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 9, 2021

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 2.02. Results of Operations and Financial Conditions.

On August 9, 2021, Arcturus Therapeutics Holdings Inc. (the "Company" or "Arcturus") issued a press release, a copy of which is furnished herewith as Exhibit 99.1, announcing the Company's financial results for the quarter ended June 30, 2021 and providing a corporate update (the "Press Release").

The information contained in Item 2.02 of this Current Report on Form 8-K, including the Press Release, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, this information shall not be deemed incorporated by reference into any of the Company's filings with the Securities and Exchange Commission (the "SEC"), except as shall be expressly set forth by specific reference in any such filing.

Item 7.01. Regulation FD Disclosure.

The Company has made available a presentation about its business (the "Presentation"), a copy of which is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K 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 SEC and other public announcements the Company may make by press release or otherwise from time to time.

Cautionary Note Regarding Forward-Looking Statements

Certain statements in this Current Report on Form 8-K, the Press Release and the Presentation contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact included in this Current Report on Form 8-K, the Press Release and the Presentation, are forward-looking statements, including those regarding strategy, future operations, collaborations, the planned initiation, design or completion of clinical trials, anticipated sponsorship and/or funding of clinical trials of our candidates, the likelihood that the Company will obtain clearance from regulatory authorities to proceed with planned clinical trials, the ability to enroll subjects in clinical trials, 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 likelihood of success (including safety and efficacy) of the Company's pipeline, including ARCT-021, ARCT-154 and ARCT-810, the potential administration regimen or dosage, or ability to administer multiple doses of, any of the Company's drug candidates, the Company's efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company's mRNA therapeutics, the Company's manufacturing methods and technologies, the likelihood that a patent will issue from any patent application, its current cash position and adequacy of its capital to support future operations, and the impact of general business and economic conditions. Actual results and performance could differ materially from those projected in any forward-looking statements as a result of many factors including, without limitation, the ability to enroll subjects in clinical trials as a result of the COVID-19 pandemic, the impact of commercialization of third-party COVID-19 vaccines on the design, and ability to conduct, clinical trials, the availability of manufacturing capacity and raw materials, unexpected clinical results, government regulations impacting the regulatory environment or intellectual property landscape, and general market conditions that may prevent such achievements or performance. 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. Such statements are based on management's current expectations and involve 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, 2020, and in subsequent filings with, or submissions to, the SEC.

The statements made in this Current Report on Form 8-K, the Press Release and the Presentation 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 No.	**Description of Exhibit**
99.1	Press Release dated August 9, 2021
99.2	Presentation dated August 9, 2021
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.

Arcturus Therapeutics Holdings Inc.

Date: August 9, 2021

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

Arcturus Therapeutics Announces Second Quarter 2021 Financial Results and mRNA Vaccine and Therapeutics Pipeline Progress

ARCT-021, Arcturus' single shot STARR™ mRNA COVID vaccine, to begin multinational placebo-controlled Phase 3 efficacy study funded and sponsored by a global entity

ARCT-154, Arcturus' STARR™ mRNA vaccine candidate targeting COVID variants of concern, elicits robust neutralizing antibody titers against all variants tested in primates, including the Delta variant

ARCT-154 to begin staged Phase 3 study in Vietnam; potential for EUA in December

Investor conference call at 4:30 p.m. ET today

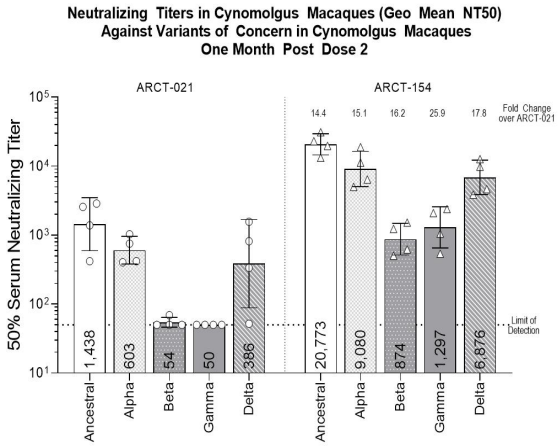
San Diego, Calif, August 9, 2021 – Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases, today announced its financial results for the second quarter ended June 30, 2021 and provided corporate updates.

"This has been an exceptionally productive period where Arcturus has made substantial progress with our mRNA-based vaccine and therapeutic platforms. We are excited about the imminent initiation of the global Phase 3 vaccine trial of ARCT-021, which is funded by a global entity. We made excellent progress advancing and partnering ARCT-154, our next generation vaccine, which targets SARS-CoV-2 variants, including the rapidly expanding and highly transmissible Delta variant. In addition to the progress with our vaccine franchise, we've also advanced our therapeutics pipeline, with the approval of a multiple dose Phase 2 study with ARCT-810, our systemically administered mRNA therapeutic candidate for individuals with OTC deficiency," said Joseph Payne, President and CEO of Arcturus.

Recent Corporate Highlights

- ARCT-021 has been selected by a global entity for inclusion in a multinational Phase 3 vaccine trial against COVID-19. The placebo-controlled study plans to enroll tens of thousands of participants and will evaluate a 5-mcg dose of ARCT-021 administered as a single injection regimen. The Phase 3 study will be sponsored and funded by the entity.
- Arcturus announced an agreement with Vinbiocare, whereby Vinbiocare will fully fund and establish a facility in Vietnam for the manufacture of Arcturus' investigational COVID-19 vaccines. In addition to the $40 million upfront payment, Vinbiocare will purchase the mRNA drug substance from Arcturus and pay a royalty on manufactured doses.
- Arcturus has advanced ARCT-154, our next generation STARR™ mRNA vaccine candidate targeting SARS-CoV-2 variants of concern, toward multiple clinical development studies. Preclinical data demonstrate strong neutralizing immunogenicity in non-human primates to SARS-CoV-2 Alpha, Beta, Gamma, and Delta variants. ARCT-154 elicits 14.4 to 25.9-fold higher neutralizing antibody titers than ARCT-021 in non-human primates, including an observed increase of 17.8-fold higher neutralizing antibody titers against the Delta variant.

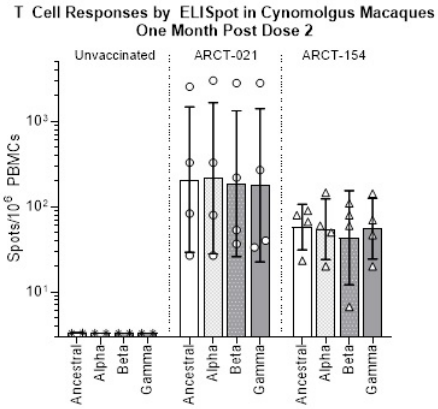
ARCT-154 utilizes an optimized STARR™ mRNA with multiple improvements, including modifications for stability and translation, increased immunogenicity of the spike protein antigen via amino acid substitution, expressing the spike protein in a pre-fusion state, and inactivating the furin cleavage site.



Neutralizing Titers (Geo Mean NT50) Against Variants of Concern in Cynomolgus Macaques One Month Post Dose 2					
STARR™ Vaccine	**Ancestral**	**Alpha**	**Beta**	**Gamma**	**Delta**
ARCT-021 (7.5 mcg x 2)	1,438	603	54	50	386
ARCT-154 (7.5 mcg x 2)	20,773	9,080	874	1,297	6,876
Fold Improvement	**14.4**	**15.1**	**16.2**	**25.9**	**17.8**

Non-Human Primate (NHP) data collected one month after second dose of 7.5 mcg; analysis of NHP serum was performed using non-replicating vesicular stomatitis virus pseudo-typed with the spike protein of the SARS-CoV-2 variants of concern indicated. Titers (geometric mean) were determined by calculating the dilution that resulted in 50% inhibition of cells expressing GFP encoded by the pseudovirus, a surrogate of virus infection. Error bars indicate geometric standard deviation.

T cell responses for ARCT-021 and ARCT-154 are robust and similar in non-human primates. Notably, STARR™ mRNA vaccines elicit similar T cell responses against all variants of concern tested. The robust T cell responses are attributed to the self-amplifying mRNA mechanism of antigen expression.



