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): August 13, 2024

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

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.

On August 13, 2024, Arcturus Therapeutics Holdings Inc. (the "Company" or "Arcturus") posted an updated corporate presentation on its website. A copy of the presentation is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

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 Securities and Exchange Commission (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 the presentation, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or submission 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 Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the presentation attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the Securities and Exchange Commission 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	Corporate Presentation dated August 13, 2024
104	Cover Page to this Current Report on Form 8-K in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 13, 2024

Arcturus Therapeutics Holdings Inc.

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

ARCTURUS® therapeutics

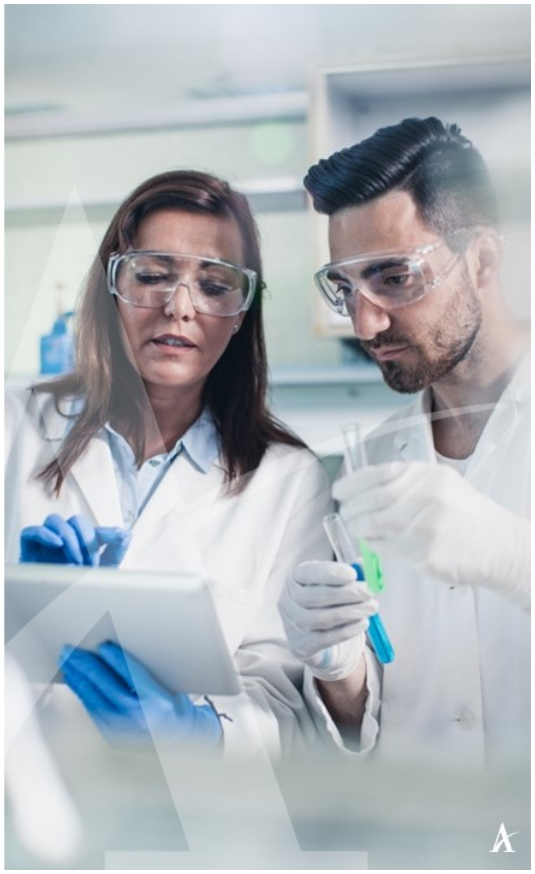
Next Generation RNA Medicines

August 2024

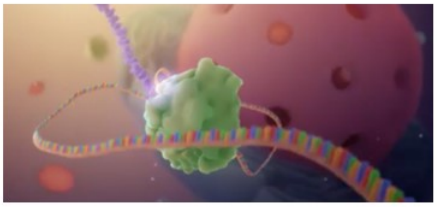
Forward Looking Statements

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: our strategy, future operations, collaborations, the likelihood of success (including safety and efficacy) and promise of our pipeline, the timing for selection of lead candidates, the development, manufacture or commercialization of our pipeline and partnered pipeline assets, the likelihood of success of, and achievement of revenues from, our partnered programs, the planned initiation, design or completion of clinical trials the likelihood that we will obtain clearance from regulatory authorities to proceed with planned clinical trials, the ability to enroll subjects in clinical trials, the timing for receipt of data, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood that clinical data will be sufficient for regulatory approval or completed in time to submit an application for regulatory approval within a particular timeframe, the anticipated timing for regulatory submissions, the timing of, and expectations for, any results of any preclinical or clinical studies or regulatory approvals, the potential administration regimen or dosage, or ability to administer multiple doses of, any of our drug candidates, our manufacturing methods and technologies (including purification, lyophilization and stability of our products), the likelihood that a patent will issue from any patent application, our current cash position and adequacy of our capital to support future operations, and any statements other than statements of historical fact.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions (including the negative thereof) intended to identify forward looking statements. Arcturus may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in any forward-looking statements such as the foregoing, and you should not place undue reliance on such forward-looking statements. The forward-looking statements contained or implied in this presentation are subject to other risks and uncertainties, including those discussed under the heading "Risk Factors" in Arcturus' most recent Annual Report on Form 10-K with the SEC and in other filings that Arcturus makes with the SEC. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.



