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): March 19, 2024

ARCTURUS THERAPEUTICS HOLDINGS INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38942**	**32-0595345**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 7.01 Regulation FD Disclosure.

On March 19, 2024, Meiji Holdings Co., Ltd. announced that its subsidiary, Meiji Seika Pharma Co., Ltd. ("Meiji"), announced today that a bivalent version of Kostaive® (ARCT-2301), Arcturus Therapeutics Holdings Inc.'s (the "Company" or "Arcturus") self-amplifying mRNA vaccine against COVID-19, met the primary endpoint in a Phase III clinical study for booster vaccination conducted in Japan.

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 the Company's self-amplifying mRNA vaccine candidate against COVID-19 in Japan.

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 partnered programs (including the COVID-19 and flu programs partnered with CSL Seqirus ("CSL")), the likelihood that preclinical or clinical data will be predictive of future clinical results, including that the results from Kostaive® (ARCT-154 or ARCT-2301) will be predictive of results for updated versions of the vaccine, the potential commercial launch of Kostaive®, the potential of the Company's platform technology to be meaningfully differentiated from other technologies, the likelihood that a patent will issue from any patent application, the likelihood or timing of collection of accounts receivables including expected payments from CSL, its current cash position and expected cash burn and runway, 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 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
99.1	Press Release dated March 19, 2024

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: March 19, 2024

Arcturus Therapeutics Holdings Inc.

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

NEWS RELEASE

Now ideas for wellness
meiji

Meiji Seika Pharma Co., Ltd.

March 19, 2024

Positive Results of Phase III Study of Bivalent Version of Kostaive®, Self-Amplifying mRNA Vaccine Against COVID-19 (Ancestral Strain and Omicron BA.4/5), for Booster Vaccination Conducted in Japan

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan, President and Representative Director: Daikichiro Kobayashi) announced today that a bivalent version of Kostaive® (ARCT-2301: ancestral strain with the D614G mutation and omicron BA.4-5 subvariant), self-amplifying mRNA vaccine against COVID-19, met the primary endpoint in phase III clinical study (jRCT2031230340) for booster vaccination conducted in Japan.

In the phase III clinical study, immunogenicity and safety of a bivalent version of Kostaive® (ARCT-2301) was compared with COMIRNATY® RTU (Bivalent: Ancestral strain and Omicron BA.4-5 subvariant) in healthy Japanese adults aged 18 years or older previously immunized with three to five doses of mRNA COVID-19 vaccine. Since non-inferiority of ARCT-2301 to COMIRNATY (BA.4/5) was confirmed both in the geometric mean titer (GMT) ratio and seroresponse rate (SRR) difference of neutralizing antibodies against SARS-CoV-2 (Omicron strain BA.4/5), the primary endpoint of the study was achieved. In addition, the superiority of ARCT-2301 to COMIRNATY (BA.4/5) was confirmed for both SARS-CoV-2 (Omicron strain BA.4/5 and Wuhan strain). There were no causally-associated severe or serious adverse events with ARCT-2301.

These results support immunogenicity and safety of Kostaive®'s self-amplifying mRNA platform enable Meiji Seika Pharma's timely release of update version of Kostaive® against novel variants of concern in 2024 in Japan.

Meiji conducted the study in collaboration with Arcturus Therapeutics and under its exclusive partnership with CSL Seqirus for the distribution of Kostaive® in Japan.

About sa-mRNA

In contrast to standard messenger RNA vaccine technology, self-amplifying messenger RNA (sa-mRNA) vaccine technology helps protect against infectious diseases by not only instructing cells in the body to make a specific protein, but also by making copies of these instructions. The produced protein antigen stimulates the immune response and leaves a blueprint to recognize and fight future infection. Because of the self-amplifying element of the vaccine, more protein is produced compared to an equivalent amount of standard mRNA, allowing for lower doses of sa-mRNA to be used. sa-mRNA also has the potential to prompt a potent and durable cellular immune response in addition to producing effective antibodies against the targeted virus.

About CSL Seqirus

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)

About Arcturus Therapeutics

Arcturus Therapeutics Holdings Inc. founded in 2013, is a global messenger RNA Medicines Company focused on the development of infectious disease vaccines and therapeutic opportunities within liver and respiratory rare diseases. (https://arcturusrx.com/)