

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 1, 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))
- 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 1.01 Entry into a Material Definitive Agreement.**

On August 1, 2019, Arcturus Therapeutics, Inc. (“Arcturus”), a subsidiary of Arcturus Therapeutics Holdings Inc. (the “Company”), entered into an amendment (the “Amendment”) to its Development Program Letter Agreement of May 16, 2017, as amended by Amendment No. 1 dated July 13, 2018 (the “Underlying Agreement”) with the Cystic Fibrosis Foundation (“CFF”), pursuant to which Arcturus and CFF agreed to: (a) increase the Amount of Award (as defined in the Underlying Agreement) from CFF to advance LUNAR-CF to \$15 million from approximately \$3.1 million, require Arcturus to provide \$5 million in matching funds for remaining budgeted costs, and modify the disbursement schedule from CFF to Arcturus related thereto such that (i) \$4 million will be disbursed upon execution of the Amendment, (ii) \$2 million will be disbursed within 30 days of the first day of each of January, April, July and October 2020 upon Arcturus invoicing CFF to meet project goals, and (iii) the last payment of \$3.0 million less the prior award previously paid out, equaling approximately \$2.1 million, will be disbursed upon Arcturus invoicing CFF to meet good manufacturing practices and opening an IND application; (b) replace the existing royalties due to CFF under the Underlying Agreement with specified royalties expressed as a percentage of net sales, subject to specified royalty caps expressed as a multiple of the Actual Award (as defined in the Amendment) and expiration of the royalties upon specified time limitations or patent or exclusivity expiration, among other limitations and exclusions; (c) define conditions under which Arcturus shall pay to CFF disposition payments in the event of a Disposition Transaction (as defined in the Amendment), including a license, sale or other transfer of a Covered Product or Arcturus Development Program Technology (excluding Net Sales) or a Change of Control Transaction; (d) provide a termination right to CFF; and (e) make corresponding changes to exhibits, definitions and other provisions of the Underlying Agreement consistent with the Amendment, including the replacement of references to Cystic Fibrosis Foundation Therapeutics, Inc. with CFF to reflect the prior assignment of the Underlying Agreement to CFF.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, a copy of which the Company intends to file with the Securities and Exchange Commission as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

**Item 8.01 Other Events.**

On August 1, 2019, the Company issued a press release, a copy of which is filed herewith as Exhibit 99.1, announcing the entry into the Amendment.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release of the Company, dated August 1, 2019</a>

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**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 1, 2019

**Arcturus Therapeutics Holdings Inc.**

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

## **Arcturus Therapeutics Receives up to \$15 Million Commitment from the Cystic Fibrosis Foundation to Create mRNA Therapies to Treat Cystic Fibrosis Patients**

**San Diego, Calif, August 1, 2019** - Arcturus Therapeutics (“Arcturus” or the “Company”), a leading RNA medicines company, today announced that the Cystic Fibrosis Foundation (CF Foundation), has increased its commitment to \$15 million in conjunction with an amended agreement to advance LUNAR-CF, a novel messenger RNA (mRNA) therapeutic formulated with Arcturus’ LUNAR® delivery technology.

The goal of the multi-year program is to create mRNA therapies to treat people with cystic fibrosis (CF), develop methods to deliver RNA components to cells in the lung and file an Investigational New Drug (IND) application for a therapeutic candidate.

“We are pleased with the progress we have made in our agreement with the CF Foundation, including preclinical proof of concept studies, demonstrating that LUNAR is able to deliver mRNA efficiently into lung epithelial cells in animals and is compatible with nebulization,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “We are delighted with the expanded financial support from the CF Foundation, and we believe that we are now sufficiently funded to advance the LUNAR-CF program into filing an IND application.”

Arcturus has collaborated with the CF Foundation since 2017.

### **About LUNAR-CF**

LUNAR-CF, Arcturus’ first inhaled mRNA therapeutic targeting the lung, represents a novel approach to treat cystic fibrosis (CF). LUNAR-CF is based on Arcturus messenger RNA (mRNA) design construct and proprietary manufacturing process. LUNAR-CF also utilizes Arcturus’ propriety lipid library and employs the Company’s LUNAR® delivery platform to safely and effectively deliver CFTR mRNA to the lung. LUNAR-CF is an mRNA replacement therapy designed to enable CFTR-deficient patients to naturally produce healthy functional CFTR in their own lung cells. Arcturus plans to submit an Investigational New Drug (IND) application to the FDA in the second half of 2020. LUNAR-CF is advancing toward the clinic on the strength of preclinical proof-of-concept data, demonstrating that LUNAR technology can deliver mRNA to bronchial epithelial cells and results in expression of CFTR protein in animal models.

### **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 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 [www.ArcturusRx.com](http://www.ArcturusRx.com).

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## **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, future financial position, prospects, plans and objectives of management, the likelihood of success of the Company's technology or potential development of any products, the status of the preclinical development program for any of the clinical development programs of Arcturus, the status of IND-enabling studies and early clinical development related to any of the clinical development programs of Arcturus, the sufficiency of any drug substances or drug products of the Company to meet the Company's current clinical goals or expectations, the date that an IND may be filed with the FDA, the Company's ability or expectation to file an IND for any of its product candidates, the potential market or success for the clinical development programs of Arcturus, current standards of care, 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. 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, inability to generate positive verifiable data, unexpected clinical results, unforeseen expenses 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 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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