Arcutis Announces First Quarter 2025 Financial Results and Provides Business Update

May 6, 2025

- Q1 2025 net product revenue for ZORYVE® (roflumilast) was $63.8 million, a 196% increase compared to Q1 of 2024, and a 2% decrease compared to Q4 of 2024, due to typical first-quarter deductible resets and insurance changes, and excluding the non-recurring reduction in reserves for product return of $4.1 million reported in Q4 2024
- Continued demand growth for ZORYVE of 10%, solidifying its position as most prescribed branded non-steroidal topical treatment across three major inflammatory skin conditions
- All three largest national Pharmacy Benefit Managers (PBMs) covering entire ZORYVE portfolio and Medicaid coverage continues to expand
- On April 3, 2025, the patent litigation against Padagis was stayed and the court cancelled all case deadlines, including the trial
- May 22, 2025 Prescription Drug User Fee Act (PDUFA) action date for ZORYVE foam 0.3% for treatment of individuals with plaque psoriasis of the scalp and body, 12 years and older

WESTLAKE VILLAGE, Calif., May 06, 2025 (GLOBE NEWSWIRE) -- 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 March 31, 2025, and provided a business update.

“In the first quarter we again delivered excellent performance driven by strong demand growth for our ZORYVE portfolio, which offers a distinct and compelling value proposition and provides healthcare providers and their patients with an effective and safe alternative to steroids. We have broad commercial coverage, are continuing to expand Medicaid coverage — with more than 1 in 2 recipients having coverage — and are maintaining our gross-to-net in the 50s,” said Frank Watanabe, president and chief executive officer. “With our team's execution of our strategy, strong financial position, multiple upcoming catalysts and market expansion opportunities, including additional indications and further coverage expansion for ZORYVE, as well as a promising pipeline, we are confident in our continued growth in 2025 and beyond.”

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 425,000 prescriptions filled since launch by over 18,000 unique prescribers, reflecting the high levels of patient and physician satisfaction with the ZORYVE cream clinical profile. ZORYVE cream 0.3% has reached its steady state gross-to-net (GTN).
- Launch of ZORYVE cream 0.15% in atopic dermatitis continues to gain momentum with over 69,000 prescriptions filled since launch, with coverage by the three largest national PBMs. The Company anticipates continued improvement in GTN for ZORYVE cream 0.15% in 2025, converging on the GTN of our other products.
- The Company submitted a supplemental New Drug Application (sNDA) for ZORYVE cream 0.05% to the FDA for the treatment of atopic dermatitis in children ages 2 to 5, and has been assigned a PDUFA action date of October 13, 2025.

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 343,000 prescriptions filled since launch, reflecting the high unmet need in this disease. ZORYVE foam has gained commercial and Medicaid coverage in line with ZORYVE cream 0.3% and is nearing its 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, and has been assigned a PDUFA action date of 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 the middle of 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

- The Company appointed Latha Vairavan as Chief Financial Officer effective May 6, 2025.
- Obtained two new U.S. patents in Q1 2025 related to topical roflumilast compositions.
- In March 2025, at the request of Padagis, Arcutis agreed to a joint stipulation to stay the ongoing patent litigation with Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (Padagis). On April 3, 2025, the court stayed the case and cancelled all case deadlines, including the trial. The 30-month stay will be extended for each day the stay is in place starting March 24, 2025, until the stay is lifted. The parties are not in settlement discussions.
- In March 2025, Health Canada approved ZORYVE® (roflumilast) cream 0.15% for the treatment of atopic dermatitis in individuals 6 years of age and older, and the Company commenced sales in April.
- The positive results from Arcutis's pivotal Phase 3 trial of the efficacy and safety of ZORYVE cream 0.05% for the treatment of mild to moderate atopic dermatitis in children 2 to 5 years old was published in *Pediatric Dermatology.*

