Arcutis Announces Third Quarter 2024 Financial Results and Provides Business Update

November 6, 2024

- Third quarter net product revenues for ZORYVE® (roflumilast) franchise of $44.8M, with $22.0M for ZORYVE cream 0.3%, $20.3M for ZORYVE topical foam 0.3%, and $2.5M for ZORYVE cream 0.15%; sales growth of 452% vs. Q3 '23 and 45% vs. Q2 '24
- Continued gross-to-net (GTN) improvement with blended GTN across products now in the low 50 percent range, improving from the high 50 percent range last quarter
- Sustained growth in prescriptions for both cream and foam, with total U.S. franchise unit demand increase of 25% quarter over quarter
- Supplemental New Drug Application (sNDA) for ZORYVE foam accepted by Food & Drug Administration (FDA) for the treatment of scalp and body psoriasis in adults and adolescents ages 12 and over with Prescription Drug User Fee Act (PDUFA) action date of May 22, 2025
- Announced Health Canada approval of ZORYVE foam for seborrheic dermatitis on October 18 and plan to commercially launch by end of 2024

WESTLAKE VILLAGE, Calif., Nov. 06, 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 September 30, 2024, and provided a business update.

“Arcutis continues to execute our strategy successfully, with 45% revenue growth this quarter, marking sequential quarter growth since January of 2023. Product revenue for the quarter was driven by strong demand growth, and product preference by both patients and providers for ZORYVE across our three approved indications, as well as continued improvements in GTN. We are in the early stages of our launch of ZORYVE cream in mild to moderate atopic dermatitis, which has been well received for its effective, safe, and well-tolerated profile,” said Frank Watanabe, president and chief executive officer. “We have a strong revenue trajectory for the future, with a large addressable market that will continue to expand with further Medicaid wins, expected Medicare coverage wins, expansion into pediatric and primary care practices, and an expected FDA approval next year of ZORYVE foam for scalp and body psoriasis. We also continue to progress our pipeline, with the last subject enrolled in our ARQ-255 alopecia areata phase 1 trial and steady progress towards an IND for ARQ-234. Our strong balance sheet positions us to fuel our 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 in plaque psoriasis continues to grow, with over 304,000 prescriptions filled to date since launch by over 14,000 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 expanded its Medicaid coverage to four additional states, Michigan, Arizona, California and Indiana, and anticipates it will obtain Medicaid coverage in additional states during 2024. ZORYVE cream 0.3% saw some GTN improvement in the third quarter compared to Q2 '24, and is approaching its steady state GTN.

- 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, which will translate into improving GTN for ZORYVE cream 0.15% and the portfolio.

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 168,000 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 approach steady state by the end of 2024.

- 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, which was accepted by the FDA in September with a PDUFA action date set for May 22, 2025.

- The Company announced Health Canada approval of ZORYVE foam for seborrheic dermatitis on October 18, and

anticipates making the foam commercially available in Canada prior to the end 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 September 2024, Arcutis announced that it completed enrollment in a Phase 1b study evaluating ARQ-255 for the treatment of alopecia areata, with data expected in 1H '25.

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 (IND) in 2025.

Recent Corporate Highlights

- In July, the Company announced a co-promotion agreement with Kowa Pharmaceuticals America, Inc., whereby Kowa markets and promotes ZORYVE cream and ZORYVE foam to primary care practitioners and pediatricians for all FDA approved indications in the United States. Kowa began promoting ZORYVE in the second half of September.

- Amended the $200 million term-loan with SLR Investment Corp., lowering the interest rate, extending the maturity to August 2029, and obtaining an option to prepay up to $100 million of the principal and re-draw it by the first half of 2026 at the Company’s discretion. The Company made a partial prepayment of the principal of $100 million on October 8, 2024.

- Obtained two new U.S. patents in Q3 2024 related to ZORYVE. These patents cover, in part, formulations and methods of treatment resulting in unexpected and beneficial properties of ZORYVE, including the beneficial pharmacokinetic profile of ZORYVE. Arcutis also obtained a new U.S. patent covering the novel formulation of ARQ-255.

- Published positive results from two pivotal Phase 3 studies (INTEGUMENT-1 and INTEGUMENT-2) evaluating the efficacy and safety of ZORYVE cream 0.15% as a once-daily, steroid-free treatment for mild to moderate atopic dermatitis in the Journal of American Medical Association Dermatology (JAMA Dermatology).

