Arcutis Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

February 28, 2023

- Achieved net revenues of $3.0 million for ZORYVE® (roflumilast) cream 0.3% in the first full quarter since the August 2022 launch, driven by continued unit demand growth
- Secured expanded commercial payer coverage for ZORYVE in plaque psoriasis with the second of the top three pharmacy benefit managers in the U.S., as well as an additional national health plan
- Announced positive topline results from INTEGUMENT-1 and INTEGUMENT-2, the two pivotal Phase 3 trials in individuals with atopic dermatitis ages 6 years and older
- Submitted New Drug Application (NDA) for roflumilast foam for the treatment of seborrheic dermatitis in adults and adolescents
- Enrolled first patient in Phase 1b alopecia areata study evaluating ARQ-255
- Strong financial position with approximately $410 million in cash, cash equivalents, and marketable securities

WESTLAKE VILLAGE, Calif., Feb. 28, 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 and year ended December 31, 2022, and provided a business update.

“Arcutis' execution in 2022 was extraordinary, setting us up very well for 2023 and beyond. We are well on our way towards building one of the industry's leading medical dermatology companies focused on long-term growth from our broad, innovative pipeline,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “From June to December last year, we delivered four successful pivotal Phase 3 trial readouts, secured an on-time approval for ZORYVE in plaque psoriasis, and raised nearly $300 million to bolster a strong balance sheet. The momentum around the ZORYVE psoriasis launch continues to build, with confirmatory feedback on our differentiated product profile and access strategy setting the foundation for commercial success in psoriasis as well as our next three indications.”

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 U.S. for the treatment of plaque psoriasis and under development for atopic dermatitis

- The launch of ZORYVE continues to build momentum, with over 20,000 prescriptions written by over 4,000 unique prescribers since launch in August 2022. ZORYVE has secured high-quality coverage, without prior authorization, at two of the three largest national pharmacy benefit managers, as well as two large national health plans and numerous downstream regional plans. The Company anticipates continued patient demand growth and penetration into the topical steroid market as formulary coverage builds.

- 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 U.S. Food and Drug Administration (FDA) for ages 6 and above in the second half of 2023. Patient enrollment continues in INTEGUMENT-PED, the third pivotal Phase 3 trial in patients aged 2 to 5 years old. Topline data from INTEGUMENT-PED are expected in the second half of 2023.

- 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 February 2023, Arcutis submitted an NDA for the treatment of moderate-to-severe seborrheic dermatitis to the FDA, supported by the positive results from the pivotal Phase 3 STRATUM trial. The Company anticipates potential FDA approval at the end of 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 in the

first quarter of 2024, 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 continues its reformulation efforts to develop an enhanced formulation of ARQ-252 that delivers more active drug to targets in the skin.

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 initiated preclinical efforts.

Recent Corporate Highlights

- In November 2022, the Company published its first Environmental, Social, and Governance (ESG) report, highlighting efforts to advance diversity and inclusion, access to medicines, sustainable business practices, and corporate governance.

Fourth Quarter and Full Year 2022 Summary Financial Results

Net product revenues for the quarter ended December 31, 2022 related to sales of ZORYVE were $3.0 million driven by unit demand. Net product revenues for the year ended December 31, 2022 were $3.7 million.

Cost of sales for the quarter ended December 31, 2022 were $0.5 million. Cost of sales for the year ended December 31, 2022 were $0.8 million.

Research and development (R&D) expenses for the quarter ended December 31, 2022 were $33.9 million compared to $52.6 million for the corresponding period in 2021. The year-over-year decrease was primarily due to decreased clinical development costs related to our topical roflumilast program. R&D expenses for the year ended December 31, 2022 were $182.4 million compared to $145.6 million for the corresponding period in 2021. The year-over-year increase for the year was due to the approximately $30 million upfront expense for the Ducentis acquisition in the third quarter of 2022, as well as higher headcount and professional services expenses, partially offset by decreased clinical development costs related to our topical roflumilast and topical JAK1 inhibitor programs.

Selling, general, and administrative (SG&A) expenses for the quarter ended December 31, 2022 were $37.0 million compared to $18.7 million for the corresponding period in 2021. SG&A expenses for the year ended December 31, 2022 were $122.1 million compared to $61.0 million for the corresponding period in 2021. These year-over-year increases were primarily due to higher headcount and professional services expenses related to the launch of ZORYVE.

Net loss was $72.0 million, or $1.18 per basic and diluted share, for the quarter ended December 31, 2022 compared to $71.3 million, or $1.42 per basic and diluted share, for the corresponding period in 2021. Net loss was $311.5 million, or $5.66 per basic and diluted share, for the year ended December 31, 2022 compared to $206.4 million, or $4.18 per basic and diluted share, for the corresponding period in 2021.

Cash, cash equivalents, restricted cash, and marketable securities were $410.8 million as of December 31, 2022, compared to $388.6 million as of December 31, 2021. Net cash used in operating activities was $71.1 during the fourth quarter and $257.7 million during the full year 2022.

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)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 53,641	$ 96,449
Restricted cash	1,234	1,542
Marketable securities	355,948	290,610
Trade receivable, net	8,458	—
Inventories	7,514	—
Prepaid expenses and other current assets	10,611	14,172
Total current assets	437,406	402,773
Property and equipment, net	1,881	2,261
Intangible assets, net	7,188	—
Operating lease right-of-use asset	2,721	3,040
Other assets	78	78
Total assets	$ 449,274	$ 408,152
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 8,827	$ 7,353
Accrued liabilities	28,323	25,540
Operating lease liability	657	433
Total current liabilities	37,807	33,326
Operating lease liability, noncurrent	4,117	4,774
Long-term debt, net	197,769	72,350
Other long-term liabilities	—	25
Total liabilities	239,693	110,475
Stockholders’ equity:		
Common stock	6	5
Additional paid-in capital	930,425	706,233
Accumulated other comprehensive loss	(1,086)	(255)
Accumulated deficit	(719,764)	(408,306)
Total stockholders’ equity	209,581	297,677
Total liabilities and stockholders’ equity	$ 449,274	$ 408,152

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
	(unaudited)			
Revenues:				
Product revenue, net	$ 2,961	$ —	$ 3,686	$ —
Total revenues	2,961	—	3,686	—
Operating expenses:				
Cost of sales	485	—	754	—
Research and development	33,877	52,558	182,435	145,558
Selling, general, and administrative	37,023	18,728	122,124	60,971
Total operating expenses	71,385	71,286	305,313	206,529
Loss from operations	(68,424)	(71,286)	(301,627)	(206,529)
Other income (expense):				
Other income, net	3,320	(40)	5,821	173
Interest expense	(6,915)	—	(15,652)	—
Total other income (expense)	(3,595)	(40)	(9,831)	173
Net loss	$ (72,019)	$ (71,326)	$ (311,458)	$ (206,356)
Per share information:				
Net loss per share, basic and diluted	$ (1.18)	$ (1.42)	$ (5.66)	$ (4.18)
Weighted-average shares used in computing net loss per share, basic and diluted	60,959,523	50,202,491	55,032,265	49,405,575