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): August 9, 2022

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 August 9, 2022, 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 June 30, 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 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, the promise of the company's platform technologies for multiple types of nucleic acid medicines, the likelihood of success (including safety and efficacy) of the Company's pipeline (including ARCT-154, ARCT-810, ARCT-032 and a STARR mRNA candidate for influenza), the likelihood that any independent verification by Arcturus, or any regulatory body's assessment of data will be consistent with the information shared by Vinbiocare from the ARCT-154 study in Vietnam, the likelihood that the clinical results of ARCT-154 studies (including the efficacy, booster durability or other antibody responses), or any other non-clinical or clinical data, will be predictive of future clinical results or efficacy, predictive of results against existing or future COVID variants, or sufficient for any regulatory approval, completion and final data readouts of, our Phase 1/2 booster study of ARCT-154, our ability to enroll and timing of enrollment of subjects in clinical trials, including the planned Phase 2 study for ARCT-810, or any other clinical trials, the timing of interim data from the ARCT-810 study or any other data, the likelihood or timing of an EUA or regulatory approval in Vietnam for ARCT-154 or for any regulatory approval, the likelihood, and timing for, a filing to proceed with a clinical study of ARCT-032, the completion (including timing) of Vinbiocare's manufacturing facility (including actual commercial production capabilities, if any), the likelihood that a patent will issue from any patent application, its financial projections, 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, most recent Quarterly Report on Form 10-Q, and in subsequent filings with, or submissions to, the U.S. Securities and Exchange Commission (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 August 9, 2022
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: August 9, 2022

Arcturus Therapeutics Holdings Inc.

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

Arcturus Therapeutics Announces Second Quarter 2022 Financial Update and Pipeline Progress

New ARCT-154 clinical booster data demonstrate promising durability; 44- and 39-fold increases in neutralizing antibody response against Omicron BA.1 and BA.2 at Day 91

New cold chain data for Arcturus' lyophilized vaccine platform shows favorable stability, shipping, and storage advantages

European Commission grants Orphan Medicinal Product Designation to ARCT-810, a novel mRNA candidate for ornithine transcarbamylase (OTC) deficiency

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

SAN DIEGO--(BUSINESS WIRE)--August 9, 2022 -- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", "Arcturus Therapeutics", Nasdaq: ARCT), a global, late-stage clinical 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 second quarter ended June 30, 2022, and provided corporate updates.

"Arcturus continues to demonstrate increasing value of our next generation mRNA vaccine and therapeutic platforms," said Joseph Payne, President and CEO of Arcturus Therapeutics. "Additional data from our Phase 1/2 booster study demonstrates that ARCT-154 provides sustained neutralizing antibodies against Omicron variants BA.1/BA.2 three months after booster vaccination. We are further pleased to share new data demonstrating the stability of our lyophilized vaccines under a broad range of transportation and storage conditions. Our work on the LUNAR-OTC program has been acknowledged with Orphan Medicinal Product Designation issued by the European Commission, which is promising news for the continued development of ARCT-810 for OTC deficient patients."

Recent Corporate Highlights

- Arcturus shared additional data from the ARCT-154 arm of its ongoing Phase 1/2 study in the U.S., Singapore, and South Africa evaluating a single 5-mcg booster dose of ARCT-154 given at least five months following two primary doses of Comirnaty®. In exploratory microneutralization titer (MNT) assays, ARCT-154 demonstrates a robust neutralizing antibody response against the Omicron BA.1 and BA.2 variants up to 91 days after administration. Against BA.1 the Geometric Mean Fold Rise (GMFR) was 44-fold at Day 91 compared to 54-fold at Day 29. Against BA.2 the GMFR was 39-fold at Day 91 compared to 47-fold at Day 29 (Figure 1). Six-month data for Omicron variants, including BA.5, is being collected and will be shared this quarter.

