Arcturus Therapeutics Announces Second Quarter 2024 Financial Update and Pipeline Progress

August 5, 2024

IND submitted for Phase 2 trial of ARCT-032 targeting cystic fibrosis (CF)

ARCT-810 (OTC deficiency) Phase 2 interim data on track for Q4

Kostaive® on track for Q4 commercial launch in Japan

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

SAN DIEGO--(BUSINESS WIRE)--Aug. 5, 2024-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a global messenger RNA medicines company focused on the development of infectious disease vaccines and addressing unmet medical needs within liver and respiratory rare diseases, today announced its financial results for the second quarter ended June 30, 2024, and provided corporate updates.

“We are pleased to remain on track for our first commercial product launch of Kostaive® in Japan later this year,” said Joseph Payne, President & CEO of Arcturus Therapeutics. “We are also encouraged by the clinical progress of our mRNA therapeutics pipeline, especially the collection of meaningful safety data for CF and OTC deficiency candidates, ARCT-032 and ARCT-810.”

“The aggregate safety data of ARCT-032 and ARCT-810 support continuing clinical development of these rare disease programs,” said Dr. Juergen Froehlich, Chief Medical Officer of Arcturus Therapeutics. “The planned ARCT-032 Phase 2 study advances our efforts to provide a potential treatment for CF patients who have genotypes making them ineligible for modulator treatment and the additional CF population who are eligible but are not prescribed modulators.”

Dr. Froehlich added: “We are also pleased to report that the dosing phase in our European Phase 2 ARCT-810 study is near completion with interim data to be available in Q4. The additional Phase 2 study in the United States has initiated and is designed to expand our OTC deficiency program into more severe and younger patients.”

Recent Corporate Highlights

- In July, the Company submitted an IND application for a Phase 2 multiple ascending dose study to evaluate the safety, tolerability and efficacy of ARCT-032 in subjects with cystic fibrosis (CF). The planned Phase 2 study intends to recruit CF patients who are ineligible for CFTR modulator treatment and additional CF subjects who are eligible but are not prescribed modulators.
- In June, Arcturus presented Phase 1 interim data of ARCT-032 at the 47th Annual European Cystic Fibrosis Conference.
  - ARCT-032 administration was generally safe and well tolerated with no serious or severe adverse events in healthy volunteers (N = 32) and the first four dosed participants with CF in Phase 1b, of which one had two Class I mutations and the other three had F508del mutations and were being treated with Trikafta®.
- In July, the Company announced that the double blind ARCT-810 Phase 2 study in the EU and UK completed enrollment of eight (8) participants with ornithine transcarbamylase (OTC) deficiency, including adolescents and adults, at the 0.3 mg/kg dose level.
- To access younger patients with more serious disease, the Company expanded the Phase 2 clinical program of ARCT-810 into the United States. Patient screening has been initiated and the Company expects the Phase 2 clinical program enrollment to be completed in the United States.
- In May, the Company announced the publication in *Nature Communications* of pivotal data from a Phase 3 efficacy, immunogenicity and safety study of Kostaive®.
  - The results demonstrate that 2-dose primary vaccination (5 µg dose) of Kostaive® (sa-mRNA vaccine) were well-tolerated and immunogenic, and provided significant protection against COVID-19 disease. The efficacy of Kostaive® against severe COVID-19 was 100 percent in healthy persons aged 18-59 and more than 90 percent in persons at risk of severe consequences of the disease due to co-morbidities or older age.
- In May, Meiji initiated a partial change application to Japan’s PMDA to support the use of the updated Kostaive® JN.1 COVID-19 vaccine for the upcoming 2024/2025 season.
- Kostaive® European Medicine Agency (EMA) review is ongoing as planned.
- Enrollment for the ARCT-2303 (Omicron XBB.1.5 variant version of Kostaive®) Phase 3 study is complete. The purpose of this Phase 3 study is to generate additional immunogenicity and safety data in multiple ethnicities to support regulatory filings globally.
- Arcturus is on track to initiate a Phase 1 H5N1 pandemic flu study in Q4. The clinical study is funded by BARDA and

designed to enroll approximately 200 healthy adults in the United States. This vaccine, named ARCT-2304, utilizes the Company's proprietary STARR® self-amplifying mRNA and LUNAR® delivery technologies.
- In June, the Company announced the appointment of a new independent director, Moncef Slaoui, Ph.D., to its Board of Directors.

