

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 27, 2019**

ARCTURUS THERAPEUTICS LTD.

(Exact Name of Registrant as Specified in Charter)

State of Israel

(State or Other Jurisdiction of Incorporation)

001-35932

(Commission File Number)

Not applicable

(I.R.S. Employer Identification No.)

**10628 Science Center Drive, Suite 250
San Diego, California**

(Address of Principal Executive Offices)

92121

(Zip Code)

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

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 (see General Instruction A.2. below):

- 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 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 Ltd. (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.

The information set forth in this Item 7.01 or the Presentation is not deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this communication, including statements relating to the Company’s future ownership, capitalization, listing status, financial condition, performance, operating results, strategy and plans are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 giving the Company’s expectations or predictions of future financial or business performance or conditions. 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 20-F, Form 6-K, and other documents on file with the SEC.

Other risks and uncertainties are more fully described in the Company’s Annual Report on Form 20-F for the year ended December 31, 2017 and Amendment No. 1 thereto, each filed with the SEC, 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.

Exhibit Number

Description

99.1

[Presentation of Arcturus Therapeutics Ltd., dated February 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.

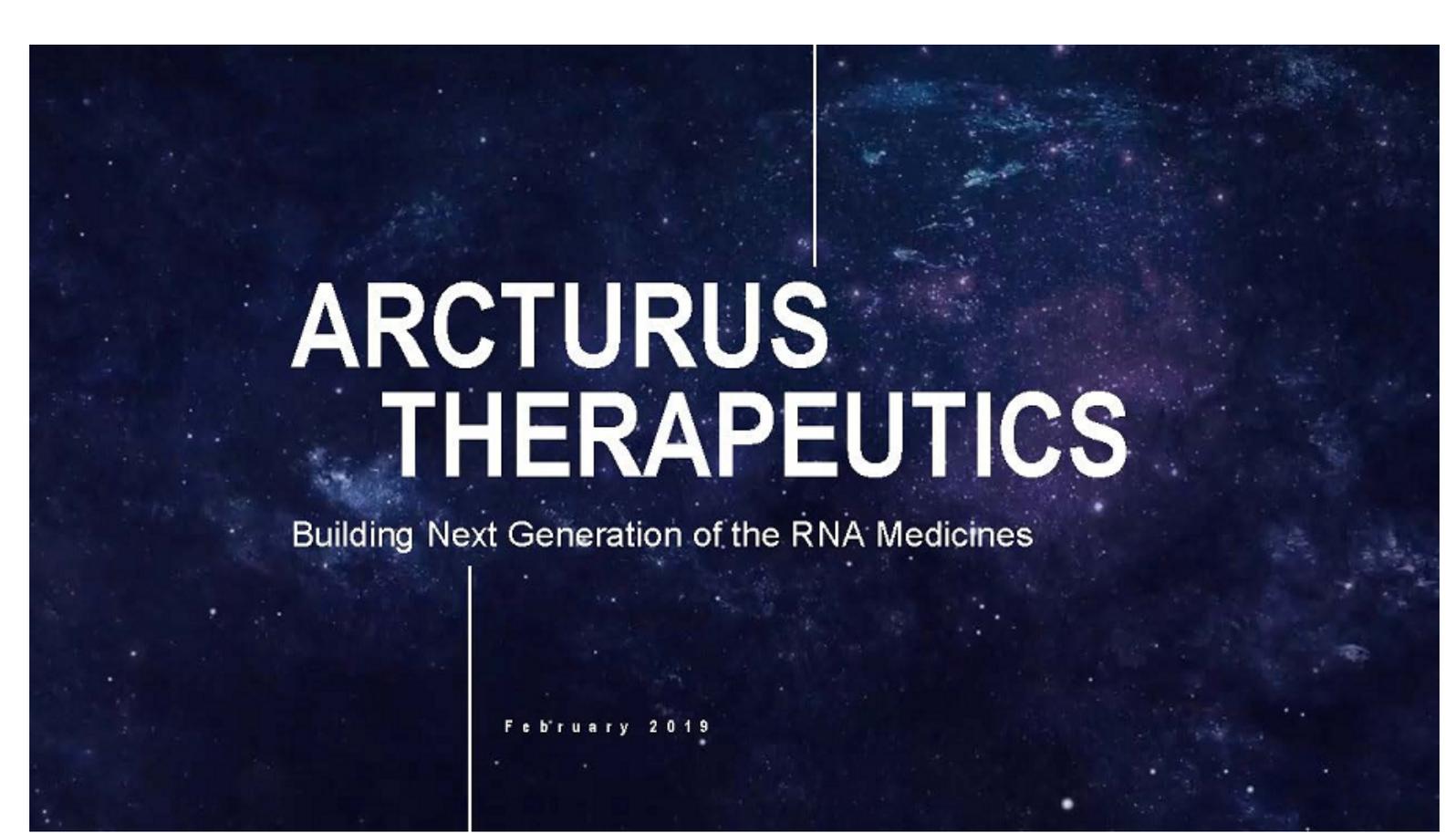
ARCTURUS THERAPEUTICS LTD.

