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 7, 2024

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 7, 2024, 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 ended December 31, 2023 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 likelihood that preclinical or clinical data will be predictive of future clinical results, including that the results from Kostaive® (or ARCT-154) will be predictive of results for updated versions of the vaccine, the potential commercial launch of Kostaive®, the continued advancement ARCT-032 or its potential as a treatment for any of the CF population, the continued advancement of ARCT-810, the anticipated timing and sharing of clinical data including for the Company's ARCT810 Phase 2 study and the ARCT-032 Phase 1b study, the continued efforts for our vaccine discovery programs for lyme disease or gonorrhea, the potential of the Company's platform technology to be meaningfully differentiated from other technologies, the continued progress of the LUNAR-FLU program, the ability to enroll participants in clinical studies including the Company's ARCT-810 and ARCT-032 programs, the likelihood and timing of commercial activities for the Company's LUNAR-COVID program, the likelihood that a patent will issue from any patent application, the likelihood or timing of collection of accounts receivables including expected 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description of Exhibit**
99.1	Press Release dated March 7, 2024
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.

Arcturus Therapeutics Holdings Inc.

Date: March 7, 2024

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

Arcturus Therapeutics Announces Fourth Quarter and Fiscal Year 2023 Financial Update and Pipeline Progress

Kostaive® anticipated to launch in Japan this year

ARCT-032 remains on track for Phase 1b interim data in Q2

ARCT-810 remains on track for Phase 2 interim data by the end of Q2

ARCT-2138 (Quadrivalent LUNAR-FLU) Phase 1 study for seasonal influenza vaccine initiated

New STARR® vaccine discovery programs initiated for Lyme Disease and Gonorrhea

Cash runway extended to Q1 2027

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

SAN DIEGO--(BUSINESS WIRE)--March. 7, 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 fourth quarter ended December 31, 2023, and provided corporate updates.

"I am excited about the continued pipeline progress and efforts toward commercialization achieved by Arcturus in 2023," said Joseph Payne, President & CEO of Arcturus Therapeutics. "Alongside our global vaccine partner CSL Seqirus and their COVID vaccine partner in Japan, Meiji, Kostaive® was granted historic approval as the world's first self-amplifying mRNA (sa-mRNA) product. Recently released clinical trial data, demonstrated Kostaive® induced a stronger, broader, and more durable immune response compared to an approved conventional mRNA vaccine."

Mr. Payne continued: "We are especially pleased to announce the U.S. FDA and the European Commission recently granted Orphan Drug Designation for ARCT-032, an inhaled mRNA therapeutic candidate for individuals with cystic fibrosis. These regulatory designations will help advance ARCT-032 to become a potential treatment for the segment of the CF population who are not candidates for any of the currently approved drugs for this disease."

Andy Sassine, Chief Financial Officer of Arcturus said, "I am pleased to announce the cash runway was extended to the first quarter 2027 due to disciplined cost management and progression of the CSL collaboration. This is the second sequential quarter our runway was extended without including any contributions from Kostaive® revenues or commercial milestones."

Recent Corporate Highlights

- In February 2024, the Company announced new COVID-19 sa-mRNA results in collaboration with CSL, demonstrating a longer duration of immunity compared to conventional COVID-19 mRNA vaccine booster. Short communication follows previously published data in *The Lancet Infectious Diseases* in December 2023. The randomized, double-blind, active-controlled study, conducted at 11 sites in Japan assessed the immunogenicity of Kostaive® and Comirnaty® at one, three- and six-months post-booster.

- The new analysis extends the time of observation of immune response from 3 months to 6 months post booster dose, demonstrating an advantage in antibody persistence of Kostaive® over Comirnaty against both the original Wuhan strain and the Omicron BA.4/5 variant.
- The superior immune response of Kostaive® in terms of magnitude and duration of antibody persistence was achieved with one sixth the dose of Comirnaty (5 µg vs 30 µg).

