

**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 9, 2020

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 9, 2020, 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, 2020 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

Certain statements in this communication and the Press Release are 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.

The 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 the Press Release, including those regarding strategy, future operations, collaborations, the likelihood of success, efficacy or safety of ARCT-021 or ARCT-810, the ability to initiate or complete preclinical and clinical development programs, including as a result of the COVID-19 pandemic, are forward-looking statements. 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. Such statements are based on management’s current expectations and involve risks and uncertainties, including those discussed under the heading “Risk Factors” in Arcturus’ Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020 and in subsequent filings with, or submissions to, the SEC.

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
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99.1	<u>Press Release dated November 9, 2020</u>
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 9, 2020

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

Arcturus Therapeutics Announces Third Quarter 2020 Financial Results and Positive Clinical Updates for ARCT-810 Phase I Study and Additional ARCT-021 Interim Data

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

San Diego, Calif, Nov 9, 2020 – 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 quarter and nine months ended September 30, 2020, and provided a corporate update.

“This has been an exciting period for Arcturus highlighted by our preliminary ARCT-021 Phase 1/2 COVID-19 vaccine study results. These data, as well as those from our ARCT-810 Phase 1 study, illustrate a highly productive period of clinical advancement of our novel mRNA based therapeutic candidates. The ARCT-021 Phase 1/2 data provide clinical validation for our unique vaccine candidate and suggest that our self-replicating mRNA-based investigational vaccine could have a differentiated clinical profile and may allow vaccination at low doses. We believe that ARCT-021 could play an important role in the massive global vaccination campaigns that will be necessary to control the COVID-19 pandemic. We look forward to rapidly moving ARCT-021 forward in later stage clinical studies.” said Joseph Payne, President & CEO of Arcturus.

“The initial ARCT-810 Phase 1/2 study results, showing good tolerability and favorable pharmacokinetics, provide support for the further development of this drug candidate in Ornithine Transcarbamylase (OTC) deficiency, a severe monogenic rare disease where new medicines are urgently needed. These data also provide additional validation for the systemic administration of Arcturus’ novel LUNAR technology. We believe that we have developed a powerful and broadly applicable mRNA delivery approach that may be useful for the treatment of numerous serious diseases, and we look forward to continuing to advancing the development of our investigational therapeutics” said Pad Chivukula, Ph.D., Chief Scientific Officer and Chief Operating Officer of Arcturus.

Highlights

ARCT-021, Vaccine Candidate for SARS-CoV-2

- Announced interim Phase 1/2 data; favorable immunogenicity and safety results for both single-dose and prime-boost regimens
 - Observed 100% seroconversion for IgG binding antibodies in younger adults; 1 out of 5 older adult participants has not yet seroconverted; observed GMT > 2300 in all cohorts
 - Doses to advance to later stage clinical trials include single dose 7.5 µg (GMT > 15,000 for younger adults and > 2300 in older adults at this dose)
 - Published preclinical data, including successful challenge model data
 - Secured manufacturing slots with Recipharm to support cGMP manufacture; lyophilization technology transfer completed
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ARCT-810, Therapeutic Candidate for Ornithine Transcarbamylase (OTC) Deficiency

- Completed dose escalation of all cohorts (0.1, 0.2, 0.3, 0.4 mg/kg) in Phase 1 Study
- Commenced enrollment in Phase 1b study in OTC-deficient patients in U.S.; first subject in screening

Agreements

- Executed Definitive Supply Agreement with the Israeli Ministry of Health; up to \$275 million
- Executed Agreement with Singapore; \$45 million limited recourse loan facility and up to \$175 million in vaccine purchases

Financial results for the quarter ended September 30, 2020

Revenues in conjunction with strategic alliances and collaborations: Arcturus' primary source of revenues is from license fees and collaborative payments received from research and development arrangements with pharmaceutical and biotechnology partners. For the three months ended September 30, 2020, the Company reported revenue of \$2.3 million, compared with \$3.3 million in the three months ended September 30, 2019. The decline in collaboration revenues primarily relates to a \$0.8 million decrease in reimbursements from CureVac associated with the OTC collaboration that ended in the third quarter of 2019.

Operating expenses: Total operating expenses for the three months ended September 30, 2020 were \$23.3 million compared with \$10.9 million for the same period of 2019. The current quarter operating expenses were partially offset with \$3.7 million of funds earned under the Singapore vaccine grant and \$0.7 million in funds awarded by the CF Foundation. Research and Development expenses increased approximately \$10 million sequentially from the June 30, 2020 quarter driven primarily by an approximate increase of \$4 million in each of our Lunar-OTC (ARCT-810) and Lunar-Covid19 (ARCT-021) programs mostly due to clinical and manufacturing expenses. Additionally, approximately \$2 million was driven by increased personnel expenses and costs of our two new pipeline programs Lunar-Lung and Lunar CV.

