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): May 9, 2023

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 May 9, 2023, 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 March 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 contain 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 or 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 potential of ARCT-154 to offer effective or long-lasting protection against COVID-19 disease, the potential for the Company’s platform to result in novel vaccines or therapeutics, the anticipated timing and sharing of Phase 3 pivotal ARCT-154 results and data, the planned production of ARCT-154 doses, the likelihood and timing of regulatory approvals or orders for, or commercialization of, ARCT-154 in Japan or anywhere else, the planned submissions to regulatory authorities relating to ARCT- 154 including interim data, the anticipated enrollment of the ARCT-810 Phase 2 study, the anticipated sharing of interim Phase 2 data for ARCT-810, the anticipated expansion of the ARCT-032 study to allow the dosing of patients with CF and its anticipated enrollment, the potential of the LUNAR-HBV program, the likelihood of success of the collaboration with CSL Seqirus or any collaborations including the achievement of any milestones or other payments, the initiation or completion of any clinical trial, the likelihood that preclinical or clinical data will be predictive of future clinical results, the timing and nature of any study results, 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 Seqirus, its current cash position and expected cash burn 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 May 9, 2023
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: May 9, 2023

Arcturus Therapeutics Holdings Inc.

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

Arcturus Therapeutics Announces First Quarter 2023 Financial Update and Pipeline Progress

New Drug Application (NDA) for ARCT-154, a next generation COVID-19 vaccine, was submitted in Japan, leading to potential approval in 2023

$23.6 Million advanced for the manufacturing and supply of ARCT-154

ARCT-032 Phase 1 enrollment and administration completed successfully; trial expansion to include Cystic Fibrosis patients planned in third quarter

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

SAN DIEGO--May 9, 2023-- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a global late-stage clinical 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, 2023, and provided corporate updates.

"We are very pleased to announce the first NDA submission for the COVID-19 vaccine, ARCT-154, in Japan by Meiji Seika Pharma Co., Ltd., leading to potential approval later this year. ARCT-154 has the potential to offer effective and longer-lasting protection against COVID-19. We believe this meaningful milestone is indicative of the broader platform opportunity for our mRNA medicine technologies to result in novel vaccines and therapeutics over the coming years," said Joseph Payne, President & CEO of Arcturus Therapeutics. "We have also made meaningful operational and pipeline progress across several clinical and pre-clinical mRNA therapeutic programs with the completion of enrollment of a Phase 3 study evaluating the safety and immunogenicity of ARCT-154 as a booster against COVID-19 conducted by Meiji Seika Pharma in Japan, with interim results expected later this quarter."

In April 2023 we received an advance payment of $23.6 million for the manufacturing and supply of ARCT-154 from CSL Seqirus. The advance payment was for specified manufacturing runs of ARCT-154 which includes the drug substance utilized, as well as the reservation fees and related manufacturing requirements.

"As we mentioned on the year end conference call last month, we took a number of positive steps to improve our balance sheet this quarter with the elimination of $34 million in principal and accrued interest on the Singapore Loan," stated Andrew Sassine, Chief Financial Officer of Arcturus Therapeutics. "On March 31, 2023, we have no long-term debt on our balance sheet and current assets increased by $21 million sequentially due to $90 million in accounts receivable from CSL Seqirus which is expected to be collected during the second quarter of 2023. Consequently, I am happy to report that our cash runway continues to extend into the beginning of 2026 assuming no changes to our clinical programs and expected development milestones and do not include any expectations of commercial milestones or revenues."

