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 8, 2021

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

(Former name or former address, if changed since last report)

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 8, 2021, 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, 2021 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 and the Press Release, are forward-looking statements, including those regarding strategy, future operations, the expectations for or likelihood of success of any collaborations (including with respect to LUNAR-HBV), the likelihood of success (including safety and efficacy) of the Company’s pipeline (including LUNAR-FLU, ARCT-021, ARCT-032, ARCT-154, ARCT-165 and ARCT-810), anticipated sponsorship and/or funding of clinical trials of the Company’s candidates, the Company’s efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company’s mRNA therapeutics, the planned initiation, design or completion of clinical trials, the likelihood that the Company will obtain clearance from regulatory authorities to proceed with future planned clinical trials, the likelihood that preclinical or clinical data will be predictive of future clinical results (including with respect to safety, immunogenicity and efficacy), the ability to enroll, and timing for enrollment of, subjects in clinical trials, the timing and nature of any study results, the likelihood that clinical data will be sufficient for regulatory approval or completed in time to submit an application for regulatory approval within a particular timeframe, the likelihood or timing of any regulatory approval, the Company’s manufacturing plans or technologies (including with its partner, Vinbiotech), the likelihood that a patent will issue from any patent application, its current cash position and adequacy of its capital to support future operations, 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 for the fiscal year ended December 31, 2020 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 made in this Current Report on Form 8-K and the Press Release, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

The statements made in this Current Report on Form 8-K and the Press Release speak only as of the date stated herein, and subsequent events and developments may cause the Company's expectations and beliefs to change. While the Company may elect to update these forward-looking statements publicly at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date stated herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description of Exhibit**
99.1	Press Release dated November 8, 2021
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: November 8, 2021

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

Arcturus Therapeutics Announces Third Quarter 2021 Financial Update and Pipeline Progress

Phase 1/2/3a and 3b study of ARCT-154 COVID-19 vaccine candidate completed enrollment with over 17,000 participants

Initiated ~2,000 participant ARCT-154 Phase 3c sub-study to compare immunogenicity noninferiority to AstraZeneca COVID-19 vaccine; enrollment to be completed this week

Preparing to file Emergency Use Authorization (EUA) application for ARCT-154, pending interim study results, with the Vietnam Ministry of Health in December 2021; potential for EUA approval in Q1 2022

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

San Diego, Calif., Nov. 8, 2021 – Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the development of infectious disease vaccines and significant opportunities within liver and respiratory rare diseases, today announced its financial results for the third quarter ended September 30, 2021 and provided corporate updates.

"We are extremely pleased to have rapidly completed full enrollment of the Phase 1/2/3a and 3b cohorts and are looking forward to completing enrollment in the Phase 3c sub-study of the ARCT-154 pivotal trial this week, in collaboration with Vinbiotech. Assuming favorable data, we look forward to filing for Emergency Use Authorization as soon as December of this year," said Joseph Payne, President and CEO of Arcturus Therapeutics. "ARCT-154 has an attractive and differentiated profile as a low dose, self-amplifying mRNA vaccine candidate that targets multiple SARS-CoV2 variants of concern, and we are working diligently with our global manufacturing partners to make it available as soon as possible."

Recent Corporate Highlights

- In August, Arcturus, together with Vinbiotech, advanced ARCT-154 into a Phase 1/2/3 study in Vietnam.
- In October, Arcturus received approval to proceed with enrollment of the Phase 3b cohort of the study following a review by the Vietnam Ministry of Health of early safety data from the initial 1,000 participants enrolled in the Phase 1/2/3a cohorts.
- In November, the Phase 3b cohort of this randomized, placebo-controlled portion of the trial was modified to enroll approximately 16,000 participants with a Phase 3c sub-study of approximately 2,000 participants added to evaluate immunogenicity noninferiority compared to AstraZeneca COVID-19 vaccine. This sub-study provides an additional path to potential full approval.
- The Phase 3b cohort is now fully enrolled. Enrollment in the Phase 3c sub-study is underway and expected to be completed this week.
- All phases (1, 2, 3a, 3b and 3c) of the ARCT-154 clinical trial in Vietnam are sponsored and funded by Arcturus' partner Vinbiotech.
- Arcturus and Vinbiotech continue to make progress towards completion of a manufacturing facility in Hanoi capable of producing 200 million doses per year, and technology transfer for commercial manufacturing is in process.

- In August, Arcturus announced approval from the Singapore Health Sciences Authority (HSA) to advance ARCT-154 and ARCT-165 into a Phase 1/2 clinical trial to evaluate the vaccines both as a primary vaccination series and as a booster following initial vaccination with Comirnaty®. This study was also approved by U.S. Food and Drug Administration (FDA). The Comirnaty booster cohort (with ARCT-021, ARCT-154, ARCT-165) in this study is now fully enrolled. Previously disclosed preclinical data demonstrate that ARCT-154 elicits strong neutralizing immunogenicity in non-human primates to SARS-CoV-2 Alpha, Beta, Gamma, and Delta variants.
- ARCT-021 has been selected by a global entity for inclusion in a multinational Phase 3 vaccine trial against COVID-19.
- In October, we successfully achieved a milestone in our ongoing LUNAR-HBV program licensed by Janssen Pharmaceuticals (a subsidiary of Johnson and Johnson) and anticipate receiving one million dollars in the fourth quarter.
- In July, Arcturus announced approval from the UK Health Research Authority to advance ARCT-810, a novel mRNA-based therapeutic candidate for Ornithine Transcarbamylase (OTC) Deficiency, into a multi-dose Phase 2 clinical study. The ARCT-810 Phase 2 study is a randomized, double-blind, placebo-controlled, nested single and multiple ascending dose study designed to enroll 24 adolescents and adults with OTC deficiency. We anticipate dosing will commence in the first quarter of 2022 and remain on track for interim data in the second half of 2022.
- ARCT-032, our mRNA therapeutic candidate for cystic fibrosis, is on track for a Clinical Trial Application (CTA) in first half of 2022.
- The LUNAR-FLU mRNA vaccine candidate targeting influenza is on track for a CTA in the second half of 2022.

