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): February 16, 2021

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)**

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 2.02 Results of Operations and Financial Condition.

On February 16, 2021, Arcutis Biotherapeutics, Inc. (the "Company" or "Arcutis") issued a press release relating to its financial results for the quarter and year ended December 31, 2020. The full text of the press release is furnished herewith as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto 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, or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release February 16, 2021.

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.

February 16, 2021

By: /s/ John W. Smither

John W. Smither

Chief Financial Officer

Arcutis Announces Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

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- NDA submission for topical roflumilast cream as a potential treatment for plaque psoriasis anticipated in the second half of 2021
- Positive Phase 3 data on topical roflumilast cream in plaque psoriasis reported in February
- Advancing topical roflumilast into Phase 3 programs for atopic dermatitis, seborrheic dermatitis, and scalp psoriasis during 2021
- Robust pipeline addressing unmet medical needs of over 20 million patients
- Strong financial position with over $470 million in cash, cash equivalents and marketable securities, including the proceeds from recent equity offering, providing cash runway into 2023

Westlake Village, CA, Feb. 16, 2021 – 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 reported financial results for the quarter and year ended December 31, 2020, and provided a business update.

“2020 was a year of incredibly strong execution for Arcutis,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “From our initial public offering in February through implementation of 18 clinical trials with three different product candidates involving more than 3,200 patients, we made tremendous progress advancing our mission of addressing significant unmet needs in medical dermatology. I am unbelievably grateful to the patients and physicians participating in our clinical trials, and to our amazing Arcutis team. This effort culminated in multiple notable milestones, including our recently reported positive pivotal Phase 3 results in plaque psoriasis, positive Phase 2 results in atopic dermatitis, seborrheic dermatitis, and scalp psoriasis, and the landmark publication of plaque psoriasis Phase 2b data in the New England Journal of Medicine.”

Mr. Watanabe continued, “2021 will be a transformational year for Arcutis as we continue to rapidly advance our innovative and differentiated late-stage pipeline of potential best-in-class topical dermatology therapies. Based on positive Phase 3 data, we anticipate submitting a New Drug Application to the FDA for topical roflumilast cream as a potential once daily topical treatment for plaque psoriasis this year. We are excited to advance three additional programs into pivotal Phase 3 trials in 2021. Our focus on addressing the gap in dermatology drug development currently includes four product candidates in development for seven indications, with an addressable U.S. market of over 20 million patients, representing a potential revenue opportunity of between $3 billion and $8 billion.”

Pipeline Updates

ARQ-151 (topical roflumilast cream) - a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor in a cream formulation, being developed as a potential treatment for plaque psoriasis, including intertriginous psoriasis, and atopic dermatitis.

- Reported positive results from the two pivotal Phase 3 clinical trials (DERMIS-1 and DERMIS-2) in patients with plaque psoriasis; New Drug Application (NDA) submission to U.S. FDA anticipated in the second half of 2021.
- Pivotal Phase 3 trials in patients with atopic dermatitis (INTEGUMENT-1 and INTEGUMENT-2) initiated in January 2021 with topline data anticipated in the second half of 2022.
- Reported positive results from the Phase 2 long-term safety study as a potential once-daily chronic topical treatment for plaque psoriasis.

ARQ-154 (topical roflumilast foam) - a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor in a foam formulation, designed to overcome the challenges of delivering topical drugs in hair-bearing areas of the body, being developed as a potential treatment for seborrheic dermatitis and scalp psoriasis.

- Reported positive topline data from Phase 2b study in patients with scalp and body psoriasis which affects more than 2.5 million of the 6 million psoriasis patients in U.S with active disease.
- Announced advancement of seborrheic dermatitis into Phase 3 development, anticipating initiation of a single pivotal Phase 3 study (STRATUM) in the second or third quarter of 2021, with topline data anticipated in the second or third quarter of 2022.
- Pending discussions with regulators, the Company expects to initiate its Phase 3 program in scalp psoriasis in the second half of 2021, with topline data anticipated in the second half of 2022.

ARQ-252 - a potent and highly selective topical small molecule inhibitor of Janus kinase type 1 (JAK1), being developed as a potential treatment for chronic hand eczema and other inflammatory dermatoses.