T cell responses from non-human primates assessed one month after second dose of 7.5 mcg; SARS-CoV-2 spike specific T cell responses were analyzed by ELISpot assay using overlapping 15-mer peptides spanning the entire spike antigen from the ancestral SARS-CoV-2 strains or the Alpha, Beta, and Gamma variants of concern. Spot Forming Units (SFU) were determined after background subtraction of unstimulated controls. Bars indicate mean values and error bars indicate standard deviation.

- Arcturus announced approval of a Clinical Trial Application (CTA) from the Singapore Health Sciences Authority (HSA) enabling the advancement of ARCT-154 into a Phase 1/2 clinical trial to evaluate the vaccine as a primary vaccination series and as a booster following initial vaccination with Comirnaty® (marketed by Pfizer and BioNTech). The Phase 1/2 trial costs are funded in part from a previously secured grant from Singapore.

- Arcturus announced that the company's partner Vinbiocare received approval for a CTA from the Vietnam Ministry of Health to advance ARCT-154 into a Phase 1/2/3 clinical study. The trial is a randomized, observer-blind, placebo-controlled design, and is sponsored and completely funded by Vinbiocare. The Phase 1/2/3 study will assess the safety, immunogenicity and efficacy in up to 21,000 adults, with potential Emergency Use Authorization (EUA) by the Vietnam Ministry of Health in December 2021.

- Arcturus announced approval from the UK Health Research Authority to initiate a multiple dose Phase 2 clinical study for ARCT-810, a novel mRNA-based therapeutic candidate for Ornithine Transcarbamylase (OTC) Deficiency. The ARCT-810 Phase 2 study is a randomized, double-blind, placebo-controlled, nested single and multiple ascending dose design for adolescents and adults with OTC deficiency. ARCT-810 Phase 2 study interim results in a subset of participants are expected in H2 2022.

Financial Results for the Quarter Ended June 30, 2021
Revenues in conjunction with strategic alliances and collaborations: Arcturus' primary sources of revenues were from license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended June 30, 2021, the Company reported revenue of $2.0 million compared with $2.3 million for the three months ended June 30, 2020.

Operating expenses: Total operating expenses for the three months ended June 30, 2021, were $55.7 million compared with $12.4 million for the three months ended June 30, 2020 and $59.8 million for the three months ended March 31, 2021.

Research and development expenses increased by approximately $37.7 million year over year in the second quarter ended June 30, 2021 due to increased personnel costs as well as expenses related to our ARCT-810 and ARCT-021 programs. Research and development declined by approximately $5 million sequentially in the June 2021 quarter due primarily to the one-time $5 million exclusive license cost from Alexion Pharmaceuticals in the first quarter of 2021.

For the three months ended June 30, 2021, Arcturus reported a net loss of approximately $54.6 million, or ($2.07) per basic and diluted share, compared with a net loss of $10.3 million, or ($0.55) per basic and diluted share in the three months ended June 30, 2020.

The Company's cash balance totaled $433.6 million as of June 30, 2021, compared to a cash balance of $462.9 million at December 31, 2020. Subsequent to the end of the quarter, the company received the remaining $30 million of our upfront payment from Vinbiocare. Based on our current pipeline, the Company's cash position is expected to be sufficient to support operations for more than two years.

Monday, August 9th @ 4:30 p.m. ET

Domestic:	877-407-0784
International:	201-689-8560
Conference ID:	13721797
Webcast:	http://public.viavid.com/index.php?id=145873

About Arcturus Therapeutics
Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a clinical-stage mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic and vaccine candidates includes mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, and Cystic Fibrosis along with partnered programs including Glycogen Storage Disease Type 3, Hepatitis B Virus, and non-alcoholic steatohepatitis (NASH). Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, replicon RNA, antisense RNA, microRNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (229 patents and patent applications, issued in the U.S., Europe, Japan, China and other countries). Arcturus' commitment to the development of novel RNA therapeutics has led to collaborations with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., Takeda Pharmaceutical Company Limited, CureVac AG, Synthetic Genomics Inc., Duke-NUS Medical School, and the Cystic Fibrosis Foundation. For more information visit www.ArcturusRx.com. In addition, please connect with us on Twitter and LinkedIn.

Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact included in this press release, are forward-looking statements, including those regarding strategy, future operations, collaborations, the planned initiation, design or completion of clinical trials, anticipated sponsorship and/or funding of clinical trials of our candidates, the likelihood that the Company will obtain clearance from regulatory authorities to proceed with planned clinical trials, the ability to enroll subjects in clinical trials, 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 likelihood of success (including safety and efficacy) of the Company's pipeline, including ARCT-021, ARCT-154 and ARCT-810, the potential administration regimen or dosage, or ability to administer multiple doses of, any of the Company's drug candidates, the Company's efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company's mRNA therapeutics, the Company's manufacturing methods and technologies, the likelihood that a patent will issue from any patent application, its current cash position and adequacy of its capital to support future operations, and the impact of general business and economic conditions. Actual results and performance could differ materially from those projected in any forward-looking statements as a result of many factors including, without limitation, the ability to enroll subjects in clinical trials as a result of the COVID-19 pandemic, the impact of commercialization of third-party COVID-19 vaccines on the design, and ability to conduct, clinical trials, the availability of manufacturing capacity and raw materials, unexpected clinical results, government regulations impacting the regulatory environment or intellectual property landscape, and general market conditions that may prevent such achievements or performance. 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. Such statements are based on management's current expectations and involve 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, 2020, and in subsequent filings with, or submissions to, the SEC. Except as otherwise required by law, Arcturus disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

Trademark Acknowledgements

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)

	June 30, 2021	March 31, 2020	December 31, 2020
	(unaudited)	(unaudited)	
Assets			
Current assets:			
Cash and cash equivalents	$ 433,574	$ 466,839	$ 462,895
Accounts receivable	2,163	2,007	2,125
Prepaid expenses and other current assets	2,301	1,150	2,769
Total current assets	438,038	469,996	467,789
Property and equipment, net	3,407	3,427	3,378
Operating lease right-of-use asset, net	6,341	6,690	5,182
Equity-method investment	920	1,248	—
Non-current restricted cash	107	107	107
Total assets	$ 448,813	$ 481,468	$ 476,456
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	$ 10,084	$ 5,597	$ 10,774
Accrued liabilities	42,614	29,800	20,639
Deferred revenue	18,071	17,936	18,108
Total current liabilities	70,769	53,333	49,521
Deferred revenue, net of current portion	9,850	11,313	12,512
Long-term debt, net of current portion	56,309	58,147	13,845
Operating lease liability, net of current portion	5,359	5,710	4,025
Other long-term liabilities	878	358	—
Total liabilities	$ 143,165	$ 128,861	$ 79,903
Stockholders' equity			
Common stock: $0.001 par value; 60,000 shares authorized; 26,327 issued and outstanding at June 30, 2021, 26,319 issued and outstanding at March 31, 2021 and 26,192 issued and outstanding at December 31, 2020	26	26	26
Additional paid-in capital	560,365	552,743	540,343
Accumulated deficit	(254,743)	(200,162)	(143,816)
Total stockholders' equity	305,648	352,607	396,553
Total liabilities and stockholders' equity	$ 448,813	$ 481,468	$ 476,456

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)

(in thousands except per share data)

	Three Months Ended		
	June 30,		March 31,
	2021	2020	2021
Collaboration revenue	$ 2,001	$ 2,322	$ 2,127
Operating expenses:			
Research and development, net	45,679	7,944	50,050
General and administrative	10,042	4,420	9,743
Total operating expenses	55,721	12,364	59,793
Loss from operations	(53,720)	(10,042)	(57,666)
(Loss) gain from equity-method investment	(328)	(100)	1,248
(Loss) gain from foreign currency	(13)	—	430
Finance expense, net	(520)	(121)	(358)
Net loss	$ (54,581)	$ (10,263)	$ (56,346)
Net loss per share, basic and diluted	$ (2.07)	$ (0.55)	$ (2.15)
Weighted-average shares outstanding, basic and diluted	26,323	18,794	26,243
Comprehensive loss:			
Net loss	$ (54,581)	$ (10,263)	$ (56,346)
Comprehensive loss	$ (54,581)	$ (10,263)	$ (56,346)

IR and Media Contacts
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Carlo Tanzi, Ph.D.
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ctanzi@kendallir.com

ARCTURUS THERAPEUTICS

Building the Next Generation of RNA Medicines

August 2021

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 planned initiation, design or completion of clinical trials, anticipated sponsorship and/or funding of clinical trials of our candidates, 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 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.

