICS

LUNAR® Mechanism of Delivery

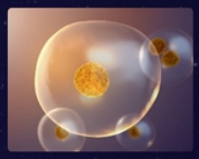
BUILDING INNOVATIVE RNA MEDICINES



LUNAR Associates with Cell Membrane

Enters Cell Via Endocytosis

Lipid Particle in Endosome

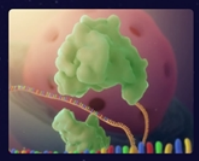


Increased Acidity as Endosome Ages

pH-Mediated Disruption

Rapid Biodegradation of Vehicle

RNA in Cytosol



RNA Processing and Translation

Arcturus Platform: Enabling Genetic Medicines

BUILDING INNOVATIVE RNA MEDICINES

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

- **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) is a licensed program, partnered with Ultragenyx – IND Target 2020**

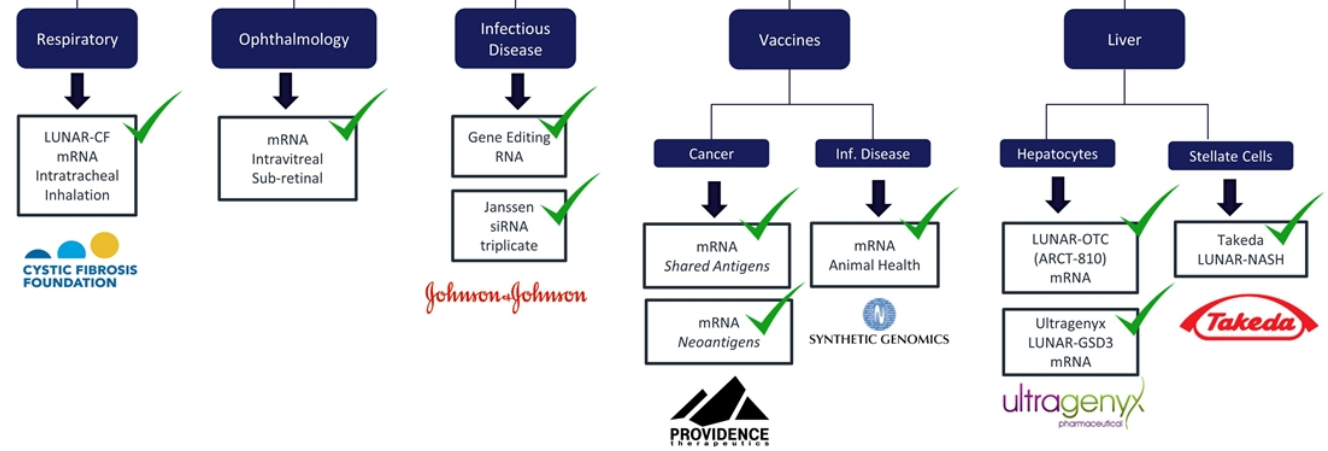
Arcturus Pipeline of mRNA Medicines

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 to Lung	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

