Arcutis Announces First Quarter 2024 Financial Results and Provides Business Update

May 14, 2024

- First quarter net product revenues for ZORYVE® franchise of $21.6M, with $15M for ZORYVE (roflumilast) cream 0.3%, and $6.5M for ZORYVE (roflumilast) topical foam, 0.3%; sales growth of 675% vs. Q1 '23 and 59% vs. Q4 '23
- Continued gross-to-net (GTN) improvement with blended GTN across products now in the low 60 percent range
- Sustained growth in demand for cream and remarkable uptake of foam launched in January
- July 7, 2024 Prescription Drug User Fee Act (PDUFA) action date for roflumilast cream, 0.15%, for treatment of mild to moderate atopic dermatitis in adults and children down to age 6
- Strong cash position following a public offering raising gross proceeds of $172.5 million and a strategic licensing agreement in Japan

WESTLAKE VILLAGE, Calif., May 14, 2024 (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, 2024, and provided a business update.

“Our strong performance in the first quarter, with the incredibly well received launch of ZORYVE foam for seborrheic dermatitis, and continued growth of ZORYVE cream in psoriasis, reinforces the demand for new and novel steroid-free treatment options and physician adoption of the ZORYVE portfolio,” said Frank Watanabe, president and chief executive officer. “The growth of ZORYVE cream and foam, along with a July 7 th PDUFA date for ZORYVE cream as a potential treatment for atopic dermatitis, as well as our robust development pipeline, position Arcutis for a potentially transformative year in 2024.”

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 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 208,000 prescriptions filled to date since launch by close to 12,000 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 and multiple other commercial insurers, and the Company anticipates beginning to obtain Medicare and Medicaid coverage during 2024. The Company experienced another significant GTN improvement in the first quarter compared to Q4 '23, and anticipates additional GTN improvement throughout 2024 as GTN for the cream approaches steady state.
- The Food & Drug Administration (FDA) has accepted the Company’s supplemental new drug application (sNDA) for roflumilast cream 0.15% for the treatment of mild to moderate atopic dermatitis in adults and children down to age 6, and assigned the application a PDUFA target action date of July 07, 2024. The sNDA is supported by positive results from three Phase 3 studies as well as a Phase 2 dose ranging study, and two Phase 1 pharmacokinetic studies.

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, approved in the United States for the treatment of seborrheic dermatitis and in development for scalp and body psoriasis

- The launch in January of ZORYVE foam in seborrheic dermatitis has been incredibly well received by healthcare providers and patients, with over 46,000 prescriptions filled since launch, reflecting the high unmet need in this disease. ZORYVE foam is also covered by the three largest Pharmacy Benefit Managers. For the partial first quarter of launch, GTN is favorable and improving rapidly.
- 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 third quarter 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 February, the Company completed a public offering raising gross proceeds of $172.5 million including the underwriters' 30-day option to purchase additional shares at the public offering price per share, which was fully exercised.
- In February, the Company announced a strategic collaboration and licensing agreement for the development, manufacture, and commercialization of topical roflumilast in Japan with Sato Pharmaceutical Co., Ltd.
- In April, the Company announced David Topper has been appointed Chief Financial Officer (CFO) effective April 10, 2024. He replaced John Smither, who had rejoined Arcutis as interim CFO in August 2023.

First Quarter 2024 Summary Financial Results

Product revenues for the quarter ended March 31, 2024 were $21.6 million compared to $2.8 million for the corresponding period in 2023. Revenues for the quarter were $15.0 million for ZORYVE (roflumilast) cream 0.3% and $6.5 million for ZORYVE (roflumilast) topical foam, 0.3%. Year-over-year increases were due to strong unit demand as well as improvements in GTN sales deductions. In addition, the first quarter of 2024 included **Other revenues** of $28.0 million related to the upfront and milestone payments in connection with the Sato Pharmaceutical and Huadong Pharmaceutical collaboration and licensing agreements.

Cost of sales for the quarter ended March 31, 2024 were $3.3 million compared to $0.8 million for the corresponding period in 2023.

Research and development (R&D) expenses for the quarter ended March 31, 2024 were $23.1 million compared to $35.3 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 March 31, 2024 were $54.8 million compared to $42.9 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 $35.4 million, or $0.32 per basic and diluted share, for the quarter ended March 31, 2024 compared to $80.1 million, or $1.31 per basic and diluted share, for the corresponding period in 2023.

Cash, cash equivalents, restricted cash, and marketable securities were $404.5 million as of March 31, 2024, compared to $272.8 million as of December 31, 2023. Net cash used in operating activities was $31.6 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 including two 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, 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 in plaque psoriasis and ZORYVE foam in 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)

	March 31, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 190,097	$ 88,398
Restricted cash	617	925
Marketable securities	213,769	183,463
Trade receivable, net	37,154	25,807
Inventories	13,247	13,134
Prepaid expenses and other current assets	13,178	18,704
Total current assets	468,062	330,431
Property and equipment, net	1,369	1,539
Intangible assets, net	6,250	6,438
Operating lease right-of-use asset	2,264	2,361
Other assets	596	596
Total assets	$ 478,541	$ 341,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,969	$ 11,992
Accrued liabilities	33,584	33,941
Operating lease liability	756	735
Total current liabilities	47,309	46,668
Operating lease liability, noncurrent	3,181	3,382
Long-term debt, net	202,803	201,799
Other long-term liabilities	306	849
Total liabilities	253,599	252,698
Stockholders' equity:		
Common stock	12	9
Additional paid-in capital	1,242,349	1,070,558
Accumulated other comprehensive loss	(133)	4
Accumulated deficit	(1,017,286)	(981,904)
Total stockholders' equity	224,942	88,667
Total liabilities and stockholders' equity	$ 478,541	$ 341,365

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

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Product revenue, net	$ 21,569	$ 2,781
Other revenue	28,000	—
Total revenues	49,569	2,781
Operating expenses:		
Cost of sales	3,256	783
Research and development	23,141	35,345
Selling, general, and administrative	54,794	42,918

Total operating expenses	81,191	79,046
Loss from operations	(31,622)	(76,265)
Other income (expense):		
Other income, net	4,044	3,207
Interest expense	(7,480)	(7,042)
Loss before income taxes	(35,058)	(80,100)
Provision for income taxes	$ 324	$ —
Net loss	$ (35,382)	$ (80,100)
Per share information:		
Net loss per share, basic and diluted	$ (0.32)	$ (1.31)
Weighted-average shares used in computing net loss per share, basic and diluted	111,048,525	61,169,089