Company Highlights

BUILDING INNOVATIVE RNA MEDICINES

Arcturus is a Clinical-Stage mRNA Vaccines and Medicines Company

Publicly Traded (Nasdaq: ARCT)

- Headquarters: San Diego, CA
- Number of Employees: 154
- Founded: 2013

Promising Vaccine and Therapeutic Candidates

- LUNAR-COV19 (COVID-19 Vaccine)
- LUNAR-OTC (Ornithine Transcarbamylase Deficiency)
- LUNAR-CF (Cystic Fibrosis)
- Additional Earlier Stage Programs

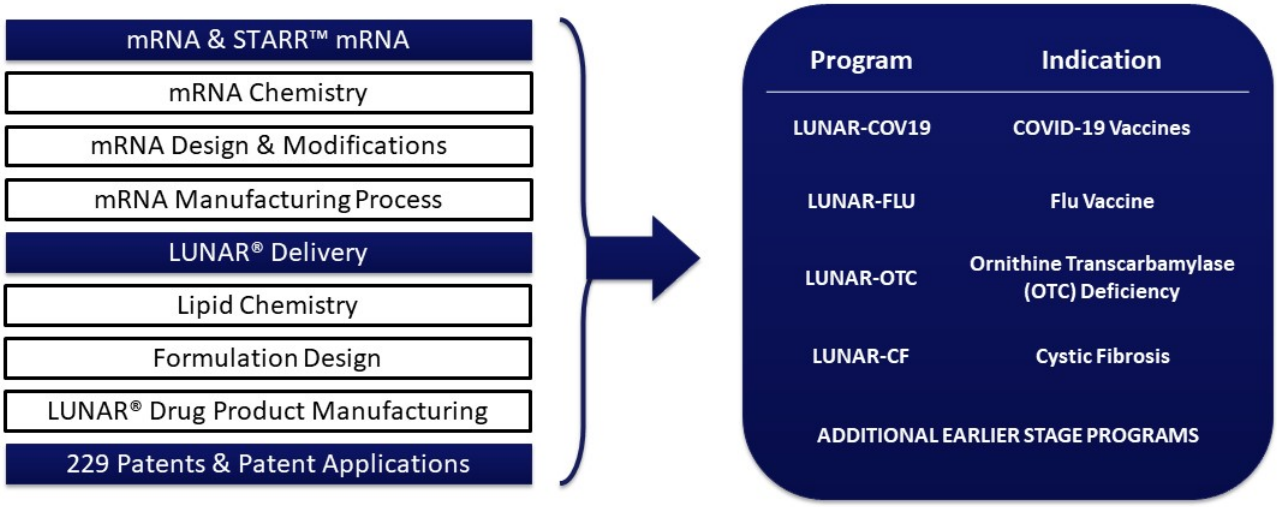
Arcturus Technologies And Programs Validated by Multiple Strategic Partners

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

Proprietary mRNA Technologies Driving Promising Vaccine and Therapeutic Programs

BUILDING INNOVATIVE RNA MEDICINES

Broad and Strong Intellectual Property Portfolio



Arcturus Pipeline of mRNA Medicines

Franchise	Product Name	Indication	Route of Administration	Cell Target	Prevalence Worldwide	Stage	Anticipated Milestones
VACCINES	**LUNAR-COV19** (ARCT-021)	COVID-19 (Single Shot)	Intramuscular	Myocytes & Dendritic Cells	Global	Phase3	Initiation H2 2021
	LUNAR-COV19 (ARCT-154)	COVID-19 (Targeting VOCs)	Intramuscular	Myocytes & Dendritic Cells	Global	Phase 1/2/3	Interim Data Q4 2021
	LUNAR-FLU	Influenza	Intramuscular	Myocytes & Dendritic Cells	Global	Preclinical	IND/CTA H1 2022
HEPATIC	**LUNAR-OTC** (ARCT-810)	Ornithine Transcarbamylase Deficiency	Intravenous	Periportal Hepatocytes	> 10,000	Phase 2	Interim Data H2 2022
RESPIRATORY	**LUNAR-CF** (ARCT-032)	Cystic Fibrosis	Inhaled	Bronchial Epithelial Cells	> 70,000	Preclinical	CTA H1 2022

EUA = Emergency Use Authorization; CTA = Clinical Trial Application; IND = Investigational New Drug Application; VOC= Variant Of Concern

Multiple mRNA Vaccine & Therapeutic Programs in Clinical Development with Milestones

Partnerships Maximize Platform

Program	Partner	Indication
LUNAR-HBV	Johnson & Johnson	Hepatitis B Virus (HBV)
LUNAR-NASH	Takeda	Nonalcoholic Steatohepatitis (NASH)
LUNAR-GSD3	ultragenyx pharmaceutical	Glycogen Storage Disease Type III
LUNAR-RARE	ultragenyx pharmaceutical	Undisclosed Rare Disease
LUNAR-COV19 (ARCT-021)	Undisclosed Global Entity	Covid-19 Vaccine
LUNAR-COV19 (ARCT-154)	VINGROUP	Covid-19 Vaccine

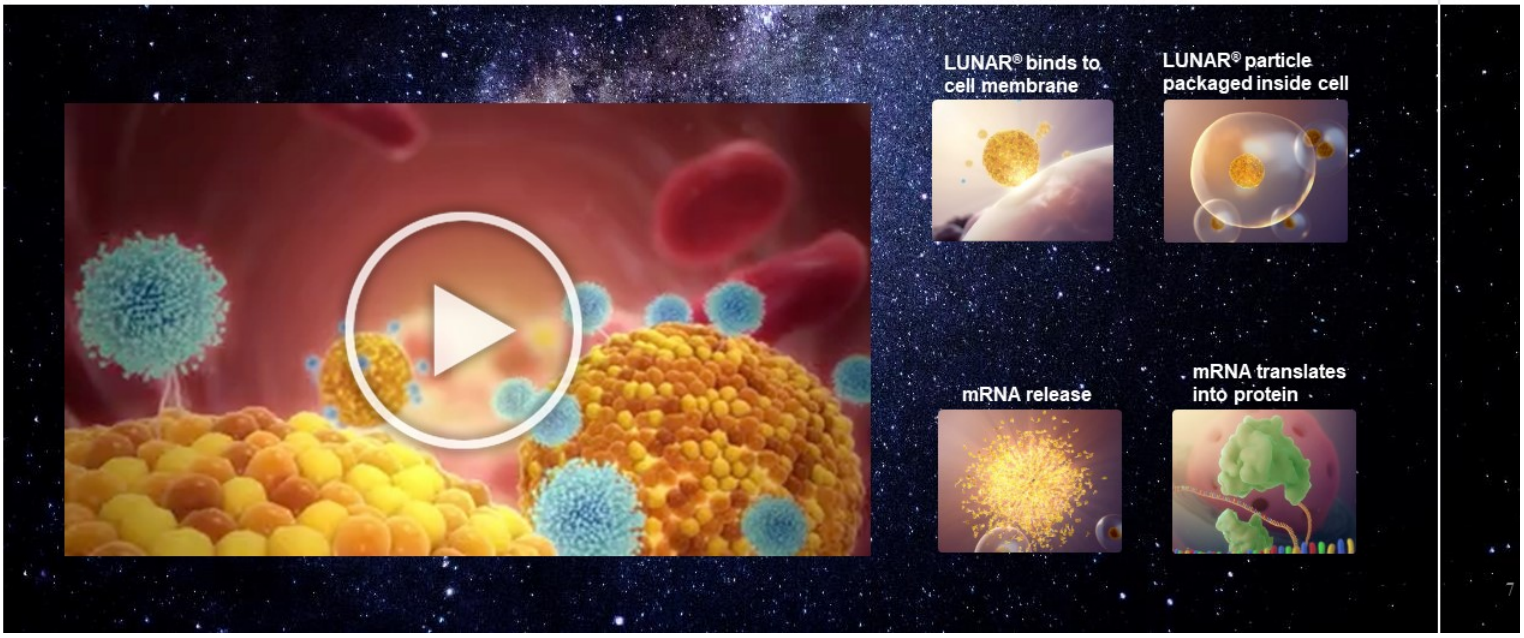
Greater than $1 Billion in Potential Milestones & Royalties

