Arcturus Therapeutics Announces Third Quarter 2025 Financial Update and Pipeline Progress

November 10, 2025

Encouraging CF interim Phase 2 data support continued and expanded trial design

12-week safety and preliminary efficacy study in up to 20 CF participants planned to start H1 2026

Additional cost reductions planned in fourth quarter to extend cash runway

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

SAN DIEGO--(BUSINESS WIRE)--Nov. 10, 2025-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a commercial messenger RNA medicines company focused on the development of liver and respiratory rare disease therapeutics and infectious disease vaccines, today announced its financial results for the third quarter ended September 30, 2025, and provided corporate updates.

“We were pleased to share the initial findings of ARCT-032 clinical activity with the CF community last month at the NACFC,” said Joseph Payne, President & CEO of Arcturus Therapeutics. “Conversations at NACFC with CF patients, physicians, investigators and global experts reinforced our commitment to advance ARCT-032 further into development. We look forward to initiating a 12-week safety and preliminary efficacy study in first half of 2026. Our team is also working diligently to achieve alignment with regulatory agencies regarding pivotal studies of ARCT-810 in adults and young children with OTC deficiency.”

“The observed mucus plug reduction after 28 days of treatment with ARCT-032 in people with Class I CF is encouraging,” said Denis Hadjiliadis, MD, MMHS, FRCP(C), Professor and Cystic Fibrosis Program Director, Perelman School of Medicine, University of Pennsylvania. “Clearance of mucus suggests that treatment with ARCT-032 is acting on the thick mucus defect which is fundamental in CF; more extended treatment with ARCT-032 could provide further reduction in mucus burden leading to more meaningful benefits, including lung function and structural lung defect improvement. These changes could ultimately lead to reduction in exacerbations and change the clinical course of this progressive disease.”

“The sudden changes in regulatory requirements by the FDA for COVID-19 vaccines have delayed the U.S. BLA filing for KOSTAIVE® indefinitely. We have decided to reduce additional expenses to extend the runway for the CF and OTC deficiency programs,” said Andy Sassine, CFO of Arcturus Therapeutics. “We anticipate continued support from CSL to commercialize KOSTAIVE in Asia and Europe and will provide more details on our year end call.”

Recent Corporate Highlights

- Arcturus continues to advance the ARCT-810 program for OTC deficiency. Planned alignment with regulatory agencies around pivotal trial strategy for both pediatric and adult populations remain on track for the first half of 2026.
- In October, the Company announced interim data from its ongoing Phase 2 clinical trial of ARCT-032 in cystic fibrosis:
  - Treatment with inhaled 10 mg doses of ARCT-032 daily over 28 days in six Class I CF adults received was generally safe and well tolerated.
  - Protocol prespecified analyses of high-resolution computed tomography (HRCT) lung scans using FDA 501(k)-cleared AI technology revealed reductions in mucus burden in four of the six Class I CF participants.
  - The ongoing third cohort is enrolling up to six subjects to assess the safety and tolerability of the 15 mg dose daily over 28 days and the impact on the efficacy endpoints.
  - The Company intends to initiate up to 20 CF participants for 12-weeks of dosing with ARCT-032 in a safety and preliminary efficacy study in the first half of 2026.
- Meiji Seika Pharma launched the two-dose vial of KOSTAIVE updated for the JN.1 variant XEC in Japan. Meiji received approval from the Pharmaceuticals and Medical Devices Agency (PMDA) in August 2025.
- In August, the Company published the Phase 3 manuscript on the immunogenicity and safety of a self-amplifying mRNA COVID-19 vaccine (ARCT-2303), with or without co-administration of seasonal inactivated influenza vaccine in adults.
  - The study shows that ARCT-2303 induces a robust immune response against the vaccine variant of SARS-CoV-2 and can be co-administered with licensed influenza vaccines in adults with no impact on the safety or immunogenicity of either vaccine. The results were published in eClinicalMedicine.
- The Company conducted a Phase 1 study of ARCT-2304 (NCT06602531), an sa-mRNA vaccine candidate for Pandemic Influenza A Virus H5N1. The study objectives were to evaluate the safety and tolerability and to describe the immune response of three different dose levels in 132 young adults (18-59 years of age) and 80 older adults (60-80 years old).
  - ARCT-2304 induced a humoral immune response after a single dose at all tested dose levels. The administration of a second dose of ARCT-2304 further increases immune responses.
  - ARCT-2304 at dose levels 1.5, 5 and 12 µg induce a hemagglutinin-specific immune response similar to or higher

than that after the MF59-adjuvanted pandemic vaccine.
- No safety or tolerability concerns were raised from available data.
- Overall, the study results support the further development of a self-amplifying mRNA pandemic influenza vaccine candidate.
- These new data further validate Arcturus' STARR® sa-mRNA vaccine platform.
- This work was funded in part with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50122C00007. The contract and federal funding are not an endorsement of the study results, product, or company.

Financial Results for the three months ended September 30, 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. Revenue for the three and nine months ended September 30, 2025, was $17.2 million and $74.8 million, respectively, representing decreases of $24.5 million and $54.7 million compared to the same periods in 2024. These declines were primarily driven by reduced revenue from the CSL collaboration, reflecting lower supply agreement activity and lower amortization of the upfront payment as KOSTAIVE progresses toward commercialization.