Arcturus Therapeutics



Global mRNA Medicines Company

Nasdaq: ARCT

Headquarters: San Diego, CA

Founded: 2013

mRNA Medicine Candidates

LUNAR-OTC *Ornithine Transcarbamylase Deficiency*

LUNAR-CF *Cystic Fibrosis*

Additional Earlier Stage Programs

Strategic Partners

CSL

CYSTIC FIBROSIS FOUNDATION

BARDA

Proprietary mRNA Technologies Driving Therapeutic Programs

Broad Intellectual Property Portfolio

mRNA Technology

mRNA for protein replacement

Self-amplifying mRNA (STARR®) low-dose vaccine technology

LUNAR® Delivery

Hepatocytes – *intravenous*

Myocytes – *intramuscular*

Bronchial Cells – *inhaled*

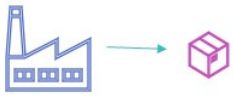
Manufacturing Know-How

mRNA Drug Substance Production

mRNA Purification

LNP Drug Product Production

Fill Finish / Lyophilization

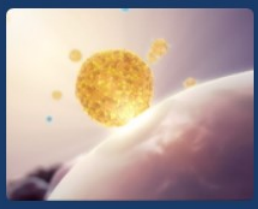


400+ Patents & Patent Applications

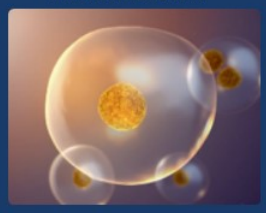
LUNAR® - Lipid Nanoparticle (LNP) Delivery Technology

Proprietary, Biodegradable, Optimized for Each Cell Type

LUNAR® interacts with cell membrane

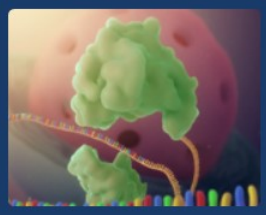


LUNAR® internalized inside endosome



mRNA release

mRNA translated into protein of interest



Pipeline of Arcturus-Owned mRNA Therapeutic Candidates

Franchise	Candidate	Funded By	Indication	Global Prevalence	Upcoming Milestone
Hepatic	LUNAR-OTC (ARCT-810)	ARCTURUS therapeutics	Ornithine Transcarbamylase Deficiency (OTC)	> 10,000	Phase 2 Interim Data Q4 2024
Respiratory	LUNAR-CF (ARCT-032)	CYSTIC FIBROSIS FOUNDATION	Cystic Fibrosis	85,000-100,000	Phase 2 Initiation H2 2024

Each Arcturus-Owned Program Represents a Significant Commercial Opportunity

Pipeline of Partnered Self-amplifying mRNA Vaccines

Candidate	Partner	Indication	Stage
Kostaive® (ARCT-154) Monovalent: Ancestral	CSL	COVID-19	Approved (JP) MAA Filed (EU)
Kostaive® Bivalent (ARCT-2301) Ancestral / Omicron BA.4/5	CSL	COVID-19	Phase 3
Kostaive® XBB.1.5 (ARCT-2303) Monovalent: XBB.1.5	CSL	COVID-19	Phase 3
LUNAR®-FLU (ARCT-2138) Quadrivalent	CSL	Seasonal Influenza	Phase 1
LUNAR®-FLU (ARCT-2304) Pandemic	BARDA	Pandemic Influenza	Pre-clinical

Greater than $5 Billion in Potential Milestones & Profit Sharing / Royalties

CSL: Arcturus Therapeutics Global Vaccine Partner

CSL

- $13.3 Billion USD Annual Revenue
- Operating in 40+ Countries Worldwide
- 32,000+ Employees Worldwide
- 13 Phase III programs – including Kostaive®
- Focused on four strategic technology platforms – plasma protein; recombinant technology; cell and gene therapy; and vaccines
- Therapeutic areas of focus of immunology, hematology, respiratory, cardiovascular, transplant, nephrology and vaccines

CSL Seqirus

A World Leader in Flu Vaccines

- $2.03 Billion USD Annual Revenue

CSL Seqirus is one of the Three Core Businesses of CSL

CSL Annual Report 2023, CSL Capital Markets Day 16, October 2023

CSL Vaccine Partnership

Up to $4.3 billion in Milestone Payments

- Collaboration combines CSL's global vaccine commercial and manufacturing infrastructure with Arcturus' expertise in mRNA design and modification, LUNAR® lipid nanoparticle (LNP) technology and manufacturing know-how.
- Deal terms encompass the development, manufacture, and commercialization of mRNA-based vaccines targeting COVID-19, Influenza and three additional respiratory infectious disease vaccines.

