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): November 14, 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 November 14, 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 September 30, 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 (the "Securities Act"). 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 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 ARCALIS will receive all, or any portion of, the funding under awards from the Japanese government, the continued progress of ARCALIS and expectations for ARCALIS's facility, the anticipated conduct, including continued enrollment, of the ARCT-032 study, the results of the ARCT-032 study, the likelihood of the CF program to provide benefit to the CF population, the continued progress of the LUNAR-FLU program, the likelihood and timing of regulatory approvals of any products including ARCT-154 in Japan or anywhere else, the likelihood that preclinical or clinical data will be predictive of future clinical results, the anticipated receipt of $35 million from CSL for a milestone, likelihood of a commercial launch for the COVID vaccine platform and schedule therefor, the timing for completion of the Phase 3 bivalent COVID vaccine trial, the Company's continued commitment to ARCT-810, the timing of the final database lock for the ARCT-810 Phase 1b study, the completion of enrollment of, and timing for interim data from, the ARCT-810 Phase 2 study, the Company's continued advancement of ARCT-032, the enrollment of the Phase 1b clinical study of ARCT-032, the likelihood that ARCT-032 will be approved or provide Arcturus with a priority review voucher, the likelihood of achieving future milestones under the CSL Seqirus collaboration, the anticipated expenses of the Company and the expected timelines for a manufacturing technology transfer to CSL, 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 November 14, 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: November 14, 2023

Arcturus Therapeutics Holdings Inc.

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

Arcturus Therapeutics Announces Third Quarter 2023 Financial Update

and Pipeline Progress

Expected cash runway extended to the end of 2026

$35 million milestone achieved under CSL collaboration

ARCT-154 remains on track for Japan-NDA approval in December

Enrollment target reached in Phase 3 bivalent COVID vaccine comparison trial

Enrollment initiated in ARCT-032 Phase 1b study; dosing first cystic fibrosis patient this month

ARCT-032 received Rare Pediatric Disease Designation for cystic fibrosis from the FDA

Investor conference call at 4:30 p.m. ET November 14, 2023

SAN DIEGO--(BUSINESS WIRE)--Nov. 14, 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 third quarter ended Sept. 30, 2023, and provided corporate updates.

“We had considerable progress this quarter expanding our next generation STARR® vaccine platform,” said Joseph Payne, President & CEO of Arcturus Therapeutics. “Our monovalent ARCT-154 COVID vaccine remains on track for approval in December and we reached our target enrollment for the bivalent COVID vaccine Phase 3 study, with PMDA-approval anticipated Q3 2024.”

Mr. Payne continued: “We have also advanced our mRNA therapeutic pipeline with the scheduled dosing of our first participant in our Phase 1b study with ARCT-032, an inhaled mRNA therapeutic candidate for individuals with cystic fibrosis. This study will advance our understanding of the safety and tolerability of ARCT-032 in patients. It advances our effort to provide benefit to the CF population with the largest unmet need, including those who are not candidates for any of the currently approved CFTR modulators.”

“We are happy to announce our expected cash runway was extended to the end of 2026,” announced Andrew Sassine, Chief Financial Officer. “A combination of lower expenses, additional development milestones and accelerated timelines for manufacturing technology transfer to CSL have contributed to the extended runway. Additionally, substantial funding was obtained by ARCALIS, our joint venture mRNA manufacturing partner, from the Japanese Government with up to $165 million committed to date. We expect this facility to become a leading manufacturer of mRNA-based vaccines and therapeutics, with the ability to manufacture vaccines within 100 days of an emerging viral strain.”

