Arcutis Announces Second Quarter 2025 Financial Results and Provides Business Update

- Q2 2025 net product revenue for ZORYVE® (roflumilast) was $81.5 million, a 164% increase compared to Q2 of 2024, and a 28% increase compared to Q1 of 2025, driven by strong portfolio demand growth
- ZORYVE foam 0.3% received U.S. Food and Drug Administration (FDA) approval for the treatment of plaque psoriasis of the scalp and body in adults and adolescents 12 years of age and older
- Initiated INTEGUMENT-INFANT study to evaluate the safety and efficacy of ZORYVE cream 0.05% in infants with atopic dermatitis ages 3 months to 24 months
- Submitted Investigational New Drug Application (IND) for ARQ-234, a novel fusion protein for the potential treatment of patients with atopic dermatitis

WESTLAKE VILLAGE, Calif., Aug. 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 June 30, 2025, and provided a business update.

“We continue to advance our strategy to become the leading medical dermatology company. This quarter, we generated strong net product revenues of $81.5 million from our ZORYVE portfolio, launched a new indication for ZORYVE foam for scalp and body psoriasis, and continued to advance our pipeline. Demand for ZORYVE continues to grow steadily, and we recently surpassed 1 million prescriptions dispensed, underscoring clinicians’ trust in ZORYVE as their preferred steroid-free topical treatment across our four approved indications, thanks to its consistent, robust efficacy and favorable safety and tolerability,” said Frank Watanabe, president and chief executive officer. “Looking ahead, we remain focused on expanding the approved uses of ZORYVE to the youngest patients, with the potential Q4 approval of ZORYVE cream 0.05% for 2 to 5 year olds with atopic dermatitis and the initiation of an infant

atopic dermatitis study. Together with our efforts to evaluate potential further indications for ZORYVE and the continued advancement of ARQ-234, we are well positioned for long-term, sustainable growth."

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 439,000 prescriptions filled since launch, reflecting the high levels of patient and physician satisfaction with the ZORYVE cream clinical profile.
- Launch of ZORYVE cream 0.15% in atopic dermatitis continues to gain momentum with over 99,000 prescriptions filled since launch. ZORYVE cream 0.15% received a strong recommendation from the American Association of Dermatology (AAD) in its recently updated guidelines for atopic dermatitis treatments for adults.
- The Company has been assigned a Prescription Drug User Fee Act (PDUFA) action date of October 13, 2025 for the supplemental New Drug Application (sNDA) for ZORYVE cream 0.05% for the treatment of atopic dermatitis in children ages 2 to 5 years old. In addition, the Company commenced a four-week Phase 2 study to evaluate investigational, once-daily ZORYVE cream 0.05% in infants as young as 3 months to less than 2 years with atopic dermatitis, which could potentially be the basis for further indication expansion.

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 plaque psoriasis of the scalp and body.

- The Company received FDA approval for its sNDA for ZORYVE foam for scalp and body psoriasis in adult and adolescents 12 years of age and older in May 2025 and commenced sales in June 2025.
- Demand for ZORYVE foam 0.3% in seborrheic dermatitis and plaque psoriasis of the scalp and body continues to grow robustly each quarter, with over 405,000 prescriptions filled since launch, reflecting the high unmet need in these diseases.

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 submitted its IND for ARQ-234 in July 2025.

Other Pipeline Updates

- Following the evaluation of results from the Phase 1b trial of ARQ-255, a penetrating topical formulation of ivarmacitinib for the treatment of alopecia areata, the Company has elected to halt further development of this program. While clinical and biomarker results indicated some level of efficacy, the results did not meet the Company's threshold for advancement, and the Company has deprioritized the program given other R&D priorities across its portfolio.
- The Company has begun to investigate further indication expansion opportunities for ZORYVE, beginning with two recently initiated Phase 2 studies.

Recent Corporate Highlights

- ZORYVE cream and ZORYVE foam received the Seal of Recognition from the National Psoriasis Foundation (NPF) in June 2025, the first time that the NPF has recognized a prescription product.
- ZORYVE cream 0.15% received a strong recommendation in the updated AAD guidelines for atopic dermatitis treatments for adults.
- The Company's successful pivotal Phase 3 ARRECTOR trial for ZORYVE foam 0.3% in scalp and body psoriasis was published in the Journal of the American Medical Association Dermatology in May 2025.
- Obtained three new U.S. patents in Q2 2025 related to topical roflumilast compositions.

