

**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 7, 2019

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)

46-1981974
(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

Arcturus Therapeutics Ltd.
(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 Condition.

On November 7, 2019, Arcturus Therapeutics Holdings Inc. (the “Company”) issued a press release, a copy of which is furnished herewith as Exhibit 99.1, announcing the Company’s financial results for the three-month and nine-month periods ended September 30, 2019 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 attached hereto as Exhibit 99.1, 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, 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” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements about: expectations regarding our capitalization, strategy, future operations, collaborations or resources; the adequacy of our capital to support our future operations and our ability to successfully initiate and complete clinical trials; our strategy and focus; the development and commercial potential of any of our product candidates; the timing and success of our development efforts; the success of any of our trials and our ability to achieve regulatory approval for any product candidate; the entry into, modification or termination of collaborative agreements; the date that an IND may be filed with the FDA; the potential market or success for the clinical development programs of the Company; the likelihood of success of the Company’s technology or potential development of any of the Company’s products, preclinical or clinical development programs; the expected employment of key personnel; the yield of preventative and therapeutic treatments or commercial or therapeutic success of the Company’s products or programs, including those for the treatment of cystic fibrosis; or any statements other than statements of historical fact, including those related to the Company’s future cash, market or financial position. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time. Forward-looking statements speak only as of the date they are made and the Company assumes no duty to update forward-looking statements, except as required by law.

In addition to factors previously disclosed in the Company’s reports filed with the SEC and those identified elsewhere in this communication, the following factors, among others, could cause actual results to differ materially from forward-looking statements and historical performance: the availability and access, in general, of funds to fund operations and necessary capital expenditures, the strength of our intellectual property portfolio, the expected safety profiles of our product candidates, the proof of concept of our product candidates, the target opportunities for certain of our product candidates, our expected dates of submission of one or more Investigational New Drug Applications to the FDA, market opportunities with respect to certain diseases connected with our product candidates, manufacturing and formulation capabilities of the Company or our manufacturing partners with respect to our product candidates, as well as our management’s response to the preceding factors. The foregoing factors are in addition to the other factors set forth in the Company’s reports on Form 10-K, Form 8-K, and other documents on file with the SEC.

Other risks and uncertainties are more fully described under the heading “Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 18, 2019, and in other filings that the Company makes and will make with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The statements made in this Current Report on Form 8-K and the exhibit(s) attached hereto 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
Number**

Description

99.1 [Press Release of Arcturus Therapeutics Holdings Inc., dated November 7, 2019](#)

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 7, 2019

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

Arcturus Therapeutics Announces Third Quarter Financial Results and Provides Corporate Update

San Diego, Calif, November 7, 2019 – Arcturus Therapeutics Holdings Inc. (“Arcturus Therapeutics”) (NASDAQ: ARCT), a leading messenger RNA medicines company focused on the discovery, development and commercialization of therapeutics for rare diseases, today reported its financial results for the three- and nine-month periods ended September 30, 2019 and provided a corporate update.

Highlights

- IND application for ARCT-810, a treatment of ornithine transcarbamylase (OTC) deficiency, is on track for Q1 2020 filing
- Expanded platform with STARR technology™ to enable LUNAR® formulated RNA-based vaccines
- Raised \$23 Million from institutional investors at \$11.50 per share of Common Stock
- Strengthened the Board of Directors with the addition of Edward W. Holmes, M.D.

“We continue to develop our LUNAR® delivery and mRNA technology platforms, strengthening our leadership position in mRNA medicines. Our flagship program, ARCT-810, remains on track – we have successfully completed a GMP-manufactured batch of drug product, initiated IND-enabling toxicology studies, and plan to file an IND application during the first quarter of 2020,” said Joseph Payne, President and Chief Executive Officer of Arcturus. “Earlier this morning, we announced the expansion of our technology platform to include self-replicating RNA (STARR technology™) for human and animal health vaccine applications. Furthermore, we have successfully raised significant capital from institutional and strategic investors to fund our operations into 2021,” concluded Payne.

Financial Results for the Third quarter Ended September 30, 2019

Revenues in conjunction with strategic alliances and collaborations: Collaboration revenue was \$3.3 million during the quarter ended September 30, 2019, compared to \$3.4 million in the quarter ended September 30, 2018.

Operating Expenses: Operating expenses were \$10.9 million in the quarter ended September 30, 2019, compared to \$7.8 million in the quarter ended September 30, 2018.

Net Loss: Net loss for the quarter ended September 30, 2019 was approximately \$7.4 million, or (\$0.56) per basic and diluted share, compared with a net loss of \$4.3 million, or (\$0.42) per basic and diluted share, in the quarter ended September 30, 2018.

