Arcturus Therapeutics Announces First Quarter 2024 Financial Update and Pipeline Progress

May 8, 2024

Commercial manufacture of Kostaive® on track for delivery of initial 4 million doses in Q3

Kostaive® European Marketing Authorization Application approval decision expected Q3

Multiple Kostaive® Phase 3 trials further demonstrate breadth and durability of STARR® vaccine platform

ARCT-2138 (LUNAR-FLU) Phase 1 topline immunogenicity and safety data, anticipated in Q3

ARCT-810 (LUNAR-OTC) Phase 2 and ARCT-032 (LUNAR-CF) Phase 1b interim data and update to be provided on July 1st

JP Morgan engaged to monetize investment in ARCALIS JV in Japan

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

SAN DIEGO--(BUSINESS WIRE)--May 8, 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 opportunities within liver and respiratory rare diseases, today announced its financial results for the first quarter ended March 31, 2024, and provided corporate updates.

"Arcturus continues to make encouraging progress in both our vaccine and therapeutics pipeline," said Joseph Payne, President & CEO of Arcturus. "In collaboration with our global vaccine partner CSL and their partner Meiji Seika Pharma, we are excited to begin the commercialization of Kostaive this year."

Mr. Payne continued, "We also look forward to providing meaningful clinical study data updates July 1st, for each of our flagship mRNA therapeutic programs, ARCT-810 (OTC deficiency) and ARCT-032 (CF)."

"I am pleased to announce that we have engaged JP Morgan to monetize our stake in ARCALIS, our JV manufacturing operation in Japan," stated Andrew Sassine, Chief Financial Officer of Arcturus Therapeutics. "Additionally, I am pleased to announce we will begin to qualify for commercial milestones under our CSL collaboration upon commencement of Kostaive revenues in Japan this year. Finally, our cash runway remains strong for at least three years into the first quarter of fiscal year 2027."

Recent Corporate Highlights

- In March, Meiji Seika Pharma announced plans to supply Japan with 4 million doses of Kostaive for fall/winter season of 2024. To support this effort, Arcturus along with CDMO partners are on track to deliver the initial 4 million commercial doses of Kostaive in Q3.
- In March, the Company, along with partners CSL and Meiji, announced that the Company's bivalent COVID-19 Vaccine candidate, ARCT-2301 (Wuhan strain and Omicron BA.4/5), met the primary endpoint (non-inferiority) in a Phase 3 clinical study in Japan. The study enrolled 930 healthy adults and individuals with comorbidities, who previously received three to five doses of mRNA COVID-19 vaccines, including the last booster at least three months prior to recruitment.
    - Both the geometric mean titer (GMT) ratio and seroresponse rate (SRR) difference of neutralizing antibodies against SARS-CoV-2 (Omicron BA.4/5) and Wuhan strains met pre-specified non-inferiority and superiority criteria versus a licensed mRNA vaccine comparator. There were no causally-associated serious adverse events with ARCT-2301.
- In March, Arcturus and CSL initiated a Phase 3 pivotal study with the ARCT-2303 candidate vaccine containing the Omicron XBB.1.5 variant.
    - The purpose of this study is to generate additional immunogenicity and safety data to support product licensure in the U.S.
    - The study will also assess the co-administration of ARCT-2303 with the age-appropriate seasonal influenza vaccines.
    - Approximately 1,680 young and older adults are planned to be recruited in the southern hemisphere.
- The Company has filed a Marketing Authorization Application (MAA) for Kostaive to the European Medicines Agency (EMA), with the European Commission (EC) expected to provide an approval decision in Q3.
- ARCT-2138 (LUNAR-FLU, Quadrivalent Seasonal Influenza), is progressing well through Arcturus' partner CSL. As of May 1, 2024, 84 healthy young adults were recruited in a Phase 1 dose-finding and immunogenicity study and received one of four dose levels of the study vaccine or a licensed influenza vaccine. The recruitment of older adults is ongoing.

- In April, the Company presented Phase 1 single ascending dose (SAD) studies for ARCT-810, an mRNA therapeutic candidate for ornithine transcarbamylase (OTC) deficiency, at the Society for Inherited Metabolic Diseases (SIMD) annual conference.
    - ARCT-810-01 was a Phase 1 SAD study that enrolled 30 healthy adults, randomized 2:1 to receive ARCT-810 (0.1, 0.2, 0.3 or 0.4 mg/kg) or placebo as an intravenous infusion. ARCT-810-02 is a recently completed Phase 1b SAD study that enrolled 16 adults with mild OTC deficiency, randomized 3:1 to receive single doses of ARCT-810 (0.2, 0.3, 0.4, or 0.5 mg/kg) or placebo as an intravenous infusion.
    - The results showed that ARCT-810 was generally well tolerated with no serious or severe adverse events in both studies.
    - The results from ARCT-810-01 and ARCT-810-02 studies facilitated the initiation of a Phase 2 multiple ascending dose study of ARCT-810 (ARCT-810-03) in OTC deficiency adolescents and adults which is ongoing in the UK and EU. Subjects are randomized to receive 6 doses of ARCT-810 or placebo (randomized 3:1) administered every 14 days.
    - The Company will share a progress update on the Phase 2 study on July 1, 2024.
- Arcturus is advancing ARCT-032, an inhaled mRNA therapeutic for cystic fibrosis. The Company remains on track to share Phase 1b interim data on July 1, 2024. Each CF patient in this trial receives two inhaled administrations of ARCT-032.

