

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): September 25, 2023

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 September 25, 2023, 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, Amendment No. 2 dated July 30, 2019 and Amendment No. 3 dated December 21, 2021 (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 by up to \$9 million (for a total to date of up to approximately \$25 million), and required Arcturus to provide \$15 million in matching funds for remaining budgeted costs; (b) modify the existing rates and caps on royalties due to CFF under the Underlying Agreement, including the addition of an option for Arcturus to reduce the royalty rate through a one-time payment; (c) modify the calculation of payments from Arcturus to CFF in the event of certain dispositions or licensing of cystic fibrosis or other pulmonary assets or of a change of control of Arcturus; and (d) make corresponding changes to exhibits, definitions and other provisions of the Underlying Agreement consistent with the Amendment.

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 September 30, 2023.

Item 8.01 Other Events.

On September 26, 2023, the Company issued a press release regarding the transactions described under Item 1.01 of this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.	Description
99.1	Press Release dated September 26, 2023.

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: September 26, 2023

Arcturus Therapeutics Holdings Inc.

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

Arcturus Therapeutics and Cystic Fibrosis Foundation Extend Agreement to Advance ARCT-032, an Investigational Messenger RNA (mRNA) Therapeutic to Treat Cystic Fibrosis

CF Foundation Increases Financial Commitment to ~\$25 Million

SAN DIEGO--(BUSINESS WIRE)--Sept. 26, 2023-- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a global late-stage clinical messenger RNA medicines company focused on the development of infectious disease vaccines and opportunities within liver and respiratory rare diseases, announced today that Arcturus and the Cystic Fibrosis Foundation (CF Foundation) have extended their ongoing agreement. The CF Foundation agreed to increase its financial commitment to ~\$25 million to advance ARCT-032, a novel messenger RNA (mRNA) therapeutic candidate formulated with Arcturus’ LUNAR® delivery technology. This agreement extends a prior research program, initiated in 2017, which has resulted in the advancement of ARCT-032 into ongoing clinical studies.

“We are thrilled to extend our productive relationship with the Cystic Fibrosis Foundation, and we are grateful for their meaningful financial support,” said Pad Chivukula, Ph.D., Chief Scientific Officer of Arcturus. “ARCT-032 has the potential to express fully functional CFTR protein in the lung, thereby addressing the root cause of cystic fibrosis. The resources and valuable expertise provided by the CF Foundation will support the continued clinical development of ARCT-032, including the completion of a Phase 1b study that we plan to initiate imminently in adults living with cystic fibrosis.”

ARCT-032 is made up of mRNA that codes for CFTR, encapsulated by lipid nanoparticles utilizing LUNAR delivery technology that has been optimized for inhaled lung delivery. ARCT-032 is agnostic to the underlying mutations associated with the disease and has the potential to provide clinical benefits across a wide range of those living with CF, including those not served by currently approved CFTR modulators. The program has completed dosing in a Phase 1 study in healthy volunteers.

About Cystic Fibrosis

Cystic fibrosis is a life-shortening disease with a worldwide distribution. Mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene result in a reduction or absence of CFTR protein and/or function in the airways, causing insufficient chloride transport to maintain airway surface homeostasis. CF mucus is more difficult to clear, thus clogging the airways and leading to infection, inflammation, respiratory failure, or other life-threatening complications. Currently approved CFTR modulator therapies are designed to increase function of the CFTR channel to help reduce symptoms yet are ineffective in some people with CF because of their underlying mutations.

About ARCT-032

ARCT-032 will utilize Arcturus’ LUNAR® lipid-mediated aerosolized platform to deliver CFTR messenger RNA to the lungs. Expression of a functional copy of the CFTR mRNA in the lungs of people with CF has the potential to restore CFTR activity and mitigate the downstream effects that cause progressive lung disease. The ARCT-032 program is supported by preclinical data in rodents, ferrets and primates, as well as demonstrating restoration of expression and function in human bronchial epithelial cells.

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 (sa-mRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. The Company has ongoing collaborations with CSL Seqirus and Meiji Seika Pharma, and a joint venture with ARCALIS. Arcturus' pipeline includes RNA therapeutic candidates to potentially treat ornithine transcarbamylase deficiency and cystic fibrosis, along with its partnered mRNA vaccine programs for SARS-CoV-2 (COVID-19) and influenza. Arcturus' versatile RNA therapeutics platforms can be applied toward multiple types of nucleic acid medicines including messenger RNA, small interfering RNA, circular RNA, antisense RNA, self-amplifying RNA, DNA, and gene editing therapeutics. Arcturus' technologies are covered by its extensive patent portfolio (patents and patent applications issued in the U.S., Europe, Japan, China, and other countries). 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, are forward-looking statements, including those regarding strategy, future operations, the expectations for or likelihood of success of any collaborations, the continued clinical development of ARCT-032, likelihood of success (including safety and efficacy) of ARCT-032, the planned initiation, design or completion of clinical trials (including the planned ARCT-032 Phase 1b study), the likelihood that preclinical data will be predictive of future clinical results, the likelihood that ARCT-032 will provide broad, or any, clinical benefit (including the ability of ARCT-032 to restore healthy CFTR protein), the ability to enroll, and timing for enrollment of, subjects in clinical trials, the timing and nature of any study results, the likelihood that a patent will issue from any patent application, 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, and in subsequent filings with, or submissions to, 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.

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