Cash: At September 30, 2019, Arcturus had cash and cash equivalents totaling \$74.2 million, compared to cash, cash equivalents of \$36.7 million at December 31, 2018. Subsequent to the end of the fiscal quarter we received approximately \$7.0 million as a result of increasing our bank facility and an insurance settlement. This provides adequate funding to support the Company’s current programs through at least the first quarter of 2021.

Financial Results for the Nine months Ended September 30, 2019

Revenues in conjunction with strategic alliances and collaborations: Collaboration revenue was \$17.8 million during the nine months ended September 30, 2019, compared to \$8.2 million in the nine months ended September 30, 2018.

Operating expenses: Operating expenses were \$32.5 million in the nine months ended September 30, 2019, compared to \$29.3 million in the nine months ended September 30, 2018.

Net Loss: Net loss for the nine-month period ended September 30, 2019 was approximately \$15.0 million, or (\$1.18) per basic and diluted share, compared with a net loss of \$20.8 million, or (\$2.07) per basic and diluted share, in the nine-month period ended September 30, 2018.

Conference Call

Thursday, November 7th @ 4:30pm Eastern Time

Domestic: 800-458-4121
International: 323-794-2597
Conference ID: 7909937
Webcast: <http://public.viavid.com/index.php?id=136708>

About Arcturus Therapeutics

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is an RNA medicines company with enabling technologies – **LUNAR® lipid-mediated delivery, Unlocked Nucleomonomer Analog (UNA) chemistry, STARR technology™** – and mRNA drug substance along with drug product manufacturing. Arcturus' diverse pipeline of RNA therapeutics includes programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Glycogen Storage Disease Type 3, Hepatitis B, 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 (177 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. and the Cystic Fibrosis Foundation. For more information visit www.Arcturusrx.com.

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 of the Company's technology or potential development of any products, the status of preclinical and clinical development programs, the planned initiation of clinical trials, the expected employment of key personnel, the adequacy of the Company's funding relative to its capital requirements and the Company's future cash and financial position, 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, 2018, filed with the SEC on March 18, 2019 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.

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ARCTURUS THERAPEUTICS HOLDINGS INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(In U.S. dollars in thousands, except par value information)

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 74,172	\$ 36,709
Accounts receivable	2,625	4,481
Prepaid expenses and other current assets	2,611	638
Total current assets	79,408	41,828
Property and equipment, net	2,073	1,975
Operating lease right-of-use asset, net	5,324	—
Equity-method investment	303	288
Non-current restricted cash	107	107
Total assets	\$ 87,215	\$ 44,198
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 4,013	\$ 2,398
Accrued liabilities	6,676	3,907
Deferred revenue	10,999	6,272
Total current liabilities	21,688	12,577
Deferred revenue, net of current portion	14,551	7,534
Long-term debt	10,016	9,911
Operating lease liability, net of current portion	5,065	—
Deferred rent	—	534
Total liabilities	51,320	30,556
Total stockholders' equity	35,895	13,642
Total liabilities and stockholders' equity	\$ 87,215	\$ 44,198

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

U.S. dollars in thousands (except per share data)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Collaboration revenue	\$ 3,318	\$ 3,423	\$ 17,821	\$ 8,176
Operating expenses:				
Research and development, net	7,053	3,969	21,646	12,135
General and administrative	3,881	3,810	10,871	17,141
Total operating expenses	<u>10,934</u>	<u>7,779</u>	<u>32,517</u>	<u>29,276</u>
Loss from operations	(7,616)	(4,356)	(14,696)	(21,100)
Gain (loss) from equity-method investment	303	(47)	15	(47)
Finance (expense) income, net	(120)	150	(321)	373
Net loss	<u>\$ (7,433)</u>	<u>\$ (4,253)</u>	<u>\$ (15,002)</u>	<u>\$ (20,774)</u>
Net loss per share, basic and diluted	\$ (0.56)	\$ (0.42)	\$ (1.18)	\$ (2.07)
Weighted-average shares outstanding, basic and diluted	13,201	10,093	12,734	10,059
Comprehensive loss:				
Net loss	\$ (7,433)	\$ (4,253)	\$ (15,002)	\$ (20,774)
Unrealized gain on short-term investments	<u>—</u>	<u>2</u>	<u>—</u>	<u>7</u>
Comprehensive loss	<u>\$ (7,433)</u>	<u>\$ (4,251)</u>	<u>\$ (15,002)</u>	<u>\$ (20,767)</u>