

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 31, 2022

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)

33-0595345
(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 31, 2022, Arcturus Therapeutics Holdings Inc. (“Arcturus”) entered into a cost reimbursement contract (the “Contract”) with the Biomedical Advanced Research and Development Authority (“BARDA”) of the U.S. Department of Health and Human Services to support the development of a low-dose pandemic influenza candidate based on Arcturus’ proprietary self-amplifying messenger RNA-based vaccine platform.

The Contract is to support Arcturus’ non-clinical and pre-clinical development, early-stage clinical development through Phase 1, and associated drug product manufacturing, regulatory and quality-assurance activities over a period of three years. The Contract provides for reimbursement by BARDA of Arcturus’ permitted costs incorporated into the Contract, up to \$63.2 million. The Contract does not include the purchase of any pandemic influenza vaccine that eventually may be developed. The Contract is terminable by BARDA at any time under specified circumstances, including for convenience.

This “partnership” with Arcturus is part of BARDA’s ongoing efforts to bolster pandemic preparedness and response capabilities by investing in innovative medical counter-measures that can help prevent the medical consequences that result from outbreaks caused by pandemic influenza and emerging infectious diseases.

The foregoing is only a summary of the material terms of the Contract, does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Contract that will be filed as an exhibit to Arcturus’ Quarterly Report on Form 10-Q for the quarter ending September 30, 2022.

(d) Exhibits.**Exhibit No. Description of Exhibit**

99.1	Press Release dated August 31, 2022
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.

Date: September 1, 2022

Arcturus Therapeutics Holdings Inc.

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

Arcturus Announces \$63.2 Million Award from the U.S. Government to Support Development of Self-amplifying mRNA Vaccine for Rapid Pandemic Influenza Response

- Arcturus will expand its current influenza vaccine program to include development of a pandemic influenza vaccine based on its proprietary self-amplifying mRNA platform with the support of the Biomedical Advanced Research and Development Authority.
- The \$63.2 Million base award will fund development from the preclinical stage through Phase 1 over a three-year period.
- A lower-dose, freeze-dried, pandemic influenza vaccine candidate will use Arcturus' STARR™ self-amplifying mRNA vaccine platform technology which demonstrated favorable safety and efficacy against SARS-CoV-2 infection combined with a stable cold chain profile that may help support U.S. government pandemic preparedness goals.

San Diego, California – 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 significant opportunities within liver and respiratory rare diseases, today announced that it has obtained an award for up to \$63.2 million from the Biomedical Advanced Research and Development Authority (BARDA). The award provides \$63.2 million over three years to support preclinical, manufacturing, nonclinical safety studies, along with development and regulatory support for Arcturus' self-amplifying mRNA vaccine platform technology for rapid pandemic influenza response through Phase 1 clinical studies.

“We are very pleased to have won this substantial award from the BARDA and look forward to working with the U.S. government to support the development of our proprietary self-amplifying mRNA vaccine technology for rapid pandemic influenza response. Arcturus' next generation mRNA platform has been administered to over 10,000 individuals globally demonstrating favorable safety, strong immunogenicity, and protection against SARS-CoV-2 infection,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “Our lyophilized vaccines have the potential to provide safe and effective protection against disease with the specific advantage of rapid scale-up, lower doses, and easier transport and storage. These are qualities that are essential to a rapid response against pandemic influenza and are consistent with strategic objectives of the U.S. government's National Strategy for Pandemic Influenza.”

This project has been supported in whole or in part with federal funds from the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under Contract Number: 75A50122C00007

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 (samRNA) and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic and vaccine candidates includes mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat ornithine transcarbamylase (OTC) deficiency, and cystic fibrosis, along with partnered programs including glycogen storage disease type III, and hepatitis B virus. 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 (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 including, amongst others, Janssen Pharmaceuticals, Inc., part of the Janssen Pharmaceutical Companies of Johnson & Johnson, Ultragenyx Pharmaceutical, Inc., and the Cystic Fibrosis Foundation. In addition, please connect with us on Twitter and LinkedIn. 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, are forward-looking statements, including those regarding strategy, the expectations for or likelihood of success of any collaborations, the likelihood of success of the Company's development and related efforts for an influenza vaccine candidate, the likelihood of the Company's lyophilized vaccines to provide safe and effective protection against disease, the future activities under and fulfillment of the Company's contract with BARDA, the ability of the Company's influenza vaccine program to support U.S. government pandemic preparedness goals, 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.

Trademark Acknowledgements

The Arcturus logo and other trademarks of Arcturus appearing in this announcement, including LUNAR® and STARR™, are the property of Arcturus. All other trademarks, services marks, and trade names in this announcement are the property of their respective owners.

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