

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): November 1, 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.

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

On November 1, 2022, Arcturus Therapeutics Holdings Inc. (“Arcturus”) entered into a Collaboration and License Agreement (the “Collaboration Agreement”) with CSL Seqirus, Inc., a part of CSL Limited (“CSL Seqirus”), one of the world’s leading influenza vaccine providers, for the research, development, manufacture and global commercialization of self-amplifying mRNA vaccines.

CSL Seqirus will receive exclusive global access to Arcturus’ technology for vaccines against SARS-CoV-2 (COVID-19), influenza and three other globally prevalent respiratory infectious diseases. Specifically, the Collaboration Agreement grants CSL Seqirus a license to Arcturus’ STARR™ mRNA technology and LUNAR® lipid-mediated delivery, as well as mRNA drug substance and drug product manufacturing expertise. CSL Seqirus would also receive global non-exclusive access to Arcturus’ intellectual property rights in the field of pandemic preparedness (*i.e.*, pathogens identified as priority diseases by the World Health Organization), with the right to convert to an exclusive license.

Arcturus will receive an up-front payment of \$200 million. Arcturus will be eligible to potentially receive development milestones totaling more than \$1.3 billion if all products are registered in the licensed fields. Arcturus will also be entitled to potentially receive up to \$3 billion in commercial milestones based on “net sales” of vaccines in the various fields. In addition, Arcturus is entitled to receive a 40% share of net profits from COVID-19 vaccine sales and up to low double digit royalties of annual net sales for vaccines against influenza and the other three specified infectious disease pathogens, as well as royalties on revenues from vaccines that may be developed for pandemic preparedness. Entitlement to all such payments is subject to the strict conditions, requirements, royalties reduction provisions and other limitations set forth in the Collaboration Agreement.

The Collaboration Agreement sets forth how Arcturus and CSL Seqirus shall collaborate to research and develop vaccine candidates. In the COVID-19 field, Arcturus will lead activities for certain regulatory filings for ARCT-154 in the US and Europe and for research and development activities of a next-generation COVID vaccine candidate. CSL Seqirus will lead and be responsible for all other research and development in COVID-19, influenza and the other fields. Arcturus will provide to CSL Seqirus a credit against milestone payments over five years to offset expenses of research and development activities on non-COVID-19 programs that Arcturus conducts at the request of CSL Seqirus. CSL Seqirus will have the sole exclusive right to commercialize any products that may be developed.

The Collaboration Agreement will not become effective until expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act. Either party may terminate the Collaboration Agreement on a field-by-field basis for material breach by the other party, following notice and opportunity to cure. CSL Seqirus may also terminate the Collaboration Agreement in its entirety or on a field-by-field basis for any reason or no reason whatsoever, but may not exercise this termination “for convenience” of the entire agreement or with respect to the influenza field prior to the first commercial sale of a “vaccine product” in the US, Japan, Australia or specified European countries. The Collaboration Agreement may also be terminated by CSL Seqirus for safety reasons, clinical data nonviability, commercial nonviability and other specified reasons.

The Collaboration Agreement allows Arcturus to fulfill its obligations under its award from the Biomedical Advanced Research and Development Authority (BARDA) relating to rapid pandemic influenza response and announced by Arcturus in August 2022.

The foregoing is only a partial summary of the material terms of the Collaboration Agreement, 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 Collaboration Agreement that will be filed as an exhibit to a subsequent filing on a periodic report.

### **Item 9.01 Financial Statements and Exhibits.**

#### **(d) Exhibits.**

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
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99.1	<a href="#">Press Release dated November 1, 2022</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: November 1, 2022

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

## Arcturus Announces Collaboration with CSL to Develop and Commercialize Self-amplifying mRNA Vaccines

- *Arcturus to receive upfront payment of \$200 million and more than \$4 billion in potential development and commercial milestones*
- *40% profit sharing for COVID-19 vaccines, up to double digit royalties for influenza, pandemic preparedness and three additional respiratory infectious disease vaccines*
- *Combines Arcturus' self-amplifying mRNA vaccine technologies with CSL's world-leading capabilities as a commercial scale manufacturer and global distributor of influenza and pandemic vaccines*

**San Diego, Calif, November 1, 2022** – 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 a strategic collaboration with CSL Seqirus, a global vaccine leader, for the research, development, manufacture, and global commercialization of vaccines. CSL Seqirus' vaccine portfolio includes the world's second largest influenza vaccine franchise. CSL Seqirus is part of CSL Limited (ASX:CSL; USOTC:CSLLY).

