Arcturus Therapeutics Announces Second Quarter 2020 Financial Results and Provides a Corporate Update

August 10, 2020

COVID-19 STARR™ mRNA vaccine candidate, ARCT-021 (LUNAR-COV19) has initiated Phase 1/2 clinical study with Duke-NUS Medical School; Dosing anticipated imminently, initial data expected Q4

ARCT-810 (LUNAR-OTC), mRNA therapeutic candidate for ornithine transcarbamylase (OTC) deficiency, Phase 1 healthy volunteer study continues to advance, initial results expected Q4

Successfully raised approximately $280 million in gross proceeds through two public equity offerings in 2020 to advance promising clinical stage pipeline

Investor Conference Call at 4:30 p.m. ET Today

SAN DIEGO, Aug. 10, 2020 (GLOBE NEWSWIRE) -- 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 quarter ended June 30, 2020, and provided a corporate update.

"Arcturus has made substantial recent corporate progress highlighted by the advancement of two of our programs, ARCT-021 and ARCT-810, into clinical studies. ARCT-021 has the potential to be an effective and safe vaccine for COVID-19 with a differentiated profile characterized by a very low dose, and a single shot administration. We have also continued to advance our Phase 1 ARCT-810 clinical study in healthy volunteers. ARCT-810 is being developed for ornithine transcarbamylase (OTC) deficiency, a serious disease with limited treatment options. We look forward to obtaining clinical data from both of these important programs this year," said Joseph Payne, President & CEO of Arcturus.

Recent corporate highlights

- ARCT-021 program update: Phase 1/2 study with ARCT-021, COVID-19 STARR™ mRNA vaccine candidate (LUNAR-COV19), which is being conducted in collaboration with Duke-NUS Medical School and performed in Singapore, has initiated and commenced screening subjects. Dosing of the first subject anticipated imminently. Arcturus has provided preclinical data demonstrating a robust cellular (CD8+ cells) and balanced (Th1/Th2) immune response following ARCT-021 administration. Data demonstrate a strong antibody response (anti-spike protein IgG and 100% virus neutralization) at a very low vaccine dose, and a single administration. Neutralizing antibody levels continue to increase out to 60 days post administration. Preclinical data indicate that ARCT-021 is effectively activating the two important components of the adaptive immune response, providing strong support for the ongoing clinical program.
- The Company continues to advance its ARCT-021 manufacturing activities. With the Company's manufacturing partners, Arcturus is positioned to manufacture millions of doses in 2020 and potentially hundreds of millions of doses annually thereafter.
- Executed binding term sheet with the Israeli Ministry of Health to supply ARCT-021. A definitive supply agreement is expected shortly. Israel is the second country, in addition to Singapore, to reserve supply of ARCT-021 from the Company.
- Announced the formation of a vaccine platform Scientific Advisory Board. The SAB includes renowned experts in virology, infectious disease, vaccine development and public health.
- Initiated a Phase 1 study with ARCT-810, a mRNA-based therapeutic candidate for ornithine transcarbamylase (OTC) deficiency (LUNAR-OTC). The ARCT-810 program is supported by preclinical data in OTC deficiency murine models demonstrating that dosing of ARCT-810 results in robust OTC protein expression and improvements in ureagenesis and plasma ammonia, and increased survival. The Company expects to obtain initial Phase 1 healthy volunteer study data in Q4 2020. The phase 1b study in patients has, like many other studies, been affected by the COVID situation, but remains on track to dose by end of year.
- Successfully raised approximately $280 million in gross proceeds through public equity offerings in 2020 to date. The Company intends to use the net proceeds of the offerings to develop, test and manufacture the Company's LUNAR-COV19 vaccine candidate and to continue clinical development of LUNAR-OTC; to advance the Company's LUNAR-CF, LUNAR-CV and LUNAR-FLU preclinical programs into clinical development; to fund early research and development of novel and proprietary RNA medicines; and for general corporate and working capital purposes.

Financial results for the quarter ended June 30, 2020

Revenues in conjunction with strategic alliances and collaborations: Arcturus' primary source of revenues is from license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended June

30, 2020, the Company reported revenue of $2.3 million, compared with $10.2 million in the three months ended June 30, 2019. The decline in collaboration revenues primarily relates to a $3.1 million decrease in reimbursements from CureVac associated with the OTC collaboration that ended in the second quarter of 2019. Additionally, in 2019 we recorded $3.1 million in sublicense revenues related to our agreement with Synthetic Genomics which was a one-time event.

