

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 29, 2025

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.

Item 7.01 Regulation FD Disclosure.

On August 29, 2025, Meiji Holdings Co., Ltd. announced that its subsidiary, Meiji Seika Pharma Co., Ltd. (“Meiji”), announced today that it has received manufacturing and marketing approval in Japan for a new presentation of KOSTAIVE® (ARCT-2301), a self-amplifying mRNA vaccine against COVID-19. The product targets the SARS-CoV-2 Omicron sub lineage JN.1 variant XEC. In non-clinical studies, it induced neutralizing antibodies not only against Omicron JN.1 and XEC, but also against LP.8.1 and the currently circulating variants XFG and NB.1.8.1. The formulation is supplied as a two-dose vial, with one vial per carton.

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 Arcturus Therapeutics Holdings Inc.’s (the “Company” or “Arcturus”) 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 non-clinical data will be predictive of future results, the potential supply of KOSTAIVE® in 2025 and timing therefor, 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 August 29, 2025

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 29, 2025

Arcturus Therapeutics Holdings Inc.

By: /s/ Joseph E. Payne

Name: Joseph E. Payne

Title: Chief Executive Officer

Meiji Seika Pharma Receives Approval in Japan for Two-Dose Vial of KOSTAIVE[®], a Self-Amplifying mRNA COVID-19 Vaccine

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, Japan; President and Representative Director: Toshiaki Nagasato) announced today that it has received manufacturing and marketing approval dated August 28 in Japan for a new presentation of KOSTAIVE[®], a self-amplifying mRNA vaccine against COVID-19, supplied in vials containing two doses.



The product targets the SARS-CoV-2 Omicron sub lineage JN.1 variant XEC. In non-clinical studies, it induced neutralizing antibodies not only against Omicron JN.1 and XEC, but also against LP.8.1 and the currently circulating variants XFG and NB.1.8.1. The formulation is supplied as a two-dose vial, with one vial per carton.

Meiji Seika Pharma is preparing to supply the product starting in late September 2025 and remains committed to help prevent COVID-19.

About sa-mRNA

mRNA vaccines help protect against infectious diseases by providing a blueprint for cells in the body to make a protein to help our immune systems recognize and fight the disease. Compared to standard mRNA vaccines, self-amplifying mRNA vaccines instruct the body to make more mRNA and spike protein to generate a more durable immune response