# 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 15, 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) 32-0595345 (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))

Dere-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:

	Trading	Name of each exchange
Title of each class	Symbol(s)	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  $\Box$ 

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 7.01 Regulation FD Disclosure.

On August 15, 2019, 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, 2019 (the "Press Release").

The information contained in Item 7.01 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 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 regarding strategy, future operations, the status of preclinical and clinical development programs, the potential success of clinical development programs, and the Company's future cash and financial position are forward-looking statements. Actual results and performance could differ materially from those projected in any forward-looking statements as a result of many factors, including without limitation an inability to develop and market product candidates, unexpected clinical results and general market conditions that may prevent such achievement or performance. 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, in Arcturus' Quarterly Report on Form 10-Q filed with the SEC on August 14, 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.

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.

 Exhibit
 Description

 99.1
 Press Release of Arcturus Therapeutics Holdings Inc., dated August 15, 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.

By: <u>/s/ Joseph E. Payne</u>

Joseph E. Payne Chief Executive Officer

Dated: August 15, 2019

#### Arcturus Therapeutics Announces Second Quarter Financial Results and Provides a Corporate Update

- Ultragenyx Pharmaceutical, Inc. expands collaboration, becoming Arcturus' largest shareholder
- Cystic Fibrosis Foundation increases commitment to \$15 million
- Arcturus receives Orphan Drug Designation from the U.S. FDA for ARCT-810
- Conference call and audio webcast at 4:30 PM ET today

**San Diego, Calif, August 15, 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 six month periods ended June 30, 2019 and provided a corporate update.

"We are pleased with the progress we have made with our LUNAR<sup>®</sup> delivery and mRNA technology platform, and for the continued support of our partners and shareholders," said Joseph Payne, President & CEO of Arcturus Therapeutics. "Our long-term collaboration partner, Ultragenyx, became our largest shareholder with a substantial investment, while the Cystic Fibrosis Foundation increased its financial support for our LUNAR-CF program, and we've added several key institutional investors. We intend to use these resources to advance our proprietary preclinical mRNA therapeutics pipeline, as well as any potential value-added assets we may acquire through our business development efforts."

#### Highlights

- Received \$30 million from Ultragenyx comprised of a \$24 million equity investment at \$10 per share and a \$6 million upfront payment, which expanded the collaboration with Ultragenyx to discover and develop mRNA, DNA and siRNA therapeutics for selected rare disease targets
- Cystic Fibrosis Foundation increased its commitment up to \$15 million to fund LUNAR-CF program through IND filing, with the first payment of \$4 million expected by the end of August 2019
- Received Orphan Drug Designation from the U.S. FDA for ARCT-810, for treatment of ornithine transcarbamylase (OTC) deficiency
- Recognized \$3.3 million from Synthetic Genomics agreement related to sub-license revenues from multiple parties
- Raised more than \$13 million in gross proceeds from two registered direct offerings of common stock, by institutional investors subsequent to the end of quarter
- Redomiciled in the United States as a Delaware corporation

#### Financial Results for the Second Quarter Ended June 30, 2019

<u>Revenues in conjunction with strategic alliances and collaborations</u>: Collaboration revenue was \$10.2 million during the quarter ended June 30, 2019, compared to \$2.4 million in the quarter ended June 30, 2018. Approximately \$7 million in revenues were non-recurring in the 2019 second quarter.

*<u>Operating Expenses</u>*: Operating expenses were \$10.7 million in the quarter ended June 30, 2019, compared to \$12.5 million in the quarter ended June 30, 2018. The June 30, 2018 quarter included approximately \$5 million in proxy-related expenses.

<u>Net Loss</u>: Net loss for the quarter ended June 30, 2019 was approximately \$0.7 million, or (\$0.07) per basic and diluted share, compared with a net loss of \$10.0 million, or (\$0.99) per basic and diluted share, in the quarter ended June 30, 2018.

*Cash*: At June 30, 2019, Arcturus had cash and cash equivalents totaling \$55.8 million, compared to cash, cash equivalents of \$36.7 million at December 31, 2018.

Subsequent to the end of the fiscal quarter, we announced three significant transactions which further improved our liquidity.

First, we received a \$4 million payment from CureVac at the end of July in connection with the Termination Agreement for the co-development of ARCT-810 as a therapy for OTC deficiency.

