UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 6, 2025

ARCTURUS THERAPEUTICS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38942**	**32-0595345**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10628 Science Center Drive, Suite 250
San Diego, California 92121
(Address of principal executive offices)

Registrant's telephone number, including area code: (858) 900-2660

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	**ARCT**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Conditions.

On March 6, 2025, Arcturus Therapeutics Holdings Inc. (the "Company" or "Arcturus") issued a press release, a copy of which is furnished herewith as Exhibit 99.1, announcing the Company's financial results for the quarter and year ended December 31, 2024 and providing a corporate update (the "Press Release").

The information contained in Item 2.02 of this Current Report on Form 8-K, including the Press Release, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, this information shall not be deemed incorporated by reference into any of the Company's filings with the Securities and Exchange Commission (the "SEC"), except as shall be expressly set forth by specific reference in any such filing.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K and the 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 Current Report on Form 8-K and the 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 anticipated timing for providing interim data from the ARCT-032 Phase 2 CF study and the ARCT-810 Phase 2 OTC deficiency study, the completion of and timing for KOSTAIVE regulatory filings for the United States and United Kingdom, the expected treatment protocol for the ARCT-032 Phase 2 CF study, the expected infusions and timing therefor for the ARCT-810 Phase 2 OTC deficiency study, the potential supply of mRNA vaccines by Meiji Seika Pharma and ARCALIS, the likelihood that CSL Seqirus will recoup the development costs of the COVID-19 program and that Arcturus will receive net profit payments from CSL Seqirus for sales of KOSTAIVE, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood or timing of collection of accounts receivables including expected payments from CSL Seqirus, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description of Exhibit**
99.1	Press Release dated March 6, 2025
104	Cover Page to this Current Report on Form 8-K in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 6, 2025

Arcturus Therapeutics Holdings Inc.

By: /s/ Joseph E. Payne
Name: Joseph E. Payne
Title: Chief Executive Officer

Arcturus Therapeutics Announces Fourth Quarter and Fiscal Year 2024 Financial Update and Pipeline Progress

Phase 2 interim data for ARCT-032 (CF) & ARCT-810 (OTCD) on track for Q2 2025
Meiji Seika Pharma and ARCALIS received MHLW approval for commercial manufacturing of KOSTAIVE®
Meiji Seika Pharma Submitted Application for Two-Dose Vial of KOSTAIVE®
KOSTAIVE® U.S. BLA filing anticipated 2025

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

SAN DIEGO--(BUSINESS WIRE)--March 6, 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 fourth quarter ended December 31, 2024, and provided corporate updates.

"We continue to progress our flagship rare disease programs and look forward to sharing meaningful Phase 2 interim data from our cystic fibrosis (CF) and ornithine transcarbamylase (OTC) deficiency programs in Q2 2025," said Joseph Payne, President & CEO of Arcturus Therapeutics. "Arcturus continues to make excellent progress with our STARR® sa-mRNA vaccines pipeline and platform. We are very pleased to have recently received European Commission approval for KOSTAIVE® and MHLW approval for Meiji Seika Pharma and ARCALIS to add commercial manufacturing sites in Japan. Our team continues to work diligently with CSL Seqirus to prepare KOSTAIVE regulatory filings for the United States and the United Kingdom."

Recent Corporate Highlights

- Arcturus has advanced the development of ARCT-032, an mRNA therapeutic candidate for cystic fibrosis. In December 2024, the Company initiated dosing of the first CF participant in an open label Phase 2 multiple ascending dose study.
    - Each adult participant in the Phase 2 CF study (NCT06747858) is expected to receive daily inhaled treatments of ARCT-032 over a period of 28 days. The trial involves a relatively low number of study visits and 12 weeks of follow up.
    - The Company expects to provide interim data from participants who completed dosing in the ARCT-032 Phase 2 study by the end of Q2 2025.
- Arcturus has advanced the development of ARCT-810, an mRNA therapeutic candidate for ornithine transcarbamylase (OTC) deficiency. In December 2024, the Company initiated dosing of the first OTC deficient participant who received 0.5 mg/kg in the Phase 2 multiple ascending dose study.
    - Each adult and adolescent participant in the open label Phase 2 OTC deficiency study (NCT06488313) is expected to receive five intravenous infusions of ARCT-810 over a period of two months. The Company previously announced the completion of the dosing phase (N = 8; 0.3 mg/kg) in a placebo-controlled European study enrolling OTC deficient individuals.
    - The Company expects to provide interim data from participants who completed dosing in the ARCT-810 Phase 2 study by the end of Q2 2025.