Partnership Terms

CSL	ARCTURUS therapeutics
$200 million	Upfront Payment
$1.3 billion	Development Milestones
$3.0 billion	Commercial Milestones

40% profit sharing for COVID-19 vaccines (defined as 40% of gross profits, less 40% of development costs)

Up to **double digit royalties** for influenza and three additional respiratory infectious disease vaccines

Meiji: Background Information

The Meiji Group provides food and pharmaceuticals indispensable to their customers

- $7.9 Billion USD Net Sales (As of March 31, 2023)
- 113 Locations Worldwide with 17,290 Employees

Meiji Seika Pharma provides antibacterial drugs, vaccines, central nervous system drugs, and generic drugs

- $1.4 Billion USD Net Sales (As of March 31, 2023)
- Received rights in Q4 2022 to conduct Kostaive® clinical study in Japan
- Granted significant subsidy from Japanese government in Q4 2022
- Entered into agreement with CSL Seqirus in April 2023, responsible for obtaining regulatory approval, distribution, sales and marketing Kostaive® of in Japan

Meiji Seika Pharma, a Subsidiary of Meiji Holdings Co. Ltd., Funded and Conducted the Kostaive® Phase 3 Comparator Booster Study and Obtained Regulatory Approval in Japan

Meiji Holdings Co., Ltd., IR Team, Corporate Communications Dept. Data Book, Fiscal Year 2022, May 11, 2023
Meiji Holdings Co., Ltd., IR Team, Corporate Communications Dept. Data Book, H1 of FYE March 2024, November 9, 2023

ARCALIS: Arcturus' Joint Venture mRNA Manufacturing Partner

ARCALIS is a CDMO Specializing in Manufacturing of mRNA Vaccines and Therapeutics

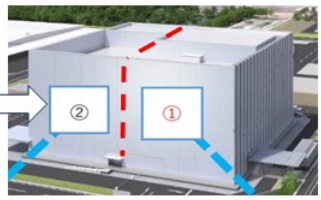
- Joint Venture Founded in 2021
- Major Equity Owners: Axcelead & Arcturus, subject to dilution
- Meiji Seika Pharma is collaborating with ARCALIS for domestic mRNA vaccine production

ARCALIS' cGMP mRNA Drug Substance Manufacturing Plant

- Completed July 2023; Located in Minamisoma City, Japan
- Capacity: Up to 5 kg in bulk mRNA drug substance per year
- 78,059 sq ft (7,252 sq m) floor space

ARCALIS' cGMP mRNA Drug Product Manufacturing Expansion

- Capacity: 30 L (3 Lines); building to 100 L (2 Lines)



ARCALIS Awarded with $165 Million in Grants from the Japanese Government

Kostaive® Phase 3 Clinical Studies

Kostaive® (Monovalent, Kostaive®)

Phase 3 Non-inferiority safety and immunogenicity trial

- Kostaive® administered at an 83.3% lower dose than Comirnaty® (N = 828)
- 50% of participants received Kostaive® (5 mcg); 50% of participants received Comirnaty® (30 mcg)
- Conducted in Japan

Achieved Primary Endpoint of non-inferiority of neutralizing antibody response against SARS-CoV-2 Ancestral strain compared to Comirnaty®
Achieved Secondary Endpoint of superiority of Kostaive® in neutralizing antibody response against SARS-CoV-2 Omicron BA.4/5 variant; increased immunogenicity associated with Kostaive® versus Comirnaty® at Day 29, with a geometric mean ratio of neutralizing antibodies against the vaccine strain of 1.43
Generally safe and well tolerated
Phase 3 Study published in *The Lancet Infectious Diseases*[1]

THE LANCET Infectious Diseases

Kostaive® (Bivalent, ARCT-2301)