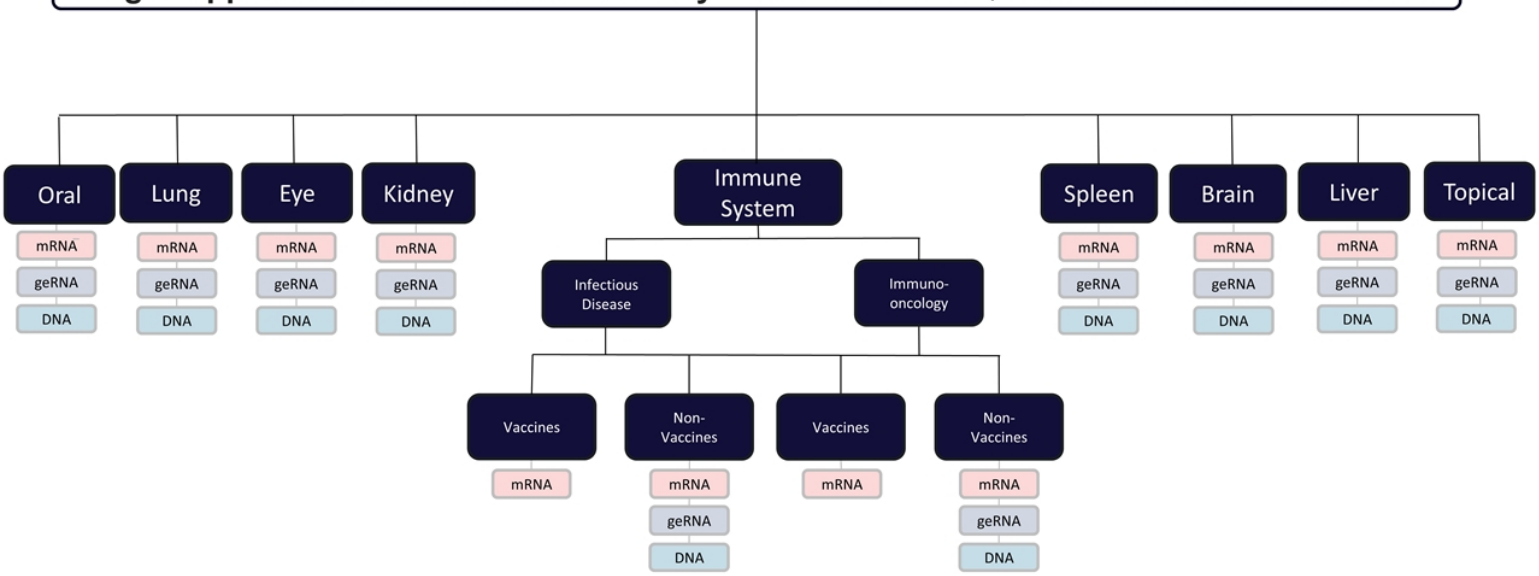
LUNAR® Platform Substantial Preclinical Proof-of-Concept Demonstrated



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

BUILDING INNOVATIVE
RNA MEDICINES

Target Opportunities for LUNAR® Delivery Platform Exceed $100 Billion in Potential Value



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 spikes of ammonia.
- OTC Deficiency patients are typically referred for liver transplant.

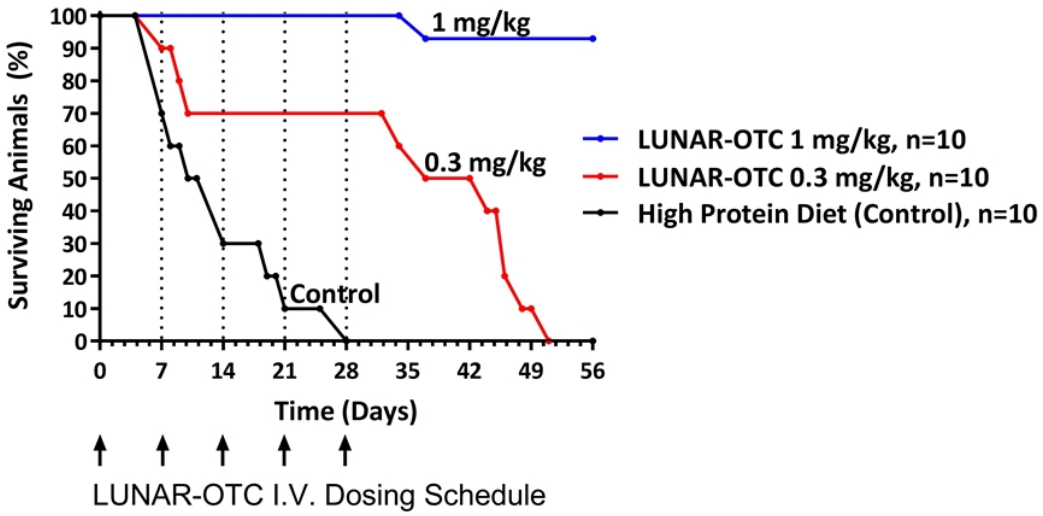
LUNAR-OTC Aims to Restore Enzyme Function