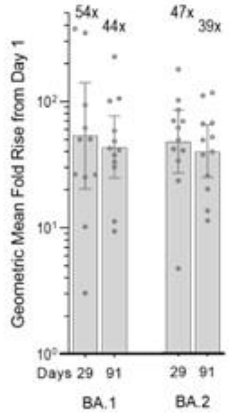

Figure 1: Exploratory pseudovirus microneutralization (MNT) assay results (left: BA.1, right: BA.2), showing GMFR levels of neutralizing antibody responses over Day 1 (baseline levels prior to boosting with ARCT-154) calculated with virus neutralization concentrations (with 95% confidence intervals) obtained for participants (for BA.1 and BA.2: n = 12/12, Day 91).

- New stability data supports the advantages of using a lyophilized vaccine powder to mitigate the cold chain challenges associated with frozen liquid mRNA vaccines. Our lyophilized COVID vaccine powder demonstrated room temperature stability (25°C RT; 60% RH) for 4 days, refrigerator stability (2-8°C) for 6 months, and a predicted long-term stability (-25°C to -15°C) for 18 months. Importantly, the lyophilized powder was not impacted by multiple temperature cycling stress (-20°C to 2-8°C or RT) enabling global shipping logistics and supply of a stable usable solid COVID vaccine product at 2-8°C.
- ARCT-810 Orphan Medicinal Product Designation: Arcturus was notified by the European Commission that ARCT-810 has been designated as an Orphan Medicinal Product for the treatment of OTC deficiency. The designation provides significant incentives to promote the development of the drug including protocol assistance, access to the centralized authorization procedure, fee reductions, and research grants, as well as 10 years of market exclusivity.
- ARCT-810, the Company's mRNA therapeutic candidate for OTC deficiency will be evaluated in a randomized, double-blind, placebo-controlled, nested single and multiple ascending dose Phase 2 study in 24 adolescents and adults with OTC deficiency. Participating sites have identified several dozen patients in pre-screening, with the goal of obtaining interim proof-of-concept data by year end.
- Due to additional non-clinical data requirements, ARCT-032 (the Company's inhaled mRNA therapeutic candidate for cystic fibrosis) is now expected to file for a Clinical Trial Application in Q4 2022.
- The Vinbiocare manufacturing facility in Hanoi, Vietnam, is anticipated to achieve commercial scale production capability in Q4 2022.
- The Vietnam Ministry of Health (MOH) is undergoing a significant reorganization resulting in a delay of the ARCT-154 Emergency Use Authorization (EUA) for the primary series. During the reorganization, the MOH communicated that the Clinical section review is complete and adequate. The MOH provided comments to the Chemistry, Manufacturing, and Controls (CMC) section, requesting three manufacturing runs to support full Market Authorization. ARCT-154 is now expected to receive EUA in Q4 2022, with full Marketing Authorization anticipated in early 2023 if booster studies meet noninferior immunogenicity and safety objectives.
- Arcturus expects a registrational booster study for ARCT-154 to begin in Q4 2022. Based on recent health authority guidance, the Company is considering an updated design consisting of two trials to support global registration of ARCT-154 as a booster.

Financial Results for Second Quarter Ended June 30, 2022

Revenues in conjunction with strategic alliances and collaborations: Arcturus' primary sources of revenues were from consulting and related technology transfer fees, reservation fees, license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended June 30, 2022, the Company reported revenue of $27.1 million compared with $2.0 million for the three months ended June 30, 2021, and $5.2 million for the three months ended March 31, 2022. The increase in revenue during the three months ended June 30, 2022, as compared to the three months ended March 31, 2022, and June 30, 2021, was primarily due to revenue of $12.5 million related to the one time recognition of reservation fees from the Israel MOH and an increase in revenue from Vinbiocare related to shipments of drug substance to validate their manufacturing facility.

Operating expenses: Total operating expenses for the three months ended June 30, 2022, were $49.2 million compared with $55.7 million for the three months ended June 30, 2021, and $55.7 million for the three months ended March 31, 2022. The decline in operating expenses during the three months ended June 30, 2022, as compared to the three months ended March 31, 2022 was due primarily to a decrease in clinical trial expenses related to ARCT-154.

