Arcturus Therapeutics Announces Fourth Quarter and Full Year 2021 Financial Update and Pipeline Progress

February 28, 2022

Emergency Use Authorization (EUA) application for ARCT-154 submitted to Vietnam Ministry of Health

ARCT-154 Phase 1/2 booster study data in U.S. and Singapore demonstrated 28-, and 54-fold increases in neutralizing antibody activity against SARS-CoV-2 *ancestral and Omicron strains, respectively*

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

SAN DIEGO--(BUSINESS WIRE)--Feb. 28, 2022-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a late-stage clinical 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 fourth quarter and year ended December 31, 2021 and provided additional corporate updates.

“We have continued to execute across our organization, highlighted by completion of filing for Emergency Use Authorization of ARCT-154 in Vietnam,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “ARCT-154 has an attractive and differentiated profile as a low-dose, self-amplifying mRNA vaccine candidate that has been generally safe and well tolerated based on review of blinded data from clinical trials to date. The EUA filing is based on safety and immunogenicity data from the ongoing Phase 1/2/3 study. In addition to the Vietnam Ministry of Health, we continue to engage other regulatory authorities to clarify the potential path to product approval as a booster vaccine.”

Recent Corporate Highlights

- LUNAR-COV19; ARCT-154: Arcturus’ collaborator Vinbiocare has completed filing of an application for EUA with the Vietnam Ministry of Health. The EUA application is based on available safety and immunogenicity data from the first 1,000 participants in the Phase 1/2/3a portions of the ongoing study being conducted in Vietnam. The trial is sponsored by Vinbiocare and has completed enrollment and priming vaccination in all portions of the study with over 19,000 participants.
- In January 2022, Arcturus announced data from Phase 1/2 clinical development programs for ARCT-154 and ARCT-165 used as boosters following primary vaccination with Comirnaty®. Data demonstrated robust neutralizing antibody responses against SARS-CoV-2 ancestral D614G strain as well as several variants of concern, including Beta, Delta, and Omicron.
- Arcturus’ global manufacturing footprint continues to mature, and the Company’s technology transfer to its collaborator’s facility in Hanoi, Vietnam continues to progress toward a production capacity of 200 million doses per year.
- LUNAR-OTC; ARCT-810: Phase 2 multiple-dose study for ARCT-810, a novel mRNA-based therapeutic candidate for ornithine transcarbamylase (OTC) deficiency, is anticipated to begin screening patients in second quarter 2022, and interim data is anticipated in the second half of 2022. This trial is a randomized, double-blind, placebo-controlled, nested single and multiple ascending dose study, designed to enroll approximately 24 adolescents and adults with OTC deficiency.
- LUNAR-CF; ARCT-032: Arcturus has completed non-human primate (NHP) toxicological studies for ARCT-032, the Company’s mRNA therapeutic candidate for cystic fibrosis, and plans to file a CTA in the third quarter of 2022.
- LUNAR-FLU: Based on data from internal programs and human data from the Company’s COVID vaccine trials, a self-amplifying mRNA approach has been prioritized over a conventional mRNA approach for the LUNAR-FLU program. A lead STARR™ mRNA candidate targeting seasonal influenza is expected to be identified in 2022.

Financial Results for the Fourth Quarter and Full Year Ended Dec. 31, 2021 (Unaudited)

Revenues in conjunction with strategic alliances and collaborations: Arcturus’ primary sources of revenues were from consulting and related technology transfer fees, license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. Total revenue for the three months ended December 31, 2021 was $5.8 million, compared with $2.2 million in the three months ended December 31, 2020 and $2.4 million for the three months ended September 30, 2021. The increase in revenue for the quarter was primarily due to the partial recognition of the manufacturing technology transfer services upfront payment that was received from Vinbiocare during the quarter ended September 30, 2021. Total revenue for the year ended December 31, 2021 was $12.4 million compared with $9.5 million for the year ended December 31, 2020.

Operating expenses: Total operating expenses for the three months ended December 31, 2021 were $43.4 million compared with $33.3 million for the three months ended December 31, 2020 and $56.3 million for the three months ended September 30, 2021. The sequential decline in operating expenses was due to the reduction in manufacturing and clinical costs primarily associated with the LUNAR-COV19 program CMC requirements necessary for regulatory filings. Total operating expenses for the year ended December 31, 2021 were $215.2 million compared with $81.1 million for

the year ended December 31, 2020.

Research and development expenses: Research and development expenses for the three months ended December 31, 2021 were $32.6 million compared with $24.3 million for the three months ended December 31, 2020 and $45.4 million for the three months ended September 30, 2021. Research and development expenses for the year ended December 31, 2021 were $173.8 million compared with $57.8 million for the year ended December 31, 2020. The decrease in the three months ended December 31, 2021 when compared with the three months ended September 30, 2021 is primarily attributable to a decrease in manufacturing costs related to the LUNAR-COV19 program as our stockpiling and CMC regulatory requirements were met during the three months ended September 30, 2021. The year over year increases were primarily attributable to the development of the LUNAR-COV19 program to late-stage clinical trials, including an increase in personnel related costs, primarily driven by an increase in the number of employees supporting our LUNAR-COV19 program activities.

Net Loss: For the three months ended December 31, 2021, Arcturus reported a net loss of approximately $38.7 million, or ($1.47) per basic and diluted share, compared with a net loss of $31.1 million, or ($1.25) per basic and diluted share in the three months ended December 31, 2020 and a net loss of $54.1 million, or ($2.05) per basic and diluted share in the three months ended September 30, 2021. For the year ended December 31, 2021, Arcturus reported a net loss of approximately $203.7 million, or ($7.74) per basic and diluted share, compared with a net loss of $72.1 million, or ($3.55) per basic and diluted share in the year ended December 31, 2020.

