# 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 8, 2023

# 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 8, 2023, Arcutis Biotherapeutics, Inc. (the "Company" or "Arcutis") issued a press release relating to its financial results for the quarter ended June 30, 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 August 8, 2023. |
| 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 8, 2023

By: /s/ Scott L. Burrows

Scott L. Burrows

Chief Financial Officer

**Arcutis Announces Second Quarter 2023 Financial Results and Provides Business Update**

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- Achieved total revenues of $5.2 million in the second quarter of 2023. Net product revenues for ZORYVE® (roflumilast) cream 0.3% were $4.8 million, a 72% increase compared to the first quarter of 2023, driven by nearly 40% demand growth as well as gross-to-net improvement
- Continued expansion of commercial payer coverage for ZORYVE in plaque psoriasis with over 130 million commercial lives covered in the United States, including all three of the largest pharmacy benefit managers (PBMs)
- Launched ZORYVE for plaque psoriasis in Canada in June 2023, with excellent early reception from patients, physicians, and payers
- Strong financial position with approximately $270 million in cash, cash equivalents, and marketable securities as of June 30, 2023

**Westlake Village, CA, August 8, 2023** – Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today reported financial results for the quarter ended June 30, 2023, and provided a business update.

“We continue to execute on our strategy to build the leading innovation-driven dermatology company in the industry. With our world-class formulation expertise, track record of clinical and regulatory success, and robust commercial infrastructure, topical roflumilast represents a truly unique, de-risked asset, with significant operating leverage and multiple catalysts ahead,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “The ZORYVE launch in plaque psoriasis is strengthening on all fronts, and notably with our high-quality commercial coverage now reaching a critical mass, we will continue to invest to fuel the next leg of the psoriasis launch, while also preparing for the upcoming launches in seborrheic dermatitis and atopic dermatitis in 2024, upon their respective anticipated U.S. Food and Drug Administration (FDA) approvals.”

**Program Updates / Key Milestones**

**Roflumilast 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 under development for atopic dermatitis

- The launch of ZORYVE in plaque psoriasis continued to build momentum in the second quarter, with strong demand growth, commercial formulary access expansion, and gross-to-net improvement. Over 70,000 prescriptions have been filled since launch by over 7,500 unique prescribers, reflecting the high levels of patient and physician satisfaction with the ZORYVE clinical profile. In less than 12 months since launch, the Company has secured high-quality payer coverage for ZORYVE at all three of the largest PBMs in the United States, now totaling more than 130 million commercially-insured lives. This coverage represents roughly 80% of the total commercial lives. Importantly, over 90% of those 130 million covered lives have access to ZORYVE without a prior authorization, aligned with our corporate access goals. The Company anticipates the benefits of this coverage and our efforts to accelerate coverage pull-through will drive further gross-to-net improvement in the second half of 2023.

- In December 2022, Arcutis submitted a supplemental New Drug Application (sNDA) to the FDA for ZORYVE for an expanded indication for the treatment of plaque psoriasis in children down to 2 years of age. The Company anticipates potential FDA approval in the fourth quarter of 2023.

- In the fourth quarter of 2022, Arcutis announced positive topline results from INTEGUMENT-1 and INTEGUMENT-2, the two pivotal Phase 3 trials evaluating roflumilast cream 0.15% for the treatment of atopic dermatitis in individuals 6 years of age or older. The Company anticipates submitting, an sNDA to the FDA for ages 6 and above late in the third quarter or early in the fourth quarter of 2023.

- In May 2023, Arcutis announced the completion of enrollment in INTEGUMENT-PED, the third Pivotal Phase 3 trial in atopic dermatitis, in individuals aged 2 to 5 years old. Topline data from INTEGUMENT-PED are expected in the third quarter of 2023. If positive, the Company expects these data to be sufficient basis for an sNDA submission, after the anticipated approval of roflumilast cream in atopic dermatitis for ages 6 and above.

**Roflumilast 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, being developed as a potential treatment for seborrheic dermatitis and scalp and body psoriasis

- In April 2023, the FDA accepted Arcutis' New Drug Application (NDA) submission for the treatment of moderate-to-severe seborrheic dermatitis, assigning a target action date of December 16, 2023.
- In September 2022, Arcutis announced 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 following the potential approval of roflumilast foam for seborrheic dermatitis.

**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 July 2023, the United States Patent and Trademark Office awarded the Company a new method of treatment patent that provides relevant patent protection for roflumilast foam in the treatment of seborrheic dermatitis until 2041.
- In July 2023, Great Place To Work® and *Fortune* magazine named the Company to the Best Workplaces for Millennials™ list for 2023.
- In May 2023, Ayisha Jeter was appointed interim Chief Commercial Officer. Ms. Jeter has led Arcutis' access and reimbursement team since joining the Company in 2020, and brings more than 20 years of broad commercial experience in the pharmaceutical industry, including multiple product launches across therapeutic areas.

