

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 28, 2023

**ARCTURUS THERAPEUTICS HOLDINGS INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-38942  
(Commission  
File Number)

32-0595345  
(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 28, 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 December 31, 2022 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 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 or 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 receipt of \$90 million in milestone payments from CSL Seqirus, the period of the Company’s cash runway, the anticipated timing and filing of a J-NDA submission and opportunity for Japanese regulatory PMDA approval of ARCT-154, the sharing of interim Phase 2 data for ARCT-810, the anticipated timing and completion of study enrollment in the ARCT-032 Phase 1 study, the likelihood of success of the collaboration with CSL Seqirus or any collaborations including the achievement of any milestones or other payments, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood that results to date for ARCT-154 or any other clinical candidate 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, 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](http://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
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99.1	<a href="#">Press Release dated March 28, 2023</a>
104	Cover Page to this Current Report on Form 8-K in Inline XBRL

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**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 28, 2023

**Arcturus Therapeutics Holdings Inc.**

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

## Arcturus Therapeutics Announces Fourth Quarter 2022 Financial Update and Pipeline Progress

*\$200 million upfront payment received in December 2022 from CSL collaboration*

*Achieved \$90 million in development milestones in March 2023 under CSL collaboration*

*ARCT-154 Phase 3 COVID-19 booster trial enrollment completed in Japan*

*Multiple patients enrolled in ARCT-810 Phase 2 multiple ascending dose trial for OTC deficiency*

*ARCT-032 Phase 1 Cystic Fibrosis trial initiated and enrollment of first two cohorts successfully completed*

*Investor conference call at 4:30 p.m. EST today*

SAN DIEGO--Mar. 28, 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 fourth quarter ended December 31, 2022, and provided corporate updates.

“Arcturus has continued to make remarkable operational and pipeline progress. This was recently exemplified by the completion of the initial objectives with our partnered COVID-19 and Flu vaccine programs with CSL,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “We are also pleased to report the completion of full enrollment ahead of schedule in the Phase 3 study being conducted by Meiji Pharma to evaluate ARCT-154 as a booster vaccine for COVID-19.”

“Within the first four months of our CSL collaboration, we successfully achieved multiple program objectives, triggering \$90 million in milestone payments,” said Andrew Sassine, CFO of Arcturus Therapeutics, “Additionally, with the elimination of \$33.3 million of non-recourse debt to Singapore, our cash runway now extends into the beginning of 2026.”

### Recent Corporate Highlights

- In December 2022, the Company received a \$200 million upfront payment associated with the exclusive global collaboration and license agreement with CSL Seqirus, for the research, development, manufacture, and commercialization of next generation mRNA vaccines. Arcturus is eligible to receive up to \$4.3 billion in potential development and commercial milestones if all products are registered in the licensed fields, 40% profit sharing for COVID-19 vaccines and up to low double-digit royalties on influenza vaccine revenues.
  - Arcturus achieved development milestones in March 2023, including milestones associated with nominating next generation vaccine candidates, resulting in \$90 million invoiced to CSL Seqirus.
  - In December 2022, the Company announced an agreement with Meiji Pharma to conduct a Phase 3 comparative study to evaluate the safety and immunogenicity of ARCT-154, a self-amplifying mRNA vaccine, as a booster for COVID-19. The ARCT-154 Phase 3 non-inferiority study, now fully enrolled, is being conducted in Japan to compare the immunogenicity of ARCT-154 to Comirnaty® (Pfizer/BioNTech) in over 800 adult participants. Meiji Pharma and the Japanese government are funding the study.
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- ARCT-810, the Company's mRNA therapeutic candidate for OTC deficiency, is being evaluated in a Phase 2 study, presently enrolling up to 24 adolescents and adults with OTC deficiency. The Phase 2 study is being conducted in the UK and Europe and 9 sites in 6 countries have been activated to date. Multiple patients have been enrolled. The study is designed to evaluate two dose levels and allow for six (6) bi-weekly administrations for each participant. The Company expects 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, has advanced to a Phase 1 study, presently enrolling up to 32 participants in New Zealand. The primary objective of this study is to assess safety and tolerability at four (4) dose levels. The first two cohorts have been dosed successfully with no significant adverse events reported to date. The Company expects to complete the full 32 subject study enrollment in Q2 2023.
- Arcturus will present LUNAR-HBV pre-clinical gene editing mRNA platform data for Hepatitis B Virus on April 27, 2023, at the 18<sup>th</sup> annual Global Hepatitis Summit Conference in Paris, France.