Bivalent Kostaive® (ARCT-2301: ancestral D614G and Omicron BA.4-5)

- Results consistent with monovalent Kostaive®
- Phase 3 clinical booster vaccination study was also conducted in Japan

Bivalent Kostaive® was assessed in comparison with bivalent conventional mRNA vaccine (Comirnaty®):

- Day 29 superiority of neutralizing antibody response against SARS-CoV-2 Ancestral strain was established
- Day 29 superiority of neutralizing antibody response against SARS-CoV-2 Omicron BA.4/5 subvariant was established
- Day 29 neutralizing immune response against SARS-CoV-2 Omicron XBB.1.5 subvariant was higher compared to Comirnaty

Kostaive® Received Approval Nov 2023 from Japan's Ministry of Health, Labor and Welfare (MHLW)

[1]Yoshiaki Oda, Yuji Kumagai, Manabu Kanai, Yasuhiro Iwama, Iori Okura, Takeshi Minamida, Yukihiro Yagi, Toru Kurosawa, Benjamin Greener, Ye Zhang, Judd L Walson. Immunogenicity and safety of a booster dose of a self-amplifying RNA COVID-19 vaccine Kostaive® versus BNT162b2 mRNA COVID-19 vaccine: a double-blind, multicentre, randomised, controlled, phase 3, non-inferiority trial. *The Lancet Infectious Diseases*, 2023, https://doi.org/10.1016/S1473-3099(23)00650-3.

Historic Approval of World's First sa-mRNA Product

CSL-Arcturus Collaboration Results in Groundbreaking Approval of Kostaive®

First Arcturus Approval

Kostaive® self-amplifying mRNA COVID vaccine was **approved in Japan by the MHLW in November 2023**

The STARR® vaccine was created, optimized, clinically developed and approved in under 4 years

MHLW
Ministry of Health, Labour and Welfare of Japan

Enduring Vaccine with Strong Clinical Data

Approval based on positive clinical data from several Kostaive® studies

- 18,000+ subjects have received sa-mRNA COVID vaccines

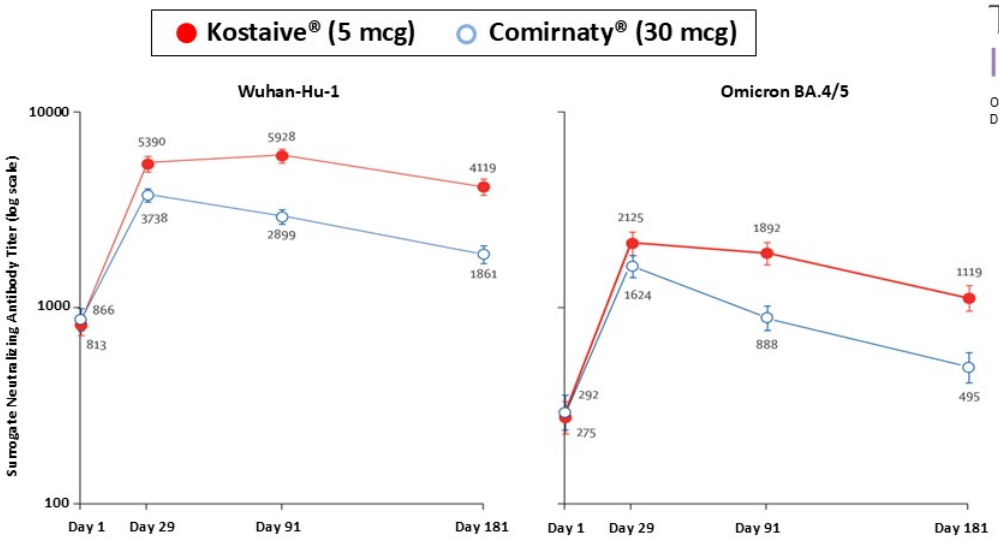
Partner **Meiji Seika Pharma** advanced the MHLW approval and is the exclusive distributor of Kostaive® in Japan

CSL ARCTURUS therapeutics meiji Meiji Seika Pharma

Unprecedented approval paves the way for additional sa-mRNA vaccines

Kostaive®: More Durable Post-boost Immune Response

Phase 3 Persistence Data Comparing Kostaive® (5 mcg) to Comirnaty® (30 mcg)