By: /s/ Joseph E. Payne

Joseph E. Payne

Chief Executive Officer

Dated: February 27, 2019



ARCTURUS THERAPEUTICS

Building Next Generation of the RNA Medicines

February 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 and the entry into or modification or termination of collaborative agreements.

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. Given the risks and uncertainties, you should not place undue reliance on 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 our Annual Report on Form 20-F for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission (SEC) and in subsequent filings 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.

Investment Highlights

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

Broad and Strong Intellectual Property Portfolio

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



HQ: **San Diego**; Founded: **2013**; Nasdaq: **ARCT**
Outstanding Shares: **10.8 M**; Employees: **80**;
Insider Ownership: **24%**

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

Key Value Drivers: mRNA Medicines & Platform

Arcturus LUNAR® Delivery Platform: Enabling Genetic Medicines



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

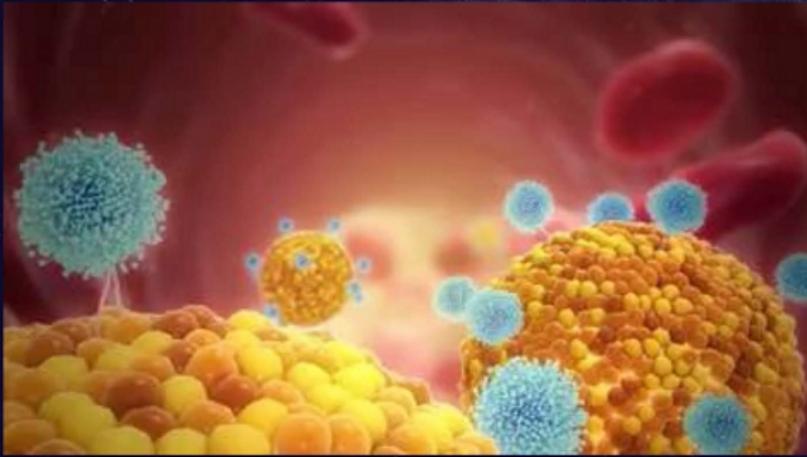
Arcturus mRNA Medicines

LUNAR-OTC (ARCT-810) to treat Ornithine Transcarbamylase (OTC) Deficiency
OTC Deficiency market potential \$500M annual sales

