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 25, 2025

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 25, 2025, Arcutis Biotherapeutics, Inc. (the "Company" or "Arcutis") issued a press release relating to its financial results for the quarter ended December 31, 2024. 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 25, 2025.
104	Cover Page Interactive Data File (formatted as 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.

February 25, 2025

By: /s/ David Topper

David Topper

Chief Financial Officer

Arcutis Announces Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

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- Q4 2024 net product revenue for ZORYVE® (roflumilast) was $69.4 million, a 413% increase compared to Q4 of 2023 and a 55% increase compared to Q3 of 2024; driven by strong portfolio demand growth and including a non-recurring adjustment of $4.1 million due to a reduction in reserves for product returns
- Full Year 2024 net product revenue for ZORYVE was $166.5 million, an increase of 471% over the prior year, setting the stage for sustained growth and strong financial position in 2025
- ZORYVE is now the most prescribed branded non-steroidal topical treatment across three major inflammatory skin conditions combined in the United States
- Supplemental New Drug Application (sNDA) for ZORYVE (roflumilast) cream, 0.05%, submitted to the Food and Drug Administration (FDA) for the treatment of atopic dermatitis in children ages 2 to 5
- Made a partial prepayment of $100 million of principal on $200 million of then outstanding debt with the ability to re-draw it in whole or in part

Westlake Village, CA, February 25, 2025 – Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today reported financial results for the quarter and year ended December 31, 2024, and provided a business update.

“Our success in 2024 was driven by growing ZORYVE momentum, including commercial launches for two new indications for ZORYVE, and our pricing and access strategy that led to strong commercial and government reimbursement. ZORYVE is the number one prescribed branded non-steroidal topical, due to its compelling value proposition of effectively and safely relieving multiple inflammatory skin conditions anywhere on the body for any duration,” said Frank Watanabe, president and chief executive officer. “We are also continuing to advance our product pipeline and, along with strong stewardship of our financial resources and management of expenses, we believe we are well positioned to realize our mission of addressing unmet needs and the lack of innovation in medical dermatology.”

Program Updates / Key Milestones

ZORYVE cream - a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor in a once-daily cream formulation, approved in the United States for the treatment of plaque psoriasis and atopic dermatitis.

- U.S. demand for ZORYVE cream 0.3% in plaque psoriasis continues to grow, with over 360,000 prescriptions filled since launch by over 14,000 unique prescribers, reflecting the high levels of patient and physician satisfaction with the ZORYVE cream clinical profile. ZORYVE cream is covered by the three largest Pharmacy Benefit Managers (PBMs) and multiple other commercial insurers, and during the quarter the Company expanded its Medicaid coverage to two additional states, Ohio and Illinois. The Company aims to obtain Medicaid coverage in additional states, as well as some Medicare coverage, during 2025. ZORYVE cream 0.3% saw significant gross-to-net (GTN) improvement in 2024 and has reached its steady state GTN.
- Initial launch of ZORYVE cream 0.15% in atopic dermatitis has been strong with over 33,000 prescriptions filled since launch, and is covered as a line extension by two of the largest national PBMs. The Company anticipates continued improvement in coverage during 2025.
- The Company submitted an sNDA for ZORYVE cream 0.05% to the FDA for the treatment of atopic dermatitis in children ages 2 to 5 with an anticipated target action date in Q4 of 2025, if accepted as submitted.

ZORYVE foam - a once-daily foam formulation of topical roflumilast designed to overcome the challenges of delivering topical drugs in hair-bearing areas of the body, approved in the United States for the treatment of seborrheic dermatitis, and under FDA review for scalp and body psoriasis.

- Demand for ZORYVE foam, 0.3% in seborrheic dermatitis continues to grow robustly each quarter, with over 246,000 prescriptions filled since launch, reflecting the high unmet need in this disease. ZORYVE foam is also covered by the three largest PBMs and has steadily improved coverage over the course of 2024. ZORYVE foam has gained Medicaid coverage in line with ZORYVE cream 0.3% and is nearing a steady state GTN.
- The Company submitted an sNDA for ZORYVE foam for scalp and body psoriasis to the FDA based on the positive results from the pivotal ARRECTOR Phase 3 trial and a Phase 2b trial, which was accepted by the FDA in September with a PDUFA action date set for May 22, 2025.

ARQ-255 - a topical suspension formulation of ivarmacitinib, a potent and highly selective topical Janus kinase type 1 (JAK1) inhibitor, designed to preferentially deliver the drug deep into the hair follicle, in order to potentially treat alopecia areata at the site of inflammation.

- In September 2024, the Company announced that it completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata, with data expected in H1 2025.

ARQ-234 - a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 Receptor (CD200R), being developed as a potential biologic treatment in atopic dermatitis.

- The Company has continued preclinical development efforts and is working towards submitting an Investigational New Drug application in 2025.

Recent Corporate Highlights

- In October 2024, the Company made a partial prepayment of $100 million of principal on $200 million of then outstanding debt. The Company amended the $200 million term-loan with SLR Investment Corp. in August 2024, obtaining an option to prepay up to $100 million of the principal and re-draw it in whole or in part, at the Company's discretion.
- In October 2024, Health Canada approved ZORYVE® (roflumilast) foam 0.3% for the treatment of seborrheic dermatitis in individuals 9 years of age and older, and the Company commenced sales in December.
- In November 2024, ZORYVE cream 0.15% received *Glamour's* 2024 Health and Wellness Award for "Best Eczema Product".
- Obtained one new U.S. patent in Q4 2024 related to topical roflumilast compositions.
- In February 2025, announced a partnership with the iconic professional football player Odell Beckham Jr., to help raise awareness of seborrheic dermatitis and share his positive experience with ZORYVE foam.

