
**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): September 7, 2022

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, Suite300
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 September 7, 2022, Arcutis Biotherapeutics, Inc., a Delaware corporation (“Arcutis”), entered into a Share Purchase Agreement (the “Purchase Agreement”) with Ducentis Biotherapeutics LTD., a private company limited by shares, incorporated and registered in England and Wales (“Ducentis”) and the holders of the equity interests in Ducentis (the “Sellers”), pursuant to which Arcutis will acquire (the “Acquisition”) all of the outstanding equity interests in Ducentis for (i) aggregate upfront consideration of approximately \$30 million (the “Upfront Consideration”), consisting of 610,258 shares of Arcutis common stock valued at approximately \$14.1 million based on the average closing price of Arcutis common stock over a 60-trading day period ending on August 31, 2022, with the balance of the upfront consideration to be paid in cash and (ii) contingent payments, the amount of which is indeterminable until achieved, which may become payable upon the achievement of certain development, regulatory and commercial milestones. Arcutis currently estimates that these contingent payments may be up to an aggregate of approximately \$400 million (although the actual amount may differ depending on whether the applicable milestones are achieved). In addition, if applicable, Arcutis will make payments amounting to a mid-single-digit percentage of any annual net sales of Ducentis’s products exceeding \$1.5 billion. The cash portion of the Upfront Consideration is subject to customary adjustments based on Ducentis’s balance sheet as of closing.

Under the terms of the Purchase Agreement, following the closing Arcutis will be required to use its commercially reasonable efforts to develop and seek FDA approval of a therapeutic product containing Ducentis’s DS-234 product candidate (a “DS-234 Product”) for an atopic dermatitis indication, and if FDA approval of a DS-234 Product is obtained by Arcutis, to launch a Product in the United States. Arcutis may elect to substitute and pursue a different Ducentis product candidate, in which case the development and regulatory approval commitments described above will apply to the substituted product candidate.

The Purchase Agreement contains customary representations and warranties and covenants from each of Arcutis, Ducentis and the Sellers. The closing of the Acquisition is subject to customary closing conditions. No antitrust or competition clearances, or Arcutis stockholder approvals, will be required for closing which is anticipated to occur in the third quarter of 2022.

The foregoing description of the Purchase Agreement and the transactions contemplated thereby does not purport to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement, a copy of which will be filed, with confidential terms redacted, as an exhibit to Arcutis’s Quarterly Report on Form 10-Q for the quarter ending September 30, 2022.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

To the extent required by Item 2.03 of Form 8-K, reference is made to the disclosures set forth in Item 1.01, which are incorporated by reference into this Item 2.03.

Item 3.02 Unregistered Sales of Equity Securities

To the extent required by Item 3.02 of Form 8-K, reference is made to the disclosures set forth in Item 1.01, which are incorporated by reference into this Item 3.02. Arcutis issued the shares of its Common Stock in reliance on one or more exemptions from registration provided for under Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”), including Regulation S and Regulation D thereunder.

Item 7.01 Regulation FD Disclosure.

On September 7, 2022, the Company issued a press release announcing entry into the Purchase Agreement. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Item 7.01, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), as amended, or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act, regardless of any general incorporation language in any such filings, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Arcutis Announces Acquisition of Ducentis BioTherapeutics Ltd.
104	Cover Page Interactive Data File, formatted in inline XBRL.

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.

September 7, 2022

ARCUTIS BIOTHERAPEUTICS, INC.

By: /s/ Scott L. Burrows

Scott L. Burrows

Chief Financial Officer



Arcutis Announces Acquisition of Ducentis BioTherapeutics Ltd.

- Leverages Arcutis' deep dermatology expertise and broad biologics experience to accelerate Ducentis' lead compound, DS-234, in atopic dermatitis
- Lead indication, atopic dermatitis, is a rapidly growing, significantly underserved market with large unmet need
- Checkpoint agonism is a promising emerging pathway for the treatment of atopic dermatitis, with preclinical and clinical validation data suggesting a durable biologic response
- DS-234 offers a potential best-in-class profile, as well as a highly complementary treatment option to roflumilast cream which is in late-stage development for atopic dermatitis

WESTLAKE VILLAGE, Calif., September 7, 2022 -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced it has entered into an agreement to acquire Ducentis BioTherapeutics Ltd., a privately held, preclinical-stage biotechnology company focused on developing novel therapies for inflammation and autoimmune diseases. Under the terms of the share purchase agreement, Arcutis will acquire the outstanding shares of Ducentis for an upfront cash payment of approximately \$16 million and Arcutis stock valued at approximately \$14 million, as well as future contingent payments based on development and commercial success. Closing of the transaction will be subject to customary closing conditions.

Ducentis' lead asset is DS-234, a fusion protein that is a highly selective and potent agonist of the CD200 receptor (CD200R). CD200R is an immune-regulatory receptor that is thought to be an important immunological checkpoint with a pivotal role in the maintenance of immune tolerance. Checkpoint agonism is an emerging immunomodulatory approach that works to amplify pathways that inhibit over-active immune cells and suppress unwanted immune responses. DS-234 binds to CD200R, restoring immune homeostasis by inducing inhibitory signaling on immune cells that regulate inflammation.