Second, we announced two registered direct offerings of our common stock at \$11.50 per share to certain investors that in aggregate raised net proceeds of approximately \$12.2 million.

Finally, the Cystic Fibrosis Foundation is expected to make an upfront payment to Arcturus of \$4 million by August 30, 2019.

Including the upfront payment by the Cystic Fibrosis Foundation, we will have added an additional \$20 million in cash since the end of the quarter, and we believe our cash resources should be sufficient to support our operations through the end of Fiscal Year 2020.

#### Financial Results for the Six Months Ended June 30, 2019

<u>Revenues in conjunction with strategic alliances and collaborations</u>: Collaboration revenue was \$14.5 million during the six months ended June 30, 2019, compared to \$4.7 million in the six months ended June 30, 2018.

*<u>Operating expenses</u>*: Operating expenses were \$21.6 million in the six months ended June 30, 2019, compared to \$21.5 million in the six months ended June 30, 2018.

<u>Net Loss</u>: Net loss for the six-month period ended June 30, 2019 was approximately \$7.6 million, or (\$0.74) per basic and diluted share, compared with a net loss of \$16.5 million, or (\$1.65) per basic and diluted share, in the six-month period ended June 30, 2018.

#### Conference Call

Date:	Thursday, August 15
Time:	4:30 PM Eastern Time
Domestic:	877-407-0784
International:	201-689-8560
Conference ID:	13693103
Webcast:	http://public.viavid.com/index.php?id=135619

#### **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<sup>®</sup> lipid-mediated delivery and Unlocked Nucleomonomer Analog (UNA) chemistry – 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 (167 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 <u>www.Arcturusrx.com</u>

#### **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 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 sufficiency of any drug substances or drug products to meet current goals or expectations, and the potential market or success of clinical development programs, 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.

#### Contact

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Arcturus Investor Contacts Michael Wood LifeSci Advisors LLC (646) 597-6983 <u>mwood@lifesciadvisors.com</u>

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

	June 30, 2019 (unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 55,840	\$ 36,709
Accounts receivable	5,817	4,481
Prepaid expenses and other current assets	1,681	638
Total current assets	63,338	41,828
Property and equipment, net	1,986	1,975
Operating lease right-of-use asset, net	5,509	
Equity-method investment	—	288
Non-current restricted cash	107	107
Total assets	\$ 70,940	\$ 44,198
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 3,187	\$ 2,398
Accrued liabilities	3,497	3,907
Deferred revenue	9,730	6,272
Total current liabilities	16,414	12,577
Deferred revenue, net of current portion	17,652	7,534
Long-term debt	9,980	9,911
Operating lease liability, net of current portion	5,276	
Deferred rent	—	534
Total liabilities	\$ 49,322	\$ 30,556
Stockholders' equity		
Common stock: \$0.001 par value; 30,000 shares authorized; 13,120 issued and outstanding at June 30, 2019; NIS 0.07 par value; 30,000 shares authorized, 10,762 issued, 10,719 outstanding and 43 held in treasury at		
December 31, 2018	13	214

December 31, 2018	13	214
Additional paid-in capital	74,851	58,302
Accumulated deficit	(53,246)	(44,874)
Total stockholders' equity	21,618	13,642
Total liabilities and stockholders' equity	\$ 70,940	\$ 44,198

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$10,153	\$ 2,386	\$14,503	\$ 4,753
Operating expenses:				
Research and development, net	7,269	4,225	14,593	8,166
General and administrative	3,456	8,233	6,990	13,331
Total operating expenses	10,725	12,458	21,583	21,497
Loss from operations	(572)	(10,072)	(7,080)	(16,744)
Loss from equity-method investment	—	(47)	(288)	(47)
Finance (expense) income, net	(113)	169	(201)	270
Net loss	\$ (685)	\$ (9,950)	\$(7,569)	\$(16,521)
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.99)	\$ (0.74)	\$ (1.65)
Weighted-average shares outstanding, basic and diluted	10,412	10,057	10,255	10,043
Comprehensive loss:				
Net loss	\$ (685)	\$ (9,950)	\$ (7,569)	\$(16,521)
Unrealized gain on short-term investments		7		5
Comprehensive loss	\$ (685)	\$ (9,943)	\$ (7,569)	\$(16,516)