ARCTURUS THERAPEUTICS

LUNAR® Delivery Technology

Biodegradable, highly optimized for each cell type

BUILDING INNOVATIVE RNA MEDICINES

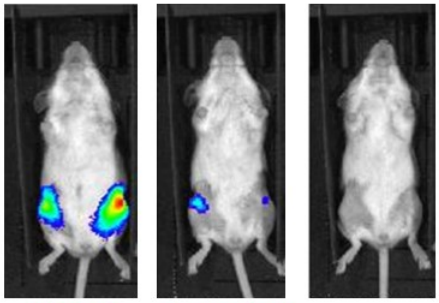


BUILDING INNOVATIVE RNA MEDICINES

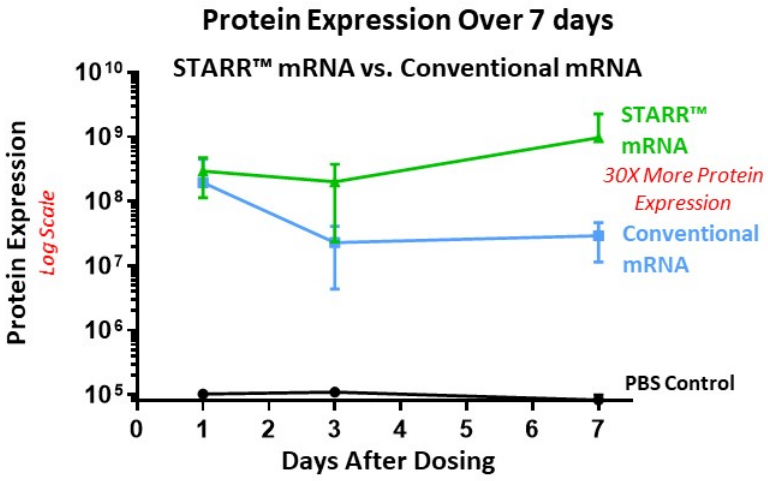
STARR™ mRNA Expression Superior to Conventional mRNA

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

STARR™ Technology
30-Fold Higher Protein Expression



STARR™ Technology | Conventional mRNA | PBS Control



Single dose of STARR™ mRNA technology with LUNAR® delivery provided enhanced protein expression *in vivo* (mouse)

STARR™ COVID Vaccine Candidates
ARCT-021
ARCT-154

STARR™ COVID Vaccine Candidates Have Significant Advantages

STARR™ mRNA technology

- Lower dose level than conventional mRNA provides manufacturing efficiencies and potential safety benefits
- Self-amplifying mechanism of mRNA expression provides superior T cell responses

LUNAR® Delivery Technology

- Non-viral and biodegradable technology that provides potential safety benefits
- Re-dosable delivery technology, helpful for boosting, if needed

Rapidly Updatable as new variants of concern arise

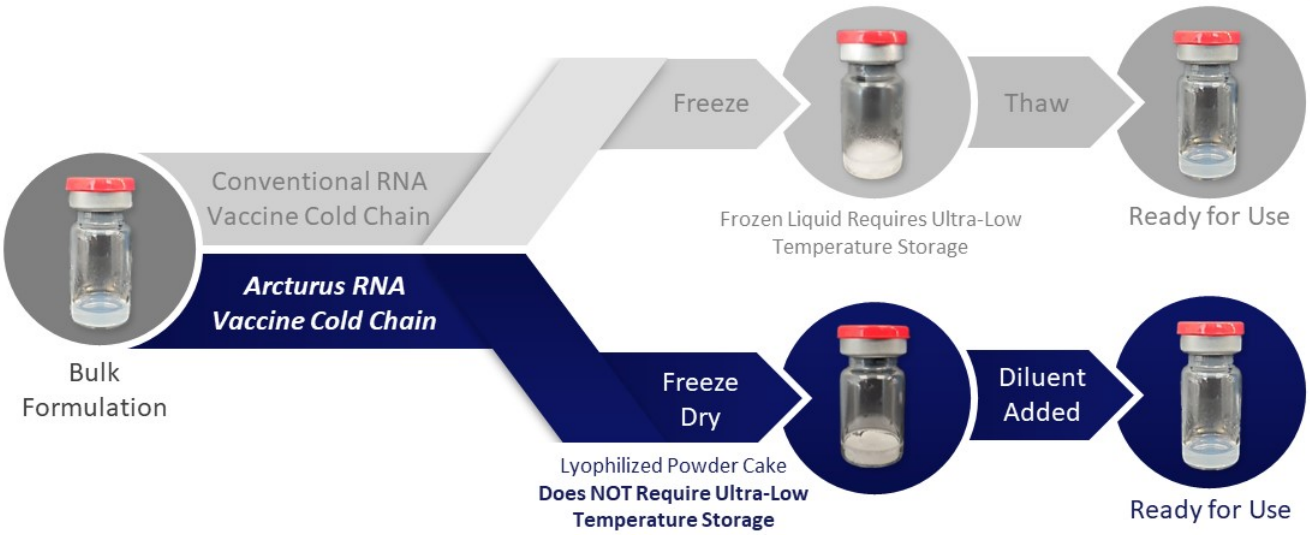
Readily Manufacturable using Arcturus proprietary processes; no adjuvants

Promising Clinical Data that demonstrate humoral and cellular immunogenicity, and tolerability

ARCT-021: Designed as a single shot vaccine; more convenient, simpler distribution logistics
ARCT-154: Designed to target variants of concern

Lyophilized Product Advantages Over Conventional Frozen Liquid

BUILDING INNOVATIVE RNA MEDICINES



Lyophilized ARCT-021 and ARCT-154 maintain key quality attributes

Simpler handling: No dry ice at point of care, lower risk of degradation from uncontrolled temperature fluctuation

Global Manufacturing Partners

BUILDING INNOVATIVE RNA MEDICINES

Global manufacturing partners include Aldevron, ARCALIS, Catalent, Polymun, Recipharm and Vingroup
Manufactured GMP finished doses of lyophilized ARCT-021 (> 15 Million) for stockpiling purposes
Forecast Capacity: More than hundred million doses annually

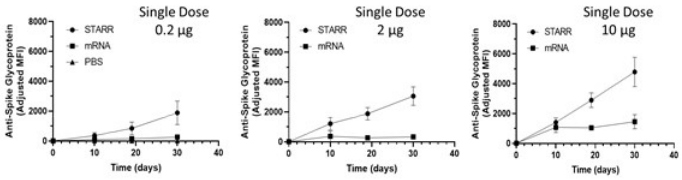
ARCT-021

Single Shot COVID STARR™ mRNA Vaccine

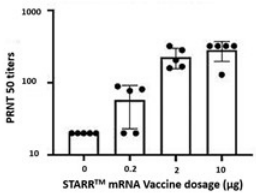
Preclinical Data: Robust Immune Response

Humoral Immunity

STARR™ induces more robust titers compared to conventional mRNA



Neutralizing antibody titers and high seroconversion at low doses

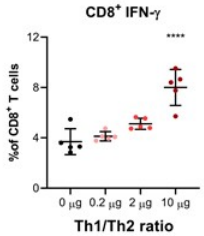


Single Dose (µg)	Seroconversion	Neutralizing Antibody Titers (Geometric Mean)
0.2	80 %	58
2	100 %	218
10	100 %	≥ 320

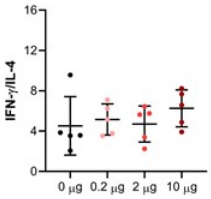
Cellular Immunity

7 Days Post Single Dose

Adaptive Cellular Response (CD8+ cells)



Balanced Th1/Th2 Immune Response (CD4+ cells)



