Arcturus Therapeutics Announces First Quarter 2025 Financial Update and Pipeline Progress

May 12, 2025

Prioritization of mRNA therapeutics pipeline extends cash runway into 2028

ARCT-032 (CF) Phase 2 interim data from first two cohorts expected in mid-2025

ARCT-032 (CF) Phase 2 expected to complete enrollment by year end

ARCT-810 (OTC) Phase 2 interim data expected Q2 2025

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

SAN DIEGO--(BUSINESS WIRE)--May 12, 2025-- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a commercial 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, 2025, and provided corporate updates.

"We are delighted with enrollment in our cystic fibrosis (CF) program, and the company is working diligently to provide meaningful Phase 2 interim data mid-year," said Joseph Payne, President & CEO of Arcturus Therapeutics. "We are encouraged by the clinical progress of our CF and OTC programs, and given the current market conditions, we made a strategic decision to streamline resources to focus on our mRNA therapeutics pipeline."

"I am happy to report we have received the initial European Union (EU) approval milestone payment from our partnership with CSL," said Andy Sassine, Chief Financial Officer of Arcturus. "I am also pleased to report that the cash runway now extends into 2028 with the re-allocation of resources to our therapeutics pipeline."

Recent Corporate Highlights

- Arcturus is advancing enrollment of adult CF participants in the open label Phase 2 multiple ascending dose CF study (NCT06747858) with daily inhaled treatments of ARCT-032 over a period of 28 days and expects to complete enrollment by year end. The Company expects to provide Phase 2 interim data from the first two cohorts in mid-2025.
- Arcturus continues to enroll participants in the open label Phase 2 OTC deficiency study (NCT06488313) with five intravenous infusions of ARCT-810 over a period of two months. The Company previously completed the dosing phase (N = 8; 0.3 mg/kg) of a placebo-controlled European study enrolling OTC deficient individuals. The Company expects to provide Phase 2 interim data in Q2 2025.
- In April, Arcturus received U.S. FDA Fast Track Designation for ARCT-2304, an sa-mRNA vaccine candidate for Pandemic Influenza A Virus H5N1.
    - The Company recently completed the recruitment of 212 adults in Phase 1 (132 participants 18-59 years old; 80 participants over 60 years old) for the randomized placebo-controlled Phase 1 trial (NCT06602531), which is being conducted at multiple sites in the U.S.
    - This project has been supported in whole with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50122C0007.
    - The Company expects interim Phase 1 data in H2 2025.
- Arcturus received the initial milestone payment from CSL in relation to the EU approval of KOSTAIVE®, a self-amplifying mRNA COVID-19 vaccine.
- KOSTAIVE regulatory guidance includes an MAA filing in the United Kingdom anticipated in Q2 2025, followed by a U.S. BLA filing expected in Q3 2025.
- Arcturus recently published a comprehensive analysis of safety data for KOSTAIVE, with a 12-month follow-up from the pivotal clinical study in Vietnam (NCT05012943), which had 17,582 participants who received at least one dose of the study vaccine.
    - The study confirmed the favorable reactogenicity profile. Acceptable tolerability of ARCT-154 (KOSTAIVE) was also observed in older participants and individuals at high risk of severe COVID-19 due to underlying medical conditions.
    - Long-term follow-up has not revealed any safety concerns, with no reports of myocarditis or pericarditis.
    - No serious consequences occurred in several pregnancies reported after vaccination, with normal outcomes when followed to term.
    - Long-term data from this large trial suggest that the sa-mRNA COVID-19 vaccine (ARCT-154; KOSTAIVE) is safe and well-tolerated.

- In April, Arcturus' Japanese partner, Meiji Seika Pharma, published an analysis characterizing the distribution and clearance of ARCT-154 encoded spike protein and non-structural proteins nsP1, nsP2, nsP3 and nsP4 in the lymph nodes and injection-site muscle in mice following a single IM vaccination.
    - The study showed the encoded spike protein reached its highest level approximately three days after vaccination and quickly disappeared from the injection site muscle.
    - The spike protein levels also peaked at an early time point in the lymph nodes, remained detectable 28 days after the vaccination and disappeared by 44 days after the vaccination.
    - Expression of nsP1, nsP2 and nsP4 was observed in the injected muscle and/or the lymph nodes for up to 15 days post-vaccination.
    - The data indicate that the extended expression of spike proteins in lymph nodes may be responsible for the induction of higher and prolonged levels of neutralizing antibodies. The study also confirmed that the replication is limited over time.

Financial Results for the three months ended March 31, 2025

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 March 31, 2025, revenues were $29.4 million compared to $38.0 million in the same period in 2024. The decrease primarily reflects lower milestone revenues recognized under the CSL collaboration agreement as KOSTAIVE transitions from a development program to the commercial phase.

Operating expenses:

Total operating expenses for the three months ended March 31, 2025, were $46.2 million compared to $68.4 million for the three months ended March 31, 2024.