Operating expenses:

Total operating expenses for the three months ended September 30, 2025, were $33.7 million compared with $52.4 million for the three months ended September 30, 2024. Total operating expenses for the nine months ended September 30, 2025, were $119.8 million compared with $191.8 million for the nine months ended September 30, 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 $23.3 million for the three months ended September 30, 2025, compared with $39.1 million for the three months ended September 30, 2024. The decrease was primarily driven by lower manufacturing costs for the LUNAR-COVID, LUNAR-FLU, and LUNAR-CF programs, as well as reduced clinical trial expenses for LUNAR-COVID and LUNAR-CF. Lower payroll and employee benefits further contributed to the decrease.

Research and development expenses were $87.7 million for the nine months ended September 30, 2025, compared with $151.4 million for the nine months ended September 30, 2024. The decrease was primarily driven by lower manufacturing and clinical costs related to the LUNAR-COVID program, reflecting the program's transition from a development program to the commercial phase. Additional decreases were attributable to lower manufacturing costs for the LUNAR-CF and LUNAR-FLU programs. These reductions were partially offset by higher clinical costs for Phase 2 of the LUNAR-CF program. Payroll and benefits expenses also decreased, primarily due to lower stock-based compensation expense.

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 $10.4 million and $32.1 million for the three and nine months ended September 30, 2025, respectively, compared with $13.3 million and $40.4 million in the comparable periods last year. The decreases in both periods were primarily due to reduced share-based compensation expense as well as reduced payroll and benefits. We expect general and administrative expenses to continue to decrease slightly during the next twelve months driven by lower share-based compensation costs.

Net Loss:

For the three months ended September 30, 2025, Arcturus reported a net loss of approximately $13.5 million, or ($0.49) per diluted share, compared with a net loss of $6.9 million, or ($0.26) per diluted share in the three months ended September 30, 2024. For the nine months ended September 30, 2025, Arcturus reported a net loss of approximately $36.7 million, or ($1.35) per diluted share, compared with a net loss of $50.9 million, or ($1.89) per diluted share in the nine months ended September 30, 2024.

Cash Position and Balance Sheet:

Cash, cash equivalents and restricted cash were $237.3 million as of September 30, 2025, compared to $293.9 million on December 31, 2024. Based on the additional planned cost reduction in Q4 2025 and the delay in Phase 3 CF clinical trial commencement until 2027, the cash runway remains extended into 2028.

Earnings Call: Monday, November 10, 2025 @ 4:30 p.m. ET

- Domestic: 1-800-274-8461
- International: 1-203-518-9814
- 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 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 X (formerly 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 that clinical data, including interim data, will be predictive of future clinical results, the likelihood that observed mucus plug reduction is predictive of future and future reduction and will lead to lung function or structural lung defect improvements, the plans to enroll subjects in the third cohort of the Phase 2 clinical trial of ARCT-032, the likelihood and timing for initiation, and size and scope, of a planned 12-week safety and preliminary efficacy study for ARCT-032, plans to advance ARCT-032 further into development, the likelihood and timing for achieving alignment with regulatory agencies on pivotal studies for ARCT-810, the likelihood of success of any collaboration including the anticipated continued support from CSL to commercialize KOSTAIVE, the continued determination that ARCT-032 is generally safe and well tolerated, the likelihood of further development of a self-amplifying mRNA pandemic influenza vaccine candidate, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood that general and administrative expenses will continue to decrease, 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.

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 180,360	$ 237,028
Restricted cash	55,000	55,000
Accounts receivable	7,951	3,974
Prepaid expenses and other current assets	5,889	9,977
Total current assets	249,200	305,979
Property and equipment, net	7,419	9,531
Operating lease right-of-use assets, net	23,839	26,674
Non-current restricted cash	1,885	1,885
Total assets	$ 282,343	$ 344,069
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,491	$ 7,194
Accrued liabilities	19,382	38,781
Deferred revenue	6,826	19,514
Total current liabilities	31,699	65,489
Deferred revenue, net of current portion	4,220	12,604
Operating lease liability, net of current portion	21,865	24,998
Total liabilities	57,784	103,091
Stockholders' equity		
Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 27,235 at September 30, 2025 and 27,096 at December 31, 2024	27	27
Additional paid-in capital	710,043	689,758
Accumulated deficit	(485,511)	(448,807)
Total stockholders' equity	224,559	240,978

Total liabilities and stockholders' equity	$ 282,343	$ 344,069

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share data)	2025	2024	2025	2024
Revenue:				
Collaboration revenue	$ 14,153	$ 38,815	$ 64,140	$ 117,389
Grant revenue	2,998	2,858	10,695	12,155
Total revenue	17,151	41,673	74,835	129,544
Operating expenses:				
Research and development, net	23,265	39,134	87,736	151,376
General and administrative	10,398	13,276	32,052	40,443
Total operating expenses	33,663	52,410	119,788	191,819
Loss from operations	(16,512)	(10,737)	(44,953)	(62,275)
Loss from foreign currency	(170)	(201)	(319)	(642)
Finance income, net	3,234	3,818	8,572	11,981
Net loss before income taxes	(13,448)	(7,120)	(36,700)	(50,936)
Provision (benefit) for income taxes	—	(217)	4	—
Net loss	$ (13,448)	$ (6,903)	$ (36,704)	$ (50,936)
Net loss per share, basic and diluted	$ (0.49)	$ (0.26)	$ (1.35)	$ (1.89)
Weighted-average shares outstanding, basic and diluted	27,188	27,062	27,142	26,970
Comprehensive loss:				
Net loss	$ (13,448)	$ (6,903)	$ (36,704)	$ (50,936)
Comprehensive loss	$ (13,448)	$ (6,903)	$ (36,704)	$ (50,936)

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