- Single administration with a very low dose of Arcturus COVID vaccine results in potent immune reaction
- STARR™ mRNA generates neutralizing antibodies (anti-SARS-CoV-2 Spike Glycoprotein IgG) and a cellular T-cell mediated immune response at a much lower dose level compared to conventional mRNA

ARCT-021 Significantly Effective in Challenge Models

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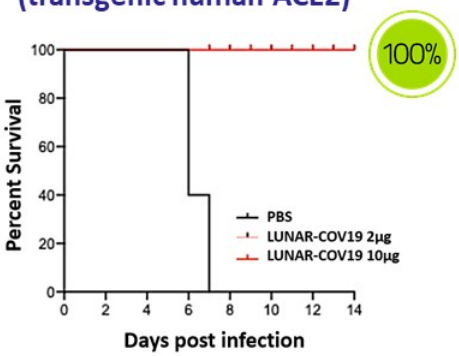
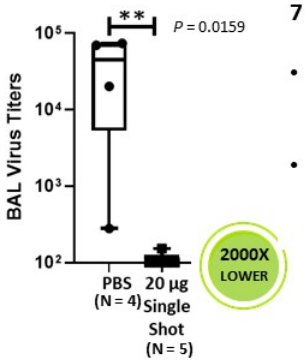
Mouse Model (transgenic human ACE2)



ARCT-021 significantly effective in a virus challenge study in the human ACE2 transgenic mouse model; single dose provided complete protection from SARS-CoV-2 infection and death, compared to control mice which experienced 100% mortality

Primate Model (macaque)



7 Days After SARS-CoV-2 Virus Challenge

- Lung viral titers exceeded 13,100 (median) in non-vaccinated primates (PBS)
- Lung viral titers = 6.5 (median); more than 2000X lower in primates administered a single shot of ARCT-021

Single administration of ARCT-021 significantly effective in primate model (macaque); vaccinated macaques show substantial (3.30 log lower) reductions in median lung viral titers

ARCT-021 Clinical Trial Update

Phase 1/2 Clinical Trial

- Completed dosing all subjects (n = 106), including older adults
- High seroconversion rates for IgG binding antibodies, and Th1 dominant CD4+ immune responses, neutralizing antibodies (PRNT50) Geometric Mean Titer (GMT) levels in the range of titers observed in convalescent serum
- Favorable safety and tolerability; no subjects withdrawn from dosing

Phase 2 Clinical Trial Ongoing

- Fully enrolled with 579 participants dosed across USA and Singapore;
- Two dose levels evaluated: 5mcg and 7.5 mcg
- Two interim analysis conducted; DSMB recommended to proceed with no modifications to protocol
- >90% seroconversion after single 5mcg dose for IgG antibodies binding SARS-CoV-2 spike protein
- Interim analysis #3 expected Q4 2021

Phase 3 Clinical Trial

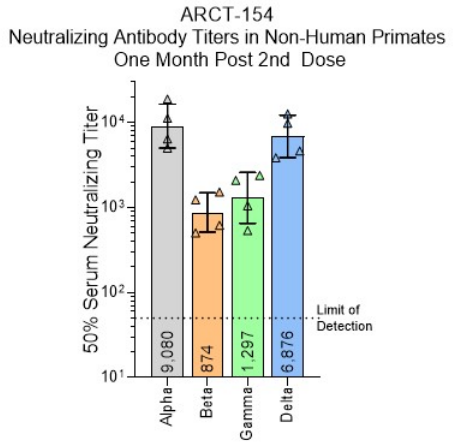
- Undisclosed global entity to sponsor and fund
- Multinational
- Placebo-controlled
- To enroll tens of thousands of participants
- 5-mcg dose, single injection regimen

ARCT-154

STARR™ mRNA COVID Vaccine Targeting Variants of Concern

ARCT-154 Preclinical Data and Clinical Trial Update

Preclinical Data



Non-Human primate (NHP) data collected one month after second dose of 7.5 mcg; Analysis of NHP serum was performed using non-replicating vesicular stomatitis virus pseudo-typed with the spike protein of the SARS-CoV-2 variants of concern indicated. Titers (geometric mean) were determined by calculating the dilution that resulted in 50% inhibition of cells expressing GFP encoded by the pseudovirus, a surrogate of virus infection. Error bars indicate geometric standard deviation.

Phase 1/2/3 Clinical Trial in Vietnam; CTA Approved to Proceed

- Phases 1/2/3 sponsored & funded by Vinbiocare
- Randomized, observer-blind, placebo-controlled design
- To enroll up to 21,000 participants (20,000 in Phase 3)
- Participants will receive two doses of study vaccine separated by 28 days. Placebo participants receive ARCT-154 after 6 months

Phase 1/2 Clinical Trial in Singapore; CTA Approved to Proceed

- Two Cohorts:
  - Primary vaccination evaluation
  - Booster evaluation following initial vaccination with Comirnaty®

LUNAR-OTC (ARCT-810)

Ornithine Transcarbamylase (OTC) Deficiency

Ornithine Transcarbamylayse (OTC) Deficiency

ARCT-810 Market Opportunity

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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

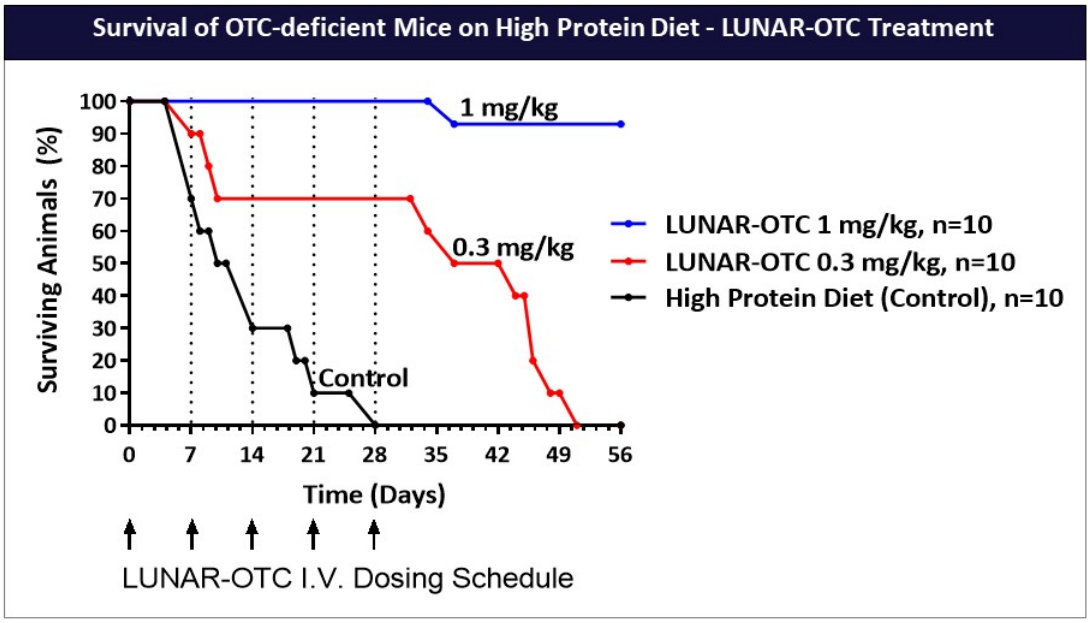
- Present standard of care involves a strict diet (low protein, high fluid intake) plus ammonia scavengers (sodium or glycerol phenylbutyrate)
- Present standard of care does not effectively prevent life-threatening spikes of ammonia
- Liver transplant currently the only known cure for severe OTC Deficiency patients