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



LUNAR[®] Mechanism of Delivery

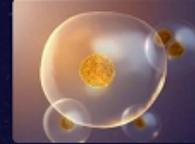


LUNAR Associates with Cell Membrane



Enters Cell Via Endocytosis

Lipid Particle in Endosome



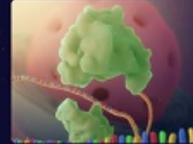
Increased Acidity as Endosome Ages

pH-Mediated Disruption



Rapid Biodegradation of Vehicle

RNA in Cytosol



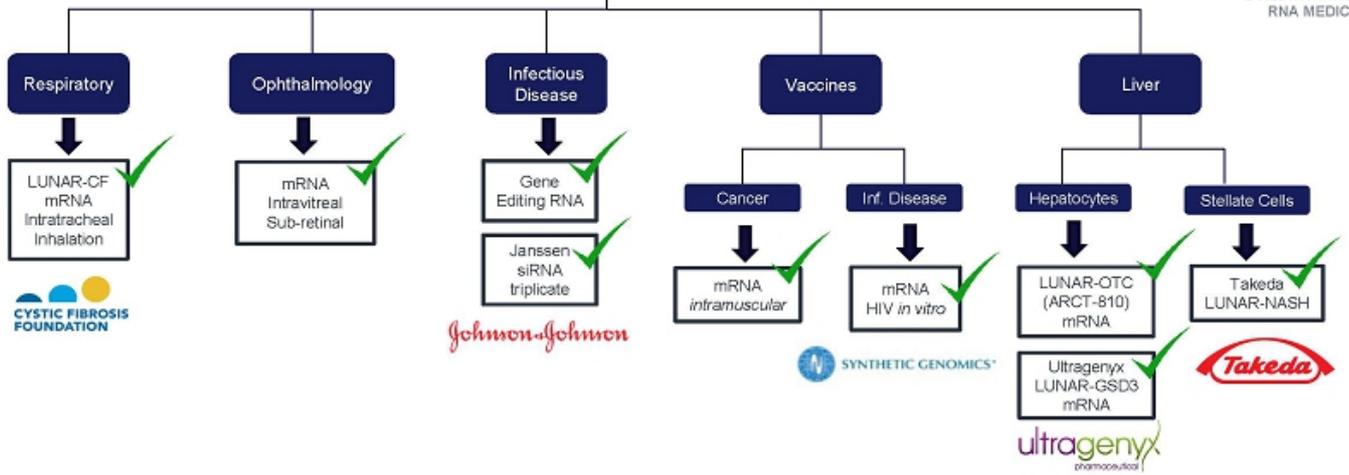
RNA Processing and Translation

Arcturus Platform: Enabling Genetic Medicines

Name	Partner	Year of Initiation	Indication	Arcturus Chemistry	Arcturus Delivery	mRNA Process
LUNAR-HBV		2015	Hepatitis B	RNA	LUNAR® Hepatocytes	ARCT
LUNAR-NASH		2017	NASH	RNA	LUNAR® Stellate Cells	ARCT
LUNAR-GSD3		2016	Glycogen Storage Disease Type III	mRNA	LUNAR® Hepatocytes	ARCT
LUNAR-RARE		2016	Rare Disease	mRNA	LUNAR® Hepatocytes	ARCT
LUNAR-RPL		2017	Vaccines	SGI's Replicon RNA	LUNAR® Intramuscular	SGI

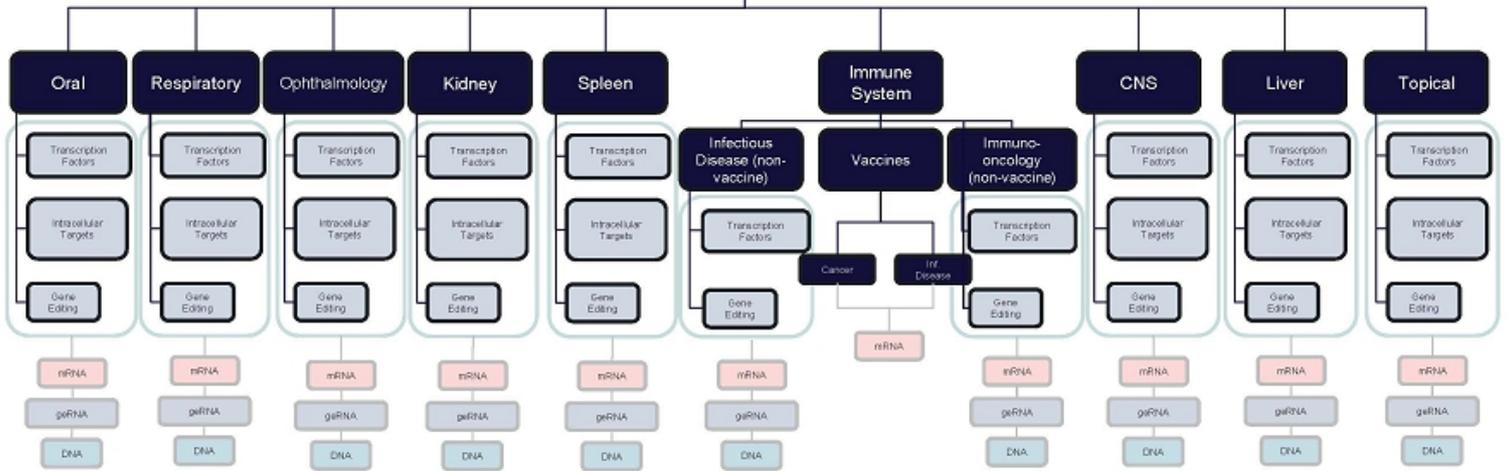
- Greater than \$1 Billion in Potential Milestones & Royalties
- Enabling Different Types of RNA – Messenger RNA, Gene Editing RNA, Replicon RNA
- Multiple Cell Types Targeted