Financial Results for the three months ended June 30, 2024

Revenues in conjunction with strategic alliances and collaborations:

Arcturus' primary revenue streams include license fees, consulting and related technology transfer fees, reservation fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended June 30, 2024, we reported revenue of $49.9 million, a significant increase of $39.4 million from the $10.5 million reported in the same period in 2023. The increase was primarily due to the CSL agreement during the second quarter of 2024. This increase in CSL revenue recognized was driven by the recognition of Kostaive® manufacturing activities and clinical trial expenses. Additionally, revenue related to the BARDA agreement increased due to advancements in the pandemic flu program.

Revenue decreased by $2.9 million during the six months ended June 30, 2024, as compared to the same period in 2023. The decrease was primarily due to lower CSL revenue resulting from the timing and value of milestone achievements. The overall decrease was offset by higher BARDA revenue due to increased progress of the pandemic flu program.

Operating expenses:

Total operating expenses for the three months ended June 30, 2024, were $71.0 million compared with $65.9 million for the three months ended June 30, 2023. Total operating expenses for the six months ended June 30, 2024, were $139.4 million compared with $131.4 million for the six months ended June 30, 2023.

Research and development expenses:

Research and development expenses consist primarily of external manufacturing costs, *in vivo* research studies and clinical trials performed by contract research organizations, clinical and regulatory consultants, personnel-related expenses, facility-related expenses and laboratory supplies related to conducting research and development activities. Research and development expenses were $58.7 million for the three months ended June 30, 2024, compared with $52.7 million for the three months ended June 30, 2023. Research and development expenses were $112.2 million for the six months ended June 30, 2024, compared with $104.4 million for the three months ended June 30, 2023. The increases in research and development expenses were primarily driven by higher clinical and manufacturing expenses. Additionally, investments increased in early stage and discovery technologies, including the initiation of preclinical research related to its Gonorrhea and Lyme disease vaccine discovery programs.

General and Administrative Expenses:

General and administrative expenses primarily consist of salaries and related benefits for executive, administrative, legal and accounting functions and professional service fees for legal and accounting services as well as other general and administrative expenses. General and administrative expenses were $12.3 million and $27.2 million for the three and six months ended June 30, 2024, respectively, compared with $13.2 million and $27.0 million in the comparable periods last year. These expenses remained relatively consistent between the two periods. The Company does not expect that general and administrative expenses will increase on a yearly basis.

Net Loss:

For the three months ended June 30, 2024, Arcturus reported a net loss of approximately $17.2 million, or ($0.64) per diluted share, compared with a net loss of $52.6 million, or ($1.98) per diluted share in the three months ended June 30, 2023. For the six months ended June 30, 2024, Arcturus reported a net loss of approximately $44.0 million, or ($1.64) per diluted share, compared with a net loss of $1.8 million, or ($0.07) per diluted share in the six months ended June 30, 2023.

Cash Position and Balance Sheet:

Cash, cash equivalents and restricted cash were $317.2 million as of June 30, 2024, and $348.9 million on December 31, 2023. Arcturus achieved a total of approximately $437.1 million in upfront payments and milestones from CSL as of June 30, 2024, and expects to continue to receive future milestone payments from CSL supporting the ongoing development of the COVID and flu programs and three additional vaccine programs by CSL. The expected cash runway extends approximately three years based on the current pipeline and programs through the first quarter of fiscal year 2027.