THE LANCET
Infectious Diseases

Oda Y et al. Lancet Infect Diseases; February 1, 2024
DOI: (10.1016/S1473-3099 mcg(mcg 24)00060-4)

Comirnaty® is the brand name of BNT162b

Kostaive® sa-mRNA Booster Shows Higher Durability of Immune Response Compared to Approved mRNA Vaccine

ARCT-032

Inhaled mRNA Therapeutic Candidate for Cystic Fibrosis

Cystic Fibrosis

ARCT-032 Market Opportunity

Cystic Fibrosis

85,000-100,000 worldwide prevalence

Caused by mutations in the CFTR gene, resulting in poor chloride transport and dehydrated, sticky mucus in the airways

Chronic airway obstruction leads to infection and inflammation, which causes progressive airway damage and ultimately, respiratory failure

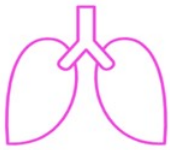
Unmet Medical Need

Highly effective CFTR modulators are not approved for treatment of all people with CF and may not be tolerated in others

Standard of care therapies do not prevent the chronic, progressive loss of lung function that ultimately requires lung transplantation or leads to early death

8% of CF patients have genotypes making them ineligible for modulators[1]

Additional 10% of CF patients are eligible but not prescribed modulators[1]



LUNAR-CF Aims to Restore CFTR Function

An mRNA replacement therapy has the potential to produce wild-type CFTR into the lungs of CF patients, independent of genotype

Functional CFTR protein can restore chloride efflux in the airways, reducing mucus accumulation and airway damage and minimizing the progressive respiratory impairment observed in people with CF

[1]Cystic Fibrosis Foundation. (2024). 2023 CYSTIC FIBROSIS FOUNDATION PATIENT REGISTRY HIGHLIGHTS. In https://www.cff.org/medical-professionals/patient-registry.

ARCT-032 Clinical Update

Phase 1 Study in Healthy Volunteers (New Zealand)

- Objectives: Assess safety, tolerability and PK of ARCT-032 in healthy adults
- Status: Completed dosing across 4 ascending single-dose cohorts (8 subject per cohort)
- Total number of subjects N = 32
- Safety and tolerability data supported transition to Phase 1b study

Phase 1b Study in Adults with Cystic Fibrosis (NZ)

- Objectives: Assess safety, tolerability and PK of ARCT-032 in adults with CF
- Status: Completed enrollment and dosing of 7 adults with CF
- Safety and tolerability data support transition to Phase 2 study

Phase 2 Study

- Submitted IND application for multiple ascending dose study to determine safety, tolerability and efficacy

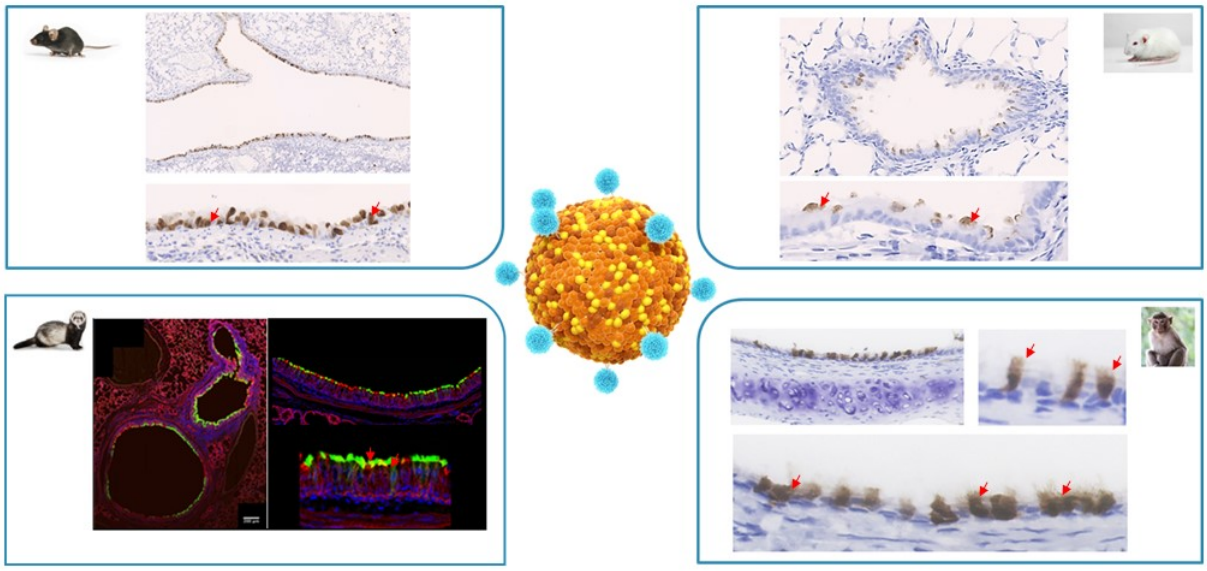
The Cystic Fibrosis Foundation has committed ~$25 Million to advance ARCT-032

