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.

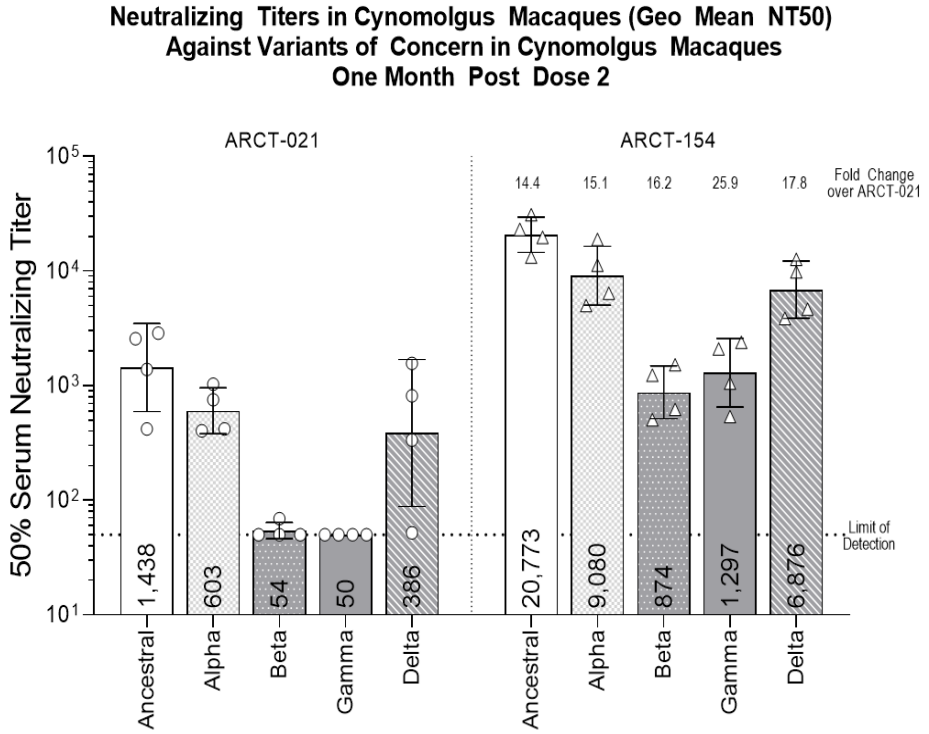
Recent Corporate Highlights

- 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.

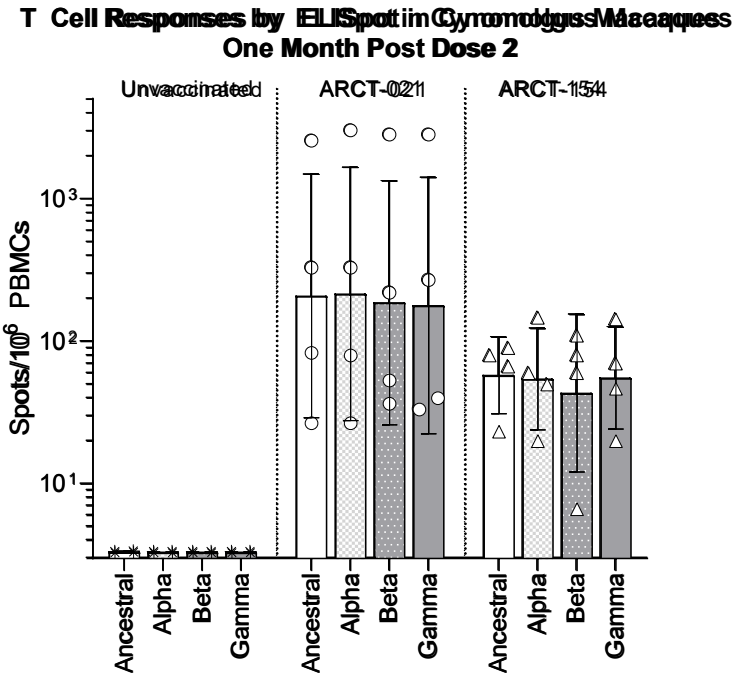
ARCT-154 utilizes an optimized STARR™ mRNA with multiple improvements, including modifications for stability and translation, increased immunogenicity of the spike protein antigen via amino acid substitution, expressing the spike protein in a pre-fusion state, and inactivating the furin cleavage site.



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 (unaudited)	March 31, 2021 (unaudited)	December 31, 2020
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)

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