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

May 7, 2020

Important progress advancing COVID-19 STARR™ mRNA vaccine candidate (LUNAR-COV19);
New preclinical data demonstrate robust immunogenicity with a single, low dose

Company remains on track to begin clinical trial for COVID-19 vaccine this summer

Successfully raised net of $75.5 million in secondary common stock offering;
Current resources sufficient to support operations for more than two years

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

SAN DIEGO, May 07, 2020 (GLOBE NEWSWIRE) -- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the discovery, development and commercialization of therapeutics for vaccines and rare diseases, today announced its financial results for the quarter ended March 31, 2020, and provided a corporate update.

"This has been a highly productive period for Arcturus highlighted by the rapid advancement of our COVID-19 vaccine program. We are encouraged by the robust immunogenicity observed in preclinical studies with a very low dose, single administration of LUNAR-COV19. The single, low dose is made possible because of our efficient, proprietary self-replicating mRNA-based approach," said Joseph Payne, President & CEO of Arcturus. "We are very pleased to have recently entered into a manufacturing partnership with Catalent, a leading producer of complex biologics, and expect to have the capacity to produce hundreds of millions of doses of LUNAR-COV19. Our immediate priority and focus are to initiate clinical trials this summer."

COVID-19 STARR ™mRNA vaccine candidate (LUNAR-COV19) update
Arcturus today provided new preclinical immunogenicity data from its COVID-19 vaccine candidate, extending previously disclosed neutralizing antibody seroconversion results (demonstrating 100% seroconversion at single 2 µg dose, day 19).

In the study, rodents were immunized with either a single dose (0.2, 2, and 10 µg, intramuscular) of self-replicating STARR™ mRNA (LUNAR-COV19), or conventional mRNA, both formulated in LUNAR® delivery technology. The results at day 30 demonstrated that the LUNAR-COV19 vaccine generated a robust antibody response to SARS-CoV-2 spike protein at all doses, even at 1:2000 dilution.

The antibody data also showed that the Company's proprietary self-replicating mRNA approach resulted in superior immunogenicity to conventional mRNA technology.

The robust immune response generated with single, very low doses of LUNAR-COV19 may allow effective vaccination with a single dose, thereby enabling rapid manufacturing scale up to hundreds of millions of doses in 2021, an important logistical consideration given the global nature of the COVID-19 pandemic.

The Company believes that the LUNAR-COV19 preclinical data provide additional compelling support for the upcoming clinical trial. Efforts are ongoing to obtain initial regulatory approval in Singapore to begin human dosing as rapidly as possible. In parallel, activities are underway to support global development of the COVID-19 vaccine.

Other recent corporate highlights

- Announced a partnership with Catalent, Inc. to support the manufacture of the COVID-19 STARR™ mRNA vaccine candidate (LUNAR-COV19)
- Investigational New Drug (IND) application for a Phase 1b study in patients with Ornithine Transcarbamylase (OTC) deficiency was allowed to proceed by the U.S. Food and Drug Administration (FDA)
- Clinical Trial Application (CTA) for a Phase 1 study to support the OTC program in healthy volunteers was approved by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe)

Financial results for the quarter ended March 31, 2020
Revenues in conjunction with strategic alliances and collaborations: Arcturus's primary source of revenues is currently from license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended March 31, 2020, the Company reported revenue of $2.6 million, compared with $4.3 million in the three months ended March 31, 2019. The decline in collaboration revenues primarily relates to a $1.6 million decrease in reimbursements from CureVac associated with the OTC collaboration that ended in the second quarter of 2019.

Operating expenses: Total operating expenses for the three months ended March 31, 2020 were $12.1 million compared with $10.9 million for the same period of 2019. The current quarter operating expenses were partially offset with $2.0 million in funds awarded by the CF Foundation and $0.5 million of funds earned under the Singapore vaccine contract.

Net loss: For the three months ended March 31, 2020, Arcturus reported a net loss of approximately $9.8 million, or ($0.67) per basic and diluted share, compared with a net loss in the three months ended March 31, 2019 of $6.9 million, or ($0.68) per basic and diluted share.