Cash Position: Cash and cash equivalents were $370.5 million as of December 31, 2021, $413.9 million at September 30, 2021 and $462.9 million at December 31, 2020. Based on the current pipeline, the Company's cash position is expected to be sufficient to support operations into late 2023.

Earnings Call Monday, February 28 @ 4:30 p.m. ET

Domestic:	877-407-0784
International:	201-689-8560
Conference ID:	13726793
Webcast:	Link

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 III, 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 (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, 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, the expectations for or likelihood of success of any collaborations, the likelihood of success (including safety and efficacy) of the Company's pipeline (including ARCT-154, ARCT-165, ARCT-810, ARCT-032 and LUNAR-FLU), the Company's efforts to develop a vaccine against COVID-19, the timing for selection of a LUNAR-FLU candidate, the timing of any regulatory submissions and the likelihood that the Company will obtain clearance from regulatory authorities to proceed with future planned clinical trials (including the planned CTA filing for ARCT-032), the planned initiation, design or completion of clinical trials (including the initiation of a Phase 2 trial for ARCT-810), the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood that an interim or partial data set will be representative of a complete or larger data set or that blinded data will be predictive of unblinded data (including with respect to the blinded data from ARCT-154 studies), the ability to enroll, and timing for enrollment of, subjects in clinical trials (including for the planned ARCT-810 Phase 2 trial), the timing and nature of any study results (including the timing for ARCT-810 Phase 2 interim data), 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 (including with respect to the planned filing for an EUA for ARCT-154), the likelihood or timing of any regulatory approval (including with respect to an EUA for ARCT-154), the likelihood and timing of a regulatory path to approval of ARCT-154 as a booster series, the Company's manufacturing plans or technologies (including the timing and anticipated capacity of the manufacturing facility in Hanoi, Vietnam), the likelihood that a patent will issue from any patent application, its current cash position, expected cash burn, and adequacy of its capital to support future operations and the impact of general business and economic conditions. 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. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties, and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements, including those discussed under the heading "Risk Factors" in Arcturus' most recent Annual Report on Form 10-K, and in subsequent filings with, or submissions to, the SEC, which are available on the SEC's website at www.sec.gov. 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

The Arcturus logo and other trademarks of Arcturus appearing in this announcement, including LUNAR® and STARR™, are the property of Arcturus. All other trademarks, services marks, and trade names in this announcement are the property of their respective owners.

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(in thousands, except par value information)

	December 31, 2021	September 30, 2021	December 31, 2020
	(unaudited)	(unaudited)	
Assets			
Current assets:			
Cash and cash equivalents	$ 370,492	$ 413,880	$ 462,895
Accounts receivable	3,367	2,015	2,125
Prepaid expenses and other current assets	5,102	6,473	2,769
Total current assets	378,961	422,368	467,789
Property and equipment, net	5,643	3,441	3,378
Operating lease right-of-use asset, net	5,618	5,983	5,182
Equity-method investment	515	670	—
Non-current restricted cash	2,077	2,074	107
Total assets	$ 392,814	$ 434,536	$ 476,456
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	$ 10,058	$ 8,265	$ 10,774
Accrued liabilities	23,523	33,877	19,389
Current portion of long-term debt	22,474	18,482	1,250
Deferred revenue	43,482	57,616	18,108
Total current liabilities	99,537	118,240	49,521
Deferred revenue, net of current portion	19,931	8,497	12,512
Long-term debt, net of current portion	40,633	56,660	13,845
Operating lease liability, net of current portion	4,502	4,935	4,025
Other long-term liabilities	—	1,394	—
Total liabilities	$ 164,603	$ 175,410	$ 79,903
Stockholders' equity			
Common stock: $0.001 par value; 60,000 shares authorized; 26,372 issued and outstanding at December 31, 2021, 26,349 issued and outstanding at September 30, 2021 and 26,192 issued and outstanding at December 31, 2020	26	26	26
Additional paid-in capital	575,675	567,927	540,343
Accumulated deficit	(347,490)	(308,827)	(143,816)
Total stockholders' equity	228,211	259,126	396,553
Total liabilities and stockholders' equity	$ 392,814	$ 434,536	$ 476,456

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except per share data)

	Three Months Ended		
	December 30,		September 30,
	2021	2020	2021
Collaboration revenue	$ 5,794	$ 2,238	$ 2,437
Operating expenses:			
Research and development, net	32,633	24,286	45,398
General and administrative	10,806	9,034	10,860
Total operating expenses	43,439	33,320	56,258
Loss from operations	(37,645)	(31,082)	(53,821)
(Loss) gain from equity-method investment	(156)	—	(250)
(Loss) gain from foreign currency	(338)	16	506
Finance expense, net	(525)	(38)	(519)
Net loss	$ (38,664)	$ (31,104)	$ (54,084)
Net loss per share, basic and diluted	$ (1.47)	$ (1.25)	$ (2.05)
Weighted-average shares outstanding, basic and diluted	26,359	24,886	26,338
Comprehensive loss:			
Net loss	$ (38,664)	$ (31,104)	$ (54,084)
Comprehensive loss	$ (38,664)	$ (31,104)	$ (54,084)

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Source: Arcturus Therapeutics Holdings Inc.