Arcutis Announces Third Quarter 2023 Financial Results and Provides Business Update

November 3, 2023

- Achieved total revenues of $38.1 million in the third quarter of 2023. Net product revenues for ZORYVE® (roflumilast) cream 0.3% were $8.1 million, a 70% increase compared to the second quarter of 2023, driven by sequential improvement in gross-to-net (GTN) down to the low 70 percent range, as well as continued demand growth
- Received U.S. Food and Drug Administration (FDA) approval for the expanded indication of ZORYVE in plaque psoriasis down to the age of 6
- Substantially advanced our atopic dermatitis program with the supplemental New Drug Application (sNDA) submission, and positive read-outs from the INTEGUMENT-PED and long-term trials
- Appointed industry veterans Todd Edwards and John W. Smither as new Chief Commercial Officer and interim Chief Financial Officer, respectively
- Strengthened balance sheet with $100 million follow-on offering, and negotiated improvements in the financial covenants on the SLR debt facility

WESTLAKE VILLAGE, Calif., Nov. 03, 2023 (GLOBE NEWSWIRE) -- 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 September 30, 2023, and provided a business update.

“We are very pleased with the performance this quarter, and believe we are well-positioned for continued strong net product revenue growth in the fourth quarter and to accelerate that momentum into 2024. We are on the cusp of a very significant expansion of the topical roflumilast opportunity during 2024 with the potential approvals and subsequent launches of topical roflumilast for seborrheic dermatitis and atopic dermatitis as well as expected further expansion of payer coverage,” said Frank Watanabe, President and CEO of Arcutis. “The Arcutis commercial team made significant progress in improving gross-to-net and laying the foundation for sustained growth during the quarter, and now, with Todd's leadership and proven credentials in topical dermatology, we expect to further enhance our commercial execution.”

“The track record of our clinical and regulatory teams speaks for itself, and the steady flow of clinical successes and regulatory milestones achieved during this quarter alone is a testament to their exceptional execution against our strategic goals. With a strengthened balance sheet position after our recent financing, we are now better-positioned to progress through the upcoming inflection points with our additional topical roflumilast launches, and address the urgent needs of millions of patients living with immune-mediated dermatological diseases and conditions,” concluded Mr. Watanabe.

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 continues to progress, laying a foundation for sustained growth in psoriasis and further acceleration from expected new indications. Over 110,000 prescriptions have been filled since launch by nearly 9,000 unique prescribers, reflecting the high levels of patient and physician satisfaction with the ZORYVE clinical profile. Continued launch investments, including a targeted increase in field force size to drive share of voice and the recently launched connected television campaign, should drive continued demand growth. The high-quality coverage secured for ZORYVE across the three largest payers, coupled with strategies to accelerate covered prescription pull-through, drove significant GTN improvement in the third quarter compared to the second quarter. The Company anticipates further GTN improvement in the fourth quarter of 2023.

- In October 2023, Arcutis received FDA approval for ZORYVE for an expanded indication for the treatment of plaque psoriasis in children down to 6 years of age. The Company is working with the FDA on the further expansion of this indication down to the age of 2.

- In September 2023, Arcutis submitted an sNDA to the FDA for roflumilast cream 0.15% for the treatment of atopic dermatitis down to the age of 6, with potential approval as early as the third quarter of 2024.

- In September 2023, Arcutis announced positive long-term results from the INTEGUMENT-OLE trial in adults and children ages 6 and older, showing durable and improved efficacy out to 56 weeks, favorable safety profile, and dependable disease control.

- In September 2023, Arcutis announced positive topline results from the INTEGUMENT-PED pivotal Phase 3 trial of roflumilast cream 0.05% for the treatment of atopic dermatitis in children ages 2 to 5. The Company expects to submit a supplemental sNDA submission for this population 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 November 2023, the Company amended its loan agreement with SLR Investment Corp. (SLR), modifying the financial covenants by removing the minimum market capitalization requirement, changing specific product revenue minimums to at least 75% of the Company's plan, and requiring the Company to obtain additional capital (non-dilutive or otherwise) of $31 million before April 1, 2024. The final undrawn tranche of $25 million was also eliminated from the agreement.
- In October 2023, the United States Patent and Trademark Office awarded the Company a new formulation patent that covers a means for inhibiting roflumilast crystal growth. This patent will expire in 2037.
- In October 2023, the Company completed a public offering of $100 million gross, extending cash runway into 2025. The Company also granted the underwriters a 30-day option to purchase an additional 6 million shares at the public offering price per share.
- In August 2023, the Company announced a strategic collaboration and licensing agreement with Huadong for topical roflumilast in Greater China and Southeast Asia, with an upfront payment of $30.0 million received by Arcutis and an additional $64.25 million available upon the achievement of certain regulatory and commercial milestones.
    - During the third quarter, the Company announced the appointments of industry veterans Todd Edwards and John W. Smither as new Chief Commercial Officer and interim Chief Financial Officer, respectively, and the promotion of Ayisha Jeter to Senior Vice President, Marketing and Market Access.
    - In August 2023, the Company published its annual Environmental, Social, and Governance (ESG) report, detailing advancement across a number of key initiatives.