## **Financial Results for Fourth Quarter and Year Ended December 31, 2022**

**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. For the three months ended December 31, 2022, the Company reported revenue of \$160.3 million compared with \$5.8 million for the three months ended December 31, 2021, and \$13.4 million for the three months ended September 30, 2022. Total revenue for the year ended December 31, 2022, was \$206.0 million compared with \$12.4 million for the year ended December 31, 2021. The increase in fourth quarter and year-over-year revenues primarily relates to the \$200 million upfront payment we received from the CSL transaction.

**Operating expenses:** Total operating expenses for the three months ended December 31, 2022, were \$38.8 million compared with \$43.4 million for the three months ended December 31, 2021, and \$50.2 million for the three months ended September 30, 2022. The decline in operating expenses when compared to the three months ended December 31, 2021, was primarily due to lower Covid-19 manufacturing and clinical related expenses. Total operating expenses for the year ended December 31, 2022, were \$193.8 million compared with \$215.2 million for the year ended December 31, 2021.

**Research and development expenses:** Research and development expenses for the three months ended December 31, 2022, were \$27.0 million compared with \$32.6 million for the three months ended December 31, 2021, and \$37.7 million for the three months ended September 30, 2022. The decline in research and development expenses when compared to the three months ended December 31, 2021, was primarily due to lower Covid-19 manufacturing and clinical related expenses. Research and development expenses for the year ended December 31, 2022, were \$147.8 million compared with \$173.8 million for the year ended December 31, 2021.

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**Net Income:** For the three months ended December 31, 2022, Arcturus reported net income of approximately \$117.3 million or \$4.33 per diluted share, compared with a net loss of \$38.7 million, or \$1.47 per diluted share in the three months ended December 31, 2021, and a net loss of \$35.3 million, or \$1.33 per diluted share in the three months ended September 30, 2022. For the year ended December 31, 2022, Arcturus reported a net income of approximately \$9.3 million, or \$0.35 per diluted share, compared with a net loss of \$203.7 million, or \$7.74 per diluted share in the year ended December 31, 2021.

**Cash Position and Balance Sheet:** The Company's cash balance totaled \$391.9 million at December 31, 2022, compared to a cash balance of \$370.5 million at December 31, 2021. In March 2023, the Company repaid Singapore \$17.1 million which triggered the elimination of \$33.3 million in non-recourse debt pertaining to the ARCT-021 program.

**Thursday, March 28, 2023 @ 4:30 pm EST**

Domestic: 1-877-407-0784

International: 1-201-689-8560

Conference ID: 13735876

Webcast: [Link](#)

### **About Arcturus Therapeutics**

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a global late-stage clinical mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology (samRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase (OTC) 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 (patents and patent applications issued in the U.S., Europe, Japan, China, and other countries). For more information, visit [www.ArcturusRx.com](http://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 receipt of \$90 million in milestone payments from CSL Seqirus, the period of the Company's cash runway, the anticipated timing and filing of a J-NDA submission and opportunity for Japanese regulatory PMDA approval of ARCT-154, the sharing of interim Phase 2 data for ARCT-810, the anticipated timing and completion of study enrollment in the ARCT-032 Phase 1 study, the likelihood of success of the collaboration with CSL Seqirus or any collaborations including the achievement of any milestones or other payments, the likelihood that preclinical or clinical data will be predictive of future clinical results, the likelihood that results to date for ARCT-154 or any other clinical candidate 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, 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](http://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.

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**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**