- 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

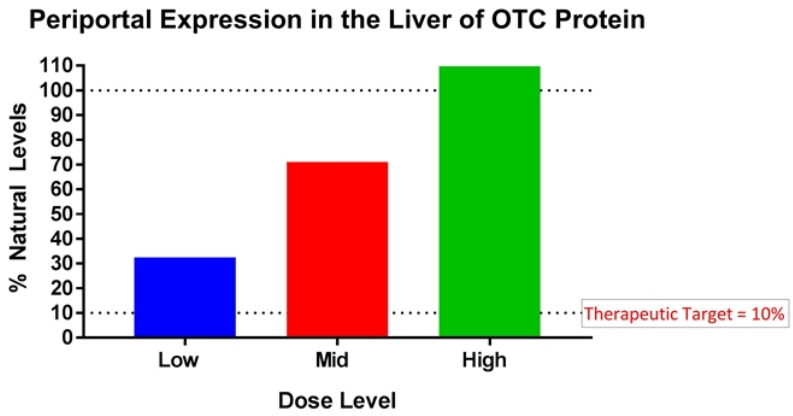


LUNAR-OTC I.V. Dosing Schedule

LUNAR-OTC

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

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



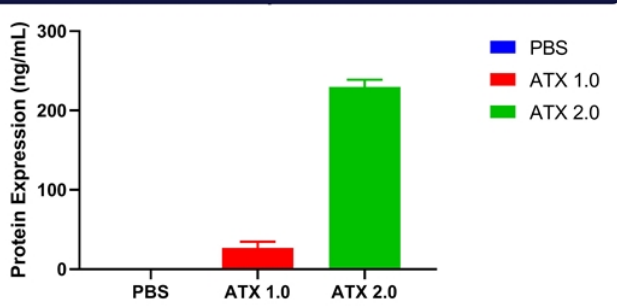
*Li, L. et al. PGC-1α Promotes Ureagenesis in Mouse Periportal Hepatocytes through SIRT3 and SIRT5 in Response to Glucagon. Scientific Reports. 6:24156 | DOI: 10.1038/srep24156, April 2016
*Lamers, W.H., Hakvoort, T.B.M., and Köhler, E.S. 'Molecular Pathology of Liver Diseases' in Monga S.P.S. (ed.),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

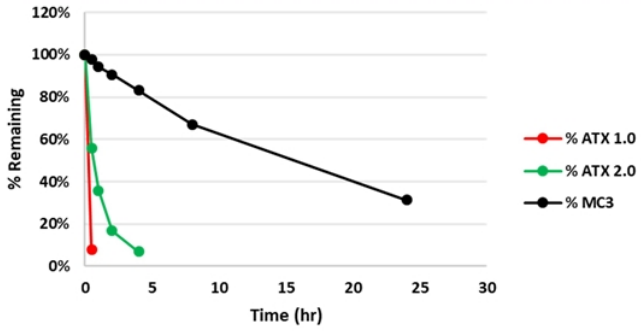
ATX Lipids are Effective and Degrade Rapidly

BUILDING INNOVATIVE RNA MEDICINES

Protein Expression (*in vivo*)



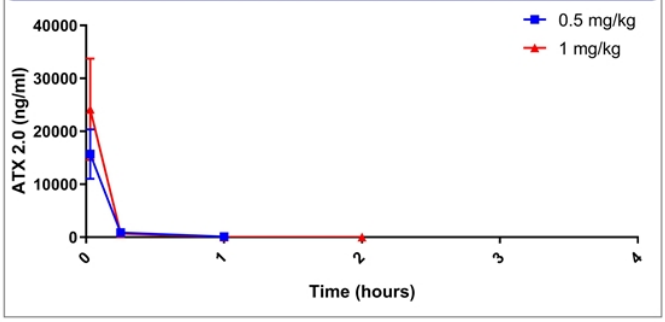
Esterase Catalyzed Degradation (*in vitro*)



