

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 17, 2020

**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

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

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**Item 1.01. Entry Into a Material Definitive Agreement.**

On August 17, 2020, a wholly owned subsidiary of Arcturus Therapeutics Holdings Inc. (the “Company”) entered into a definitive Supply Agreement (the “Supply Agreement”) with the Israeli Ministry of Health (“MOH”) which provides for the supply of the Company’s COVID-19 vaccine candidate (LUNAR-COV19) to the MOH.

Subject to its terms and conditions, the Supply Agreement provides for delivery by the Company of an initial one million doses of LUNAR-COV19 to the MOH, subject to a 50% reduction by the MOH prior to December 1, 2020 (the “Initial Reserve Doses”). The Initial Reserve Doses will be increased by a specified number if the ultimate approved dosage is below an identified microgram size per dose. The Supply Agreement also provides the MOH with the right to elect, in its discretion, to purchase additional doses of LUNAR-COV19 upon notice to the Company prior to a specified date for a specified purchase price (the “Additional Reserve Doses”) and additional doses upon notice to the Company prior to a specified date for a specified purchase price (the “Stockpiling Doses”, and together with the Initial Reserve Doses and the Additional Reserve Doses, the “Total Doses”). Each purchased dose will consist of one ready filled dose if regulatory approval is obtained for a single dose and two ready filled doses if regulatory approval is obtained for two doses within a thirty day period.

Pursuant to the terms of the Supply Agreement, the MOH has a limited right to terminate the Supply Agreement, in its discretion, without any further obligation to the Company during a ten day period that will commence after the Company commences dosing in the first expansion cohort of its existing Phase 1/2 clinical trial of LUNAR-COV19, which is currently being conducted in Singapore. An initial deposit of 12.5% of the purchase price for the Initial Reserve Doses will be due and payable after the expiration of this one-time termination right. The Supply Agreement also provides that the Company is obligated to use commercially reasonable efforts to obtain certain specified regulatory approvals which are necessary for the sale and supply of LUNAR-COV19 in the State of Israel and provides the MOH with the right to terminate the Supply Agreement if such approvals are not obtained prior to December 31, 2021.

The Supply Agreement provides that the total purchase price to be paid by the MOH, if the MOH elects to purchase the maximum number of Total Doses currently specified in the Supply Agreement, will range between \$250 million and \$275 million, with the exact price tied to when the Company obtains the required regulatory approvals. The Supply Agreement provides for a down payment to be paid by the MOH, which ranges between 12.5% and 20% of the purchase price, for each of the Total Doses that it purchases and for the release of final payment from an escrow account upon completion of the delivery of the applicable doses after the Company obtains the required regulatory approvals.

As a result of the entry into the Supply Agreement, the MOH has secured the right to receive the maximum number of Total Doses currently specified in the Supply Agreement before any third party other than Singapore, subject to certain terms and conditions.

The foregoing description of the material terms of the Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the Supply Agreement, which will be filed with the Securities and Exchange Commission as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020.

**Item 7.01. Regulation FD Disclosure.**

On August 18, 2020, the Company issued a press release announcing its entry into the Supply Agreement, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 to this Current Report on Form 8-K, and in Exhibit 99.1 furnished herewith, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
99.1	<a href="#">Press Release dated August 18, 2020.</a>
104	Cover Page to this Current Report on Form 8-K in Inline XBRL

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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 18, 2020

**Arcturus Therapeutics Holdings Inc.**

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

# Arcturus Therapeutics Executes Definitive Supply Agreement with the Israeli Ministry of Health

SAN DIEGO, Aug. 18, 2020 (GLOBE NEWSWIRE) -- Arcturus Therapeutics Holdings Inc. (the “Company”, “Arcturus”, Nasdaq: ARCT), a leading clinical-stage 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 executed the definitive supply agreement provided for in the previously announced binding term sheet agreement with the Israeli Ministry of Health, to supply COVID-19 STARR™ mRNA vaccine candidate (ARCT-021). Delivery to Israel of doses of Arcturus’ COVID-19 vaccine candidate is contingent upon achievement of near term clinical and regulatory milestones.

“We are pleased to have executed the definitive supply agreement with the Israeli Ministry of Health. Arcturus is honored to play a key role in Israel’s COVID-19 vaccination strategy. As indicated in a recent press conference on July 23<sup>rd</sup>, led by Prime Minister Netanyahu, this is considered a significant deal to the government of Israel, providing them rights and access to ARCT-021 and a path to potentially vaccinate a substantial portion of their citizens against coronavirus,” said Joseph Payne, President & CEO of Arcturus. “We value the Israeli Ministry of Health’s commitment to our differentiating STARR™ mRNA vaccine candidate and we look forward to advancing the development of ARCT-021.”

Israel is the second country, in addition to Singapore, to reserve supply of the ARCT-021 vaccine. Arcturus is in active discussions with certain government entities in major markets and other parts of the world. With the Company’s manufacturing partners, Arcturus is in the process of manufacturing millions of doses in 2020 and positioned to supply hundreds of millions of doses annually thereafter.

For more information about rights and access to Arcturus’ COVID-19 vaccine candidate, ARCT-021, please contact Arcturus at [Vax@ArcturusRx.com](mailto:Vax@ArcturusRx.com).

## **About STARR™ Technology**

The STARR™ Technology platform combines self-replicating RNA with LUNAR®<sup>®</sup>, a leading nanoparticle delivery system, into a single solution to produce proteins inside the human body. The versatility of the STARR™ Technology affords its ability upon delivery into the cell to generate a protective immune response or drive therapeutic protein expression to potentially prevent against or treat a variety of diseases. The self-replicating RNA-based therapeutic vaccine triggers rapid and prolonged antigen expression within host cells resulting in protective immunity against infectious pathogens. This combination of the LUNAR®<sup>®</sup> and STARR™ technology is expected to provide lower dose requirements due to superior immune response, sustained protein expression compared to non-self-replicating RNA-based vaccines and potentially enable us to produce vaccines more quickly and simply.

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## **About Arcturus Therapeutics**

Founded in 2013 and based in San Diego, California, Arcturus Therapeutics Holdings Inc. (Nasdaq: ARCT) is a clinical-stage mRNA medicines and vaccines company with enabling technologies: (i) LUNAR<sup>®</sup> lipid-mediated delivery, (ii) STARR<sup>™</sup> mRNA Technology and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic and vaccine candidates includes self-replicating mRNA vaccine programs for SARS-CoV-2 (COVID-19) and Influenza, and other programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Cardiovascular Disease along with partnered programs including Glycogen Storage Disease Type 3, Hepatitis B Virus, 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 (192 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., Duke-NUS, and the Cystic Fibrosis Foundation. For more information visit [www.ArcturusRx.com](http://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 the Company's efforts to develop a vaccine against COVID-19, and therapeutic potential thereof, based on the Company's mRNA therapeutics, the ability of the Company to scale up manufacturing of vaccine doses, regulatory approval of the vaccine against COVID-19, the potential supply of the vaccine to government entities in major markets and other parts of the world and the impact of general business and economic conditions 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, 2019, filed with the SEC on March 16, 2020 and in subsequent filings with, or submissions to, the SEC. No assurances can be given that any results reported in pre-clinical studies can be replicated in further studies or in human beings, or that a vaccine can or will ever be developed or approved using the Company's technology. A more fulsome description of the definitive supply agreement will be included with the current report on Form 8-K to be filed by the Company with 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.

## **IR and Media Contacts**

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