Financial Results for the three months ended March 31, 2024

Revenues in conjunction with strategic alliances and collaborations:

Arcturus' primary sources of revenues were from 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 March 31, 2024, revenues were $38.0 million compared with $80.3 million for the three months ended March 31, 2023. The decrease was primarily attributable to the CSL agreement as $78.2 million total revenue was recognized during the first quarter of 2023 upon the achievement of a conditional payment and multiple milestones, compared to $32.4 million total revenue related to CSL during the first quarter of 2024, resulting in a decrease of $45.8 million. The total decrease was primarily offset by an increase in revenue of $4.9 million related to the agreement with BARDA.

Operating expenses:

Total operating expenses for the three months ended March 31, 2024, were $68.4 million compared with $65.5 million for the three months ended March 31, 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 $53.6 million for the three months ended March 31, 2024, compared with $51.8 million in the comparable period last year. The increase in research and development expenses were primarily driven by the CSL and BARDA programs as well as Arcturus' internal OTC and Cystic Fibrosis programs. Additionally, investments increased in early stage and discovery technologies, including the initiation of preclinical research related to its Lyme Disease and Gonorrhea 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 $14.9 million for the three months ended March 31, 2024, compared with $13.8 million in the comparable period last year. The increase in expenses resulted primarily from increased personnel expenses due to increased salaries, increased travel and consulting expenses as well as escalated rent expense associated with facilities.

Net Loss:

For the three months ended March 31, 2024, Arcturus reported a net loss of approximately $26.8 million, or ($1.00) per diluted share, compared with a net income of $50.8 million, or $1.87 per diluted share in the three months ended March 31, 2023.

Cash Position and Balance Sheet:

Cash, cash equivalents and restricted cash were $345.3 million as of March 31, 2024, and $348.9 million on December 31, 2023. Arcturus achieved a total of approximately $420.1 million in upfront payments and milestones from CSL as of March 31, 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 at least three years based on the current pipeline and programs through the first quarter of fiscal year 2027.

Earnings Call: Wednesday, May 8, 2024 @ 4:30 pm ET

- Domestic: 1-888-886-7786
- International: 1-416-764-8658
- Conference ID: 96934019
- 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 the first self-amplifying messenger RNA (sa-mRNA) COVID vaccine (Kostaive®) 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 deficiency and cystic fibrosis, 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 delivery of doses of Kostaive (including timing and volume thereof), the anticipated commercialization of Kostaive and the timing thereof, the likelihood and timing of a European Marketing Authorization application approval decision for Kostaive, the monetization of Arcturus' interests in ARCALIS JV in Japan, that preclinical or clinical data will be predictive of future clinical results, the likelihood and timing of clinical study updates (including for ARCT-2138 (LUNAR-FLU), ARCT-032 (LUNAR-CF)), the qualification for commercial milestones under the CSL collaboration, the continuation and expected recruitment in the Phase 3 pivotal study of ARCT-2303 candidate vaccine containing the Omicron XBB.1.5 variant, the ongoing recruitment in the ARCT-2138 (LUNAR-FLU) Phase 1 study, 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)	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 288,396	$ 292,005
Restricted cash	55,000	55,000
Accounts receivable	27,057	32,064
Prepaid expenses and other current assets	5,335	7,521
Total current assets	375,788	386,590
Property and equipment, net	11,763	12,427
Operating lease right-of-use asset, net	29,413	28,500
Non-current restricted cash	1,885	1,885
Total assets	$ 418,849	$ 429,402
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,144	$ 5,279
Accrued liabilities	34,770	31,881
Deferred revenue	71,516	44,829
Total current liabilities	115,430	81,989
Deferred revenue, net of current portion	11,795	42,496
Operating lease liability, net of current portion	27,652	25,907
Other non-current liabilities	—	497
Total liabilities	154,877	150,889
Stockholders' equity		

Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 26,917 at March 31, 2024 and 26,828 at December 31, 2023	27	27
Additional paid-in capital	658,628	646,352
Accumulated deficit	(394,683)	(367,866)
Total stockholders' equity	263,972	278,513
Total liabilities and stockholders' equity	$ 418,849	$ 429,402

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

Unaudited

	Three Months Ended		
	March 31,		December 31,
(in thousands, except per share data)	2024	2023	2023
Revenue:			
Collaboration revenue	$ 32,598	$ 79,729	$ 25,078
Grant revenue	5,414	556	5,777
Total revenue	38,012	80,285	30,855
Operating expenses:			
Research and development, net	53,573	51,768	36,620
General and administrative	14,851	13,762	12,507
Total operating expenses	68,424	65,530	49,127
(Loss) income from operations	(30,412)	14,755	(18,272)
Loss from foreign currency	(53)	(328)	(54)
Gain on debt extinguishment	—	33,953	—
Finance income, net	4,016	2,477	6,881
Net (loss) income before income taxes	(26,449)	50,857	(11,445)
Provision for income taxes	368	103	262
Net (loss) income	$ (26,817)	$ 50,754	$ (11,707)
(Loss) earnings per share			
Basic	$ (1.00)	$ 1.91	$ (0.44)
Diluted	$ (1.00)	$ 1.87	$ (0.44)
Weighted-average shares used in calculation of (loss) earnings per share:			
Basic	26,879	26,555	26,628
Diluted	26,879	27,149	26,628
Comprehensive (loss) income:			
Net (loss) income	$ (26,817)	$ 50,754	$ (11,707)
Comprehensive (loss) income	$ (26,817)	$ 50,754	$ (11,707)

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