- Arcturus received approval from the European Commission (EC) in February for KOSTAIVE, the world's first approved sa-mRNA COVID-19 vaccine.
    - The centralized marketing authorization of KOSTAIVE provided by the EC is valid in all 27 European Union (EU) member states and 3 additional European Economic Area (EEA) countries.
    - The approval is based on positive clinical data from several studies, including an integrated phase 1/2/3 study demonstrating KOSTAIVE's efficacy and tolerability against COVID-19, and a Phase 3 COVID-19 booster trial, which achieved higher immunogenicity results compared to a conventional mRNA COVID-19 vaccine comparator. A follow-up analysis evaluating a booster dose of KOSTAIVE also showed that the vaccine elicited superior immunogenicity and antibody persistence for up to 12 months post vaccination against multiple SARS-CoV-2 strains in both younger and older adult age groups versus the mRNA comparator.
    - The approval follows a positive opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on December 12, 2024.
- In January, Meiji Seika Pharma, along with Arcturus' manufacturing joint venture ARCALIS, received Ministry of Health, Labour and Welfare (MHLW) approval for adding commercial manufacturing sites in Japan for KOSTAIVE.
    - Domestically produced products with active pharmaceutical ingredients manufactured at ARCALIS's Minami-soma facilities, and formulated at Meiji Seika Pharmatech, are now able to be shipped for commercial use in Japan.
    - Meiji Seika Pharma announced an investment in ARCALIS, Inc. in November 2024. The combination of ARCALIS' advanced technology and operations in mRNA pharmaceuticals and vaccines with Meiji Seika Pharma's expertise in manufacturing, post-marketing safety management and stable product supply is expected to significantly improve the supply of mRNA vaccines in Japan.
- In February, Meiji Seika Pharma submitted a manufacturing and marketing application for Two-Dose Vial of KOSTAIVE, to the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan.
- The Company initiated the Phase 1 study of ARCT-2304, a self-amplifying mRNA (sa-mRNA) vaccine candidate, also known as LUNAR-H5N1, for active immunization to prevent pandemic influenza disease caused by H5N1 virus. LUNAR-H5N1 is the third STARR® mRNA vaccine candidate to enter the clinic.
    - Arcturus received clearance from the FDA to begin an H5N1 pandemic flu vaccine clinical trial in November 2024. The clinical study is funded by Biomedical Advanced Research and Development Authority (BARDA) and designed to enroll approximately 200 healthy adults in the United States.
    - First Phase 1 participant was dosed December 2024, and the Company expects interim Phase 1 data in H2 2025.
    - The primary objective of this initial clinical trial is to evaluate safety and immune responses of three different dose levels and two different vaccination schedules of ARCT-2304 vaccine. Immune responses are measured by hemagglutination inhibition (HAI), virus microneutralization (MN) and neuraminidase enzyme-linked lectin assays (ELLA).
- In February, the Company announced the appointment of Moncef Slaoui, Ph.D., as Chair Designate. Dr. Slaoui is currently on the Company's Board of Directors, a position he has held since June 2024.

Financial Results for the three months ended December 31, 2024, and the year ended December 31, 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 December 31, 2024, we reported revenue of $22.8 million, a decrease of $8.1 million from the $30.9 million reported in the same period in 2023. The decline was attributable to lower milestone achievements from the CSL agreement during the fourth quarter of 2024.

For the year ended December 31, 2024, we reported revenue of $152.3 million, a decrease of $14.5 million from the $166.8 million reported for the year ended 2023. The decrease was due to lower milestone achievements from the CSL agreement, offset by increased BARDA revenue due to progress of the pandemic flu program.

Operating expenses:
Total operating expenses for the three months ended December 31, 2024, were $56.2 million compared with $49.1 million for the three months ended December 31, 2023. Total operating expenses for the year ended December 31, 2024, were $248.0 million compared with $245.0 million for the year ended December 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 $43.8 million for the three months ended December 31, 2024, compared with $36.6 million for the three months ended December 31, 2023. Additionally, research and development expenses were $195.2 million for the year ended December 31, 2024, compared with $192.1 million for the year ended December 31, 2023. The increase in research and development expenses for both the quarter and the full year was primarily driven by higher clinical trial costs associated with our OTC and CF programs, as well as the COVID-19 and LUNAR-FLU programs in collaboration with CSL. However, the increase was partially offset by a reduction in manufacturing expenses related to clinical trials and drug supply agreements as part of the COVID-19 program.

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 $12.4 million for the three months ended December 31, 2024, compared with $12.5 million for the three months ended December 31, 2023. Additionally, General and administrative expenses were $52.8 million for the year ended December 31, 2024, compared with $52.9 million for the year ended December 31, 2023. These expenses remained relatively consistent between the two periods. 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 general and administrative expenses related to the commercial transition of the COVID program to CSL.

Net Loss:
For the three months ended December 31, 2024, Arcturus reported a net loss of approximately $30.0 million, or ($1.11) per diluted share, compared with a net loss of $11.7 million, or ($0.44) per diluted share for the three months ended December 31, 2023. Additionally, for the year ended December 31, 2024, Arcturus reported a net loss of approximately $80.9 million, or ($3.00) per diluted share, compared with a net loss of $29.7 million, or ($1.12) per diluted share for the year ended December 31, 2023.