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

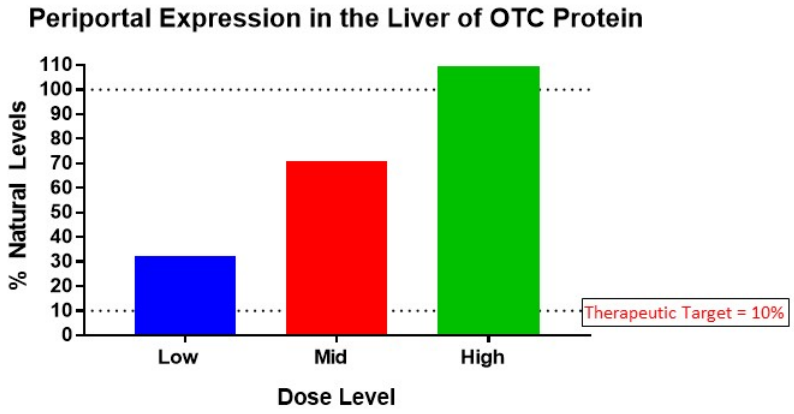
Disease Normalization Following Single and Repeat Dosing in OTC Mouse Model



LUNAR-OTC

Exceeds 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)

ARCT-810 Clinical Update

Phase 1 Clinical Trial in Healthy Volunteers Completed

Phase 1b Clinical Trial in OTC-Deficiency Adults Ongoing

Phase 2 Clinical Trial in OTC-Deficient Adolescents and Adults Approved to Proceed

- Randomized, double-blind, placebo-controlled, nested single and multiple ascending dose
- Enroll up to 24 subjects across two dose cohorts
  - **Primary Endpoints**: Safety and tolerability
  - **Secondary Endpoints**: Pharmacokinetics and pharmacodynamic measures (ureagenesis assay, 24-hr ammonia profile)
  - **Exploratory Endpoints:** Biomarkers include plasma amino acids, plasma OTC enzyme activity, and urine orotic acid levels
  - **Interim Phase 2 Data:** H2 2022 in a Subset of Participants

LUNAR-CF (ARCT-032)

Cystic Fibrosis

Cystic Fibrosis

ARCT-032 Market Opportunity

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Cystic Fibrosis: The most common rare disease in the United States

Caused by genetic mutations in the CFTR gene, resulting in aberrant anion transport in epithelial cells, causing thick mucus buildup in the lungs

- Chronic airway obstruction leads to infection and inflammation, which causes permanent tissue scarring and leads to respiratory failure
- 100,000 worldwide prevalence

Unmet Medical Need

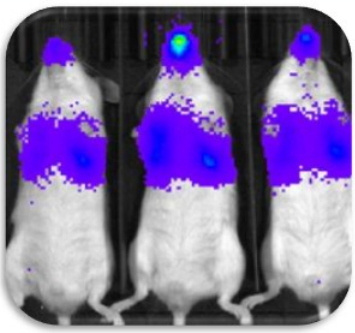
- CFTR functional modulators are not approved for treatment of all patients
- Present standard of care does not effectively prevent long-term effects of mucus accumulation. CF patients with late-stage loss of respiratory function require lung transplant

LUNAR-CF Aims to Restore CFTR Function

- An mRNA replacement therapy has the potential to deliver a new copy of CFTR into the lungs of CF patients, independent of any genotype
- A functional CFTR protein can restore chloride channel efflux in the airways, reducing mucus accumulation, tissue scarring and minimizing the progressive respiratory dysfunction observed in CF patients

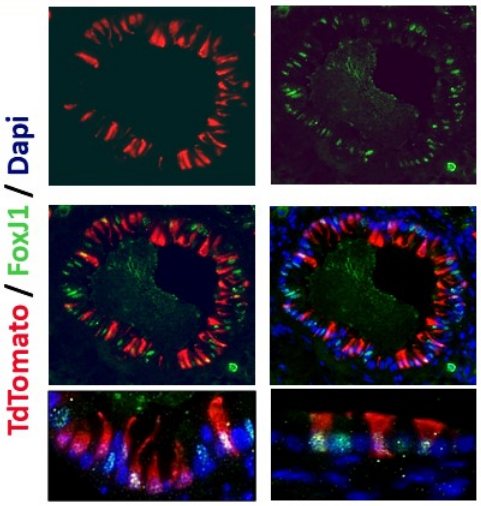
Delivery of LUNAR®-mRNA to Rodent Airways

Nebulization: Upper/Lower Airways



LUNAR® + Luciferase mRNA

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



Efficient delivery of LUNAR®-mRNA formulations in rodent airways

LUNAR®, an aerosolized delivery platform for lung

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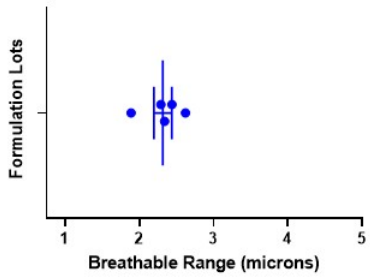
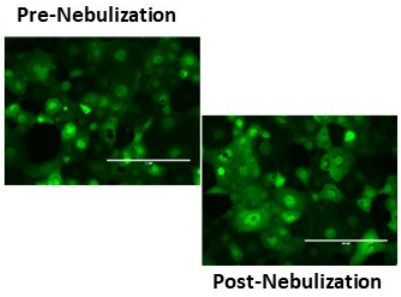
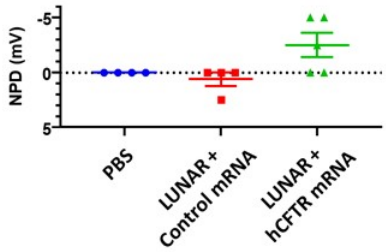
Aerosolized LUNAR® Particles are Breathable



Aerosolized LUNAR® -mRNA (EGFP) maintains activity



LUNAR®-mRNA (hCFTR) is biologically active *in vivo* (NPD, Mouse)



Aerosolized LUNAR® droplets are in the optimal breathable range (1-5 microns)
Aerosolized LUNAR® maintains activity as measured by EGFP protein expression & Nasal Potential Difference (NPD)

Delivery of LUNAR®-mRNA into Epithelial Airways in Ferret

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

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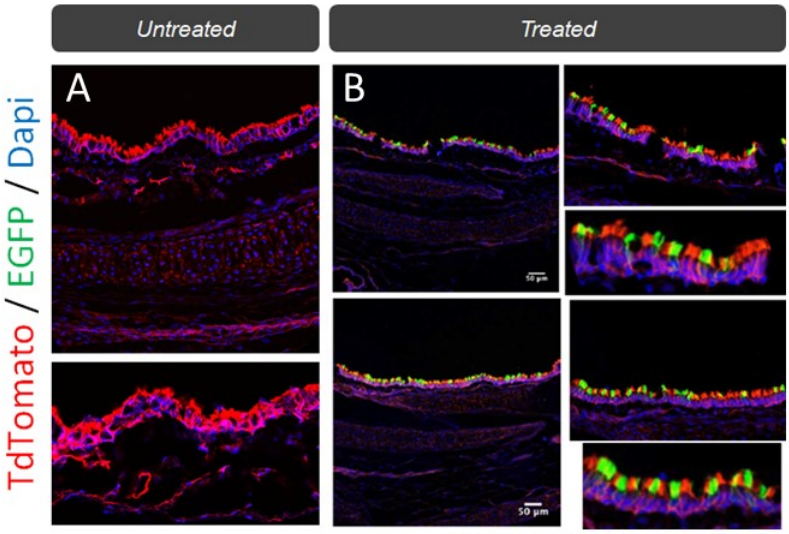
- Ferrets are an excellent species for modeling certain human lung diseases*
- Novel LUNAR® formulations of CRE mRNA were tested in a transgenic ROSA26TG ferret model
- Activation of EGFP expression indicates that LUNAR® targets epithelial airways



In collaboration with John Engelhardt

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

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

Moving Forward

Anticipated Milestones and Cash Position

ARCT-021 (single shot COVID vaccine)	
Phase 3 Initiation	**H2 2021**

ARCT-154 (COVID vaccine targeting variants of concern)	
Interim Phase 1/2/3 Data	**Q4 2021**

ARCT-810 (LUNAR-OTC)	
Interim Phase 2 Data	**H2 2022**

ARCT-032 (LUNAR-CF)	
Clinical Trial Application (CTA)	**H1 2022**

Cash Position
$433.6 Million as of June 30, 2021; based on current pipeline, funding for more than 2 years

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Management Team

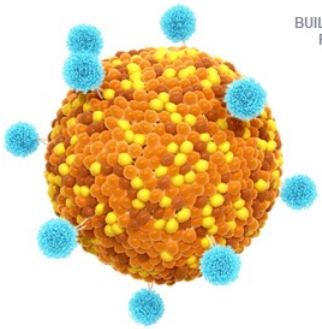
Joseph E. Payne, MSc
President & CEO
MERCK

Pad Chivukula, Ph.D.
CSO & COO
Nitto

Andrew Sassine, MBA
CFO
Fidelity INVESTMENTS

Steve Hughes, M.D.
Chief Medical Officer
IONIS PHARMACEUTICALS

Lance Kurata, J.D.
Chief Legal Officer
MINTZ



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ResMed

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ultragenyx pharmaceutical

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Director of the Board
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Professor and Deputy Director of the Emerging Infectious Diseases Programme at the Duke-NUS Medical School

DukeNUS Medical School

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Professor Emeritus of Clinical Virology and Medicine at Virginia University School of Medicine

University of Virginia School of Medicine

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Principal of Immuno-Vax LLC, and Sr. Affiliate Consultant with the Biologics Consulting Group

Biologics Consulting

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Distinguished Professor of Medicine and Sr. Director of International Initiatives at the University of California San Diego

UC San Diego

Jonathan Smith, Ph.D.