LUNAR® Platform Substantial Preclinical Proof-of-Concept Demonstrated



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

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



Arcturus Pipeline of mRNA Medicines

Name	Indication	IND Date	Route of Administration	Target Organ	Target Cells	Prevalence Worldwide
LUNAR-OTC (ARCT-810)	Ornithine Transcarbamylase (OTC) Deficiency	Q4 2019	Intravenous (i.v.)	Liver	Hepatocytes	> 10,000
LUNAR-CF	Cystic Fibrosis	H1 2020	Nebulized Aerosol to Lung	Lung	Bronchial Epithelial Cells	> 70,000
LUNAR-2020	Rare Liver Disease	2021	i.v.	Liver	Hepatocytes	
LUNAR-2020	Rare Lung Disease	2021	Nebulized	Lung	Bronchial Epithelial Cells	

- Arcturus programs focus on messenger RNA (mRNA) drug products for rare diseases
- LUNAR-OTC (ARCT-810, intravenous mRNA medicine): Investigational New Drug (IND) Filing Target Q4 2019
- LUNAR-CF is funded by the Cystic Fibrosis (CF) Foundation – IND Target H1 2020
- If resources are available, we can progress more candidates into the clinic in 2021

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.

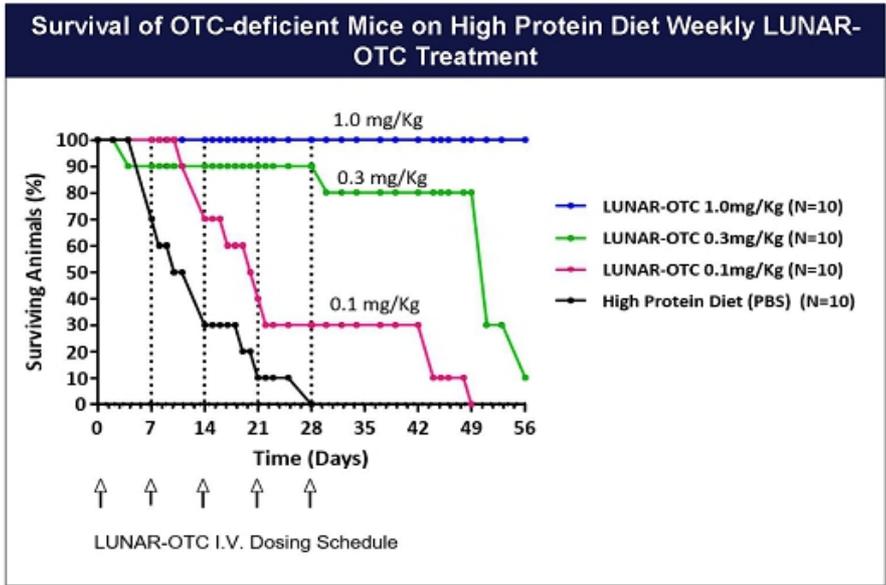


LUNAR-OTC Aims to Restore Enzyme Function

- 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

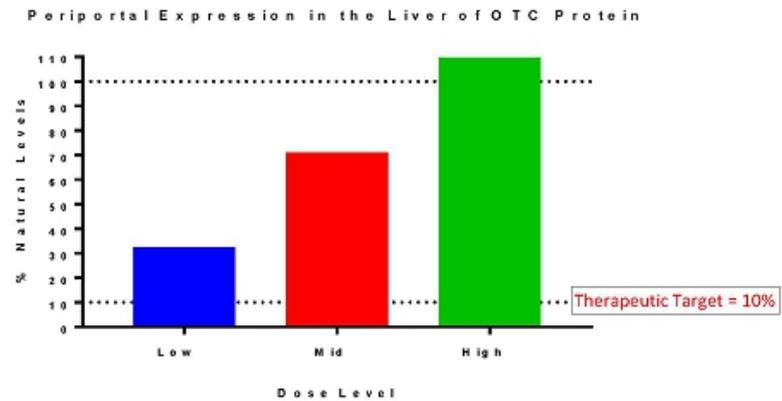
Disease Normalization Following Single and Repeat Dosing in OTC Mouse Model



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-1 α Promotes Ureagenesis in Mouse Periportal Hepatocytes through SIRT3 and SIRT5 in Response to Glucagon. *Scientific Reports*, 8:24158 | DOI: 10.1038/srep24158, April 2018

LUNAR-OTC treatment increases OTC expression in mouse periportal hepatocytes (main site of ureagenesis)

Arcturus Safety Profile

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
- Over \$3 Million invested to date

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)