ARCT-032 received Rare Pediatric Disease Designation and Orphan Drug Designation from the U.S. FDA and Orphan Medicinal Product Designation from the European Commission (EC)

IND Application Submitted July 2024; Phase 2 Study Initiation Expected H2 2024

LUNAR®-mRNA in Healthy Animals (four different species)

Successful delivery to airway epithelium; transduction demonstrated by Brown and Green staining

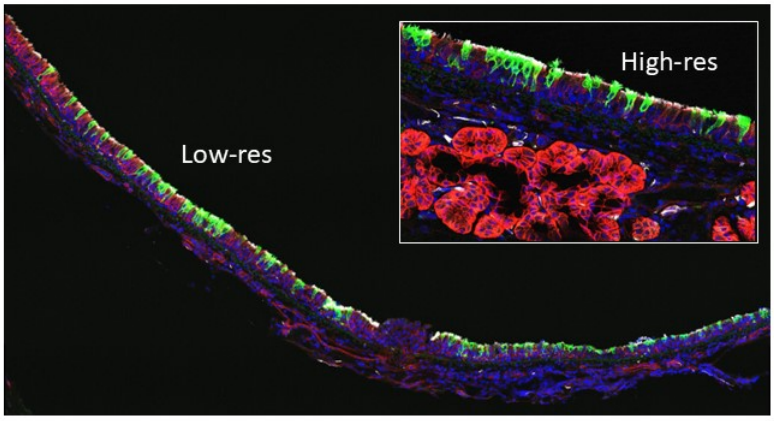


LUNAR® Delivery to Airway Epithelium is Demonstrated in Rodent and Non-Rodent Species

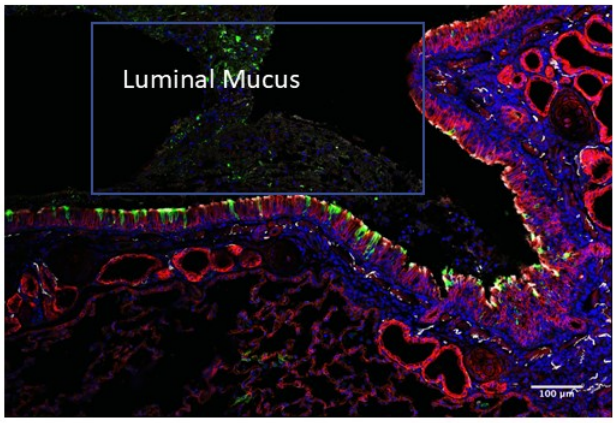
LUNAR®-mRNA in Cystic Fibrosis Ferret Model