Fourth Quarter and Full Year 2024 Summary Financial Results

Total revenues for the quarter ended December 31, 2024 were $71.4 million compared to $13.5 million for the corresponding period in 2023. The quarter ended December 31, 2024 included **Other revenue** of $2.0 million and a non-recurring adjustment of $4.1 million due to a reduction in reserves for product returns. **Total revenues** for the year ended December 31, 2024 were $196.5 million compared to $59.6 million for the corresponding period in 2023. These year-over-year increases were due to strong unit demand growth as well as improvements in GTN sales deductions. In addition, 2024 and 2023 include **Other revenue** of $5.0 million and $30.0 million, respectively, related to the Huadong License and Collaboration Agreement. 2024 also includes **Other revenue** of $25.0 million from an upfront payment in connection with the Sato License Agreement, bringing **Other revenue** in 2024 to $30.0 million.

Cost of sales for the quarter ended December 31, 2024 were $6.9 million compared to $2.2 million for the corresponding period in 2023. Cost of sales for the year ended December 31, 2024 were $19.1 million compared to $5.0 million for the corresponding period in 2023.

Research and development (R&D) expenses for the quarter ended December 31, 2024 were $14.5 million compared to $23.8 million for the corresponding period in 2023. R&D expenses for the year ended December 31, 2024 were $76.4 million compared to $110.6 million for the corresponding period in 2023. These year-over-year decreases were due to decreased clinical development costs related to our topical roflumilast programs.

Selling, general, and administrative (SG&A) expenses for the quarter ended December 31, 2024 were $57.6 million compared to $48.7 million for the corresponding period in 2023. SG&A expenses for the year ended December 31, 2024 were $229.4 million compared to $185.1 million for the corresponding period in 2023. These year-over-year increases were primarily due to higher sales force headcount and sales and marketing expenses related to the launches of ZORYVE.

Net loss was $10.8 million, or $0.09 per basic and diluted share, for the quarter ended December 31, 2024 compared to $66.3 million, or $0.72 per basic and diluted share, for the corresponding period in 2023. Net loss was $140.0 million, or $1.16 per basic and diluted share, for the year ended December 31, 2024 compared to $262.1 million, or $3.78 per basic and diluted share, for the corresponding period in 2023.

Cash, cash equivalents, restricted cash, and marketable securities were $228.6 million as of December 31, 2024, compared to $272.8 million as of December 31, 2023. Net cash used in operating activities was $0.7 million during the fourth quarter and $112.2 million during the full year 2024.

Conference Call and Webcast

Arcutis management will host a conference call and webcast today at 4:30 PM ET to discuss the financial results for the quarter and year and provide a business update. The webcast for this conference call may be accessed at the “Events” section of the Company’s website. The replay of the webcast will be available on the Arcutis website following the call.

About Arcutis

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio including three FDA approved products that harness 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 and body psoriasis, atopic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential to address large markets with significant unmet need; the development, approval and potential commercialization of product candidates; the potential commercial success and growth of ZORYVE in plaque psoriasis, seborrheic dermatitis, and atopic dermatitis, including market access and reimbursement, product demand growth and developments regarding GTN; and the timing of regulatory filings and potential approvals. 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, the timing, expenses, and success of our commercialization efforts, including uncertainty of future commercial sales and related items that can impact net sales, 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 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, 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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ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,335	$ 88,398
Restricted cash	617	925
Marketable securities	156,620	183,463
Trade receivable, net	73,066	25,807
Inventories	14,526	13,134
Prepaid expenses and other current assets	19,656	18,704
Total current assets	335,820	330,431
Property and equipment, net	1,041	1,539
Intangible assets, net	9,479	6,438
Operating lease right-of-use asset	1,953	2,361
Other assets	596	596
Total assets	$ 348,889	$ 341,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 14,220	$ 11,992
Accrued liabilities	65,973	33,941
Operating lease liability	820	735
Total current liabilities	81,013	46,668
Operating lease liability, noncurrent	2,562	3,382
Long-term debt, net	107,203	201,799
Other long-term liabilities	570	849
Total liabilities	191,348	252,698
Stockholders' equity:		
Common stock	12	9
Additional paid-in capital	1,279,479	1,070,558
Accumulated other comprehensive loss	(7)	4
Accumulated deficit	(1,121,943)	(981,904)
Total stockholders' equity	157,541	88,667
Total liabilities and stockholders' equity	$ 348,889	$ 341,365

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
	(unaudited)			
Revenues:				
Product revenue, net	$ 69,360	$ 13,526	$ 166,542	$ 29,186
Other revenue	2,000	—	30,000	30,420
Total revenues	71,360	13,526	196,542	59,606
Operating expenses:				
Cost of sales	6,905	2,246	19,128	4,987
Research and development	14,480	23,775	76,420	110,575
Selling, general, and administrative	57,607	48,674	229,391	185,145
Total operating expenses	78,992	74,695	324,939	300,707
Loss from operations	(7,632)	(61,169)	(128,397)	(241,101)
Other income (expense):				
Other income, net	2,718	2,672	16,173	11,786
Interest expense	(5,551)	(7,762)	(27,168)	(29,712)
Loss before income taxes	(10,465)	(66,259)	(139,392)	(259,027)
Provision for income taxes	$ 323	$ 25	$ 647	$ 3,113
Net loss	$ (10,788)	$ (66,284)	$ (140,039)	$ (262,140)
Per share information:				
Net loss per share, basic and diluted	$ (0.09)	$ (0.72)	$ (1.16)	$ (3.78)
Weighted-average shares used in computing net loss per share, basic and diluted	124,918,560	92,580,106	120,957,633	69,305,487