Cash, cash equivalents, and investments: Totaled $59.5 million as of March 31, 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 approximately $75.5 million from our successful secondary offering at $17 per share and $5.0 million from our Singapore vaccine contract. Our Proforma Cash balance including the subsequent events, would have been $140.0 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.

Conference Call

Thursday May 7th @ 4:30 p.m. ET

Domestic: (833) 423-0426

International: (918) 922-3070

Conference ID: 3273629

Webcast: https://edge.media-server.com/mmc/p/xy5ogcuv

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 candidates includes programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Glycogen Storage Disease Type 3, Hepatitis B, non-alcoholic steatohepatitis (NASH) and a self-replicating mRNA vaccine for SARS-CoV-2. 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 (187 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, Catalent Inc., 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 the Company's expected performance, the Company's development of any specific novel mRNA therapeutics, the Company's efforts to develop a vaccine against COVID-19 based on the Company's mRNA therapeutics, the forecasted safety, efficacy or reliability of a vaccine against COVID-19,were one to be successfully developed based on the Company's mRNA therapeutics, the timing and availability of a vaccine against COVID-19 were one to be successfully developed based on the Company's mRNA therapeutics, the potential initiation of human trials of a vaccine against COVID-19 based on the Company's mRNA therapeutics, the timing of initiation of human trials of a vaccine against COVID-19 based on the Company's mRNA therapeutics, the ability of any product to receive regulatory approval in Singapore and whether or not any other countries will accept the trials conducted in that jurisdiction, the potential market impact of a vaccine against COVID-19 based on the Company's mRNA therapeutics, the potential manufacturing capabilities of the Company's partnership with Catalent, the timing of technology transfer related to the Company's partnership with Catalent, the manufacture of GMP batches of a vaccine against COVID-19, were one to be successfully developed based on the Company's mRNA therapeutics, any expected benefit from the Company's partnership with Catalent and timing of any benefits related thereto, 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. No assurances can be given that any results reported in pre-clinical studies can be replicated in further studies or in human beings, or that a vaccine can or will ever be developed or approved using the Company's technology. 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.

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ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)

	March 31, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 59,471	$ 71,353
Accounts receivable	2,351	2,179
Prepaid expenses and other current assets	1,937	758
Total current assets	63,759	74,290
Property and equipment, net	2,571	2,349
Operating lease right-of-use asset, net	5,567	5,134
Equity-method investment	100	263
Non-current restricted cash	107	107
Total assets	$ 72,104	$ 82,143
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,779	$ 5,793
Accrued liabilities	9,775	7,134
Deferred revenue	8,096	8,397
Total current liabilities	21,650	21,324
Deferred revenue, net of current portion	13,815	15,182
Long-term debt	15,028	14,995
Operating lease liability, net of current portion	4,629	4,850
Total liabilities	$ 55,122	$ 56,351
Stockholders' equity		
Common stock: $0.001 par value; 30,000 shares authorized; 15,157 issued and outstanding at March 31, 2020; $0.001 par value; 30,000 shares authorized, 15,138 issued and outstanding at December 31, 2019	15	15
Additional paid-in capital	98,412	97,445
Accumulated deficit	(81,445)	(71,668)
Total stockholders' equity	16,982	25,792
Total liabilities and stockholders' equity	$ 72,104	$ 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 March 31,	
	2020	2019
Collaboration revenue	$ 2,646	$ 4,350
Operating expenses:		
Research and development, net	7,917	7,324
General and administrative	4,191	3,534
Total operating expenses	12,108	10,858
Loss from operations	(9,462)	(6,508)
Loss from equity-method investment	(163)	(288)
Finance expense, net	(152)	(88)
Net loss	$ (9,777)	$ (6,884)
Net loss per share, basic and diluted	$ (0.67)	$ (0.68)
Weighted-average shares outstanding, basic and diluted	14,521	10,095

Comprehensive loss:		
Net loss	$ (9,777)	$ (6,884)
Unrealized gain on short-term investments	—	—
Comprehensive loss	$ (9,777)	$ (6,884)

Source: Arcturus Therapeutics Holdings Inc.