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): November 23, 2020

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

Delaware	**001-39186**	**81-2974255**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

2945 Townsgate Road, Suite 110
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 8.01 Other Events

On November 23, 2020, Arcutis Biotherapeutics, Inc. issued a press release announcing positive top line data from its Phase 2b clinical trial evaluating ARQ-154 (topical roflumilast foam) as a potential treatment for scalp psoriasis. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 23, 2020.
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.

ARCUTIS BIOTHERAPEUTICS, INC.

Date: November 23, 2020

By: /s/ John W. Smither
John W. Smither
Chief Financial Officer

Exhibit 99.1

Arcutis Announces Positive Topline Data from Phase 2b Study of ARQ-154 (Topical Roflumilast Foam) as a Potential Treatment for Scalp and Body Psoriasis

- Roflumilast foam demonstrated statistically significant improvement on the trial's primary and multiple secondary endpoints
- Once-daily roflumilast foam demonstrated a favorable safety and tolerability profile
- Roflumilast foam potential "Best in Class" topical scalp and body psoriasis treatment
- Scalp psoriasis affects more than 2.5 million of the 6 million psoriasis patients in U.S with active disease
- Company to host a conference call today at 8:30 a.m. EST

Westlake Village, CA, Nov. 23, 2020 – Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced positive top line data from its Phase 2b clinical trial evaluating ARQ-154 (topical roflumilast foam) as a potential treatment for scalp psoriasis.

Roflumilast foam 0.3% administered once daily for 8 weeks demonstrated statistically significant improvements compared to a matching vehicle foam on key efficacy endpoints in 304 adult and adolescent patients with plaque psoriasis that included plaques on the scalp. On the study's primary endpoint of Scalp Investigator Global Assessment (S-IGA) success assessed at week 8, roflumilast foam 0.3% achieved a rate of 59.1% compared to a vehicle rate of 11.4% ($p<0.0001$). S-IGA success is defined as the achievement of an S-IGA score of 'clear' or 'almost clear' on a 5-grade scale plus at least a two-point change from baseline. Onset was rapid, with significantly higher rates of S-IGA success noted as early as 2 weeks.

Multiple secondary endpoints were also met. On the key secondary endpoint of Body Investigator Global Assessment (B-IGA) success assessed at week 8, roflumilast foam 0.3% achieved a rate of 40.3% compared to a vehicle rate of 6.8% ($p<0.0001$), with separation from vehicle on B-IGA success as early as 2 weeks. Symptomatic improvement was also demonstrated, with 71.0% of subjects treated with roflumilast foam 0.3% who had a baseline Scalp Itch Numeric Rating Scale (SI-NRS) score of 4 or greater achieving an itch reduction of at least 4 points at week 8 compared to 18.5% of vehicle treated subjects ($p<0.0001$). Consistent with other clinical trials of topical roflumilast, roflumilast foam was well-tolerated, as evidenced by subject-reported local tolerability and rates of application site adverse events, treatment-related adverse events, and discontinuations due to adverse events low and similar to vehicle. Only 5 out of 200 subjects (2.5%) in the roflumilast foam treated group discontinued the study due to an adverse event, compared to 2 out of 104 subjects (1.9%) treated with the vehicle.

“Scalp psoriasis inflicts a high burden for patients, and current treatment options often carry significant treatment limitations that result in poor outcomes and can have a negative impact on patient quality of life,” said Leon Kircik, MD, Clinical Professor of Dermatology, Icahn School of Medicine at Mount Sinai, Indiana University Medical Center, and Medical Director, Physicians Skin Care, DermResearch, and Skin Sciences. “Roflumilast once-daily foam demonstrated rapid and significant improvements in psoriasis signs and symptoms, including reducing itch in a meaningful way. These positive results are encouraging for patients and clinicians who are desperate for new treatments that can simplify disease management, can be used in all areas of the body, and can ultimately improve the patient experience.”

“Approximately 40 percent of the 6 million Americans afflicted with active, chronic psoriasis have scalp involvement, an area where treatment of scalp plaques is complicated by the difficulty of delivering topical drugs under the hair and to the surface of the skin,” said Linda F. Stein Gold, MD, Director of Dermatology Clinical Research at Henry Ford Health System in Detroit, Michigan, as well as Division Head of Dermatology at Henry Ford Health System in West Bloomfield, Michigan. “Novel treatments are needed, particularly ones like topical roflumilast foam that have the potential to be safe for chronic use; that are appropriate for application in hair-bearing areas where a cream, lotion, or ointment is not suitable; and that have demonstrated symptomatic improvement similar to high-potency steroids while also maintaining a favorable safety and tolerability profile. I believe these data demonstrate that once daily roflumilast foam could offer patients the efficacy and tolerability that they need. In my opinion, if approved, topical roflumilast foam has the potential to become an important treatment option for plaque psoriasis patients, particularly those with scalp involvement.”