- ZORYVE nominated for the Prix Galien USA for "Best Biotechnology Product", the world's highest independent distinction that awards the most critical products approved by the FDA in the last five years that demonstrate tremendous potential to improve human health.

- Board of Directors (Board) unanimously elected Keith Leonard as chair of the Board effective November 4, 2024, succeeding Patrick Heron. Mr. Leonard has served on the Board since 2021 and has more than 30 years of biopharmaceutical experience, including multiple chair, board director, and chief executive officer roles at publicly listed companies, and deep expertise in pharmaceutical commercialization. Mr. Heron, who has served on the Board since its formation and chair of the Board since 2019, will continue to serve as an independent director.

Third Quarter 2024 Summary Financial Results

Product revenues for the quarter ended September 30, 2024 were $44.8 million compared to $8.1 million for the corresponding period in 2023. Revenues for the quarter were $22.0 million for ZORYVE cream 0.3%, $20.3 million for ZORYVE topical foam 0.3%, and $2.5 million for ZORYVE cream 0.15%. 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 low 50s, driven by the high percentage of prescriptions being reimbursed.

Cost of sales for the quarter ended September 30, 2024 were $5.5 million compared to $1.2 million for the corresponding period in 2023.

Research and development (R&D) expenses for the quarter ended September 30, 2024 were $19.5 million compared to $26.2 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 September 30, 2024 were $58.8 million compared to $47.6 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 $41.5 million, or $0.33 per basic and diluted share, for the quarter ended September 30, 2024 compared to $44.8 million, or $0.73 per basic and diluted share, for the corresponding period in 2023.

Cash, cash equivalents, restricted cash, and marketable securities were $331.2 million as of September 30, 2024, compared to $272.8 million as of December 31, 2023. Net cash used in operating activities was $34.7 million during the third quarter, an improvement of 23% compared to Q2 '24. On October 8th, the Company made a partial prepayment of $100M of the outstanding debt under the SLR loan.

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 0.3% 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.

Contacts:

Media
Amanda Sheldon, Head of Corporate Communications
media@arcutis.com

Investors
Latha Vairavan, VP Finance and Corporate Controller
ir@arcutis.com

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

	September 30, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 134,851	$ 88,398
Restricted cash	617	925
Marketable securities	195,710	183,463
Trade receivable, net	60,119	25,807
Inventories	14,015	13,134
Prepaid expenses and other current assets	18,408	18,704
Total current assets	423,720	330,431
Property and equipment, net	1,186	1,539
Intangible assets, net	9,792	6,438
Operating lease right-of-use asset	2,060	2,361
Other assets	596	596
Total assets	$ 437,354	$ 341,365
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 19,325	$ 11,992
Accrued liabilities	52,790	33,941
Current portion of long-term debt, net	99,513	—

Operating lease liability	798	735
Total current liabilities	172,426	46,668
Operating lease liability, noncurrent	2,772	3,382
Long-term debt, net	105,095	201,799
Other long-term liabilities	420	849
Total liabilities	280,713	252,698
Stockholders' equity:		
Common stock	12	9
Additional paid-in capital	1,267,251	1,070,558
Accumulated other comprehensive loss	533	4
Accumulated deficit	(1,111,155)	(981,904)
Total stockholders' equity	156,641	88,667
Total liabilities and stockholders' equity	$ 437,354	$ 341,365

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product revenue, net	$ 44,755	$ 8,109	$ 97,182	$ 15,660
Other revenue	—	30,000	28,000	30,420
Total revenues	44,755	38,109	125,182	46,080
Operating expenses:				
Cost of sales	5,503	1,182	12,223	2,741
Research and development	19,501	26,236	61,940	86,800
Selling, general, and administrative	58,817	47,595	171,784	136,471
Total operating expenses	83,821	75,013	245,947	226,012
Loss from operations	(39,066)	(36,904)	(120,765)	(179,932)
Other income (expense):				
Other income, net	4,182	2,721	13,455	9,114
Interest expense	(6,653)	(7,559)	(21,617)	(21,950)
Loss before income taxes	(41,537)	(41,742)	(128,927)	(192,768)
Provision for income taxes	—	3,023	324	3,088
Net loss	$ (41,537)	$ (44,765)	$ (129,251)	$ (195,856)
Per share information:				
Net loss per share, basic and diluted	$ (0.33)	$ (0.73)	$ (1.08)	$ (3.19)
Weighted-average shares used in computing net loss per share, basic and diluted	124,302,317	61,727,278	119,627,687	61,462,025