Under the terms of the agreement, Arcturus will provide CSL Seqirus with a license to their self-amplifying mRNA technology to support the research, development, manufacture, and commercialization of vaccines for SARS-CoV-2 (COVID-19), influenza, pandemic preparedness, as well as three other globally prevalent respiratory infectious diseases.

The collaboration combines CSL Seqirus' established global vaccine commercial and manufacturing infrastructure with Arcturus' manufacturing expertise and innovative STARR™ self-amplifying mRNA vaccine and LUNAR® delivery platform technologies. Arcturus will bring its mRNA design and modification expertise, LUNAR® lipid nanoparticle (LNP) technology and manufacturing know-how, which has enabled the Company's low dose, lyophilized and durable self-amplifying mRNA vaccines against COVID-19. Previously reported clinical results from ongoing ARCT-154 studies have demonstrated a favorable efficacy and safety profile with sustained neutralizing antibodies against COVID-19, including recent variants of concern.

“We are excited to embark on this collaboration with CSL Seqirus, a respected world leader in the development, manufacture and commercialization of vaccines,” said Joseph Payne, President and CEO of Arcturus Therapeutics. “We look forward to a long and fruitful partnership as we work together to develop next generation self-amplifying mRNA vaccines to protect against the most prevalent infectious diseases.”

### **Summary of Deal Terms and Financial Considerations**

Under the terms of the agreement, Arcturus will provide CSL Seqirus with a license to its STARR™ self-amplifying mRNA technology, LUNAR® lipid-mediated delivery, along with mRNA drug substance and drug product manufacturing expertise. CSL Seqirus will lead development and commercialization of vaccines under the collaboration. The collaboration plans to advance vaccines against SARS-CoV-2 (COVID-19), influenza, pandemic preparedness as well as three other globally prevalent respiratory infectious diseases.

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Arcturus will receive \$200 million upfront and is eligible to receive over \$1.3 billion in development milestones and over \$3 billion in commercial milestones. In addition, the Company is eligible to receive a 40% net profit share for COVID-19 vaccine products and up to double-digit royalties for vaccines against flu, pandemic preparedness and three other respiratory pathogens.

J.P. Morgan Securities LLC acted as financial advisor to Arcturus on the transaction.

#### **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). For more information, visit [www.ArcturusRx.com](http://www.ArcturusRx.com). In addition, please connect with us on [Twitter](#) and [LinkedIn](#).

#### **About CSL**

CSL (ASX:CSL; USOTC:CSLLY) is a leading global biotechnology company with a dynamic portfolio of lifesaving medicines, including those that treat haemophilia and immune deficiencies, vaccines to prevent influenza, and therapies in iron deficiency, dialysis and nephrology. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL – including our three businesses, CSL Behring, CSL Seqirus and CSL Vifor – provides lifesaving products to patients in more than 100 countries and employs 30,000 people. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For inspiring stories about the promise of biotechnology, visit [CSLBehring.com/Vita](http://CSLBehring.com/Vita) and follow us on [Twitter.com/CSL](https://twitter.com/CSL). For more information about CSL, visit [www.CSL.com](http://www.CSL.com).

#### **About CSL Seqirus**

CSL Seqirus is part of CSL Limited (ASX: CSL). As one of the largest influenza vaccine providers in the world, CSL Seqirus is a major contributor to the prevention of influenza globally and a transcontinental partner in pandemic preparedness. With state-of-the-art production facilities in the U.S., the U.K. and Australia, and leading R&D capabilities, CSL Seqirus utilizes egg, cell and adjuvant technologies to offer a broad portfolio of differentiated influenza vaccines in more than 20 countries around the world. For more information about CSL Seqirus, visit [www.seqirus.com](http://www.seqirus.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, are forward-looking statements, including those regarding strategy, the expectations for beginning the collaboration with CSL Seqirus, including receiving clearance under the Hart-Scott-Rodino Antitrust Improvements Act and satisfying other closing conditions, or the likelihood of success of the collaboration with CSL Seqirus or any collaborations, the likelihood of success of the Company's efforts to design and develop a vaccine against COVID, influenza or any other infectious disease, the strength or potential of the Company's platform, the future activities under and effectiveness of the collaboration, 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](http://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.

**IR and Media Contacts**

Arcturus Therapeutics  
[IR@ArcturusRx.com](mailto:IR@ArcturusRx.com)

Kendall Investor Relations  
Carlo Tanzi, Ph.D.  
(617) 914-0008  
[ctanzi@kendallir.com](mailto:ctanzi@kendallir.com)

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