Third Quarter 2023 Summary Financial Results

Total revenues for the quarter ended September 30, 2023 were $38.1 million. **Net product revenues** related to sales of ZORYVE were $8.1 million driven by improvements in gross-to-net sales deductions as well as strong unit demand growth compared to the second quarter of 2023. **Other revenues** for the quarter ended September 30, 2023 were $30.0 million, related to the upfront payment in connection with the Huadong collaboration and licensing agreement.

Cost of sales for the quarter ended September 30, 2023 were $1.2 million.

Research and development (R&D) expenses for the quarter ended September 30, 2023 were $26.2 million compared to $69.7 million for the corresponding period in 2022. The year-over-year decrease was primarily due to the upfront milestone for the Ducentis acquisition in the third quarter last year, as well as decreased clinical development costs related to our topical roflumilast programs.

Selling, general, and administrative (SG&A) expenses for the quarter ended September 30, 2023 were $47.6 million compared to $35.5 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 $44.8 million, or $0.73 per basic and diluted share, for the quarter ended September 30, 2023 compared to $107.7 million, or $1.89 per basic and diluted share, for the corresponding period in 2022.

Cash, cash equivalents, restricted cash, and marketable securities were $228.0 million as of September 30, 2023, compared to $410.8 million as of December 31, 2022. Net cash used in operating activities was $44.0 million during the third quarter.

Conference Call and Webcast
Arcutis management will host a conference call and webcast today at 8:30am 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 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 commercial success and growth of ZORYVE in plaque psoriasis, 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 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.

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

	September 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 107,471	$ 53,641
Restricted cash	925	1,234
Marketable securities	119,642	355,948
Trade receivable, net	19,417	8,458
Inventories	13,913	7,514
Prepaid expenses and other current assets	20,180	10,611
Total current assets	281,548	437,406
Property and equipment, net	1,735	1,881
Intangible assets, net	6,625	7,188
Operating lease right-of-use asset	2,455	2,721
Other assets	596	78

Total assets	$ 292,959	$ 449,274
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,179	$ 8,827
Accrued liabilities	27,995	28,323
Operating lease liability	715	657
Total current liabilities	41,889	37,807
Operating lease liability, noncurrent	3,570	4,117
Long-term debt, net	200,783	197,769
Total liabilities	246,242	239,693
Stockholders' equity:		
Common stock	6	6
Additional paid-in capital	962,515	930,425
Accumulated other comprehensive loss	(184)	(1,086)
Accumulated deficit	(915,620)	(719,764)
Total stockholders' equity	46,717	209,581
Total liabilities and stockholders' equity	$ 292,959	$ 449,274

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,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product revenue, net	$ 8,109	$ 725	$ 15,660	$ 725
Other revenue	30,000	—	30,420	—
Total revenues	38,109	725	46,080	725
Operating expenses:				
Cost of sales	1,182	269	2,741	269
Research and development	26,236	69,731	86,800	148,558
Selling, general, and administrative	47,595	35,473	136,471	85,101
Total operating expenses	75,013	105,473	226,012	233,928
Loss from operations	(36,904)	(104,748)	(179,932)	(233,203)
Other income (expense):				
Other income, net	2,721	1,938	9,114	2,501
Interest expense	(7,559)	(4,899)	(21,950)	(8,737)
Loss before income taxes	(41,742)	(107,709)	(192,768)	(239,439)
Provision for income taxes	$ 3,023	$ —	$ 3,088	$ —
Net loss	$ (44,765)	$ (107,709)	$ (195,856)	$ (239,439)
Per share information:				
Net loss per share, basic and diluted	$ (0.73)	$ (1.89)	$ (3.19)	$ (4.52)
Weighted-average shares used in computing net loss per share, basic and diluted	61,727,278	57,091,743	61,462,025	53,028,962