Cash Position and Balance Sheet:
Cash, cash equivalents and restricted cash were $293.9 million as of December 31, 2024, and $348.9 million on December 31, 2023. Arcturus achieved a total of approximately $473.1 million in upfront payments and milestones from CSL as of December 31, 2024, and expects to continue to receive future milestone payments from CSL supporting the ongoing development of the COVID program. During the quarter ended December 31, 2024, CSL reported to Arcturus that Arcturus' share of gross profit from sales of KOSTAIVE was approximately $28.0 million. This amount will be credited against Arcturus' share of the COVID-19 program costs paid by CSL. When CSL has recouped Arcturus' share of such costs, Arcturus will begin to receive shared net profit payments from CSL for sales of KOSTAIVE, consistent with Arcturus' eligibility to receive a 40% share of net profits from COVID-19 vaccine sales. Based on the current pipeline and programs, the cash runway is expected to extend until the end of Q1 2027.

Arcturus Therapeutics Fourth Quarter and Full Year 2024 Earnings Conference Call

- Thursday, March 6, 2025 @4:30 p.m. 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 anticipated timing for providing interim data from the ARCT-032 Phase 2 CF study and the ARCT-810 Phase 2 OTC deficiency study, the completion of and timing for KOSTAIVE regulatory filings for the United States and United Kingdom, the expected treatment protocol for the ARCT-032 Phase 2 CF study, the expected infusions and timing therefor for the ARCT-810 Phase 2 OTC deficiency study, the potential supply of mRNA vaccines by Meiji Seika Pharma and ARCALIS, the likelihood that CSL Seqirus will recoup the development costs of the COVID-19 program and that Arcturus will receive net profit payments from CSL Seqirus for sales of KOSTAIVE, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood or timing of collection of accounts receivables including expected payments from CSL Seqirus, 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
Public Relations & Investor Relations
Neda Safarzadeh
VP, Head of IR/PR/Marketing
(858) 900-2682
IR@ArcturusRx.com

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)	As of December 31, 2024	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 237,028	$ 292,005
Restricted cash	55,000	55,000
Accounts receivable	3,974	32,064
Prepaid expenses and other current assets	9,977	7,521
Total current assets	305,979	386,590
Property and equipment, net	9,531	12,427
Operating lease right-of-use asset	26,674	28,500
Non-current restricted cash	1,885	1,885
Total assets	$ 344,069	$ 429,402
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,194	$ 5,279
Accrued liabilities	38,781	31,881
Deferred revenue	19,514	44,829
Total current liabilities	65,489	81,989
Deferred revenue, net of current portion	12,604	42,496
Operating lease liability, net of current portion	24,998	25,907
Other non-current liabilities	—	497
Total liabilities	103,091	150,889
Stockholders' equity:		
Common stock: $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 27,000 at December 31, 2024 and 26,828 at December 31, 2023	27	27
Additional paid-in capital	689,758	646,352
Accumulated deficit	(448,807)	(367,866)
Total stockholders' equity	240,978	278,513
Total liabilities and stockholders' equity	$ 344,069	$ 429,402

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

	Year Ended December 31,		
(in thousands, except per share data)	**2024**	**2023**	**2022**
Revenue:			
Collaboration revenue	$ 138,389	$ 157,748	$ 205,755
Grant revenue	13,921	9,051	244
Total revenue	152,310	166,799	205,999
Operating expenses:			
Research and development, net	195,156	192,133	147,751
General and administrative	52,823	52,871	46,071
Total operating expenses	247,979	245,004	193,822
(Loss) income from operations	(95,669)	(78,205)	12,177
Loss from equity-method investment	—	—	(515)
Loss from foreign currency	(471)	(229)	(598)
Finance income (expense), net	15,195	16,591	(420)
Gain on debt extinguishment	—	33,953	—
Net (loss) income before income taxes	(80,945)	(27,890)	10,644
(Benefit) provision for income taxes	(4)	1,835	1,295
Net (loss) income	(80,941)	(29,725)	9,349
Comprehensive (loss) income	$ (80,941)	$ (29,725)	$ 9,349
(Loss) earnings per share:			
Basic	$ (3.00)	$ (1.12)	$ 0.35
Diluted	$ (3.00)	$ (1.12)	$ 0.35
Weighted-average shares used in calculation of (loss) earnings per share:			
Basic	27,000	26,628	26,445
Diluted	27,000	26,628	27,093

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

	Three Months Ended December 31,	
(in thousands, except per share data)	**2024**	**2023**
Revenue:		
Collaboration revenue	$ 21,000	$ 25,078
Grant revenue	1,766	5,777
Total revenue	22,766	30,855
Operating expenses:		
Research and development, net	43,780	36,620
General and administrative	12,380	12,507
Total operating expenses	56,160	49,127
Loss from operations	(33,394)	(18,272)
Gain (loss) gain from foreign currency	171	(54)
Finance expense, net	3,214	6,881
Net loss income before income taxes	(30,009)	(11,445)
Provision for income taxes	(4)	262
Net loss	(30,005)	(11,707)
Comprehensive loss	$ (30,005)	$ (11,707)
Loss per share:		
Basic and diluted	$ (1.11)	$ (0.44)
Weighted-average shares used in calculation of loss per share:		
Basic and diluted	27,000	26,628