Financial Results for the Quarter Ended September 30, 2021

Revenues in conjunction with strategic alliances and collaborations: Arcturus' primary sources of revenues were from license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended September 30, 2021, the Company reported revenue of $2.4 million, compared with $2.3 million in the three months ended September 30, 2020 and $2.0 million for the three months ended June 30, 2021.

Operating expenses: Total operating expenses for the three months ended September 30, 2021, were $56.3 million compared with $23.3 million for the three months ended September 30, 2020 and $55.7 million for the three months ended June 30, 2021.

Research and development expenses increased to $45.4 million year over year compared to $17.7 million from the third quarter of 2020. Research and development expenses were relatively consistent compared to $45.7 million in the second quarter of 2021.

For the three months ended September 30, 2021, Arcturus reported a net loss of approximately $54.1 million, or ($2.05) per basic and diluted share, compared with a net loss of $21 million, or ($0.92) per basic and diluted share in the three months ended September 30, 2020 and a net loss of $54.6 million, or ($2.07) per basic and diluted share in the three months ended June 30, 2021.

The Company's cash balance totaled $413.9 million as of September 30, 2021, compared to a cash balance of $433.6 million at June 30, 2021 and $462.9 million at December 31, 2020. The cash balance includes $40 million received from Vinbiotech Research and Manufacture Joint Stock Company, of which $30 million was received during the current quarter ended September 30, 2021. Based on the current pipeline, the Company's cash position is expected to be sufficient to support operations for two years.

Monday, Nov. 8 at 4:30 p.m. ET
Domestic: 877-407-0784 International: 201-689-8560 Conference ID: 13724305 Webcast:
https://78449.themediaframe.com/dataconf/productusers/vvdb/mediaframe/47084/indexl.html

About Arcturus Therapeutics
Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a clinical-stage mRNA medicines and vaccines company with enabling technologies: (i) LUNAR® lipid-mediated delivery, (ii) STARR™ mRNA Technology and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic and vaccine candidates includes mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, and Cystic Fibrosis along with partnered programs including Glycogen Storage Disease Type 3, Hepatitis B Virus, and non-alcoholic steatohepatitis (NASH). Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, replicon RNA, antisense RNA, microRNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (with patents and patent applications, issued and filed in the U.S., Europe, Japan, China and other countries). Arcturus' commitment to the development of novel RNA therapeutics has led to collaborations with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., Takeda Pharmaceutical Company Limited, CureVac AG, Duke-NUS Medical School, and the Cystic Fibrosis Foundation. For more information visit www.ArcturusRx.com. In addition, please connect with us on Twitter and LinkedIn.

Forward Looking Statements

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Trademark Acknowledgements

ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)

	September 30, 2021	June 30, 2021	December 31, 2020
	(unaudited)	(unaudited)	
Assets			
Current assets:			
Cash and cash equivalents	$ 413,880	$ 433,574	$ 462,895
Accounts receivable	2,015	2,163	2,125
Prepaid expenses and other current assets	5,071	2,301	2,769
Total current assets	420,966	438,038	467,789
Property and equipment, net	4,843	3,407	3,378
Operating lease right-of-use asset, net	5,983	6,341	5,182
Equity-method investment	670	920	—
Non-current restricted cash	2,074	107	107
Total assets	$ 434,536	$ 448,813	$ 476,456
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	$ 8,265	$ 10,084	$ 10,774
Accrued liabilities	52,358	42,614	20,639
Deferred revenue	57,616	18,071	18,108
Total current liabilities	118,239	70,769	49,521
Deferred revenue, net of current portion	8,497	9,850	12,512
Long-term debt, net of current portion	42,345	56,309	13,845
Operating lease liability, net of current portion	4,935	5,359	4,025
Other long-term liabilities	1,394	878	—
Total liabilities	$ 175,410	$ 143,165	$ 79,903
Stockholders' equity			
Common stock: $0.001 par value; 60,000 shares authorized; 26,349 issued and outstanding at September 30, 2021, 26,327 issued and outstanding at June 30, 2021 and 26,192 issued and outstanding at December 31, 2020	26	26	26
Additional paid-in capital	567,927	560,365	540,343
Accumulated deficit	(308,827)	(254,743)	(143,816)
Total stockholders' equity	259,126	305,648	396,553
Total liabilities and stockholders' equity	$ 434,536	$ 448,813	$ 476,456

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,		June 30,
	2021	2020	2021
Collaboration revenue	$ 2,437	$ 2,333	$ 2,001
Operating expenses:			
Research and development, net	45,398	17,699	45,679
General and administrative	10,860	5,572	10,042
Total operating expenses	56,258	23,271	55,721
Loss from operations	(53,821)	(20,938)	(53,720)
(Loss) gain from equity-method investment	(250)	—	(328)
(Loss) gain from foreign currency	506	—	(13)
Finance expense, net	(519)	(66)	(520)
Net loss	$ (54,084)	$ (21,004)	$ (54,581)
Net loss per share, basic and diluted	$ (2.05)	$ (0.92)	$ (2.07)
Weighted-average shares outstanding, basic and diluted	26,338	22,938	26,323
Comprehensive loss:			
Net loss	$ (54,084)	$ (21,004)	$ (54,581)
Comprehensive loss	$ (54,084)	$ (21,004)	$ (54,581)

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