

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): July 23, 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

(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.

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**Item 8.01. Other Events.**

On July 23, 2020, Arcturus Therapeutics Holdings Inc., or the Company, entered into a binding term sheet with the Israeli Ministry of Health, or MUH, to supply the Company's COVID-19 vaccine candidate, LUNAR-COV19 to the MUH. The parties intend to finalize a comprehensive supply agreement within 30 days, after which time, if the Supply Agreement has not been completed, the binding term sheet will continue on a non-binding basis.

The final LUNAR-COV19 supply terms are subject to the negotiation and finalization of a definitive supply agreement and will be subject to various customary terms and conditions.

The definitive supply agreement is expected to provide that the MUH will purchase a minimum number of LUNAR-COV19 doses and a specified maximum number of doses. If the maximum number of doses is supplied by the Company, the aggregate total payments for the specified LUNAR-COV19 doses will be \$275 million. Dose prices are not contingent on the final approved dosage level.

The definitive supply agreement is expected to set forth a payment schedule which provides for a significant initial payment to the Company, upon, among other potential triggers, the initiation of dosing of an expansion cohort as permitted by the Singapore Health Sciences Authority during the phase 1/2 clinical trial in Singapore, which is expected to occur in July or August of 2020. Additional payments are required upon final regulatory clearance in at least one specified jurisdiction and delivery and, in certain cases, a deposit will be required to maintain dose priority.

**Forward Looking Statements**

This summary 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 summary, 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, the timing of the entry into a supply agreement with the State of Israel, the actual entry into a supply agreement with the State of Israel, the expected terms and conditions of the supply agreement with the State of Israel, approval of the vaccine against COVID-19 by the Ministry of Health in Israel and other jurisdictions 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. 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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**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 July 23, 2020</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: July 23, 2020

**Arcturus Therapeutics Holdings Inc.**

By: /s/ Joseph E. Payne  
Name: Joseph E. Payne  
Title: Chief Executive Officer

*Israel secures rights to stockpile and reserve doses of LUNAR-COV19 for its citizens**Israel is the second country to reserve supply of LUNAR-COV19*

SAN DIEGO, July 23, 2020 (GLOBE NEWSWIRE) -- Arcturus Therapeutics Holdings Inc. (the "Company", "Arcturus", Nasdaq: ARCT), a leading clinical-stage messenger RNA medicines company focused on the discovery, development and commercialization of therapeutics for rare diseases and vaccines, today announced a binding term sheet with the Israeli Ministry of Health to supply the Company's COVID-19 vaccine candidate, LUNAR-COV19. The parties intend to finalize a comprehensive supply agreement within 30 days.

"We are very pleased to support Israel's vaccination strategy by agreeing to supply our novel self-replicating STARR™ mRNA vaccine candidate. The Arcturus team is working diligently to advance LUNAR-COV19 through clinical development and continues to scale up manufacture for the doses required for global distribution," said Joseph Payne, President & CEO of Arcturus.

Delivery to Israel of doses of Arcturus' COVID-19 vaccine candidate is contingent upon achievement of near term clinical and regulatory milestones and other conditions to be set forth in the definitive supply agreement. The government of Israel is responsible for distributing the vaccine to its citizens subject to approval by their Ministry of Health.

The Israeli Ministry of Health is the second government authority to reserve doses of LUNAR-COV19. Arcturus previously announced its partnership with Duke-NUS in Singapore, in which the Company recently received Clinical Trial Application (CTA) approval to proceed with a Phase 1/2 trial.

Arcturus continues to scale up manufacturing to potentially produce hundreds of millions of doses across 2020 and 2021. For more information about rights and access to Arcturus' COVID-19 vaccine candidate, LUNAR-COV19, please contact Arcturus by email at [Vax@ArcturusRx.com](mailto:Vax@ArcturusRx.com).

**About STARR™ Technology**

The STARR™ Technology platform combines self-replicating RNA with LUNAR®, a proprietary 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® 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® lipid-mediated delivery, (ii) STARR™ mRNA Technology and (iii) mRNA drug substance along with drug product manufacturing expertise. Arcturus' diverse pipeline of RNA therapeutic candidates includes programs to potentially treat Ornithine Transcarbamylase (OTC) Deficiency, Cystic Fibrosis, Glycogen Storage Disease Type 3, Hepatitis B, non-alcoholic steatohepatitis (NASH) and a self-replicating mRNA vaccine for SARS-CoV-2. 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, Catalent Inc., 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 expected performance, the Company's development of any specific novel mRNA therapeutics, 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, the timing of the entry into a supply agreement with the State of Israel, the actual entry into a supply agreement with the State of Israel, the expected terms and conditions of the supply agreement with the State of Israel, approval of the vaccine against COVID-19 by the Ministry of Health in Israel 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. 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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