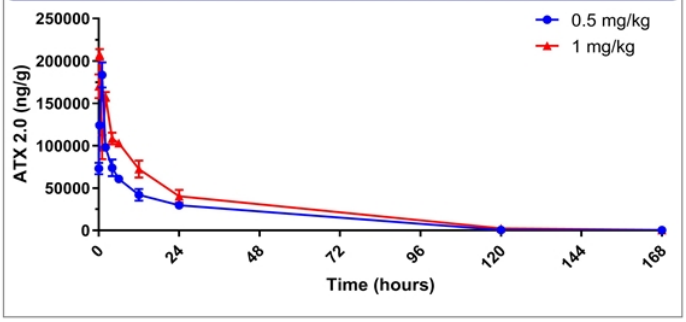
Next Generation ATX Lipids Retain Degradability & Improve Delivery Efficiency

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 RNA**
- ✓ **@ 3 mg/kg x eight (8) weekly doses of non-coding RNA (total of 24 mg/kg over 2 months)**

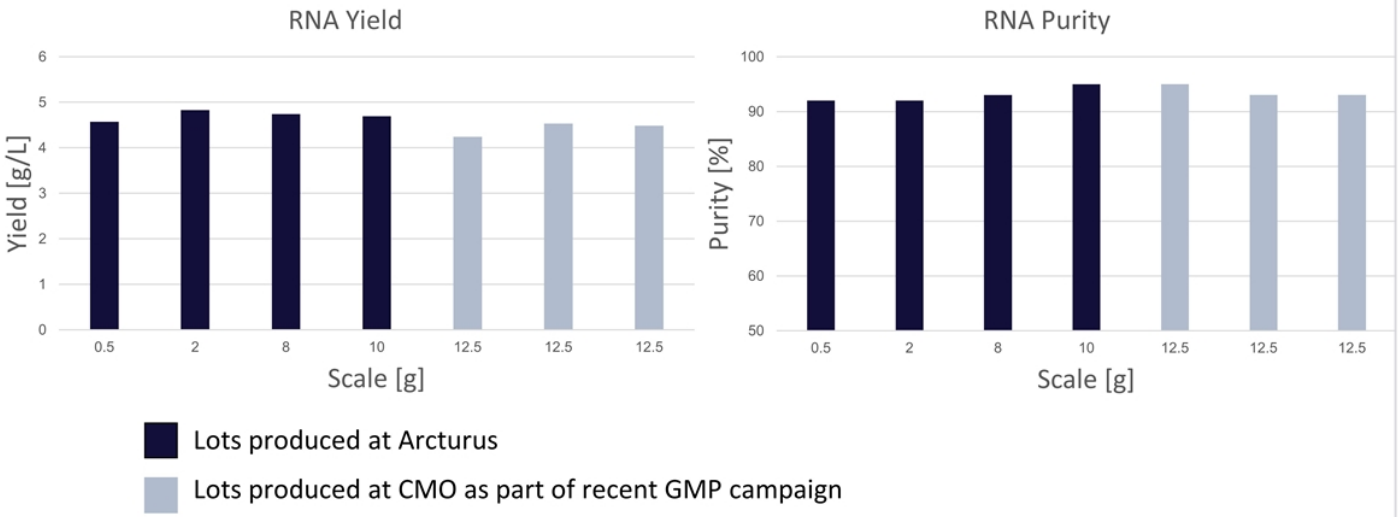
Arcturus mRNA chemistry shows promising efficacy and tolerability data

- Efficacy of OTC mRNA in mouse model @ 0.1 – 1 mg/kg
- Well tolerated in mouse @ 7 mg/kg single dose

