
**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 10, 2023

ARCUTIS BIOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39186
(Commission
File Number)

81-2974255
(IRS Employer
Identification Number)

3027 Townsgate Road, Suite 300
Westlake Village, CA 91361
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (805) 418-5006

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 (see General Instructions A.2. below):

- 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 \$0.0001 per share | ARQT | The Nasdaq Global Select Market |

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 1.01 Entry into a Material Definitive Agreement.

On August 10, 2023, Arcutis Biotherapeutics, Inc. (“Arcutis” or the “Company”) entered into a License Agreement (the “License Agreement”) with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (“Huadong”), a wholly owned subsidiary of Huadong Medicine Co., Ltd. Pursuant to the terms of the License Agreement, the Company grants to Huadong an exclusive, sublicensable (under certain circumstances) license under certain patent rights and know-how controlled by the Company for Huadong to develop, conduct medical affairs activities for, manufacture, commercialize and otherwise exploit ZORYVE® (roflumilast) cream and ARO-154 topical roflumilast foam (the “Licensed Products”) for all therapeutic uses for certain dermatological indications (the “Field”) in Greater China (mainland China, Hong Kong, Macau and Taiwan) and Southeast Asia (Indonesia, Singapore, The Philippines, Thailand, Myanmar, Brunei, Cambodia, Laos, Malaysia, and Vietnam) (the “Territory”).

The License Agreement sets forth each party’s respective obligations with respect to the development, medical affairs activities, manufacture and supply, and commercialization of the Licensed Products. Pursuant to the terms of the License Agreement, Huadong will, at its expense, develop, obtain regulatory approval for, commercialize and conduct medical affairs activities related to the Licensed Products in the Field in the Territory, subject to certain of the Company’s approval and oversight rights.

Pursuant to the terms of the License Agreement, the Company will receive an upfront payment of \$30 million and potentially receive additional payments (i) up to an aggregate amount of \$24 million upon the achievement of certain development and regulatory milestones and (ii) up to an aggregate amount of \$40.25 million upon the achievement of certain sales milestones. In addition, on a Licensed Product-by-Licensed Product and country or region-by-country or region basis, commencing from the first commercial sale of such Licensed Product in such country or region until the latest of (i) the expiration of the last valid claim in the intellectual property rights licensed by the Company to Huadong under the License Agreement covering such Licensed Product in such country or region, (ii) the expiration of regulatory exclusivity for such Licensed Product in such country or region, or (iii) ten years after the first commercial sale of such Licensed Product in such country or region (the “Royalty Term”), the Company will receive low double-digit to high-teen double-digit percentage royalties on Huadong’s, its affiliates’ and sublicensees’ total net sales, subject to certain royalty reductions.

The term of the License Agreement continues until, on a Licensed Product-by-Licensed Product and country or region-by-country or region basis, the expiration of the Royalty Term. The License Agreement may be terminated by either party in its entirety if the other party commits a material breach, subject to a cure period, or if the other party becomes insolvent. Huadong may terminate the License Agreement at-will in its entirety upon 90 days’ written notice. Unless unenforceable under applicable law, the Company may terminate the License Agreement in its entirety if Huadong, its affiliate or sublicensee contests or assists a third party in contesting the scope, validity or enforceability of any patent or patent application licensed by the Company to Huadong. The Company may also terminate the License Agreement if Huadong (a) is convicted in a final and non-appealable judgment of a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations or (b) any director, officer, employee, agent, affiliate, sublicensee or subcontractor of Huadong is convicted in a final and non-appealable judgment of a violation of any anti-corruption, anti-money laundering, sanctions or export or import control laws or regulations in relation to the performance of the License Agreement or, subject to the terms of the License Agreement, if Huadong, its affiliates and sublicensees do not conduct any material development or commercialization activities of a Licensed Product in the Territory for a certain period of time.

The foregoing description of the License Agreement is qualified in its entirety by reference to the License Agreement, a copy of which will be filed as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 14, 2023

ARCUTIS BIOTHERAPEUTICS, INC.

/s/ Scott L. Burrows

Scott L. Burrows

Chief Financial Officer