Net loss: For the three months ended September 30, 2020, Arcturus reported a net loss of approximately \$21.0 million, or (\$0.92) per basic and diluted share, compared with a net loss in the three months ended September 30, 2019 of \$7.4 million, or (\$0.56) per basic and diluted share.

Our cash balance totaled \$307.1 million as of the end of Q3, compared to cash and cash equivalents of \$71.5 million at December 31, 2019. The increase in cash, cash equivalents, and investments is primarily due to successfully raising approximately \$262.1 million in net proceeds through two public equity offerings in 2020. Based on our current pipeline, the Company's cash position is expected to be sufficient to support operations for more than two years.

Monday, Nov 9th @ 4:30 p.m. ET

Domestic:	877-407-0784
International:	201-689-8560
Conference ID:	13712208
Webcast:	http://public.viavid.com/index.php?id=142081

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 self-replicating mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Cardiovascular Disease 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 (200 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 with Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., Takeda Pharmaceutical Company Limited, CureVac AG, Synthetic Genomics Inc., Duke-NUS, 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

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, including those regarding strategy, future operations, collaborations, the likelihood of success, and the efficacy or safety, of our pipeline, including ARCT-021 or ARCT-810, the ability to initiate or complete preclinical and clinical development programs, including as a result of the COVID-19 pandemic, the supply and delivery of any product or substance, the likelihood that clinical data will be predictive of future clinical results or sufficient for regulatory approval, the ability to enroll subjects in clinical trials, the Company's efforts to develop a vaccine against COVID-19 and therapeutic potential thereof based on the Company's mRNA therapeutics, the ability of the Company to scale up manufacturing of vaccine doses, the amount and timing of any drawn down loan amounts with the EDB, our current cash position and expected cash burn and the impact of general business and economic conditions are forward-looking statements. 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. Such statements are based on management's current expectations and involve risks and uncertainties, including those discussed under the heading "Risk Factors" in Arcturus' Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020 and in subsequent filings with, or submissions to, the SEC. 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.

IR and Media Contacts

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ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value information)

	September 30, 2020 (unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 307,023	\$ 71,353
Accounts receivable	2,447	2,179
Prepaid expenses and other current assets	4,630	758
Total current assets	<u>314,100</u>	<u>74,290</u>
Property and equipment, net	3,451	2,349
Operating lease right-of-use asset, net	4,862	5,134
Equity-method investment	—	263
Non-current restricted cash	107	107
Total assets	<u>\$ 322,520</u>	<u>\$ 82,143</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,478	\$ 5,793
Accrued liabilities	15,838	7,134
Deferred revenue	5,698	8,397
Total current liabilities	<u>28,014</u>	<u>21,324</u>
Deferred revenue, net of current portion	13,645	15,182
Long-term debt	15,076	14,995
Operating lease liability, net of current portion	4,155	4,850
Total liabilities	<u>\$ 60,890</u>	<u>\$ 56,351</u>
Stockholders' equity		
Common stock: \$0.001 par value; 30,000 shares authorized; 24,473 and 15,138 issued and outstanding at September 30, 2020 and December 31, 2019, respectively.	25	15
Additional paid-in capital	374,317	97,445
Accumulated deficit	(112,712)	(71,668)
Total stockholders' equity	<u>261,630</u>	<u>25,792</u>
Total liabilities and stockholders' equity	<u>\$ 322,520</u>	<u>\$ 82,143</u>

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,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	\$ 2,333	\$ 3,318	\$ 7,301	\$ 17,821
Collaboration revenue				
Operating expenses:				
Research and development, net	17,699	7,053	33,560	21,646
General and administrative	5,572	3,881	14,183	10,871
Total operating expenses	<u>23,271</u>	<u>10,934</u>	<u>47,743</u>	<u>32,517</u>
Loss from operations	(20,938)	(7,616)	(40,442)	(14,696)
Loss from equity-method investment	—	303	(263)	15
Finance expense, net	(66)	(120)	(339)	(321)
Net loss	<u>\$ (21,004)</u>	<u>\$ (7,433)</u>	<u>\$ (41,044)</u>	<u>\$ (15,002)</u>
Net loss per share, basic and diluted	<u>\$ (0.92)</u>	<u>\$ (0.56)</u>	<u>\$ (2.19)</u>	<u>\$ (1.33)</u>
Weighted-average shares outstanding, basic and diluted	22,938	13,201	18,766	11,248
Comprehensive loss:				
Net loss	\$ (21,004)	\$ (7,433)	\$ (41,044)	\$ (15,002)
Comprehensive loss	<u>\$ (21,004)</u>	<u>\$ (7,433)</u>	<u>\$ (41,044)</u>	<u>\$ (15,002)</u>