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 27, 2024

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 27, 2024, Arcutis Biotherapeutics, Inc. (the "Company" or "Arcutis") issued a press release relating to its financial results for the quarter ended December 31, 2023. 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 27, 2024.
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 27, 2024

By: /s/ John W. Smither

John W. Smither

Chief Financial Officer

Arcutis Announces Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

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- Q4 net product revenues for ZORYVE® (roflumilast) cream 0.3% were $13.5 million, a 357% increase compared to the fourth quarter of 2022 and a 67% increase compared to the third quarter of 2023; driven by sequential improvement in gross-to-net (GTN) in the mid 60 percent range, as well as sustained demand growth
- Received U.S. Food and Drug Administration (FDA) approval for ZORYVE® (roflumilast) topical foam, 0.3%, for the treatment of seborrheic dermatitis in adults and children down to age 9 in December 2023 and launched ZORYVE foam for seborrheic dermatitis in United States in late January 2024
- July 7, 2024 PDUFA action date for roflumilast cream, 0.15%, for the treatment of atopic dermatitis in adults and children down to age 6
- Strong financial position supports investment in plaque psoriasis and seborrheic dermatitis launches and continued development of pipeline
- 2023 R&D expenses decreased 39% to $111 million, compared to 2022, and the Company expects continued reductions in R&D expenses in 2024 as it focuses investments in on-going ZORYVE commercial launches

Westlake Village, CA, February 27, 2024 – 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, 2023, and provided a business update.

“2023 was a year of successful execution and builds a strong foundation for 2024. We are very encouraged by the strong revenue growth trend we are seeing, reinforcing the demand for new treatment options and physician adoption of ZORYVE,” said Frank Watanabe, president and chief executive officer. “With two FDA-approved products in the midst of their commercial launches and the mid-year PDUFA action date for roflumilast cream for atopic dermatitis, 2024 has the potential to be a transformational year for Arcutis. Our expanding product portfolio, combined with our robust development pipeline, seek to address unmet patient needs across multiple dermatology indications, and position Arcutis to accomplish our patient-centric 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 and Canada for the treatment of plaque psoriasis and under development for atopic dermatitis

- Demand for ZORYVE cream in plaque psoriasis continues to grow, with over 165,000 prescriptions filled since launch to date by over 10,700 unique prescribers, reflecting the high levels of patient and physician satisfaction with the ZORYVE clinical profile. ZORYVE cream is covered by the three largest Pharmacy Benefit Managers. The Company saw significant GTN improvement in the fourth quarter compared to the GTN in the third quarter, and anticipates further GTN improvement in 2024. The FDA approved an expanded indication for ZORYVE cream for the treatment of plaque psoriasis in children down to age 6 in October 2023.
- The FDA has accepted the Company's supplemental new drug application (sNDA) for roflumilast cream 0.15% for the treatment of atopic dermatitis (AD) in adults and children down to age 6. The FDA assigned the application a Prescription Drug User Fee Act (PDUFA) target action date of July 07, 2024. The sNDA is supported by positive results from three Phase 3 programs as well as a Phase 2 dose ranging study, and two Phase 1 pharmacokinetic studies.

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 for seborrheic dermatitis and in development for scalp and body psoriasis

- In December 2023, the FDA approved the new drug application (NDA) for ZORYVE topical foam, 0.3%, for the treatment of seborrheic dermatitis in individuals 9 years of age and older. ZORYVE foam, the first drug approved for seborrheic dermatitis with a new mechanism of action in over two decades, provides rapid and robust disease clearance and significant reduction in itch, with nearly 80% of individuals achieving the primary efficacy endpoint of IGA Success and just over 50% of individuals reaching complete clearance at Week 8 in the STRATUM trial.
- In January 2024, Arcutis announced the acceptance of a new drug submission for roflumilast foam 0.3% for the treatment of adults and children down to age 9 by Health Canada.
- Based on the positive topline results from the ARRECTOR pivotal Phase 3 trial for the treatment of scalp and body psoriasis, the Company anticipates submitting an sNDA for scalp and body psoriasis to the FDA in the second half of 2024.

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 December 2022, Arcutis announced the enrollment of the first healthy volunteer subject in a Phase 1b study in alopecia areata. The first subject in the alopecia areata cohort enrolled in the second quarter of 2023.

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 continues preclinical development efforts.

Recent Corporate Highlights

- In October 2023, the United States Patent and Trademark Office awarded the Company a new formulation patent that covers a means for inhibiting roflumilast crystal growth, and is not limited to hexylene glycol. In November 2023, the Company was also awarded a new method of treatment patent with a topical roflumilast formulation with an extended half-life. Both patents do not expire until 2037.
- In October 2023, the Company completed a public offering raising gross proceeds of $102.3 million including the underwriters' 30-day option to purchase additional shares at the public offering price per share, which was partially exercised.
- In November 2023, the Company entered into an amendment of its loan agreement with SLR Investment Corp. (SLR), modifying the financial covenants on the existing drawn principal.