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

(in thousands, except par value information)	December 31, 2022	September 30, 2022 (unaudited)	December 31, 2021
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 391,883	\$ 237,676	\$ 370,492
Accounts receivable	2,764	2,044	3,367
Prepaid expenses and other current assets	8,686	6,960	5,102
Total current assets	403,333	246,680	378,961
Property and equipment, net	12,415	11,347	5,643
Operating lease right-of-use asset, net	32,545	33,519	5,618
Equity-method investment	—	—	515
Non-current restricted cash	2,094	2,081	2,077
<b>Total assets</b>	<b>\$ 450,387</b>	<b>\$ 293,627</b>	<b>\$ 392,814</b>
<b>Liabilities and Stockholders' Equity</b>			
Current liabilities:			
Accounts payable	\$ 7,449	\$ 17,962	\$ 10,058
Accrued liabilities	30,232	25,529	23,523
Current portion of long-term debt	60,655	27,702	22,474
Deferred revenue	28,648	4,656	43,482
Total current liabilities	126,984	75,849	99,537
Deferred revenue, net of current portion	20,071	5,179	19,931
Long-term debt, net of current portion	—	32,038	40,633
Operating lease liability, net of current portion	30,216	31,218	4,502
Other non-current liabilities	2,804	3,676	—
<b>Total liabilities</b>	<b>180,075</b>	<b>147,960</b>	<b>164,603</b>
Stockholders' equity:			
Common stock: \$0.001 par value; 60,000 shares authorized; issued and outstanding shares were 26,555 at December 31, 2022, 26,492 at September 30, 2022 and 26,372 at December 31, 2021	27	26	26
Additional paid-in capital	608,426	601,129	575,675
Accumulated deficit	(338,141)	(455,488)	(347,490)
<b>Total stockholders' equity</b>	<b>270,312</b>	<b>145,667</b>	<b>228,211</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 450,387</b>	<b>\$ 293,627</b>	<b>\$ 392,814</b>



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

(in thousands, except per share data)	<b>Three Months Ended</b>		
	<b>December 31,</b>		<b>September 30,</b>
	<b>2022</b>	<b>2021</b>	<b>2022</b>
<b>Revenue:</b>			
Collaboration revenue	\$ 160,049	\$ 5,794	\$ 13,369
Grant revenue	244	—	—
Total revenue	<u>160,293</u>	<u>5,794</u>	<u>13,369</u>
<b>Operating expenses:</b>			
Research and development, net	26,981	32,633	37,688
General and administrative	11,860	10,806	12,488
Total operating expenses	<u>38,841</u>	<u>43,439</u>	<u>50,176</u>
Income (loss) from operations	121,452	(37,645)	(36,807)
(Loss) gain from equity-method investment	—	(156)	—
(Loss) gain from foreign currency	(3,835)	(337)	1,862
Finance expense, net	1,025	(525)	(321)
Net income (loss) before income taxes	118,642	(38,663)	(35,266)
Provision for income taxes	1,295	—	—
Net income (loss)	<u>\$ 117,347</u>	<u>\$ (38,663)</u>	<u>\$ (35,266)</u>
<b>Earnings (loss) per share:</b>			
Basic	\$ 4.43	\$ (1.47)	\$ (1.33)
Diluted	\$ 4.33	\$ (1.47)	\$ (1.33)
<b>Weighted-average shares used in calculation of earnings (loss) per share:</b>			
Basic	26,508	26,359	26,467
Diluted	27,080	26,359	26,467
<b>Comprehensive income (loss):</b>			
Net income (loss)	<u>\$ 117,347</u>	<u>\$ (38,663)</u>	<u>\$ (35,266)</u>
Comprehensive income (loss)	<u>\$ 117,347</u>	<u>\$ (38,663)</u>	<u>\$ (35,266)</u>

**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,	
	2022	2021
<b>Revenue:</b>		
Collaboration revenue	\$ 205,755	\$ 12,359
Grant revenue	244	—
Total revenue	205,999	12,359
<b>Operating expenses:</b>		
Research and development, net	147,751	173,760
General and administrative	46,071	41,451
Total operating expenses	193,822	215,211
Income (loss) from operations	12,177	(202,852)
(Loss) gain from equity-method investment	(515)	515
(Loss) gain from foreign currency	(598)	584
Finance expense, net	(420)	(1,921)
Net income (loss) before income taxes	10,644	(203,674)
Provision for income taxes	1,295	—
Net income (loss)	\$ 9,349	\$ (203,674)
<b>Earnings (loss) per share:</b>		
Basic	\$ 0.35	\$ (7.74)
Diluted	\$ 0.35	\$ (7.74)
<b>Weighted-average shares used in calculation of earnings (loss) per share:</b>		
Basic	26,445	26,317
Diluted	27,093	26,317
<b>Comprehensive income (loss):</b>		
Net income (loss)	\$ 9,349	\$ (203,674)
Comprehensive income (loss)	\$ 9,349	\$ (203,674)