Arcturus Therapeutics Second Quarter 2024 Earnings Conference Call

- Monday, August 5, 2024 @ 4:30 p.m. ET
- Domestic: 1-877-407-0784
- International: 1-201-689-8560
- Conference ID: 13747924
- Webcast: Link

About Arcturus Therapeutics

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a global mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR® mRNA Technology (sa-mRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus developed Kostaive®, the first self-amplifying messenger RNA (sa-mRNA) COVID vaccine in the world to be approved. Arcturus has an ongoing global collaboration for innovative mRNA vaccines with CSL Seqirus, and a joint venture in Japan, ARCALIS, focused on the manufacture of mRNA vaccines and therapeutics. Arcturus' pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) deficiency and cystic fibrosis (CF), along with its partnered mRNA vaccine programs for

SARS-CoV-2 (COVID-19) and influenza. Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, circular RNA, antisense RNA, self-amplifying RNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (over 400 patents and patent applications in the U.S., Europe, Japan, China, and other countries). 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 likelihood of success and continued advancement of the Company's pipeline (including ARCT-032 and ARCT-810) and partnered programs (including the COVID-19 and flu programs partnered with CSL Seqirus), the likelihood of commercialization of Kostaive® and the timing thereof, the continued clinical development of the rare disease programs, the planned completion of the European Phase 2 ARCT-810 Phase 2 study and availability of interim data from the study, the likelihood and timing of a European Marketing Authorization application approval decision for Kostaive®, the anticipated enrollment in the Phase 2 clinical program for ARCT-810, that preclinical or clinical data will be predictive of future clinical results, the likelihood and timing of clinical study updates, the likelihood or timing of collection of accounts receivables including expected future milestone and other payments from CSL, its current cash position and expected cash burn and runway, 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
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)	June 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 260,329	$ 292,005
Restricted cash	55,000	55,000
Accounts receivable	24,085	32,064
Prepaid expenses and other current assets	7,594	7,521
Total current assets	347,008	386,590
Property and equipment, net	11,182	12,427
Operating lease right-of-use assets, net	28,533	28,500
Non-current restricted cash	1,885	1,885
Total assets	$ 388,608	$ 429,402
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,905	$ 5,279
Accrued liabilities	35,450	31,881
Deferred revenue	42,362	44,829
Total current liabilities	91,717	81,989
Deferred revenue, net of current portion	11,344	42,496
Operating lease liability, net of current portion	26,964	25,907
Other non-current liabilities	—	497
Total liabilities	130,025	150,889
Stockholders' equity		
Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 27,042 at June 30, 2024 and 26,828 at December 31, 2023	27	27
Additional paid-in capital	670,455	646,352
Accumulated deficit	(411,899)	(367,866)
Total stockholders' equity	258,583	278,513
Total liabilities and stockholders' equity	$ 388,608	$ 429,402

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,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue:				
Collaboration revenue	$ 45,976	$ 9,565	$ 78,574	$ 89,294
Grant revenue	3,883	954	9,297	1,510
Total revenue	49,859	10,519	87,871	90,804
Operating expenses:				
Research and development, net	58,669	52,668	112,242	104,436
General and administrative	12,316	13,225	27,167	26,987
Total operating expenses	70,985	65,893	139,409	131,423
Loss from operations	(21,126)	(55,374)	(51,538)	(40,619)
(Loss) gain from foreign currency	(388)	149	(441)	(179)
Gain on debt extinguishment	—	—	—	33,953
Finance income, net	4,148	3,252	8,164	5,729
Net loss before income taxes	(17,366)	(51,973)	(43,815)	(1,116)
Provision for income taxes	(150)	577	218	680
Net loss	$ (17,216)	$ (52,550)	$ (44,033)	$ (1,796)
Net loss per share, basic and diluted	$ (0.64)	$ (1.98)	$ (1.64)	$ (0.07)
Weighted-average shares outstanding, basic and diluted	26,967	26,563	26,923	26,557
Comprehensive loss:				
Net loss	$ (17,216)	$ (52,550)	$ (44,033)	$ (1,796)
Comprehensive loss	$ (17,216)	$ (52,550)	$ (44,033)	$ (1,796)

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