Successfully Transduces Epithelium in the Presence of CF Mucus

Trachea



Bronchus



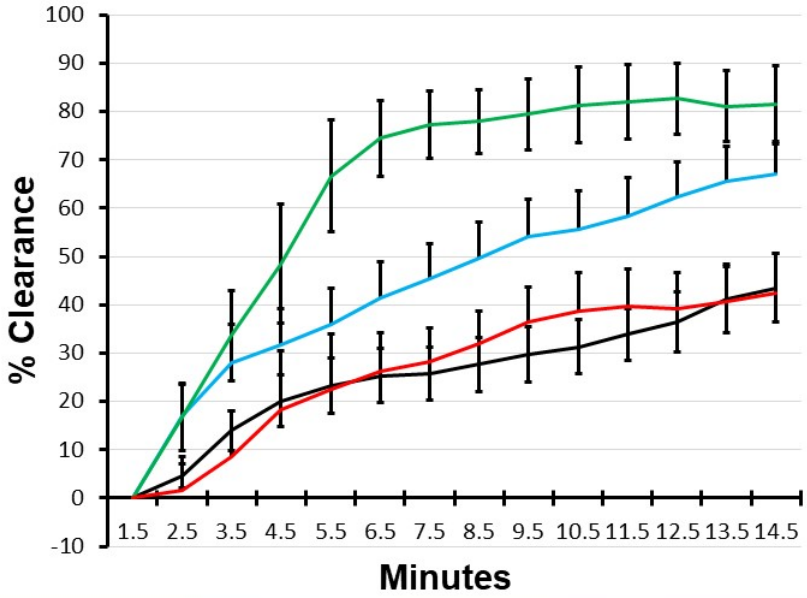
Green denotes functional expression of protein (Cre)

In collaboration with Univ. of Iowa; presented at North American CF Conference Nov 2023

LUNAR® Effectively Delivers mRNA Expressing Cre in a Ferret CF Model (G551D)

ARCT-032 in a Kalydeco®-responsive CF Ferret Model (G551D)

Proof of Activity: Mucociliary clearance improves after single administration of ARCT-032



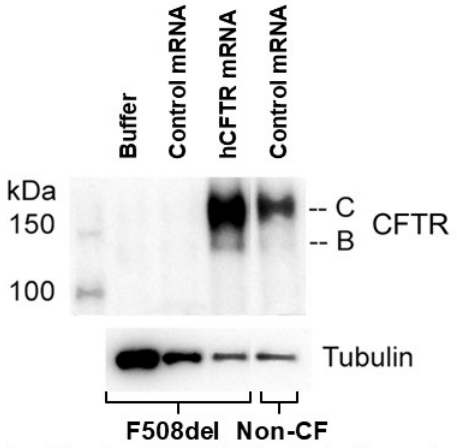
ARCT-032 (LUNAR®-CF)
Kalydeco® (Positive Control)
LUNAR-TdTomato (Negative Control)
Off Kalydeco® (Baseline)

In collaboration with Univ. of Iowa; presented at North American CF Conference Nov 2023

ARCT-032 Functionally Restores Mucociliary Clearance to Normal Levels in CF Ferrets

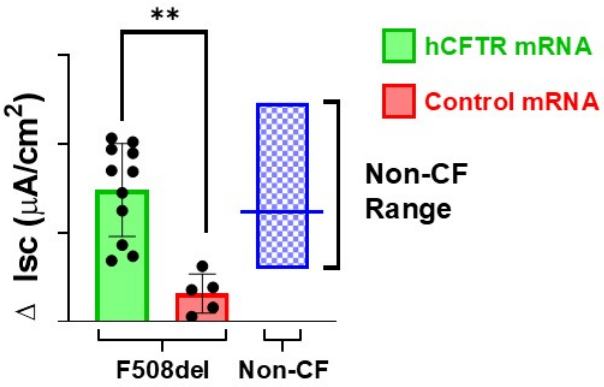
ARCT-032 Restores CFTR Expression & Function

High Expression Levels of CFTR protein



In collaboration with UAB CFRC and Javier Campos-Gomez

Restored chloride activity (chloride gradient)



**P<0.01; Data from two F508del donors; Using chamber studies performed with chloride secretory gradient

In collaboration with Univ. of Alabama-Birmingham; presented at North American CF Conference Nov 2022

Restoration of CFTR Expression and Function in CF Human Bronchial Epithelial Cells

ARCT-810

Systemically Delivered mRNA for Ornithine Transcarbamylase (OTC) Deficiency

Ornithine Transcarbamylase (OTC) Deficiency

ARCT-810 Market Opportunity

The most common urea cycle disorder

The urea cycle converts neurotoxic ammonia to water-soluble urea that can be excreted in urine