· In November, Japan's Ministry of Health, Labor and Welfare (MHLW) granted approval for Kostaive®, a self-amplifying mRNA COVID-19 vaccine for primary vaccination and booster for adults 18 years and older. This marks the first marketing approval milestone for CSL and Arcturus since signing the Collaboration and License agreement in November 2022.
  - The approval is based on positive clinical data from several Kostaive® studies, including a 16,000 subject efficacy study performed in Vietnam as well as a Phase 3 COVID-19 booster trial, which achieved higher immunogenicity results and a favorable safety profile compared to a standard mRNA COVID-19 vaccine comparator. The study results have been published in *The Lancet Infectious Diseases*.
· Kostaive® is anticipated to launch in Japan this year.
· In January 2024, the Company, under its collaboration with CSL, initiated a Phase 1 dose-finding study for ARCT-2138 (Quadrivalent LUNAR-FLU) seasonal influenza vaccine in healthy young and older adults.
· The Company continues to advance the development of ARCT-810, an mRNA therapeutic candidate for ornithine transcarbamylase (OTC) deficiency.
  - ARCT-810 Phase 1b single ascending dose study in the U.S. has completed enrollment and dosing of all cohorts (N = 16 patients).
  - ARCT-810 Phase 2 study in UK and Europe is enrolling up to 24 adolescents and adults with OTC deficiency. The ongoing study is evaluating two dose levels and includes up to six (6) bi-weekly administrations for each participant. The Company expects to share Phase 2 interim data by the end of Q2.
· In November 2023, Arcturus received Orphan Drug Designation from the U.S. FDA for ARCT-032, for the treatment of Cystic Fibrosis.
· In February 2024, Arcturus was granted Orphan Medicinal Product Designation from the European Commission for ARCT-032. ARCT-032 remains on track for Phase 1b interim data in Q2 2024.
· Based on the clinical and regulatory validation of LUNAR® and STARR® technologies provided by the approval of Kostaive® in Japan, the Company has initiated new vaccine discovery programs for Lyme Disease and Gonorrhea.

Financial Results for the Year Ended December 31, 2023

Revenues in conjunction with collaborations and grants:
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 year ended December 31, 2023, we reported revenue of $169.9 million compared with $206.0 million for the year ended December 31, 2022. Revenue recognized from CSL in 2023 was $157.4 million which slightly increased by $3.0 million compared to 2022. We made significant progress with the BARDA grant agreement that led to an increase in revenue of $8.8 million. The majority of the annual decrease in revenue was driven by the discontinuation of our collaboration agreements with Vinbiocare and Janssen. For the three months ended December 31, 2023, revenue recognized was $34.0 million compared with $160.3 million for the three months ended December 31, 2022. The $200.0 million up front payment for the execution of the CSL collaboration drove the majority of the revenue recognition during the three months ended December 31, 2022.

Operating expenses:
Total operating expenses for the year ended December 31, 2023, were $245.0 million compared with $193.8 million for the year ended December 31, 2022. For the three months ended December 31, 2023, operating expenses were $49.1 million compared with $38.8 million for the three months ended December 31, 2022.

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. Research and development expenses were $192.1 million for the year ended December 31, 2023, compared with $147.8 million for the year ended December 31, 2022. The increase in research and development expenses were primarily driven by the CSL and BARDA programs as well as our internal OTC and Cystic Fibrosis programs. Additionally, we have increased investments in early stage and discovery technologies. The Company initiated preclinical research related to its Lyme Disease and Gonorrhea vaccine discovery programs. Research and development expenses were $36.6 million for the three months ended December 31, 2023, compared with $27.0 million for the three months ended December 31, 2022. This increase was due to higher professional and personnel-related expenses as well as lower contra research and development expense from grants.

General and Administrative Expenses:
General and administrative expenses primarily consist of salaries and related benefits for our executive, administrative, legal and accounting functions and professional service fees for legal and accounting services as well as other general and administrative expenses. For the year ended December 31, 2023, general and administrative expenses were $52.9 million compared with $46.1 million for the year ended December 31, 2022. The annual increase was primarily due to personnel expenses as a result of increased headcount and salaries, travel and consulting expenses. Additionally, we incurred higher rent expenses associated with the new headquarters facility. General and administrative expenses were $12.5 million for the three months ended December 31, 2023, compared with $11.8 million for the three months ended December 31, 2022. The slight increase was due to personnel-related expenses.

Net Loss:
For the year ended December 31, 2023, we reported a net loss of approximately $26.6 million, or ($1.00) per diluted share, compared with net income of $9.3 million, or $0.35 per diluted share for the year ended December 31, 2022. For the three months ended December 31, 2023, we reported a net loss of approximately $8.6 million or ($0.32) per diluted share, compared with net income of $117.4 million or $4.33 per diluted share for the three months ended December 31, 2022.

Cash Position and Balance Sheet:
Cash, cash equivalents and restricted cash were $348.9 million at December 31, 2023, and $394.0 million at December 31, 2022. We have achieved a total of approximately $396.0 million in upfront payments and milestones from CSL as of December 31, 2023. We expect to continue to receive future milestone payments from CSL that will support 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.