IND-enabling toxicology studies at higher doses will provide Maximum Tolerated Dose (MTD)

mRNA Drug Substance

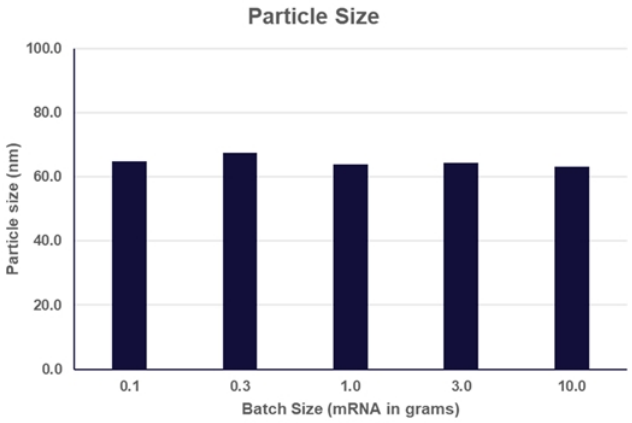
BUILDING INNOVATIVE RNA MEDICINES

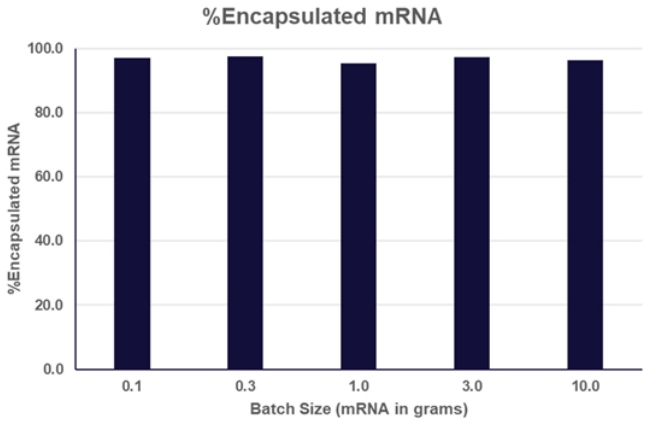


Three 12.5 g lots produced in recent campaign are of equivalent quality and yield

LUNAR®-mRNA Drug Product

BUILDING INNOVATIVE RNA MEDICINES





- **Scalability of Drug Product demonstrated from milligram to multigram scale with yields ≥ 85%**
- **Multiple batches (10g) of LUNAR®-OTC mRNA manufactured**

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

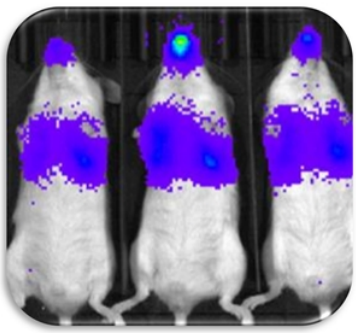
LUNAR-CF Aims to Restore CFTR Function

- 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® Targeting Lung

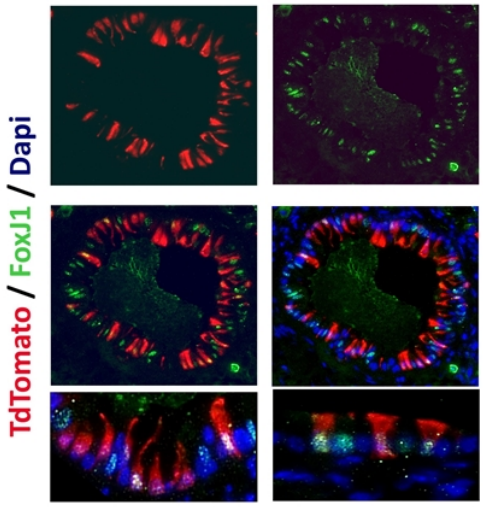
BUILDING INNOVATIVE RNA MEDICINES

Nebulization



LUNAR + Luciferase mRNA

LUNAR® Delivery into Bronchial Epithelial Cells (BECs)