“We are delighted with these data, in which topical roflumilast foam demonstrated meaningful symptomatic improvement, alongside a favorable safety and tolerability profile that supports chronic use,” said Patrick Burnett, M.D., Ph.D., FAAD, and Chief Medical Officer of Arcutis. “With once-a-day dosing, roflumilast foam potentially offers the convenience of a simple, single, non-steroidal solution for both scalp and non-scalp plaques. If successful in Phase 3 clinical trials and approved for commercialization, roflumilast foam will be the first novel mechanism of action for the treatment of scalp and body psoriasis in decades. We believe it has the potential to positively affect the symptoms and quality of life of the millions of patients who suffer from this distressing chronic skin condition.”

Management will host a conference call today at 8:30 a.m. EST to discuss these results. To access the call, please dial (833) 614-1393 (domestic) or (914) 987-7114 (international) prior to the scheduled conference call time and provide the conference ID 8960956. A live webcast of the call will be available on the “Investors” section of the company’s website, www.arcutis.com. An archived version of the webcast will be available on the Arcutis website after the call.

About Roflumilast Foam

Roflumilast foam is a once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4 inhibitor) that Arcutis is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp.

Roflumilast has been approved by the FDA for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency (25- to-300 fold) than the two other FDA-approved PDE4 inhibitors. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the FDA for the topical treatment of atopic dermatitis or the systemic treatment of plaque psoriasis.

Arcutis believes roflumilast foam has significant potential as a treatment for scalp psoriasis and seborrheic dermatitis. Roflumilast foam is nearly identical to ARQ-151 (topical roflumilast cream), Arcutis' investigational topical cream PDE4 inhibitor that has demonstrated symptomatic improvement and a favorable tolerability profile in Arcutis' clinical trials in plaque psoriasis, as well as encouraging results in atopic dermatitis. Arcutis completed enrollment in DERMIS-1 and DERMIS-2, the Company's pivotal Phase 3 clinical trials evaluating topical roflumilast cream as a potential topical treatment for plaque psoriasis, and the Company expects to announce topline data in the first quarter of 2021 and to submit a New Drug Application (NDA) submission by the end of 2021. In addition, following its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), Arcutis plans to advance its program to develop topical roflumilast cream for the treatment of atopic dermatitis into Phase 3 clinical trials beginning in early 2021.

About Scalp Psoriasis

Scalp psoriasis is a manifestation of plaque psoriasis characterized by raised, red areas of skin ("plaques") covered with a silver or white scale that occurs in the hair-bearing area of the scalp and sometimes extending to the forehead, back of the neck, or behind or inside the ears. Patients with scalp psoriasis commonly have plaques on other areas of the body as well. Approximately 40 percent of the estimated 8.6 million Americans with psoriasis have involvement of the scalp, and over a lifetime, up to 80 percent of psoriasis patients may experience scalp involvement. Scalp psoriasis plaques are identical to psoriatic plaques on other areas of the body; however, topical treatment of scalp plaques is complicated by the difficulty of delivering topical drugs under the hair and onto the

skin. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area. Often, patients require two or more medications to manage their disease when they have scalp involvement.

About Arcutis - Bioscience, applied to the skin.
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis' robust pipeline includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The company's lead product candidate, topical roflumilast, has the potential to revitalize the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow the company on LinkedIn and Twitter.

Forward Looking Statements

This press release contains "forward-looking" statements, including, among others, statements regarding roflumilast foam's potential as a scalp and body psoriasis treatment and whether roflumilast cream's Phase 2 results may be predictive of roflumilast foam's potential clinical outcomes. 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. Risks and uncertainties that may cause our actual results to differ include risks inherent in the clinical development process and regulatory approval process, the timing of regulatory filings, and our ability

to defend our intellectual property. For a further description of the risks and uncertainties applicable to our business, see the “Risk Factors” section of our Form 10-Q filed with U.S. Securities and Exchange Commission (SEC) on November 5, 2020, 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.

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