First Quarter 2025 Summary Financial Results

Product revenues for the quarter ended March 31, 2025 were $63.8 million compared to $21.6 million for the corresponding period in 2024. Revenues for the quarter were $23.4 million for ZORYVE (roflumilast) cream 0.3%, $30.2 million for ZORYVE (roflumilast) topical foam 0.3%, and $10.2 million for ZORYVE (roflumilast) cream 0.15%. Year-over-year increases were due to strong unit demand as well as improvements in GTN sales deductions. In addition, the first quarters of 2025 and 2024 included **Other revenues** of $2.0 million and $3.0 million, respectively, related to license revenues received in connection with the Huadong Pharmaceutical collaboration and licensing agreement. Q1 2024 also included **Other revenues** of $25.0 million from an upfront payment in connection with the Sato License Agreement.

Cost of sales for the quarter ended March 31, 2025 were $8.8 million compared to $3.3 million for the corresponding period in 2024. The year-over-year increase was due to the cumulative catch-up adjustment related to the $10.0 million milestone payment to AstraZeneca achieved during the quarter, coupled with higher product revenues.

Research and development (R&D) expenses for the quarter ended March 31, 2025 were $17.5 million compared to $23.1 million for the corresponding period in 2024. 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 March 31, 2025 were $64.0 million compared to $54.8 million for the corresponding period in 2024. The year-over-year increase was primarily due to compensation and personnel-related expenses for our continued commercialization efforts for ZORYVE.

Net loss was $25.1 million, or $0.20 per basic and diluted share, for the quarter ended March 31, 2025 compared to $35.4 million, or $0.32 per basic and diluted share, for the corresponding period in 2024.

Cash, cash equivalents, restricted cash, and marketable securities were $198.7 million as of March 31, 2025, compared to $228.6 million as of December 31, 2024. Net cash used in operating activities was $30.4 million during the first 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 of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis' unique dermatology development platform coupled with our dermatology expertise allows us to invent differentiated therapies against biologically validated targets, and has produced a robust pipeline with multiple follow-on clinical programs for a range of inflammatory dermatological conditions including 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)

	March 31, 2025	December 31, 2024
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,104	$ 71,335
Restricted cash	617	617
Marketable securities	144,984	156,620
Trade receivable, net	85,415	73,066
Inventories	16,614	14,526
Prepaid expenses and other current assets	22,937	19,656
Total current assets	323,671	335,820
Property and equipment, net	1,496	1,041
Intangible assets, net	16,500	9,479
Operating lease right-of-use asset	1,842	1,953
Other assets	596	596
Total assets	$ 344,105	$ 348,889
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 24,529	$ 14,220
Accrued liabilities	65,758	65,973
Operating lease liability	842	820
Total current liabilities	91,129	81,013
Operating lease liability, noncurrent	2,340	2,562
Long-term debt, net	107,618	107,203
Other long-term liabilities	360	570
Total liabilities	201,447	191,348
Stockholders' equity:		
Common stock	12	12
Additional paid-in capital	1,289,789	1,279,479
Accumulated other comprehensive loss	(140)	(7)
Accumulated deficit	(1,147,003)	(1,121,943)
Total stockholders' equity	142,658	157,541
Total liabilities and stockholders' equity	$ 344,105	$ 348,889

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

	Three Months Ended March 31,	
	2025	2024
Revenues:		

Product revenue, net	$ 63,846	$ 21,569
Other revenue	2,000	28,000
Total revenues	65,846	49,569
Operating expenses:		
Cost of sales	8,830	3,256
Research and development	17,543	23,141
Selling, general, and administrative	64,002	54,794
Total operating expenses	90,375	81,191
Loss from operations	(24,529)	(31,622)
Other income (expense):		
Other income, net	2,730	4,044
Interest expense	(2,982)	(7,480)
Loss before income taxes	(24,781)	(35,058)
Provision for income taxes	279	324
Net loss	$ (25,060)	$ (35,382)
Per share information:		
Net loss per share, basic and diluted	$ (0.20)	$ (0.32)
Weighted-average shares used in computing net loss per share, basic and diluted	126,036,862	111,048,525