Arcutis Announces First Quarter 2023 Financial Results and Provides Business Update

May 9, 2023

- Achieved net revenues of $2.8 million for ZORYVE® (roflumilast) cream 0.3% in the first quarter of 2023, with unit demand growth nearly doubling quarter-over-quarter
- Continued expansion of commercial payer coverage for ZORYVE in plaque psoriasis with over 110 million commercial lives covered in the United States
- Received Health Canada approval of ZORYVE for plaque psoriasis, with launch expected in the coming weeks
- Completed enrollment in INTEGUMENT-PED, the Pivotal Phase 3 trial in individuals with atopic dermatitis aged 2 to 5 years old, with topline data expected in the third quarter of 2023
- Received U.S. Food and Drug Administration (FDA) acceptance of our New Drug Application (NDA) for roflumilast foam for the treatment of seborrheic dermatitis in adults and adolescents, with a target action date of December 16, 2023
- Strong financial position with approximately $333 million in cash, cash equivalents, and marketable securities, with capital allocation focused on commercialization

WESTLAKE VILLAGE, Calif., May 09, 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 March 31, 2023, and provided a business update.

“We are building momentum in our ongoing launch in psoriasis as a result of ZORYVE's differentiated product profile, marked by exceptionally positive patient and physician feedback, paired with our ability to secure broad, high-quality formulary coverage. With the recent FDA acceptance of our NDA for seborrheic dermatitis and our upcoming regulatory submissions in atopic dermatitis and scalp and body psoriasis, we look forward to potentially launching a new product every two to three quarters over the next two years, leveraging the commercial infrastructure and positive tailwinds from the clinical experience we've built in plaque psoriasis,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “Our balance sheet remains strong, and we are further prioritizing capital allocation towards our commercialization efforts in order to drive long-term shareholder value.”

Program Updates / Key Milestones

ZORYVE (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 continues to build momentum, with prescription growth nearly doubling in the first quarter of 2023, compared to the fourth quarter of 2022. The Company continues to expand high-quality payer coverage for ZORYVE with more than 110 million commercially-insured lives in the United States, with over 90% of those lives devoid of prior authorizations. The Company anticipates continued patient demand growth and further expansion of commercial coverage in 2023, fueling ZORYVE's potential to meaningfully convert the topical steroid market.

- In the fourth quarter of 2022, Arcutis announced positive topline results from INTEGUMENT-1 and INTEGUMENT-2, the two pivotal Phase 3 trials evaluating roflumilast cream 0.15% for the treatment of atopic dermatitis in individuals 6 years of age or older. The Company anticipates submitting a supplemental New Drug Application (sNDA) to the FDA for ages 6 and above late in the third quarter or early in the fourth quarter of 2023.

- In May 2023, Arcutis announced the completion of enrollment in INTEGUMENT-PED, the third Pivotal Phase 3 trial in atopic dermatitis, in individuals aged 2 to 5 years old. Topline data from INTEGUMENT-PED are expected in the third quarter of 2023. If positive, the Company expects these data to be sufficient basis for an sNDA submission, after the anticipated approval of roflumilast cream in atopic dermatitis for ages 6 and above.

- In December 2022, Arcutis submitted an sNDA to the FDA for ZORYVE for an expanded indication for the treatment of plaque psoriasis in children down to 2 years of age. The Company anticipates potential FDA approval in the fourth quarter of 2023.

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' 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 patient in a Phase 1b study in alopecia areata.

ARQ-252 - an alternative topical cream formulation of ivarmacitinib, being developed as a potential treatment for chronic hand eczema, vitiligo, and other inflammatory dermatoses

- The Company has paused development of ARQ-252 as part of ongoing efforts to prioritize investments in commercialization.

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

The Health Canada approval of ZORYVE for the treatment of plaque psoriasis marks a significant milestone for Arcutis as our first approval outside of the United States. The Company has built an experienced commercial and medical organization in Canada in preparation of the launch for plaque psoriasis, and to support the continued advancement of our robust pipeline.

First Quarter 2023 Summary Financial Results

Net product revenues for the quarter ended March 31, 2023 related to sales of ZORYVE were $2.8 million driven by strong unit demand, offset by sequentially higher gross-to-net sales deductions, including higher costs of co-pay assistance, in the first quarter compared to the fourth quarter.

Cost of sales for the quarter ended March 31, 2023 were $0.8 million.

Research and development (R&D) expenses for the quarter ended March 31, 2023 were $35.3 million compared to $40.6 million for the corresponding period in 2022. The year-over-year decrease was primarily due to decreased clinical development costs related to our topical roflumilast programs.

Selling, general, and administrative (SG&A) expenses for the quarter ended March 31, 2023 were $42.9 million compared to $22.0 million for the corresponding period in 2022. These year-over-year increases were primarily due to higher headcount and sales and marketing expenses related to the launch of ZORYVE.

Net loss was $80.1 million, or $1.31 per basic and diluted share, for the quarter ended March 31, 2023 compared to $64.3 million, or $1.27 per basic and diluted share, for the corresponding period in 2022.

Cash, cash equivalents, restricted cash, and marketable securities were $333.3 million as of March 31, 2023, compared to $410.8 million as of December 31, 2022. Net cash used in operating activities was $80.3 million during the first quarter.

Conference Call and Webcast

Arcutis management will host a conference call and webcast today at 4:30pm 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 Twitter.

Forward Looking Statements

This press release contains "forward-looking" statements, including, among others, 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; expectations with regard to the timing of and successful clinical trial results anticipated during 2023; the potential commercial success and growth of ZORYVE in plaque psoriasis; and the timing of regulatory filings 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 Balance Sheets
(In thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,405	$ 53,641
Restricted cash	925	1,234
Trade receivable, net	12,769	8,458
Marketable securities	251,000	355,948
Inventories	8,551	7,514
Prepaid expenses and other current assets	13,026	10,611
Total current assets	367,676	437,406
Property and equipment, net	2,070	1,881
Intangible assets, net	7,000	7,188
Operating lease right-of-use asset	2,634	2,721
Other assets	78	78
Total assets	$ 379,458	$ 449,274
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,485	$ 8,827
Accrued liabilities	23,864	28,323
Operating lease liability	676	657
Total current liabilities	37,025	37,807
Operating lease liability, noncurrent	3,938	4,117
Long-term debt, net	198,763	197,769
Total liabilities	239,726	239,693
Stockholders' equity:		
Common stock	6	6
Additional paid-in capital	940,004	930,425
Accumulated other comprehensive loss	(414)	(1,086)
Accumulated deficit	(799,864)	(719,764)
Total stockholders' equity	139,732	209,581
Total liabilities and stockholders' equity	$ 379,458	$ 449,274

ARCUTIS BIOTHERAPEUTICS, INC.

Condensed Statements of Operations
(In thousands, except share and per share data)
(unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product revenue, net	$ 2,781	$ —
Total revenues	2,781	—

Operating expenses:		
Cost of sales	783	—
Research and development	35,345	40,622
Selling, general, and administrative	42,918	22,006
Total operating expenses	79,046	62,628
Loss from operations	(76,265)	(62,628)
Other income (expense):		
Other income, net	3,207	142
Interest expense	(7,042)	(1,838)
Total other income (expense)	(3,835)	(1,696)
Net loss	$ (80,100)	$ (64,324)
Per share information:		
Net loss per share, basic and diluted	$ (1.31)	$ (1.27)
Weighted-average shares used in computing net loss per share, basic and diluted	61,169,089	50,513,524