Operating expenses: Total operating expenses for the three months ended June 30, 2020 were $12.4 million compared with $10.7 million for the same period of 2019. The current quarter operating expenses were partially offset with $3.8 million of funds earned under the Singapore vaccine grant and $0.9 million in funds awarded by the CF Foundation.

Net loss: For the three months ended June 30, 2020, Arcturus reported a net loss of approximately $10.3 million, or ($0.55) per basic and diluted share, compared with a net loss in the three months ended June 30, 2019 of $0.7 million, or ($0.07) per basic and diluted share.

Cash, cash equivalents, and investments: Totaled $136.1 million as of June 30, 2020, compared to cash and cash equivalents of $71.4 million at December 31, 2019. Subsequent to the end of the quarter, the Company added net proceeds of $186.3 million from our successful public offering at $53 per share. Our Proforma Cash balance including the public offering, would have been $322.4 million. Based on our current pipeline, the Company's current cash position is expected to be sufficient to support operations for more than two years. We are currently comfortable with our current cash position and we believe that the Company has the resources needed to drive our pipeline forward to reach several meaningful value creation milestones.

Conference Call

Monday August 10th @ 4:30 p.m. ET

Domestic:	800-754-1346
International:	212-231-2909
Conference ID:	21967092
Webcast:	http://public.viavid.com/index.php?id=141066

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 self-replicating mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Cardiovascular Disease 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 (192 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, and the Cystic Fibrosis Foundation. For more information visit www.ArcturusRx.com

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, including those regarding strategy, future operations, collaborations, the likelihood of success efficacy or safety of ARCT-021 or ARCT-810, the ability to initiate or complete preclinical and clinical development programs, including as a result of the COVID-19 pandemic, the supply and delivery of any product or substance, the likelihood that preclinical data will be predictive of clinical data, the ability to enroll subjects therein, the Company's efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company's mRNA therapeutics, the timing of initiation of dosing in human trials of a vaccine against COVID-19, the ability of the Company to scale up manufacturing of vaccine doses, the potential manufacturing capabilities of the Company's partnership with Catalent, our current cash position and expected cash burn and the impact of general business and economic conditions are 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. 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, 2019, filed with the SEC on March 16, 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.

IR and Media Contact
Arcturus Therapeutics
Neda Safarzadeh
(858) 900-2682
IR@ArcturusRx.com

Kendall Investor Relations
Carlo Tanzi, Ph.D.
(617) 914-0008
ctanzi@kendallir.com

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)

	June 30, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 136,111	$ 71,353
Accounts receivable	2,829	2,179
Prepaid expenses and other current assets	3,060	758
Total current assets	142,000	74,290
Property and equipment, net	2,610	2,349
Operating lease right-of-use asset, net	5,218	5,134
Equity-method investment	—	263
Non-current restricted cash	107	107
Total assets	$ 149,935	$ 82,143
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,395	$ 5,793
Accrued liabilities	11,883	7,134
Deferred revenue	6,768	8,397
Total current liabilities	23,046	21,324
Deferred revenue, net of current portion	14,013	15,182
Long-term debt	15,059	14,995
Operating lease liability, net of current portion	4,394	4,850
Total liabilities	$ 56,512	$ 56,351
Stockholders' equity		
Common stock: $0.001 par value; 30,000 shares authorized; 20,610 and 15,138 issued and outstanding at June 30, 2020 and December 30, 2019, respectively.	21	15
Additional paid-in capital	185,110	97,445
Accumulated deficit	(91,708)	(71,668)
Total stockholders' equity	93,423	25,792
Total liabilities and stockholders' equity	$ 149,935	$ 82,143

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 2,322	$ 10,153	$ 4,968	$ 14,503
Operating expenses:				
Research and development, net	7,944	7,269	15,861	14,593
General and administrative	4,420	3,456	8,611	6,990
Total operating expenses	12,364	10,725	24,472	21,583
Loss from operations	(10,042)	(572)	(19,504)	(7,080)
Loss from equity-method investment	(100)	—	(263)	(288)
Finance expense, net	(121)	(113)	(273)	(201)
Net loss	$ (10,263)	$ (685)	$ (20,040)	$ (7,569)

Net loss per share, basic and diluted	$ (0.55)	$ (0.07)	$ (1.20)	$ (0.74)
Weighted-average shares outstanding, basic and diluted	18,794	10,412	16,657	10,255
Comprehensive loss:				
Net loss	$ (10,263)	$ (685)	$ (20,040)	$ (7,569)
Comprehensive loss	$ (10,263)	$ (685)	$ (20,040)	$ (7,569)

Source: Arcturus Therapeutics Holdings Inc.