Functional Nebulized Delivery of LUNAR + mRNA into Lung Epithelial Cells

Drug Substance: mRNA Design

BUILDING INNOVATIVE RNA MEDICINES

Arcturus' proprietary mRNA optimization platform

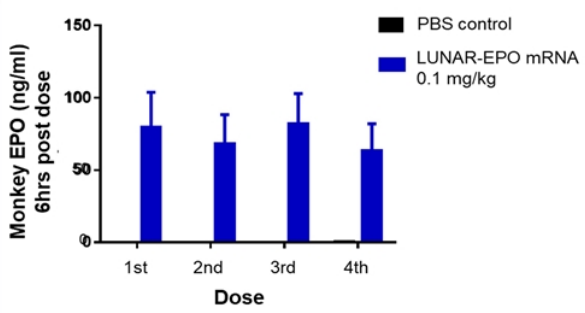
Optimize
mRNA sequence
Chemistry
Process

⇨

Improve
Protein Expression
Duration
Functional Activity

Sustained hEPO activity in NHPs upon repeat dosing

Weekly Dosing in Non-Human Primates



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

Arcturus mRNA Manufacturing

BUILDING INNOVATIVE RNA MEDICINES

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

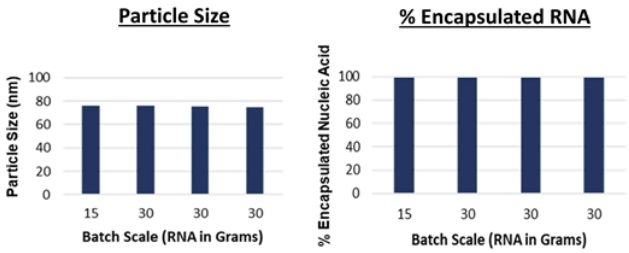
Features	Benefits
Optimized IVT Method	Reduced Cost; Higher Purity
Improved Capping Reaction	Reduced Cost of Goods
Proprietary Purification Process	Higher Purity in a Shorter Time
Efficient	Entire Process Less Than One Week
Scalable to > 1Kg	Access Large Patient Populations
Adaptable	Can Utilize a Variety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

Arcturus' Internal mRNA Production: Up to 30 g in Less Than One Week

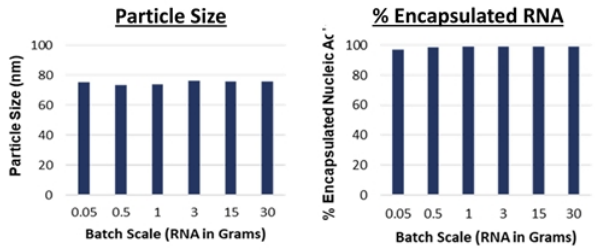
Drug Product: LUNAR® Formulation & Production

BUILDING INNOVATIVE RNA MEDICINES

LUNAR® Reproducibility



LUNAR® Scalability



- Proprietary, Reproducible & Scalable Drug Product Production Process
- LUNAR-Formulated mRNA Successfully Scaled From Milligram to Multigram Batch Sizes

Board of Directors

Dr. Peter Farrell
Chairman of the Board

Founder & Chairman of ResMed

Karah Parschauer, JD
Director of the Board

General Counsel of Ultragenyx

Dr. Edward W. Holmes
Director of the Board

President & CEO of Sanford Consortium

James Barlow, MA
Director of the Board

Former CAO of Allergan

Dr. Magda Marquet
Director of the Board

Chairman & Co-Founder of Althea

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

Andrew Sassine, MBA
Director of the Board, CFO

Former Portfolio Manager of Fidelity

Dr. Emil D. Kakkis
Board Advisor

President & CEO of Ultragenyx

ARCTURUS THERAPEUTICS

Management Team

BUILDING INNOVATIVE RNA MEDICINES

Joseph E. Payne, MSc
Founder, President & CEO

Dr. Pad Chivukula
Founder, CSO & COO

Andrew Sassine, MBA
CFO

Kevin Skol, MBA
Sr. VP of Business Development & Alliance Management

Dr. Suezanne Parker
VP of Translational Biology

MERCK Nitto Fidelity INVESTMENTS IONIS PHARMACEUTICALS Shire

ARCTURUS
therapeutics