Second Quarter 2025 Summary Financial Results

Product revenues for the quarter ended June 30, 2025 were $81.5 million compared to $30.9 million for the corresponding period in 2024. Revenues for the quarter were $27.7 million for ZORYVE cream 0.3%, $14.6 million for ZORYVE cream 0.15%, and $39.2 million for ZORYVE topical foam 0.3%. Year-over-year and quarter-over-quarter increases were due to increased unit demand. Gross-to-net (GTN) rates remain favorable for ZORYVE, driven by a high percentage of prescriptions being reimbursed.

Cost of sales for the quarter ended June 30, 2025 were $7.5 million compared to $3.5 million for the corresponding period in 2024 due to increasing ZORYVE sales.

Research and development (R&D) expenses for the quarter ended June 30, 2025 were $19.5 million compared to $19.3 million for the corresponding period in 2024. Expenses remained consistent year-over-year as decreased development costs for roflumilast in adult atopic dermatitis and plaque psoriasis were partially offset by an increase in development costs for pediatric atopic dermatitis and continued medical affairs investments to support medical education.

Selling, general, and administrative (SG&A) expenses for the quarter ended June 30, 2025 were $69.2 million compared to $58.2 million for the corresponding period in 2024. The year-over-year increase was primarily driven by increased sales and marketing and personnel-related expenses due to our continued commercialization efforts for ZORYVE.

Net loss was $15.9 million, or $0.13 per basic and diluted share, for the quarter ended June 30, 2025 compared to $52.3 million, or $0.42 per basic and diluted share, for the corresponding period in 2024.

Cash, cash equivalents, restricted cash, and marketable securities were $191.1 million as of June 30, 2025, compared to $228.6 million as of December 31, 2024. Net cash provided by operating activities was $0.3 million during the second quarter as increased gross profit and timing changes in net working capital reduced cash used in operations. The company made the $10.0 million cash milestone payment to AstraZeneca for reaching a sales milestone of $250 million that was incurred in the first quarter of 2025, which is included as an investing activity.

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 for inflammatory dermatological conditions. 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)
(unaudited)

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 72,740	$ 71,335
Restricted cash	308	617
Marketable securities	118,083	156,620
Trade receivable, net	106,688	73,066
Inventories	16,324	14,526
Prepaid expenses and other current assets	18,635	19,656
Total current assets	332,778	335,820
Property and equipment, net	1,394	1,041
Intangible assets, net	15,937	9,479
Operating lease right-of-use asset	1,728	1,953
Other assets	596	596
Total assets	$ 352,433	$ 348,889
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,082	$ 14,220
Current portion of long-term debt, net	1,000	—
Accrued and other current liabilities	87,854	66,793
Total current liabilities	103,936	81,013
Operating lease liability, noncurrent	2,114	2,562
Long-term debt, net	107,049	107,203
Other long-term liabilities	360	570
Total liabilities	213,459	191,348
Stockholders' equity:		
Common stock	12	12
Additional paid-in capital	1,301,886	1,279,479
Accumulated other comprehensive loss	(35)	(7)
Accumulated deficit	(1,162,889)	(1,121,943)
Total stockholders' equity	138,974	157,541
Total liabilities and stockholders' equity	$ 352,433	$ 348,889

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenues:				
Product revenue, net	$ 81,504	$ 30,858	$ 145,350	$ 52,427
Other revenue	—	—	2,000	28,000
Total revenues	81,504	30,858	147,350	80,427
Operating expenses:				
Cost of sales	7,492	3,464	16,322	6,720
Research and development	19,453	19,298	36,996	42,439
Selling, general, and administrative	69,170	58,173	133,172	112,967
Total operating expenses	96,115	80,935	186,490	162,126
Loss from operations	(14,611)	(50,077)	(39,140)	(81,699)
Other income (expense):				
Other income, net	2,096	5,229	4,826	9,273
Interest expense	(3,029)	(7,484)	(6,011)	(14,964)
Loss before income taxes	(15,544)	(52,332)	(40,325)	(87,390)
Provision for income taxes	342	—	621	324
Net loss	$ (15,886)	$ (52,332)	$ (40,946)	$ (87,714)
Per share information:				
Net loss per share, basic and diluted	$ (0.13)	$ (0.42)	$ (0.32)	$ (0.75)
Weighted-average shares used in computing net loss per share, basic and diluted	126,997	123,481	126,519	117,265

Tags

Earnings Call | Financial Results

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