Fourth Quarter and Full Year 2023 Summary Financial Results

Total revenues for the quarter ended December 31, 2023 were $13.5 million compared to $3.0 million for the corresponding period in 2022. Total revenues for the year ended December 31, 2023 were $59.6 million compared to $3.7 million for the corresponding period in 2022. These year-over-year increases were due to strong unit demand growth as well as improvements in gross-to-net sales deductions. In addition, the third quarter of 2023 included **Other revenues** of $30.4 million related to the upfront payment in connection with the Huadong collaboration and licensing agreement.

Cost of sales for the quarter ended December 31, 2023 were $2.2 million compared to $0.5 million for the corresponding period in 2022. Cost of sales for the year ended December 31, 2023 were $5.0 million compared to $0.8 million for the corresponding period in 2022.

Research and development (R&D) expenses for the quarter ended December 31, 2023 were $23.8 million compared to $33.9 million for the corresponding period in 2022. R&D expenses for the year ended December 31, 2023 were $110.6 million compared to $182.4 million for the corresponding period in 2022. These year-over-year decreases were due to decreased clinical development costs related to our topical roflumilast. In addition, R&D expenses for the third quarter of 2022 included approximately $30 million upfront expense for the Ducentis acquisition.

Selling, general, and administrative (SG&A) expenses for the quarter ended December 31, 2023 were $48.7 million compared to $37.0 million for the corresponding period in 2022. SG&A expenses for the year ended December 31, 2023 were $185.1 million compared to $122.1 million for the corresponding period in 2022. These year-over-year increases were primarily due to higher headcount and sales and marketing expenses related to the launch of ZORYVE.

Net loss was $66.3 million, or $0.72 per basic and diluted share, for the quarter ended December 31, 2023 compared to $72.0 million, or $1.18 per basic and diluted share, for the corresponding period in 2022. Net loss was $262.1 million, or $3.78 per basic and diluted share, for the year ended December 31, 2023 compared to $311.5 million, or $5.66 per basic and diluted share, for the corresponding period in 2022.

Cash, cash equivalents, restricted cash, and marketable securities were $272.8 million as of December 31, 2023, compared to $410.8 million as of December 31, 2022. Net cash used in operating activities was $56.2 during the fourth quarter and $247.1 million during the full year 2023.

Conference Call and Webcast

Arcutis management will host a conference call and webcast today at 8:30 am 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 two 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 differentiated 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, and X.

Forward Looking Statements

Arcutis cautions you that 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 for its topical drugs in development to address large markets with significant unmet need; the development, approval and potential commercialization of Arcutis' product candidates; the potential commercial success and growth of ZORYVE in plaque psoriasis and seborrheic dermatitis, including market access and reimbursement, product demand growth and continued improvement in gross to net; and the timing of regulatory filings and potential approvals for a number of dermatology indications for roflumilast in the United States and Canada. 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 27, 2024, 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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ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 88,398	$ 53,641
Restricted cash	925	1,234
Marketable securities	183,463	355,948
Trade receivable, net	25,807	8,458
Inventories	13,134	7,514
Prepaid expenses and other current assets	18,704	10,611
Total current assets	330,431	437,406
Property and equipment, net	1,539	1,881
Intangible assets, net	6,438	7,188
Operating lease right-of-use asset	2,361	2,721
Other assets	596	78
Total assets	$ 341,365	$ 449,274
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,992	$ 8,827
Accrued liabilities	33,941	28,323
Operating lease liability	735	657
Total current liabilities	46,668	37,807
Operating lease liability, noncurrent	3,382	4,117
Long-term debt, net	201,799	197,769
Other long-term liabilities	849	—
Total liabilities	252,698	239,693
Stockholders' equity:		
Common stock	9	6
Additional paid-in capital	1,070,558	930,425
Accumulated other comprehensive loss	4	(1,086)
Accumulated deficit	(981,904)	(719,764)
Total stockholders' equity	88,667	209,581
Total liabilities and stockholders' equity	$ 341,365	$ 449,274

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,	
	2023	2022	2023	2022
	(unaudited)			
Revenues:				
Product revenue, net	$ 13,526	$ 2,961	$ 29,186	$ 3,686
Other revenue	—	—	30,420	—
Total revenues	13,526	2,961	59,606	3,686
Operating expenses:				
Cost of sales	2,246	485	4,987	754
Research and development	23,775	33,877	110,575	182,435
Selling, general, and administrative	48,674	37,023	185,145	122,124
Total operating expenses	74,695	71,385	300,707	305,313
Loss from operations	(61,169)	(68,424)	(241,101)	(301,627)
Other income (expense):				
Other income, net	2,672	3,320	11,786	5,821
Interest expense	(7,762)	(6,915)	(29,712)	(15,652)
Loss before income taxes	(66,259)	(72,019)	(259,027)	(311,458)
Provision for income taxes	$ 25	$ —	$ 3,113	$ —
Net loss	$ (66,284)	$ (72,019)	$ (262,140)	$ (311,458)
Per share information:				
Net loss per share, basic and diluted	$ (0.72)	$ (1.18)	$ (3.78)	$ (5.66)
Weighted-average shares used in computing net loss per share, basic and diluted	92,580,106	60,959,523	69,305,487	55,032,265