Recent Corporate Highlights

- A New Drug Application (NDA) for ARCT-154 was submitted in April by Meiji Seika Pharma to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). This filing included a Phase 3 efficacy and safety study (N > 16,000), conducted in Vietnam that met its primary endpoint of prevention of COVID-19 disease during a period when there were multiple variants of concern.
- The ARCT-154 Phase 3 study being conducted by Meiji Seika Pharma has completed enrollment (N = 828). This non-inferiority study is designed to evaluate the safety and immunogenicity of ARCT-154 compared to Comirnaty® (Pfizer/BioNTech), administered as a booster dose. The interim analysis data will be submitted to the PMDA to seek registration of the ARCT-154 booster.
- In April, Meiji Seika Pharma entered into an agreement with CSL Seqirus whereby Meiji Seika Pharma will be responsible for the distribution and sales of ARCT-154 in Japan.
- ARCT-810, the Company's mRNA therapeutic candidate for ornithine transcarbamylase deficiency (OTC), is being evaluated in a Phase 2 multiple dose study, designed to enroll up to 24 adolescents and adults with OTC deficiency. The Phase 2 study is being conducted in the UK and Europe. The Company remains on track to share interim Phase 2 data on a subset of participants later in 2023.
- ARCT-032, the Company's inhaled mRNA therapeutic for cystic fibrosis (CF), has achieved the recruitment target and completed administration in a Phase 1 single ascending dosing study with 32 healthy participants (8 subjects per cohort). The safety and tolerability data support the study expansion and inclusion of patients with CF. Arcturus is amending the protocol to allow the dosing of patients with CF and expects to initiate the enrollment in Q3 2023.

Financial Results for the First Quarter Ended March 31, 2023

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. Total revenue for the three months ended March 31, 2023, was $80.3 million, compared with $5.2 million for the three months ended March 31, 2022. The increase in revenue is primarily attributable to an increase in revenue of $78.2 million related to the agreement with CSL Seqirus and the associated milestones achieved in the first quarter of 2023.

Operating expenses:
Total operating expenses for the three months ended March 31, 2023, were $65.5 million compared with $55.6 million for the three months ended March 31, 2022.

Research and development expenses:
Research and development expense was $51.8 million for the three months ended March 31, 2023, compared with $44.9 million in the comparable period last year, primarily reflecting increased manufacturing costs of $5.7 million, an increase of $2.3 million in personnel related expenses, an increase of travel and consulting expenses of $0.9 million, and increase in facility expenses of $0.7 million. The increases were offset by a decrease in clinical-related expenses of $4.4 million. We expect that our research and development efforts and associated costs will increase and continue to be substantial over the next several years as our pipeline progresses. Facilities and equipment expenses continue to increase as we expand. The three months ended March 31, 2023, includes increased rent and associated costs related to a new facility we took possession of in April 2022. Facilities and equipment expenses are expected to increase in the near term due to increased rent expenses related to our three facilities.

General and Administrative Expenses:
General and administrative expenses were $13.8 million for the three months ended March 31, 2023, compared with $10.7 million in the comparable period last year. The increase resulted primarily from personnel expenses due to increased headcount and salaries, increased travel and consulting expenses as well as increased rent expense associated with the new facility.

Net Income and other income and expense:
For the three months ended March 31, 2023, Arcturus reported net income of approximately $50.8 million, or $1.87 per diluted share, compared with a net loss of $51.2 million, or ($1.94) per diluted share in the three months ended March 31, 2022, and net income of $117.3 million, or $4.33 per diluted share in the three months ended December 31, 2022. We recorded a gain on debt extinguishment related to the Singapore Loan of $34.0 million during the three months ended March 31, 2023. Additionally, we reported net interest income of $2.5 million for the three months ended March 31, 2023.

Cash Position and Balance Sheet:
Cash, cash equivalents and restricted cash were $330.1 million as of March 31, 2023, $394.0 million on December 31, 2022, and $321.8 million on March 31, 2022. Additionally, we expect to collect $90.0 million in the second quarter of 2023, associated with the CSL Seqirus milestones which are in accounts receivable on March 31, 2023. In April we received $23.6 million related to the manufacturing and supply of ARCT-154 from CSL Seqirus. The cash runway remains extended through the beginning of 2026 based on the current pipeline and programs.