Recent Corporate Highlights

- Updated preliminary Phase 3 COVID-19 booster data were presented at the 11th International mRNA Health Conference in Berlin. In comparison to an FDA-approved monovalent mRNA vaccine, monovalent ARCT-154 showed multi-fold improvement in durability and multi-fold superior titers of neutralizing antibodies against Omicron BA.4/5 at 6 months post-boost. The Phase 3 booster durability data were consistent with the Phase 1/2 booster clinical trial durability data collected previously which were presented at the 9th ESWI Influenza Conference in Valencia.
- ARCALIS Inc., the Company's manufacturing joint venture in Japan to support the production of mRNA vaccines and therapeutics, continues to make operational progress while also obtaining financial support from the Japanese government. ARCALIS has completed the construction of a state-of-the-art mRNA drug substance manufacturing facility and based on additional funds from the Japanese government announced in August 2023, construction of an associated DNA template manufacturing facility is underway. In total to date, up to $165 million has been awarded to ARCALIS by the Japanese government to build mRNA Drug Substance and mRNA-based Drug Product manufacturing capabilities, and to construct a DNA template manufacturing facility.
- The LUNAR-FLU (ARCT-2138) program continues to progress with funding and operational support from CSL. LUNAR-FLU utilizes Arcturus' validated next-generation STARR® mRNA platform. Initiation of a Phase 1 clinical trial (N = 132) is expected to begin soon.
- Arcturus achieved a milestone for $35 million and anticipates receipt from CSL in November 2023. The milestone payment will be used to fund development activities for the LUNAR-COV19 vaccine program under its collaboration with CSL.
- The anticipated global commercial launch schedule for the Company's validated, next generation STARR® mRNA COVID vaccine platform has recently been presented by CSL with anticipated marketing authorization approvals expected to occur between 2024-2026 in key markets such as Japan, EU, United Kingdom, and the U.S.
- The initial enrollment target of 850 participants has been reached in a Phase 3 bivalent COVID vaccine trial designed to compare immunogenicity to bivalent Comirnaty®. The enrollment process will be completed in November 2023.
- The Company remains committed to 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). Arcturus expects the final database lock to occur in the fourth quarter of 2023.
    - ARCT-810 Phase 2 study in UK and Europe will enroll 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.
    - Updated guidance of interim Phase 2 data in H1 2024 and taking various actions to address the continued challenging enrollment rate in Europe, by adding study sites and patient services.
- The Company is advancing ARCT-032, an inhaled mRNA therapeutic candidate for cystic fibrosis formulated with Arcturus' LUNAR® delivery technology.
    - Completed dosing in a Phase 1 study in New Zealand of 32 healthy subjects across four (4) ascending single-dose cohorts.
    - Phase 1b enrollment initiated October 2023, with dosing of first participant scheduled this month. The study is designed to enroll up to 8 adults with cystic fibrosis, with each participant receiving two administrations of ARCT-032.
    - In September 2023, the CF Foundation agreed to increase its financial commitment to $25 million to advance ARCT-032.
    - In October 2023, ARCT-032 received Rare Pediatric Disease Designation from the FDA. As such, if ARCT-032 achieves FDA approval for a pediatric indication, Arcturus is eligible to receive a priority review voucher of a subsequent marketing application for a different product.
    - New proof of activity *in vivo* (G551D CF Ferret model) data presented at the North American Cystic Fibrosis Conference (NACFC) in November. The ferrets in the study require continuous treatment with the CFTR modulator Kalydeco® to prevent disease progression. A single administration of ARCT-032 showed successful transfection of airway epithelial cells and restoration of mucociliary clearance above the level maintained with Kalydeco.

Financial Results for the Three and Nine Months Ended September 30, 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. For the three months ended September 30, 2023, we reported revenue of $45.1 million compared with $13.4 million for the three months September 30, 2022. Revenue increased by $31.7 million during the three months ended September 30, 2023, as compared to the prior year period. The increase was primarily attributable to revenue recognized from the collaboration agreement with CSL Seqirus and grant revenue recognized from the agreement with BARDA. Revenue increased by $90.3 million during the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022. The increase was attributable to an increase in revenue of $133.0 million primarily related to the collaboration agreement with CSL Seqirus. This increase was primarily offset by less revenues in 2023 from other COVID program customers.

Operating expenses:
Total operating expenses for the three months ended September 30, 2023, were $64.5 million compared with $50.2 million for the three months ended September 30, 2022. Total operating expenses for the nine months ended September 30, 2023, were $195.9 million compared with $155.0 million for the nine months ended September 30, 2022.

Research and development expenses:
Our 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 $51.1 million for the three months ended September 30, 2023, compared with $37.7 million in the comparable period last year, primarily reflecting increased clinical research and manufacturing costs of $11.6 million and an increase of $2.0 million in personnel related expenses. Research and development expenses were $155.5 million for the nine months ended September 30, 2023, compared with $120.8 million in the comparable period last year, primarily reflecting increased manufacturing costs of $27.8 million.

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. General and administrative expenses were $13.4 million and $40.4 million for the three and nine months ended September 30, 2023, respectively, compared with $12.5 million and $34.2 million in the comparable periods last year. The increases 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 Loss:
For the three months ended September 30, 2023, Arcturus reported a net loss of approximately $16.2 million, or ($0.61) per diluted share, compared with a net loss of $35.3 million, or ($1.33) per diluted share in the three months ended September 30, 2022. For the nine months ended September 30, 2023, Arcturus reported a net loss of approximately $18.0 million, or ($0.68) per diluted share, compared with a net loss of $108.0 million, or ($4.09) per diluted share in the nine months ended September 30, 2022.