CD200R has been validated as a target in atopic dermatitis, with recent preclinical and clinical data providing evidence of a durable biologic response, even after discontinuation of treatment¹. Ducentis has completed preclinical comparisons of DS-234 against the clinically-validated CD200R antibody. The data compare favorably across key metrics including potency, efficacy, and pharmacokinetics, offering potential differentiation through an improved ability to modulate the CD200 pathway, a longer half-life, and a higher steady state volume of distribution.

“This acquisition is an important step in realizing our vision of becoming the leading, innovation-driven medical dermatology company, and leverages our deep dermatology expertise and capabilities across the organization to develop, manufacture, and commercialize therapies that address important unmet needs across the continuum of care,” said Frank Watanabe, Arcutis President and Chief Executive Officer. “Ducentis’ DS-234 fits in well with our strategy of developing potential best-in-class molecules against biologically-validated targets and is highly complementary to roflumilast cream as another potential innovative treatment option. We are excited by the promise of checkpoint agonism as an emerging strategy for the treatment of atopic dermatitis. Additionally, with the majority of our clinical, manufacturing, and commercial teams already possessing experience with biologic agents, DS-234 fits well with our team’s expertise. With a modest investment, we believe we can generate proof-of-concept data against a de-risked target in a high-value indication.”

“Ducentis is thrilled to join Arcutis, which has the resources, experience, and commitment needed to accelerate the clinical development of DS-234 as an important new treatment option for patients with atopic dermatitis, and in the future, other serious autoimmune diseases lacking effective treatment options,” said Philip Huxley, Ph.D., Founder and former Chief Executive Officer of Ducentis. “With Arcutis’ depth of knowledge and capabilities in dermatology, and its team’s experience developing, manufacturing, and commercializing biologics, we are confident that Arcutis is well positioned to build on the pre-clinical work that the Ducentis team has completed to date.”

Ducentis’ Chief Scientific Officer, Dr. Rebecca Ashfield, will be retained by Arcutis as a consultant to ensure knowledge transfer, integration of ongoing workstreams, and lead future technical and manufacturing operations related to DS-234.

As of June 30, 2022, Arcutis had approximately \$283 million in cash, cash equivalents, and marketable securities and received over \$285 million from additional financings in early August. Given the early-stage nature of the DS-234 program, the Ducentis acquisition is not expected to have a material impact on Arcutis' financial plans.

Covington and Burling LLP acted as legal advisor to Arcutis. Goodwin Procter LLP acted as legal advisor to Ducentis.

About Atopic Dermatitis

Atopic dermatitis (AD) is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms, and legs. The rash can cover significant areas of the body, in some cases impacting half of the body or more.

About Ducentis BioTherapeutics Ltd.

Ducentis Biotherapeutics is a pre-clinical stage biotech company aiming to develop novel therapies for autoimmune disease patients with poor treatment options. It was founded in 2015 by Dr. Philip Huxley, Professor David Blackburn and Dr. Rebecca Ashfield to explore the potential of the CD200 pathway to control unwanted or exaggerated immune responses. CD200R agonists offer a conceptually differentiated mechanism of action by specifically targeting overactive immune cells and restoring homeostasis, compared to conventional immunomodulators exploiting blockade mechanisms, for example cytokine blockade. CD200R is expressed on myeloid cells, which are important in the chronic phases of many autoimmune conditions, whereas many checkpoint receptors are restricted to T cell populations. The Ducentis team selected atopic dermatitis as the lead indication for the CD200 program following analysis of published genetic linkage studies which demonstrated a relationship between dysregulation of the CD200 pathway and disease incidence in atopic dermatitis patients. For more information visit www.ducentisbio.com

About Arcutis

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis harnesses our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis' dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including scalp psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

Forward-Looking Statements

This press release contains "forward-looking" statements, including, among others, statements regarding Arcutis' proposed acquisition of Ducentis, including the prospects for development of Ducentis' programs. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements and you should not place undue reliance on our forward-looking statements. These risks and uncertainties include among other things, risks related to Arcutis' and Ducentis' ability to successfully complete proposed acquisition; risks that the businesses will not be integrated successfully, including that it is more costly than expected or that the expected benefits of the proposed acquisition will not be realized; negative effects of this announcement or the consummation of the proposed acquisition on the market price of Arcutis' common stock and/or operating results; unknown liabilities; the risk of litigation and/or regulatory actions related to the proposed acquisition or Ducentis' business; the uncertainties inherent in research and development, including clinical trial results, regulatory obligations and oversight by regulatory authorities, such as the FDA, including decisions whether and when to approve a biological license application(s), the content of its label and other matters that could affect the availability or commercial potential of the associated product candidate(s); the absence of a guarantee that any product candidates, if approved, will be commercially successful; risks associated with Arcutis' and Ducentis' intellectual property and any related pending or future litigation; other business effects and uncertainties, including the effects of industry, market, business, economic, political or regulatory conditions; changes in tax and other laws, regulations, rates and policies; and uncertainties regarding impact of COVID-19 and competitive developments. While the list of factors presented here is representative, no list should be considered a statement of all potential risks, uncertainties or assumptions that could have a material adverse effect on Arcutis' consolidated financial condition or results of operations. The foregoing factors should be read in conjunction with the risks and uncertainties discussed and identified under the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as amended on March 3, 2022, as well as any subsequent filings with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

¹ Lilly 2021 Investor Community Meeting, [<https://investor.lilly.com/static-files/9efbede9-bd6a-4d7b-823e-2996b1c2d114>]

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