

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): June 30, 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

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 7.01. Regulation FD Disclosure.

On June 30, 2023, Meiji Holdings Co., Ltd. announced that its subsidiary, Meiji Seika Pharma Co., Ltd. (“Meiji”), submitted an additional application for a Booster Dose of ARCT-154 for primary immunization to prevent COVID-19 in adults in Japan. This application follows the New Drug Application for ARCT-154 for primary immunization to prevent COVID-19 in adults (two doses of ARCT-154) in Japan, announced on April 28, 2023.

As previously announced on April 11, 2023, Meiji entered into a distribution agreement with Seqirus, Inc. (“CSL Seqirus”), a part of CSL Limited, and one of the world’s leading influenza vaccine providers, for the distribution and sales of ARCT-154, Arcturus Therapeutics Holdings Inc.’s (the “Company” or “Arcturus”) self-amplifying mRNA vaccine candidate against COVID-19, in Japan.

Also as previously announced, in November 2022, the Company entered into a Collaboration and License Agreement (the “CSL Collaboration Agreement”) with CSL Seqirus, for the global exclusive rights to research, develop, manufacture and commercialize Arcturus’ self-amplifying mRNA vaccines against COVID-19, influenza and three other respiratory infectious diseases with nonexclusive rights to pandemic pathogens. The CSL Collaboration Agreement became effective on December 8, 2022.

A copy of Meiji’s press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information set forth in this Item 7.01, including Exhibit 99.1, is furnished and shall not be deemed “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. The information in this Item 7.01 shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K 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 Current Report on Form 8-K, are forward-looking statements, including those regarding the collaboration with CSL Seqirus, Meiji, or any collaborations, and the outcomes of clinical trials involving ARCT-154. 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 Securities and Exchange Commission (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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description of Exhibit

99.1	Press Release dated June 30, 2023
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: June 30, 2023

Arcturus Therapeutics Holdings Inc.

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

Name of Company: Meiji Holdings Co., Ltd.
Name of Representative: Kazuo Kawamura, CEO, President and Representative Director
Code Number: 2269, Prime Market, Tokyo Stock Exchange

Additional Application for Booster Dose of ARCT-154,
Self-Amplifying mRNA Vaccine against COVID-19, Submitted in Japan

Meiji Holdings Co., Ltd. Announces that its subsidiary, Meiji Seika Pharma Co., Ltd., submitted an additional Application for a Booster Dose of ARCT-154 in adults in Japan. ARCT-154, a self-amplifying mRNA vaccine candidate against COVID-19 that was developed by Arcturus Therapeutics Inc. ^{*1}, and on April 11, 2023 Meiji Seika Pharma obtained exclusive rights to distribute ARCT-154 in Japan from CSL Seqirus. ^{*2}

ARCT-154 uses next-generation self-amplifying mRNA technology which generates a strong immune response, a favorable tolerability profile and the potential for extended duration of protection while using lower doses of mRNA compared to existing mRNA vaccines.

Meiji Seika Pharma submitted an additional Application for a booster dose of ARCT-154 based on results of a Phase III clinical trial (jRCT2071220080) conducted in Japan involving subjects aged 18 years and older, who had received 3 complete doses of mRNA vaccine and the last dose received with COMIRNATY[®] occurred 3 months and more prior to screening. The trial evaluated the geometric mean titers and seroconversion rates of neutralizing antibodies against SARS-CoV-2(Wuhan strain) on day 29 after a booster shot of ARCT-154 or COMIRNATY[®], and the results met its primary endpoint. No clinically significant concerns were identified in safety.

In the meantime, an NDA for primary immunization of ARCT-154 was submitted on April 28, 2023. This is the first application for a next generation mRNA vaccine in a developed country.

Under the terms of an agreement with CSL Seqirus, Meiji Seika Pharma will be responsible for obtaining regulatory approval, and for distribution, sales and marketing of ARCT-154 in Japan.

Meiji Seika Pharma is collaborating with ARCALIS, Inc. ^{*3} to establish integrated mRNA vaccine manufacturing capabilities from drug substance to drug product in Japan. ARCALIS is building a manufacturing facility in Minami-soma City, Fukushima Prefecture.

Meiji Seika Pharma is working to supply ARCT-154 in Japan as soon as possible following approval. If approved, ARCT-154 will become a new vaccination option against COVID-19. The impact on the consolidated financial results forecast for the fiscal year ending March 31, 2024, has not been determined at this time. We will closely examine the situation and disclose the impact as soon as it is recognized.

Disclaimer: This English translation is prepared for the readers' convenience. When there are any discrepancies between the original Japanese version and English translation version, the original Japanese version always prevails.

- *1: Arcturus Therapeutics Holdings Inc. founded in 2013, is 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. (<https://arcturusrx.com/>)
- *2: CSL Seqirus, a subsidiary of CSL Limited, is one of the world's largest suppliers of influenza vaccines. The company has state-of-the-art manufacturing facilities in the U.S., U.K., and Australia, and leading research and development capabilities. (<https://www.cslseqirus.com/>)
- *3: ARCALIS, Inc. is a joint venture company between Axcelead Inc. and Arcturus Therapeutics Inc., which owns a group of world-class drug-discovery and healthcare platform companies. The company provides drug discovery support, as well as a contract development and manufacturing business (CDMO business), for mRNA medicines and vaccines. (<https://corp.arcalis.co.jp/en>)

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