Earnings Call: Thursday, March 7, 2024 @ 4:30 pm ET

- Domestic: 1-877-407-0784
- International: 1-201-689-8560
- Conference ID: 13744044
- 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 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 preclinical or clinical data will be predictive of future clinical results, including that the results from Kostaive® (or ARCT-154) will be predictive of results for updated versions of the vaccine, the potential commercial launch of Kostaive®, the continued advancement ARCT-032 or its potential as a treatment for any of the CF population, the continued advancement of ARCT-810, the anticipated timing and sharing of clinical data including for the Company's ARCT810 Phase 2 study and the ARCT-032 Phase 1b study, the continued efforts for our vaccine discovery programs for lyme disease or gonorrhea, the potential of the Company's platform technology to be meaningfully differentiated from other technologies, the continued progress of the LUNAR-FLU program, the ability to enroll participants in clinical studies including the Company's ARCT-810 and ARCT-032 programs, the likelihood and timing of commercial activities for the Company's LUNAR-COVID program, the likelihood that a patent will issue from any patent application, the likelihood or timing of collection of accounts receivables including expected 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
CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)	As of December 31, 2023	As of December 31, 2022
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 292,005	$ 391,883
Restricted cash	55,000	—
Accounts receivable	32,064	2,764
Prepaid expenses and other current assets	7,521	8,686
Total current assets	386,590	403,333
Property and equipment, net	12,427	12,415
Operating lease right-of-use asset, net	28,500	32,545
Non-current restricted cash	1,885	2,094
Total assets	$ 429,402	$ 450,387
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,279	$ 7,449
Accrued liabilities	31,881	30,232
Current portion of long-term debt	—	60,655
Deferred revenue	41,695	28,648
Total current liabilities	78,855	126,984
Deferred revenue, net of current portion	42,496	20,071
Operating lease liability, net of current portion	25,907	30,216
Other non-current liabilities	497	2,804
Total liabilities	147,755	180,075
Stockholders' equity:		
Common stock: $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 26,828 at December 31, 2023 and 26,555 at December 31, 2022	27	27
Additional paid-in capital	646,352	608,426
Accumulated deficit	(364,732)	(338,141)
Total stockholders' equity	281,647	270,312
Total liabilities and stockholders' equity	$ 429,402	$ 450,387

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

(in thousands, except per share data)	Year Ended December 31, 2023	2022	2021
Revenue:	(unaudited)		
Collaboration revenue	$ 160,882	$ 205,755	$ 12,359
Grant revenue	9,051	244	—
Total revenue	169,933	205,999	12,359
Operating expenses:			
Research and development, net	192,133	147,751	173,760
General and administrative	52,871	46,071	41,451
Total operating expenses	245,004	193,822	215,211
(Loss) income from operations	(75,071)	12,177	(202,852)
(Loss) gain from equity-method investment	—	(515)	515
(Loss) gain from foreign currency	(229)	(598)	584
Finance income (expense), net	16,591	(420)	(1,921)
Gain on debt extinguishment	33,953	—	—
Net (loss) income before income taxes	(24,756)	10,644	(203,674)
Provision for income taxes	1,835	1,295	—
Net (loss) income	$ (26,591)	$ 9,349	$ (203,674)
(Loss) earnings per share:			
Basic	$ (1.00)	$ 0.35	$ (7.74)
Diluted	$ (1.00)	$ 0.35	$ (7.74)
Weighted-average shares used in calculation of (loss) earnings per share:			
Basic	26,628	26,445	26,317
Diluted	26,628	27,093	26,317
Comprehensive (loss) income:			
Net (loss) income	$ (26,591)	$ 9,349	$ (203,674)
Comprehensive (loss) income:	$ (26,591)	$ 9,349	$ (203,674)

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

	Three Months Ended		
	December 31,		September 30,
(in thousands, except per share data)	2023	2022	2023
Revenue:			
Collaboration revenue	$ 28,212	$ 160,049	$ 43,376
Grant revenue	5,777	244	1,764
Total revenue	33,989	160,293	45,140
Operating expenses:			
Research and development, net	36,620	26,981	51,077
General and administrative	12,507	11,860	13,377
Total operating expenses	49,127	38,841	64,454
Income (loss) from operations	(15,138)	121,452	(19,314)
(Loss) gain from foreign currency	(54)	(3,835)	4
Finance expense, net	6,881	1,025	3,981
Net (loss) income before income taxes	(8,311)	118,642	(15,329)
Provision for income taxes	262	1,295	893
Net (loss) income	$ (8,573)	$ 117,347	$ (16,222)
(Loss) earnings per share:			
Basic	$ (0.32)	$ 4.43	$ (0.61)
Diluted	$ (0.32)	$ 4.33	$ (0.61)
Weighted-average shares used in calculation of (loss) earnings per share:			
Basic	26,628	26,508	26,574
Diluted	26,628	27,080	26,574
Comprehensive (loss) income:			
Net (loss) income	$ (8,573)	$ 117,347	$ (16,222)
Comprehensive (loss) income	$ (8,573)	$ 117,347	$ (16,222)

IR and Media Contacts
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