**Second Quarter 2023 Summary Financial Results**

**Total revenues** for the quarter ended June 30, 2023 were $5.2 million. **Net product revenues** related to sales of ZORYVE were $4.8 million driven by strong unit demand growth as well as improvements in gross-to-net sales deductions compared to the first quarter of 2023. **Other revenues** for the quarter ended June 30, 2023 were $0.4 million, related to an equity interest received as part of a previous collaboration agreement.

**Cost of sales** for the quarter ended June 30, 2023 were $0.8 million.

**Research and development (R&D) expenses** for the quarter ended June 30, 2023 were $25.2 million compared to $38.2 million for the corresponding period in 2022. The year-over-year decrease was primarily due to decreased clinical development costs related to our topical roflumilast programs.

**Selling, general, and administrative (SG&A) expenses** for the quarter ended June 30, 2023 were $46.0 million compared to $27.6 million for the corresponding period in 2022. The year-over-year increase was primarily due to higher headcount and sales and marketing expenses related to the launch of ZORYVE.

**Net loss** was $71.0 million, or $1.16 per basic and diluted share, for the quarter ended June 30, 2023 compared to $67.4 million, or $1.31 per basic and diluted share, for the corresponding period in 2022.

**Cash, cash equivalents, restricted cash, and marketable securities** were $269.6 million as of June 30, 2023, compared to $410.8 million as of December 31, 2022. Net cash used in operating activities was $66.5 million during the second quarter.

**Conference Call and Webcast**

Arcutis management will host a conference call and webcast today at 4:30pm 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 an early commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of patients 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 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, seborrheic dermatitis, and alopecia areata. For more information, visit https://www.arcutis.com or follow the company on LinkedIn, Facebook, 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; the development, approval and potential commercialization of Arcutis' product candidates; expectations with regard to the timing of and successful clinical trial results anticipated during 2023; the potential commercial success and growth of ZORYVE in plaque psoriasis, including market access and reimbursement; 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 28, 2023, 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.

**Contacts:**

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**ARCUTIS BIOTHERAPEUTICS, INC.**
**Condensed Consolidated Balance Sheets**
**(In thousands)**

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| | (unaudited) | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 105,114 | $ 53,641 |
| Restricted cash | 925 | 1,234 |
| Marketable securities | 163,557 | 355,948 |
| Trade receivable, net | 17,207 | 8,458 |
| Inventories | 10,474 | 7,514 |
| Prepaid expenses and other current assets | 11,591 | 10,611 |
| Total current assets | 308,868 | 437,406 |
| Property and equipment, net | 1,867 | 1,881 |
| Intangible assets, net | 6,812 | 7,188 |
| Operating lease right-of-use asset | 2,546 | 2,721 |
| Other assets | 596 | 78 |
| Total assets | $ 320,689 | $ 449,274 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 17,156 | $ 8,827 |
| Accrued liabilities | 18,808 | 28,323 |
| Operating lease liability | 695 | 657 |
| Total current liabilities | 36,659 | 37,807 |
| Operating lease liability, noncurrent | 3,755 | 4,117 |
| Long-term debt, net | 199,767 | 197,769 |
| Total liabilities | 240,181 | 239,693 |
| Stockholders' equity: | | |
| Common stock | 6 | 6 |
| Additional paid-in capital | 951,649 | 930,425 |
| Accumulated other comprehensive loss | (292) | (1,086) |
| Accumulated deficit | (870,855) | (719,764) |
| Total stockholders' equity | 80,508 | 209,581 |
| Total liabilities and stockholders' equity | $ 320,689 | $ 449,274 |

**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, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Revenues: | | | | |
| Product revenue, net | $ 4,770 | $ — | $ 7,551 | $ — |
| Other revenue | 420 | — | 420 | — |
| Total revenues | 5,190 | — | 7,971 | — |
| | | | | |
| Operating expenses: | | | | |
| Cost of sales | 776 | — | 1,559 | — |
| Research and development | 25,219 | 38,205 | 60,564 | 78,827 |
| Selling, general, and administrative | 45,958 | 27,622 | 88,876 | 49,628 |
| Total operating expenses | 71,953 | 65,827 | 150,999 | 128,455 |
| Loss from operations | (66,763) | (65,827) | (143,028) | (128,455) |
| | | | | |
| Other income (expense): | | | | |
| Other income, net | 3,121 | 421 | 6,328 | 563 |
| Interest expense | (7,349) | (2,000) | (14,391) | (3,838) |
| Total other income (expense) | (4,228) | (1,579) | (8,063) | (3,275) |
| | | | | |
| Net loss | $ (70,991) | $ (67,406) | $ (151,091) | $ (131,730) |
| | | | | |
| Per share information: | | | | |
| Net loss per share, basic and diluted | $ (1.16) | $ (1.31) | $ (2.46) | $ (2.58) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 61,430,620 | 51,422,386 | 61,300,577 | 50,970,465 |