Research and development expenses: Research and development expenses for the three months ended June 30, 2022, were $38.2 million compared with $45.7 million for the three months ended June 30, 2021, and $44.9 million for the three months ended March 31, 2022. The decline in operating expenses during the three months ended June 30, 2022, as compared to the three months ended March 31, 2022, and June 30, 2021, was due primarily to a decrease in clinical trial expenses.

Net Loss: For the three months ended June 30, 2022, Arcturus reported a net loss of approximately $21.6 million, or ($0.82) per basic and diluted share, compared with a net loss of $54.6 million, or ($2.07) per basic and diluted share in the three months ended June 30, 2021, and a net loss of $51.2 million, or ($1.94) per basic and diluted share in the three months ended March 31, 2022.

Cash Position: The Company's cash balance totaled $283.5 million as of June 30, 2022, compared to a cash balance of $370.5 million at December 31, 2021. Based on the current pipeline, the Company's cash position is expected to be sufficient to support operations into late 2023.

Earnings Call: Tuesday, August 9, 2022 @ 4:30 pm EDT
Domestic: 1-800-263-0877
International: 1-323-794-2094
Conference ID: 8017918
Webcast: Link

Please connect with us on Twitter and LinkedIn. For more information visit www.ArcturusRx.com.

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' 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 III, and hepatitis B virusArcturus' 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 protected by patents and patent applications issued in the U.S., Europe, Japan, China and other countries. Arcturus' commitment to the development of novel RNA therapeutics has led to collaborations including, amongst others, Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., and the Cystic Fibrosis Foundation. Please connect with us on Twitter and LinkedIn. For more information visit www.ArcturusRx.com.

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)

	June 30, 2022	December 31, 2021
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 283,491	$ 370,492
Accounts receivable	2,247	3,367
Prepaid expenses and other current assets	5,767	5,102
Total current assets	291,505	378,961
Property and equipment, net	8,951	5,643
Operating lease right-of-use asset, net	34,480	5,618
Equity-method investment	—	515
Non-current restricted cash	2,078	2,077
Total assets	$ 337,014	$ 392,814
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 5,762	$ 10,058
Accrued liabilities	33,614	23,523
Current portion of long-term debt	27,018	22,474
Deferred revenue	26,349	43,482
Total current liabilities	92,743	99,537
Deferred revenue, net of current portion	5,590	19,931
Long-term debt, net of current portion	35,761	40,633
Operating lease liability, net of current portion	32,203	4,502
Total liabilities	$ 166,297	$ 164,603
Stockholders' equity		
Common stock: $0.001 par value; 60,000 shares authorized; 26,434 issued and outstanding at June 30, 2022 and 26,372 issued and outstanding at December 31, 2021	26	26
Additional paid-in capital	590,913	575,675
Accumulated deficit	(420,222)	(347,490)
Total stockholders' equity	170,717	228,211
Total liabilities and stockholders' equity	$ 337,014	$ 392,814

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		
	June 30,		March 31,
	2022	2021	2022
Revenue	$ 27,093	$ 2,001	$ 5,244
Operating expenses:			
Research and development, net	38,189	45,679	44,893
General and administrative	10,993	10,042	10,730
Total operating expenses	49,182	55,721	55,623
Loss from operations	(22,089)	(53,720)	(50,379)
Loss from equity-method investment	(131)	(328)	(384)
Gain (loss) from foreign currency	1,217	(13)	158
Finance expense, net	(560)	(520)	(564)
Net loss	$ (21,563)	$ (54,581)	$ (51,169)
Net loss per share, basic and diluted	$ (0.82)	$ (2.07)	$ (1.94)
Weighted-average shares outstanding, basic and diluted	26,425	26,323	26,376
Comprehensive loss:			
Net loss	$ (21,563)	$ (54,581)	$ (51,169)
Comprehensive loss	$ (21,563)	$ (54,581)	$ (51,169)

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