Cystic Fibrosis Market Opportunity



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

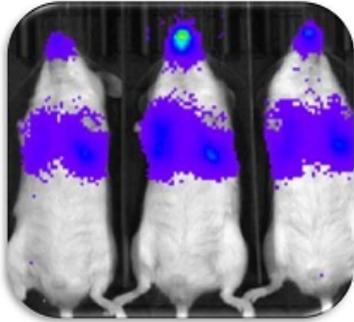


LUNAR-CF Aims to Restore CFTR Function

- 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

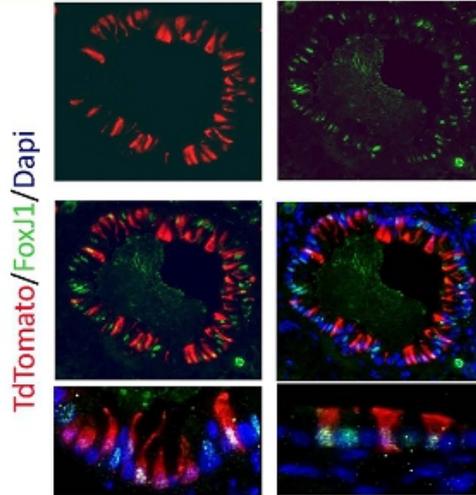
LUNAR[®] Targeting Lung

Nebulization



LUNAR-Luc mRNA

LUNAR[®] Delivery into Bronchial Epithelial Cells (BECs)



Functional Delivery of LUNAR[®]-mRNA into Lung Epithelial Cells

Drug Substance: mRNA Design

Arcturus' proprietary mRNA optimization platform

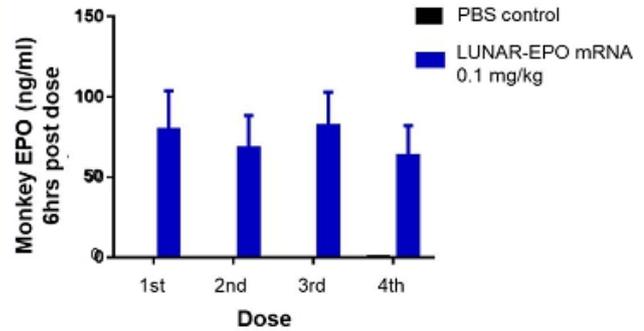
Optimized conditions

- mRNA sequence
 - Chemistry
 - Process optimization
- ➔
- Improved protein expression and duration
 - Improved 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

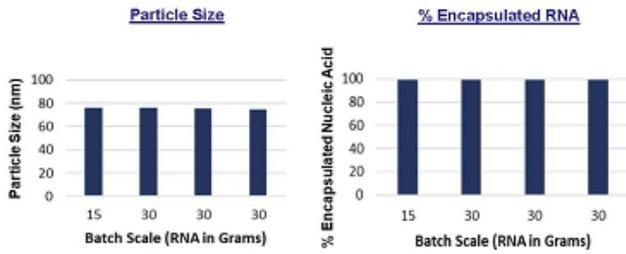


Features	Benefits
Optimized IVT Method	Reduced Cost; Higher Purity
Improved Capping Reaction	Reduced Cost of Goods
Proprietary Purification Process	Higher Purity in a Shorter Time
Efficient	Entire Process Less Than One Week
Scalable to > 1Kg	Access Large Patient Populations
Adaptable	Can Utilize a Variety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

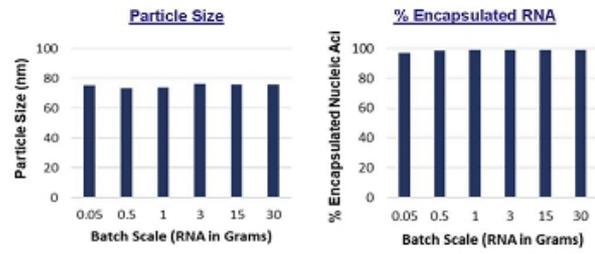
Arcturus' Internal mRNA Production: Up to 30 g in Less Than One Week

Drug Product: LUNAR[®] Formulation & Production

LUNAR[®] Reproducibility



LUNAR[®] Scalability



LUNAR[®] Has Been Successfully Scaled From Milligram to Multigram Batch Sizes

Board of Directors



Dr. Peter Farrell
Chairman of the Board



Andrew Sassine, MBA
Director of the Board



James Barlow, MA
Director of the Board



Dr. Magda Marquet
Director of the Board



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



ResMed
Founder and Chairman



Former Portfolio Manager



Former Chief Accounting Officer



Chairman and Co-Founder



Management Team



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