Deficiency in OTC causes elevated blood ammonia, which can lead to neurological damage, coma, and death

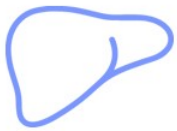
10,000 worldwide prevalence

Unmet Medical Need

Present standard of care involves a strict diet (low protein, high fluid intake) plus ammonia scavengers (e.g. glycerol phenylbutyrate)

Present standard of care does not effectively prevent life-threatening spikes of ammonia

Severe OTC Deficiency patients are referred for liver transplant, currently the only cure



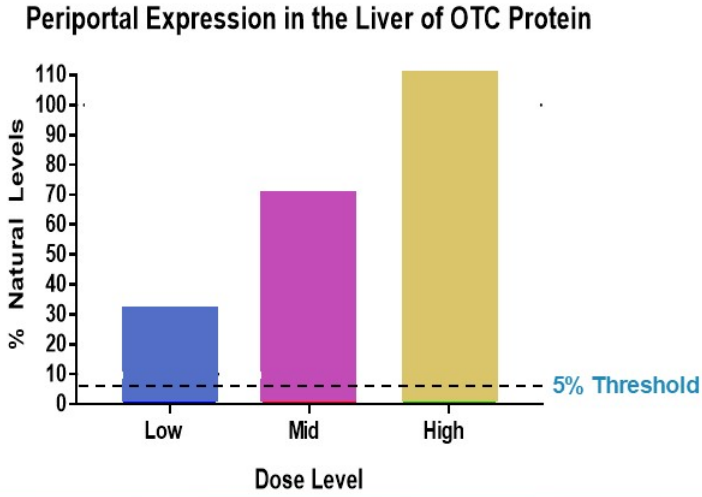
LUNAR-OTC Aims to Restore Enzyme Function

Establishing expression of OTC enzyme in liver has potential to restore urea cycle activity to detoxify ammonia, preventing neurological damage and potentially removing need for liver transplantation

LUNAR-OTC

Exceeds Target of 5% Enzyme Replacement in OTC-Deficient Mouse Model

- OTC deficiency impacts ureagenesis (ammonia detoxification)
- The main site of ureagenesis is the **periportal** region of the liver*
- The critical threshold of **5%** residual enzymatic OTC activity helps avoid severe manifestations of the disease (neonatal coma, mortality)*



LUNAR-OTC Treatment Increases OTC Expression in Mouse Periportal Hepatocytes (Main Site of Ureagenesis)

*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
*Scharre, Svenja. "*In vitro* enzyme activity predicts phenotypic severity in male individuals with ornithine transcarbamylase deficiency." SSIEM Annual Symposium 2022, Freiburg, Germany. 30 August – 2 September 2022. Poster Presentation.

ARCT-810 Clinical Update

Phase 1 (NZ) Study in Healthy Volunteers

- Completed dosing up to 0.4 mg/kg, total number of subjects N = 24, generally safe and well tolerated

Phase 1b (U.S.) Single Ascending Dose (SAD) Study in OTCD Adults

- Completed enrollment and dosing of all cohorts (N=16)
- Dose cohorts were 0.2, 0.3, 0.4 and 0.5 mg/kg; no serious or severe adverse events

Phase 2 (UK and EU) Single and Multiple Ascending Dose, Placebo-controlled Study in OTCD Adolescents & Adults

- Completed enrollment of 8 subjects at the 0.3 mg/kg dose level
- Up to 6 bi-weekly doses for each participant with the following endpoints
  - Primary Endpoints: Safety and tolerability
  - Secondary Endpoints: PK and PD (ureagenesis assay, plasma ammonia: 24-hr profile and peak level)
  - Exploratory Endpoints: Plasma amino acids and OTC enzyme activity; urine orotic acid

Phase 2 Expansion (U.S.)

- Enrolling patients with more severe disease; screening initiated

ARCT-810 received Orphan Drug Designation, Fast Track Designation & Rare Pediatric Disease Designation from the U.S. FDA and Orphan Medicinal Product Designation from the European Commission (EC)

Interim Phase 2 Data Expected Q4 2024

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