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 $34.9 million for the three months ended March 31, 2025, compared to $53.6 million in the comparable period last year. The decrease in research and development expenses was primarily driven by lower manufacturing costs associated with the KOSTAIVE®, LUNAR-FLU, and BARDA programs, partially offset by increased clinical and manufacturing costs for the CF and OTC programs. Research and development expenses also declined sequentially from the three months ended December 31, 2024, by approximately $8.9 million, and we anticipate additional quarterly declines in the second half of fiscal year 2025.

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 $11.3 million for the three months ended March 31, 2025, compared to $14.9 million in the comparable period last year. The decrease in general and administrative expenses was attributable to reduced share-based compensation costs. We expect general and administrative expenses to decrease slightly during the next twelve months driven by lower share-based compensation costs and a reduction in expenses related to the commercial transition of the COVID program to CSL.

Net Loss:

For the three months ended March 31, 2025, Arcturus reported a net loss of approximately $14.1 million, or ($0.52) per diluted share, compared to a net loss of $26.8 million, or ($1.00) per diluted share in the three months ended March 31, 2024.

Cash Position and Balance Sheet:

Cash, cash equivalents and restricted cash were $273.8 million as of March 31, 2025, and $293.9 million on December 31, 2024. Based on the current pipeline and programs, the cash runway is expected to extend into 2028 with the re-allocation of resources to the therapeutics programs.

Earnings Call: Monday, May 12, 2025 @ 4:30 PM ET

- Domestic: 1-800-267-6316
- International: 1-203-518-9783
- Conference ID: ARCTURUS
- Webcast: Link

About Arcturus

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a commercial 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 500 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 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 and timing for providing interim data from the ARCT-032 Phase 2 CF study and the ARCT-810 Phase 2 OTC deficiency study, the timing for completion of enrollment in the ARCT-032 (CF) Phase 2 study, the likelihood of obtaining additional milestone payments from CSL Seqirus, the continued enrollment in the Phase 2 OTC deficiency study, the likelihood of and timing for interim Phase 1 study data for Pandemic Influenza A virus H5N1, the completion of and timing for KOSTAIVE regulatory filings in the United States and United Kingdom, the likelihood that general and administrative expenses will decrease, the likelihood that preclinical or clinical data will be predictive of future clinical results, 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 KOSTAIVE®, 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, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 216,948	$ 237,028
Restricted cash	38,500	55,000
Accounts receivable	14,572	3,974
Prepaid expenses and other current assets	8,774	9,977
Total current assets	278,794	305,979
Property and equipment, net	8,867	9,531
Operating lease right-of-use assets, net	25,739	26,674
Non-current restricted cash	18,385	1,885
Total assets	$ 331,785	$ 344,069
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,179	$ 7,194
Accrued liabilities	30,559	38,781
Deferred revenue	12,671	19,514
Total current liabilities	49,409	65,489
Deferred revenue, net of current portion	9,630	12,604
Operating lease liability, net of current portion	23,987	24,998
Long-term debt	15,000	-
Total liabilities	98,026	103,091
Stockholders' equity		
Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 27,121 at March 31, 2025 and 27,096 at December 31, 2024	27	27
Additional paid-in capital	696,615	689,758
Accumulated deficit	(462,883)	(448,807)
Total stockholders' equity	233,759	240,978
Total liabilities and stockholders' equity	$ 331,785	$ 344,069

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

	Three Months Ended		
	March 31,		December,
(in thousands, except per share data)	2025	2024	2024
Revenue:			
Collaboration revenue	$ 25,477	$ 32,598	$ 21,000
Grant revenue	3,905	5,414	1,766
Total revenue	29,382	38,012	22,766
Operating expenses:			
Research and development, net	34,893	53,573	43,780
General and administrative	11,315	14,851	12,380
Total operating expenses	46,208	68,424	56,160
Loss from operations	(16,826)	(30,412)	(33,394)
Loss (gain) from foreign currency	(21)	(53)	171
Finance income, net	2,771	4,016	3,214
Net loss before income taxes	(14,076)	(26,449)	(30,009)
Provision for income taxes	—	368	(4)
Net loss	$ (14,076)	$ (26,817)	$ (30,005)
Net loss per share, basic and diluted	$ (0.52)	$ (1.00)	$ (1.11)
Weighted-average shares outstanding, basic and diluted	27,107	26,879	27,000
Comprehensive loss:			
Net loss	$ (14,076)	$ (26,817)	$ (30,005)
Comprehensive loss	$ (14,076)	$ (26,817)	$ (30,005)

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Arcturus Therapeutics
Public Relations & Investor Relations
Neda Safarzadeh
VP, Head of IR/PR/Marketing
(858) 900-2682
IR@ArcturusRx.com

Source: Arcturus Therapeutics Holdings Inc.