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): August 14, 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 August 14, 2024, Arcutis Biotherapeutics, Inc. (the "Company" or "Arcutis") issued a press release relating to its financial results for the quarter ended June 30, 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 August 14, 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.

August 14, 2024

By: /s/ David Topper

David Topper

Chief Financial Officer

Arcutis Announces Second Quarter 2024 Financial Results and Provides Business Update

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- Second quarter net product revenues for ZORYVE® franchise of $30.9M, with $17.3M for ZORYVE (roflumilast) cream 0.3%, and $13.6M for ZORYVE (roflumilast) topical foam, 0.3%; sales growth of 547% vs. Q2 '23 and 43% vs. Q1 '24
- Continued gross-to-net (GTN) improvement with blended GTN across products now in the high 50 percent range, improving from the low 60 percent range last quarter
- Sustained growth in prescriptions for both cream and foam, with total U.S. franchise unit demand increase of 42% quarter over quarter
- Entered into ZORYVE co-promotion agreement with Kowa Pharmaceuticals America, Inc., expanding promotional efforts to primary care and pediatric offices in the United States
- Submitted Supplemental New Drug Application (sNDA) for ZORYVE (roflumilast) foam to the Food & Drug Administration (FDA) for the treatment of scalp and body psoriasis in adults and adolescents ages 12 and over
- Amended existing $200 million term-loan on attractive terms to increase financial and strategic flexibility

Westlake Village, CA, August 14, 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 ended June 30, 2024, and provided a business update.

“In the second quarter, sales grew by a robust 43% sequentially, highlighting the strength of physician demand for ZORYVE across multiple approved indications, and our ability to continue to improve our GTN. Following the recent launch of ZORYVE cream for atopic dermatitis, we are well-positioned to drive further growth,” said Frank Watanabe, president and chief executive officer. “Our ZORYVE franchise co-promotion agreement with Kowa will further expand our total addressable market, allowing us to address millions of patients treated outside of a dermatology office. In addition, we continue to advance ZORYVE's late-stage development, with the filing of the supplemental new drug application for ZORYVE foam in scalp and body psoriasis, which will enable us to drive greater preference share, once approved.

Finally, we amended our existing debt agreement favorably, providing us with additional financial flexibility and improved liquidity to enhance our business going forward."

"We are pleased that we continued to grow sales while prudently managing operating expenses in the second quarter. These solid financial results together with our amended existing debt agreement, which provides an extended maturity, a lower interest rate and the flexibility to repay a portion and re-draw it later, give us additional financial and strategic flexibility to continue investing in our growth, especially supporting our three commercial launches and advancing our pipeline," said David Topper, chief financial officer.

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 in plaque psoriasis continues to grow, with over 252,000 prescriptions filled to date since launch by close to 13,000 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 the Company obtained its first Medicaid coverage in Texas, Florida, and New York and anticipates it will obtain Medicaid coverage in additional states during 2024. The cream 0.3% saw further GTN improvement in the second quarter compared to Q1 '24, and we anticipate modest incremental GTN improvement throughout 2024 as GTN for the cream 0.3% approaches steady state.
- The FDA approved ZORYVE cream 0.15% for the treatment of mild to moderate atopic dermatitis in adults and children down to age 6 in early Q3, and the Company commenced the commercial launch at the end of July. ZORYVE cream 0.15% is already covered as a line extension by two of the largest national PBMs, and the company anticipates continued improvement in coverage through the remainder of 2024.

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

- The launch of ZORYVE foam in seborrheic dermatitis continues to progress well, with over 98,000 prescriptions filled since launch, reflecting the high unmet need in this disease. ZORYVE foam is also covered by the three largest PBMs, and coverage for the foam is steadily improving, as evidenced by its favorable GTN, which is expected to improve over the remainder of 2024 and approach steady state in early 2025.
- The Company submitted an sNDA for ZORYVE foam for scalp and body psoriasis to the FDA in July 2024 based on the positive results from the pivotal ARRECTOR Phase 3 trial and a Phase 2b trial.

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 and is working towards submitting an Investigational New Drug Application in 2025.

Recent Corporate Highlights

- In July, the Company Received FDA approval for ZORYVE cream 0.15%, for the treatment of atopic dermatitis in adults and children down to age 6, and launched ZORYVE cream for atopic dermatitis in United States in late July.
- In July, the Company also announced a co-promotion agreement with Kowa Pharmaceuticals America, Inc., whereby Kowa will leverage its 200-person primary care sales force in the United States to market and promote ZORYVE cream and ZORYVE foam to primary care practitioners and pediatricians for all FDA approved indications.
- Amended the $200 million term-loan with SLR Investment Corp., lowering the interest rate by 150 basis points, extending the maturity to June 2029, and obtaining an option to prepay up to $100 million of the principal and re-draw it within 21-24 months at company's discretion.
- Arcutis obtained five new U.S. patents in June and July related to ZORYVE. These patents cover, in part, formulations and methods of treatment resulting in unexpected and beneficial properties of ZORYVE, including the reduced side effects of ZORYVE compared to orally administered roflumilast and the beneficial pharmacokinetic profile of ZORYVE.