- Completed enrollment of the ongoing Phase 1/2b study in chronic hand eczema, with topline data anticipated by mid-2021.
- The Company anticipates initiating a Phase 2a study in vitiligo in the first quarter of 2021.

ARQ-255 - an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata.

- Formulation and preclinical efforts are underway.

Recent Corporate Highlights

- Terrie Curran appointed to Arcutis' Board of Directors
- Arcutis common stock (ARQT) added to the Nasdaq Biotechnology Index
- Matthew Moore joined the Company as Chief Business Officer
- Completed underwritten public offering of common stock in February 2021 with gross proceeds of $221.4 million and net proceeds of $207.4 million.

Fourth Quarter and Full Year 2020 Summary Financial Results

Cash, cash equivalents, restricted cash and marketable securities were $286.0 million as of December 31, 2020, compared to $101.3 million as of December 31, 2019. Arcutis believes that its current cash, cash equivalents and marketable securities of over $470 million, including the $207.4 million net proceeds from its recent financing, will be sufficient to fund its operations into 2023.

Research and development (R&D) expenses for the quarter ended December 31, 2020 were $27.4 million compared to $10.8 million for the corresponding period in 2019. R&D expenses for the year ended December 31, 2020 were $115.3 million compared to $36.5 million for the corresponding period in 2019. These year-over-year increases were primarily due to the initiation of multiple clinical trials during the last year.

General and administrative (G&A) expenses for the quarter ended December 31, 2020 were $6.7 million compared to $2.2 million for the corresponding period in 2019. G&A expenses for the year ended December 31, 2020 were $21.3 million compared to $6.6 million for the corresponding period in 2019. These year-over-year increases were primarily due to higher headcount and professional services costs, including the costs associated with being a public company.

Net loss was $34.0 million, or $0.79 per basic and diluted share, for the quarter ended December 31, 2020 compared to $12.6 million, or $6.13 per basic and diluted share, for the corresponding period in 2019. Net loss was $135.7 million, or $3.80 per basic and diluted share, for the year ended December 31, 2020 compared to $42.0 million, or $22.78 per basic and diluted share, for the corresponding period in 2019.

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 https://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 the potential for its topical drugs in development to address large markets with significant unmet need; expectations with regard to the timing of data events anticipated during 2021/2022; and the Company's belief that its current cash, cash equivalents and marketable securities, including the net proceeds from its recent financing, will be sufficient to fund its operations into 2023. 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-K filed with U.S. Securities and Exchange Commission (SEC) on February 16, 2021, 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.

Contact:
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ARCUTIS BIOTHERAPEUTICS, INC.
Balance Sheets
(In thousands)

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 65,082	$ 63,336
Restricted cash	1,542	—
Marketable securities	219,359	37,929
Prepaid expenses and other current assets	6,843	5,209
Total current assets	292,826	106,474
Property and equipment, net	2,016	227
Operating lease right-of-use asset	3,349	264
Other assets	78	47
Total assets	$ 298,269	$ 107,012
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 7,140	$ 1,405
Accrued liabilities	15,462	3,654
Operating lease liability	—	178
Total current liabilities	22,602	5,237
Operating lease liability, noncurrent	4,964	129
Other long-term liabilities	82	184
Total liabilities	27,648	5,550
Convertible preferred stock	—	166,491
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	4	—
Additional paid-in capital	472,569	1,244
Accumulated other comprehensive loss	(2)	(1)
Accumulated deficit	(201,950)	(66,272)
Total stockholders' equity (deficit)	270,621	(65,029)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 298,269	$ 107,012

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
	(unaudited)			
Operating expenses:				
Research and development	$ 27,374	$ 10,757	$ 115,308	$ 36,522
General and administrative	6,690	2,237	21,337	6,610
Total operating expenses	34,064	12,994	136,645	43,132
Loss from operations	(34,064)	(12,994)	(136,645)	(43,132)
Other income, net	15	426	967	1,136
Net loss	$ (34,049)	$ (12,568)	$ (135,678)	$ (41,996)
Per share information:				
Net loss per share, basic and diluted	$ (0.79)	$ (6.13)	$ (3.80)	$ (22.78)
Weighted-average shares used in computing net loss per share, basic and diluted	42,977,244	2,051,584	35,668,152	1,843,213