Cash Position and Balance Sheet:
Cash, cash equivalents and restricted cash were $369.1 million as of September 30, 2023, and $394.0 million on December 31, 2022. We have achieved a total of approximately $365.0 million in upfront payments and milestones from CSL Seqirus as of September 30, 2023. We expect to continue to receive future milestone payments from CSL Seqirus that will support the ongoing development of the covid, flu and three other respiratory vaccine programs. The expected cash runway extends to the end of 2026 based on the current pipeline and programs.

Earnings Call: Tuesday, November 14, 2023 @ 4:30 pm ET

- Domestic: 1-877-407-0784
- International: 1-201-689-8560
- Conference ID: 13740896
- 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 (sa-mRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. The Company 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 (patents and patent applications issued 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 ARCALIS will receive all, or any portion of, the funding under awards from the Japanese government, the continued progress of ARCALIS and expectations for ARCALIS's facility, the anticipated conduct, including continued enrollment, of the ARCT-032 study, the results of the ARCT-032 study, the likelihood of the CF program to provide benefit to the CF population, the continued progress of the LUNAR-FLU program, the likelihood and timing of regulatory approvals of any products including ARCT-154 in Japan or anywhere else, the likelihood that preclinical or clinical data will be predictive of future clinical results, the anticipated receipt of $35 million from CSL for a milestone, likelihood of a commercial launch for the COVID vaccine platform and schedule therefor, the timing for completion of the Phase 3 bivalent COVID vaccine trial, the Company's continued commitment to ARCT-810, the timing of the final database lock for the ARCT-810 Phase 1b study, the completion of enrollment of, and timing for interim data from, the ARCT-810 Phase 2 study, the Company's continued advancement of ARCT-032, the enrollment of the Phase 1b clinical study of ARCT-032, the likelihood that ARCT-032 will be approved or provide Arcturus with a priority review voucher, the likelihood of achieving future milestones under the CSL Seqirus collaboration, the anticipated expenses of the Company and the expected timelines for a manufacturing technology transfer to CSL, 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.

Trademark Acknowledgements

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

(in thousands, except par value information)	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 311,918	$ 391,883
Restricted cash	35,000	—
Accounts receivable	38,220	2,764
Prepaid expenses and other current assets	8,130	8,686
Total current assets	393,268	403,333
Property and equipment, net	12,715	12,415
Operating lease right-of-use asset, net	29,534	32,545
Non-current restricted cash	22,133	2,094
Total assets	$ 457,650	$ 450,387
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 18,362	$ 7,449
Accrued liabilities	28,553	30,232
Current portion of long-term debt	—	60,655
Deferred revenue	40,768	28,648
Total current liabilities	87,683	126,984
Deferred revenue, net of current portion	41,911	20,071
Long-term debt	20,000	—
Operating lease liability, net of current portion	27,018	30,216
Other non-current liabilities	976	2,804
Total liabilities	177,588	180,075
Stockholders' equity		
Common stock, $0.001 par value; 60,000 shares authorized; issued and outstanding shares were 26,723 at September 30, 2023 and 26,555 at December 31, 2022	27	27
Additional paid-in capital	636,194	608,426
Accumulated deficit	(356,159)	(338,141)
Total stockholders' equity	280,062	270,312
Total liabilities and stockholders' equity	$ 457,650	$ 450,387

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

(in thousands, except per share data)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Revenue:				
Collaboration revenue	$ 43,376	$ 13,369	$ 132,670	$ 45,706
Grant revenue	1,764	—	3,274	—
Total revenue	45,140	13,369	135,944	45,706
Operating expenses:				
Research and development, net	51,077	37,688	155,513	120,770
General and administrative	13,377	12,488	40,364	34,211
Total operating expenses	64,454	50,176	195,877	154,981
Loss from operations	(19,314)	(36,807)	(59,933)	(109,275)
Loss from equity-method investment	—	—	—	(515)
Gain (loss) from foreign currency	4	1,862	(175)	3,237
Gain on debt extinguishment	—	—	33,953	—
Finance income (expense), net	3,981	(321)	9,710	(1,445)
Net loss before income taxes	(15,329)	(35,266)	(16,445)	(107,998)
Provision for income taxes	893	—	1,573	—
Net loss	$ (16,222)	$ (35,266)	$ (18,018)	$ (107,998)
Net loss per share, basic and diluted	$ (0.61)	$ (1.33)	$ (0.68)	$ (4.09)
Weighted-average shares outstanding, basic and diluted	26,574	26,467	26,559	26,423
Comprehensive loss:				
Net loss	$ (16,222)	$ (35,266)	$ (18,018)	$ (107,998)
Comprehensive loss	$ (16,222)	$ (35,266)	$ (18,018)	$ (107,998)

IR and Media Contacts
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