Chief Scientific Officer at VLP Therapeutics

VLP Therapeutics

Michael Hodges, M.D., BSc.

Chief Medical Officer (CMO) at Amplyx Pharmaceuticals

amplyx

Drew Weissman, M.D., Ph.D.

Professor of Medicine at the Perelman School of Medicine

Perelman School of Medicine University of Pennsylvania

Appendix

LUNAR-COV19 Preclinical Seroconversion Data

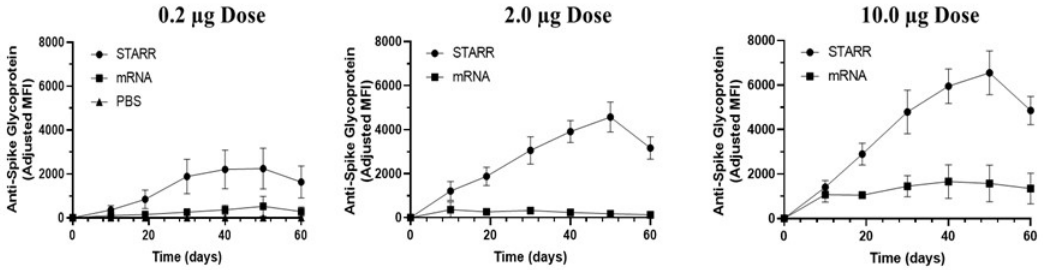
Seroconversion Rate (% of Animals) – STARR™ mRNA vs. Conventional mRNA

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

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

Preclinical Data: Anti-Spike Protein Levels Continue to Increase Up to 50 Days

Single Administration of LUNAR-COV19



- **Higher titers** (anti-SARS-CoV-2 Spike Glycoprotein IgG) elicited by STARR™ mRNA
- **Titers continue to increase up to 50 days** with STARR™ mRNA; plateau reached with conventional mRNA
- Dose dependent increase in IgG titers; Luminex bead assay, 1/2000 serum dilution

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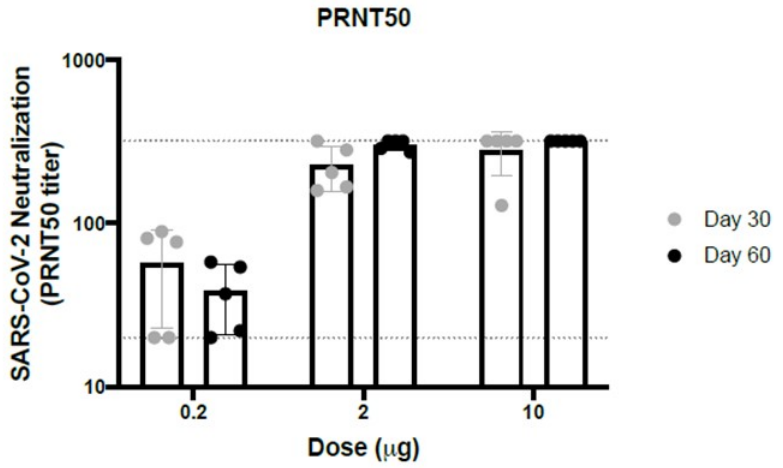
Preclinical Data: Neutralizing Antibodies Continue to Increase for 60 Days

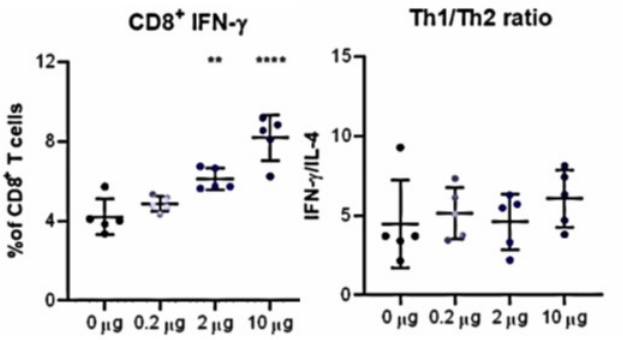
Single Administration (small dose, 2μg) of LUNAR-COV19



Virus neutralization assay: Serum dilutions are incubated with SARS-CoV-2 virus, then added to cells. The cells die forming plaques, which are counted. The serum dilution that reduces the number of plaques by 50% is recorded (PRNT50). Maximum serum dilution tested was 1/320

After single dose (2 μg) of LUNAR-COV19, neutralizing antibodies continue to increase for 60 days (>300 titer)

Preclinical Data: Arcturus Vaccine elicits a Balanced Cell Mediated Immune Response



RNA Dose (μg)	% IFN-γ+ CD8+ T Cells	CD4+ Th1/Th2 (IFN-γ/IL4)
0	4.0	4.6
0.2	4.5	5.3
2.0	6.0	5.0
10.0	8.0	6.0

Results Summary

- RNA dose dependent increase in IFN-γ positive CD8+ T-cells
- Th1 biased CD4+ response and stable Th1/Th2 ratio with increased RNA dose indicate balanced cell mediated immune response

Arcturus Safety Profile

External Validation

- Multiple strategic partnerships over many years confirms the positive potential safety profile of Arcturus LUNAR® and mRNA

Arcturus is committed to developing safe mRNA products

- 15 studies over several years with strategic partners

Top Safety Concern for RNA Medicines is Delivery

Arcturus LUNAR® Delivery Technology is well tolerated in non-human primates (NHPs)

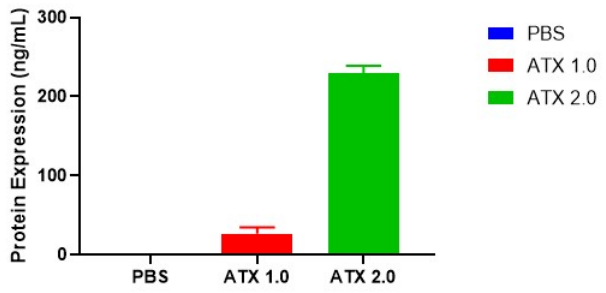
- ✓ **@ 15 mg/kg single dose of non-coding siRNA**
- ✓ **@ 3 mg/kg x eight (8) weekly doses of non-coding siRNA (total of 24 mg/kg over 2 months)**

Arcturus mRNA chemistry shows promising efficacy and tolerability data

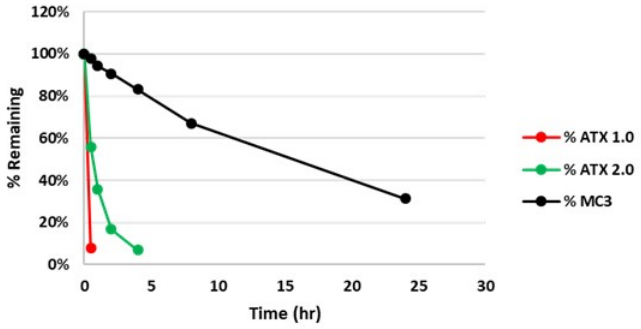
- Efficacy of OTC mRNA in mouse model @ 0.1 – 1 mg/kg