Second Quarter 2024 Summary Financial Results

Product revenues for the quarter ended June 30, 2024 were $30.9 million compared to $4.8 million for the corresponding period in 2023. Revenues for the quarter were $17.3 million for ZORYVE cream 0.3% and $13.6 million for ZORYVE topical foam, 0.3%. Year-over-year and quarter-over-quarter increases were due to strong unit demand as well as GTN improvements. Across ZORYVE cream and ZORYVE foam, blended GTN is now in the high 50s, driven by the high percentage of prescriptions being reimbursed.

Cost of sales for the quarter ended June 30, 2024 were $3.5 million compared to $0.8 million for the corresponding period in 2023.

Research and development (R&D) expenses for the quarter ended June 30, 2024 were $19.3 million compared to $25.2 million for the corresponding period in 2023. The year-over-year decrease was due to decreased clinical development costs related to our topical roflumilast program.

Selling, general, and administrative (SG&A) expenses for the quarter ended June 30, 2024 were $58.2 million compared to $46.0 million for the corresponding period in 2023. The year-over-year increase was primarily due to sales and marketing expenses related to the launches of ZORYVE cream and foam.

Net loss was $52.3 million, or $0.42 per basic and diluted share, for the quarter ended June 30, 2024 compared to $71.0 million, or $1.16 per basic and diluted share, for the corresponding period in 2023.

Cash, cash equivalents, restricted cash, and marketable securities were $363.1 million as of June 30, 2024, compared to $272.8 million as of December 31, 2023. Net cash used in operating activities was $45.2 million during the second quarter.

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 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 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 and body psoriasis, atopic dermatitis, and alopecia areata. For more information, visit https://www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, 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 continued commercial success and growth of ZORYVE cream 0.3% in plaque psoriasis, ZORYVE cream 0.15% in atopic dermatitis and ZORYVE foam in seborrheic dermatitis, including market access and reimbursement, product demand growth and continued improvement in GTN; 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)

	June 30, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 84,270	$ 88,398
Restricted cash	617	925
Marketable securities	278,167	183,463
Trade receivable, net	43,411	25,807
Inventories	13,880	13,134
Prepaid expenses and other current assets	14,246	18,704
Total current assets	434,591	330,431
Property and equipment, net	1,347	1,539
Intangible assets, net	6,063	6,438
Operating lease right-of-use asset	2,163	2,361
Other assets	595	596
Total assets	$ 444,759	$ 341,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,943	$ 11,992
Accrued liabilities	42,632	33,941
Operating lease liability	777	735
Total current liabilities	51,352	46,668
Operating lease liability, noncurrent	2,978	3,382
Long-term debt, net	203,808	201,799
Other long-term liabilities	194	849
Total liabilities	258,332	252,698
Stockholders' equity:		
Common stock	12	9
Additional paid-in capital	1,256,327	1,070,558
Accumulated other comprehensive loss	(294)	4
Accumulated deficit	(1,069,618)	(981,904)
Total stockholders' equity	186,427	88,667
Total liabilities and stockholders' equity	$ 444,759	$ 341,365

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product revenue, net	$ 30,858	$ 4,770	$ 52,427	$ 7,551
Other revenue	—	420	28,000	420
Total revenues	30,858	5,190	80,427	7,971
Operating expenses:				
Cost of sales	3,464	776	6,720	1,559
Research and development	19,298	25,219	42,439	60,564
Selling, general, and administrative	58,173	45,958	112,967	88,876
Total operating expenses	80,935	71,953	162,126	150,999
Loss from operations	(50,077)	(66,763)	(81,699)	(143,028)
Other income (expense):				
Other income, net	5,229	3,121	9,273	6,328
Interest expense	(7,484)	(7,349)	(14,964)	(14,391)
Loss before income taxes	(52,332)	(70,991)	(87,390)	(151,091)
Provision for income taxes	$ —	$ —	$ 324	$ —
Net loss	$ (52,332)	$ (70,991)	$ (87,714)	$ (151,091)
Per share information:				
Net loss per share, basic and diluted	$ (0.42)	$ (1.16)	$ (0.75)	$ (2.46)
Weighted-average shares used in computing net loss per share, basic and diluted	123,480,849	61,430,620	117,264,687	61,300,577