Arcutis Announces First Quarter 2022 Financial Results and Provides Business Update

May 5, 2022

- Increasing commercial preparations in advance of our Prescription Drug User Fee Act (PDUFA) action date of July 29, 2022 for roflumilast cream for the treatment of plaque psoriasis in adults and adolescents
- Completed enrollment of the sole pivotal Phase 3 trials of roflumilast foam in both seborrheic dermatitis and scalp and body psoriasis
- Enrolling pivotal Phase 3 trials of roflumilast cream in atopic dermatitis
- Strong financial position with approximately $345 million in cash, cash equivalents, and marketable securities which, when combined with our committed loan facility, provides cash runway into 2024

WESTLAKE VILLAGE, Calif., May 05, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today reported financial results for the quarter ended March 31, 2022, and provided a business update.

“We continue to execute against our clinical development plans and strategy, with enrollment now complete in two separate pivotal Phase 3 programs for roflumilast foam,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “At the same time, we are strategically investing to prepare for our first potential commercial launch of roflumilast cream in plaque psoriasis in the coming months, all of which brings us closer to realizing our vision to become the preeminent immuno-dermatology company and our mission to elevate the standard of care for people suffering from inflammatory skin diseases. We have four transformational catalysts ahead for the balance of 2022, with three Phase 3 topical roflumilast clinical readouts, and our potential launch in plaque psoriasis.”

Pipeline Updates

Roflumilast cream - a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor in a once-daily cream formulation, being developed as a potential treatment for plaque psoriasis and atopic dermatitis

- In December 2021, the FDA accepted Arcutis' New Drug Application (NDA) for plaque psoriasis in adults and adolescents and assigned a target PDUFA action date of July 29, 2022.
- Patient enrollment continues in the pivotal Phase 3 trials in patients with atopic dermatitis (INTEGUMENT-1, INTEGUMENT-2, and INTEGUMENT-PED). Topline data from each of INTEGUMENT-1 and INTEGUMENT-2, in subjects six years of age or older, are anticipated by the end of 2022. Topline data from INTEGUMENT-PED are expected in 2023.

Roflumilast foam - an alternative 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 2022, Arcutis announced the completion of enrollment of the sole pivotal Phase 3 trial (STRATUM) for the treatment of seborrheic dermatitis, with topline data anticipated in mid-year 2022. If positive, the Company expects the data to be sufficient basis for an NDA submission in the first half of 2023.
- In March 2022, Arcutis announced positive Phase 2 long-term data in seborrheic dermatitis demonstrating efficacy up to 52 weeks consistent with week 8 efficacy, with a favorable safety and tolerability profile.
- In April 2022, Arcutis announced the completion of enrollment of the sole pivotal Phase 3 trial (ARRECTOR) for the treatment of scalp and body psoriasis, with topline data anticipated late in the third quarter or early in the fourth quarter of 2022. If positive, the Company expects the data to be sufficient basis for a supplemental New Drug Application (sNDA) submission.

ARQ-252 - a topical small molecule inhibitor of Janus kinase type 1 (JAK1), 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-255 - an alternative topical formulation of ARQ-252 designed to reach deeper into the skin in order to potentially treat alopecia areata

- The Company continues its Investigational New Drug application (IND)-enabling efforts, and expects to enter the clinic in

2022.

Recent Corporate Highlights

- The Company recently hired its first wave of therapeutic sales specialists to begin non-promotional activities in preparation for the launch of roflumilast cream in plaque psoriasis.

First Quarter 2022 Summary Financial Results

Cash, cash equivalents, restricted cash, and marketable securities were $344.8 million as of March 31, 2022, compared to $388.6 million as of December 31, 2021, and includes $14.5 million of net proceeds from the sale of common shares from our At-the-Market (ATM) facility to a new strategic investor. Arcutis believes that its current cash, cash equivalents, and marketable securities, combined with its committed loan facility, will be sufficient to fund its operations into 2024.

Research and development (R&D) expenses for the quarter ended March 31, 2022 were $40.6 million compared to $21.6 million for the corresponding period in 2021. The year-over-year increase was primarily due to increased clinical and manufacturing costs related to our Phase 3 topical roflumilast development programs, as well as higher headcount and professional services expenses.

General and administrative (G&A) expenses for the quarter ended March 31, 2022 were $22.0 million compared to $14.5 million for the corresponding period in 2021. The year-over-year increase was primarily due to higher headcount and professional services expenses as we prepare for commercialization.

Net loss was $64.3 million, or $1.27 per basic and diluted share, for the quarter ended March 31, 2022 compared to $36.0 million, or $0.76 per basic and diluted share, for the corresponding period in 2021.

About Arcutis - Bioscience, applied to the skin.

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a 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 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, with one NDA under review with the FDA and three Phase 3 clinical data readouts anticipated by the end of 2022. The company's lead program, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit https://www.arcutis.com or follow the company on LinkedIn 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; expectations with regard to the timing of clinical trial results and regulatory events anticipated during 2022; and the Company's belief that its current cash, cash equivalents, and marketable securities, including the net proceeds from its recent debt financing, will be sufficient to fund its operations into 2024. 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 and expenses of commercialization efforts, 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 22, 2022, 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, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,795	$ 96,449
Restricted cash	1,234	1,542

Marketable securities	273,806	290,610
Prepaid expenses and other current assets	14,083	14,172
Total current assets	358,918	402,773
Property and equipment, net	2,152	2,261
Operating lease right-of-use asset	2,961	3,040
Other assets	78	78
Total assets	$ 364,109	$ 408,152
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,466	$ 7,353
Accrued liabilities	19,990	25,540
Operating lease liability	507	433
Total current liabilities	32,963	33,326
Operating lease liability, noncurrent	4,613	4,774
Long-term debt, net	72,742	72,350
Other long-term liabilities	19	25
Total liabilities	110,337	110,475
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	727,417	706,233
Accumulated other comprehensive loss	(1,020)	(255)
Accumulated deficit	(472,630)	(408,306)
Total stockholders' equity	253,772	297,677
Total liabilities and stockholders' equity	$ 364,109	$ 408,152

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2022	**2021**
	(unaudited)	
Operating expenses:		
Research and development	$ 40,622	$ 21,631
General and administrative	22,006	14,454
Total operating expenses	62,628	36,085
Loss from operations	(62,628)	(36,085)
Other income (expense):		
Other income, net	142	43
Interest expense	(1,838)	—
Total other income (expense)	(1,696)	43
Net loss	$ (64,324)	$ (36,042)
Per share information:		
Net loss per share, basic and diluted	$ (1.27)	$ (0.76)
Weighted-average shares used in computing net loss per share, basic and diluted	50,513,524	47,280,769