ATX Lipids are Effective and Biodegradable

Protein Expression (*in vivo*)



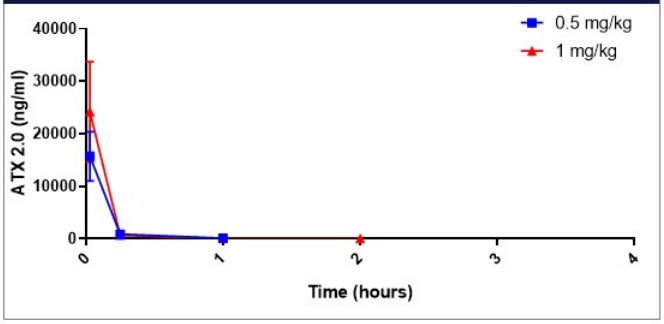
Esterase Catalyzed Degradation (*in vitro*)



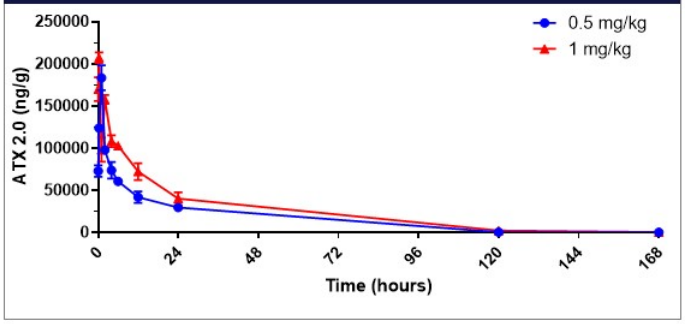
Next Generation ATX Lipids Retain Degradability & Improve Delivery Efficiency

ATX 2.0 Lipid is Biodegradable and Clears *in vivo*

Plasma



Liver



- **ATX Lipid (the major component in LUNAR® technology) is degraded *in vivo***
- **ATX 2.0 Lipid half-life in the liver is approximately 20 hours**

Key Existing Country Relationships

Singapore

Research Partnership with Duke-NUS Medical School

Financial Support from the Economic Development Board of Singapore

- $10 M Grant for Research and Preclinical Work
- $6.7 M Grant for Phase 1/2 Clinical Trial
- Executed Manufacturing Support Agreement for $46.6 Million Non-Recourse Loan
- Up to $175 Million in vaccine purchases

Israel

Supply Agreement with Israel Ministry of Health

- Announced August 18, 2020
- $12.5 M Initial Reserve Payment was paid in Oct 2020

Vietnam

Collaboration with Vingroup to Establish Manufacturing Facility

- $40 million upfront payment and potential royalties based on vaccines produced

Drug Substance: mRNA Design

Arcturus' proprietary mRNA optimization platform

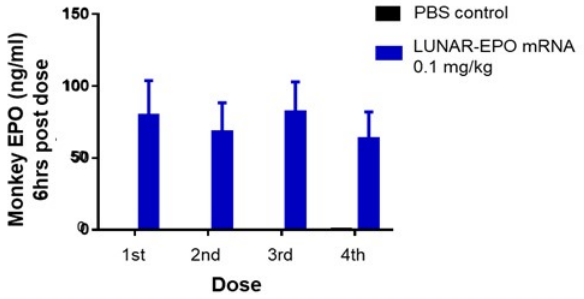
Optimize
mRNA sequence
Chemistry
Process

⇨

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

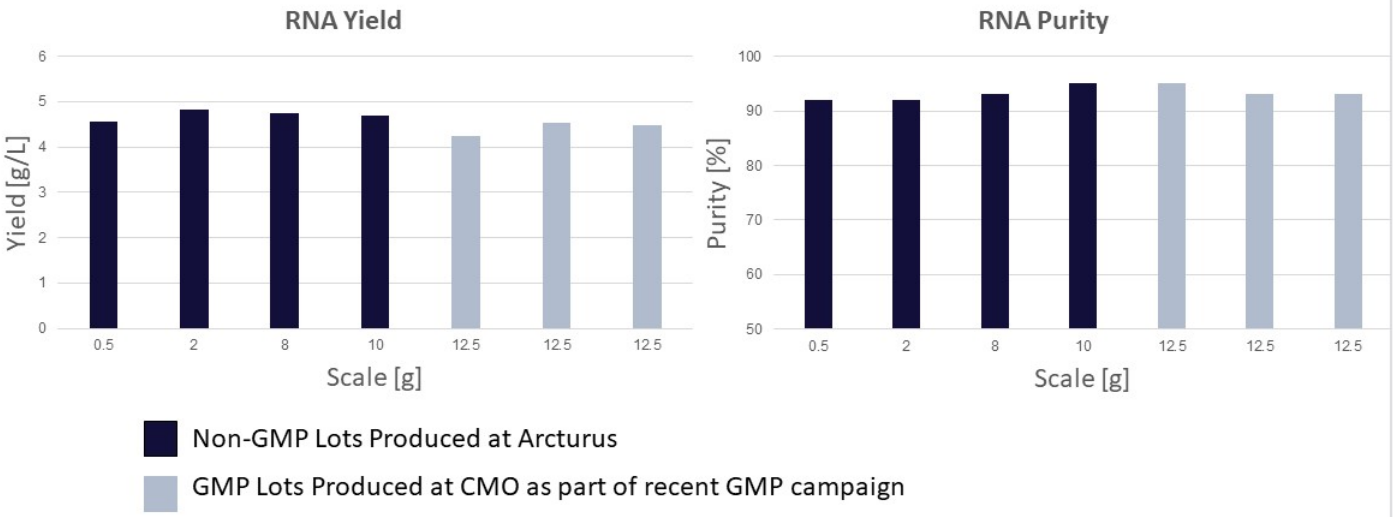
BUILDING INNOVATIVE RNA MEDICINES

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

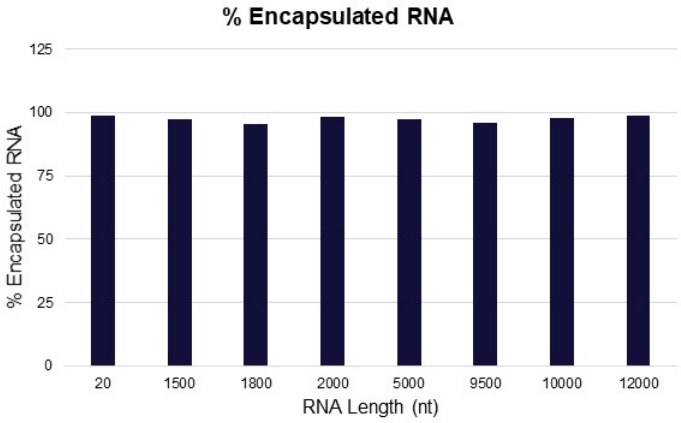
Drug Substance (mRNA) Manufacturing

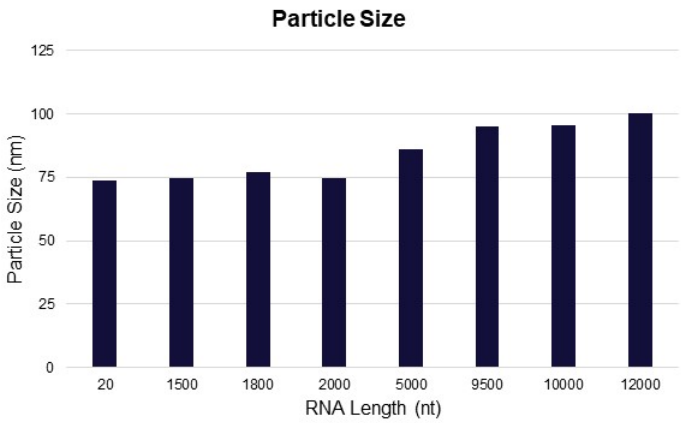


Three 12.5 g lots produced in recent GMP campaign are of equivalent quality and yield

LUNAR® Versatility

Compatible with RNA of Various size





LUNAR® Formulations Successfully Encapsulate RNA of Varying Sizes and Chemistries