Tuesday, May 9, 2023 @ 4:30 p.m. ET
- Domestic: 1-888-886-7786
- International: 1-416-764-8658
- Conference ID: 70942720
- Webcast: Link

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 potential of ARCT-154 to offer effective or long-lasting protection against COVID-19 disease, the potential for the Company's platform to result in novel vaccines or therapeutics, the anticipated timing and sharing of Phase 3 pivotal ARCT-154 results and data, the planned production of ARCT-154 doses, the likelihood and timing of regulatory approvals or orders for, or commercialization of, ARCT-154 in Japan or anywhere else, the planned submissions to regulatory authorities relating to ARCT-154 including interim data, the anticipated enrollment of the ARCT-810 Phase 2 study, the anticipated sharing of interim Phase 2 data for ARCT-810, the anticipated expansion of the ARCT-032 study to allow the dosing of patients with CF and its anticipated enrollment, the potential of the LUNAR-HBV program, the likelihood of success of the collaboration with CSL Seqirus or any collaborations including the achievement of any milestones or other payments, the initiation or completion of any clinical trial, the likelihood that preclinical or clinical data will be predictive of future clinical results, the timing and nature of any study results, 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 Seqirus, its current cash position and expected cash burn 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.

IR and Media Contacts
Arcturus Therapeutics
Neda Safarzadeh
VP, Head of IR/PR/Marketing
(858) 900-2682
IR@ArcturusRx.com

Kendall Investor Relations
Carlo Tanzi, Ph.D.
(617) 914-0008
ctanzi@kendallir.com

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

(in thousands, except par value information)	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 327,935	$ 391,883
Accounts receivable	92,483	2,764
Prepaid expenses and other current assets	4,137	8,686
Total current assets	424,555	403,333
Property and equipment, net	12,635	12,415
Operating lease right-of-use asset, net	31,557	32,545
Non-current restricted cash	2,116	2,094
Total assets	$ 470,863	$ 450,387
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 19,344	$ 7,449
Accrued liabilities	32,293	30,232
Current portion of long-term debt	—	60,655
Deferred revenue	38,493	28,648
Total current liabilities	90,130	126,984
Deferred revenue, net of current portion	20,569	20,071
Operating lease liability, net of current portion	29,187	30,216
Other non-current liabilities	1,729	2,804
Total liabilities	$ 141,615	$ 180,075
Stockholders' equity		
Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 26,555 at March 31, 2023 and 26,555 at December 31, 2022	27	27
Additional paid-in capital	616,608	608,426
Accumulated deficit	(287,387)	(338,141)
Total stockholders' equity	329,248	270,312
Total liabilities and stockholders' equity	$ 470,863	$ 450,387

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

	Three Months Ended		
	March 31,		December 31,
(in thousands, except per share data)	2023	2022	2022
Revenue:			
Collaboration revenue	$ 79,729	$ 5,244	$ 160,049
Grant revenue	556	—	244
Total revenue	80,285	5,244	160,293
Operating expenses:			
Research and development, net*	51,768	44,893	26,981
General and administrative*	13,762	10,730	11,860
Total operating expenses	65,530	55,623	38,841
Income (loss) from operations	14,755	(50,379)	121,452
Loss from equity-method investment	—	(384)	—
(Loss) gain from foreign currency	(328)	158	(3,835)
Gain on debt extinguishment	33,953	—	—
Finance income (expense), net	2,477	(564)	1,025
Net income (loss) before income taxes	50,857	(51,169)	118,642
Provision (benefit) for income taxes	103	—	1,295
Net income (loss)	50,754	(51,169)	117,347
Earnings (loss) per share:			
Basic	$ 1.91	$ (1.94)	$ 4.43
Diluted	$ 1.87	$ (1.94)	$ 4.33
Weighted-average shares used in calculation of earnings (loss) per share:			
Basic	26,555	26,376	26,508
Diluted	27,149	26,376	27,080
Comprehensive income (loss):			
Net income (loss)	50,754	(51,169)	117,347
Comprehensive income (loss)	$ 50,754	$ (51,169)	$ 117,347

*Includes share-based compensation expense as follows:

	Three Months Ended		
	March 31,		December 31,
(in thousands)	2023	2022	2022
Research and development	$ 3,508	$ 3,455	$ 3,270
General and administrative	4,674	3,916	3,260