Arcutis Announces Second Quarter 2022 Financial Results and Provides Business Update

August 4, 2022

- Received U.S. Food and Drug Administration (FDA) approval for ZORYVE™ (roflumilast) cream 0.3% for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older
- Announced positive topline results from pivotal Phase 3 trial of roflumilast foam in seborrheic dermatitis, with anticipated New Drug Application (NDA) submission in the first quarter of 2023
- Completed enrollment in INTEGUMENT-1, the first of two pivotal Phase 3 trials in subjects with atopic dermatitis six years of age and older
- Strengthened balance sheet with over $285 million from recent financings

WESTLAKE VILLAGE, Calif., Aug. 04, 2022 (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 June 30, 2022, and provided a business update.

“The FDA approval of ZORYVE for the treatment of plaque psoriasis is a pivotal milestone for the Arcutis organization, and for dermatologists and people suffering from psoriasis, who have long-awaited an innovative, steroid-free treatment option for chronic use on all affected areas of the body,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “Our organization is well prepared and excited to launch ZORYVE in the coming weeks and we have bolstered our financial strength on the back of this approval. At the same time, we continue to execute on each of our Phase 3 development programs, progressing towards topline clinical data readouts in atopic dermatitis and scalp and body psoriasis later this year, as well as the NDA submission for seborrheic dermatitis early in 2023.”

Program Updates

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

- On July 29, 2022, the FDA approved ZORYVE for the treatment of plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older. ZORYVE is approved for once-daily treatment in mild, moderate, and severe plaque psoriasis with no restrictions on location or duration of use

- In August 2022, Arcutis announced the completion of enrollment in INTEGUMENT-1, the first of two pivotal Phase 3 trials for the treatment of atopic dermatitis in subjects six years of age or older. Patient enrollment continues in the other pivotal Phase 3 trials in patients with atopic dermatitis (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.

- In July 2022, Arcutis announced that Health Canada accepted for review the New Drug Submission (NDS) for roflumilast cream for adults and adolescents with plaque psoriasis, with a target action date of April 30, 2023. Arcutis has established operations in Canada and is building a strong team to support the approval and launch.

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 June 2022, Arcutis announced positive topline results from the STRATUM pivotal Phase 3 trial for the treatment of moderate to severe seborrheic dermatitis. The Company anticipates submitting an NDA to the FDA in the first quarter of 2023.

- 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

- In August 2022, the Company priced an underwritten public offering of common stock with expected gross proceeds of $173 million and expected net proceeds of $162 million, inclusive of the underwriters' option.
- In August 2022, the Company drew an additional $125 million from its debt facility with SLR Capital Partners.
- In July 2022, Great Place to Work® and *Fortune* magazine named the Company one of the 2022 Best Workplaces for Millenials™.

Second Quarter 2022 Summary Financial Results

Cash, cash equivalents, restricted cash, and marketable securities were $283.4 million as of June 30, 2022, compared to $388.6 million as of December 31, 2021. These resources, combined with the expected $162 million in net proceeds from its August 2022 equity financing and the $125 million drawn from its existing loan facility, will provide for capital resources of approximately $570 million to support the launch and commercialization efforts for ZORYVE, as well as continue to advance the Company's pipeline development initiatives.

Research and development (R&D) expenses for the quarter ended June 30, 2022 were $38.2 million compared to $30.8 million for the corresponding period in 2021. The year-over-year increase was primarily due to higher headcount and professional services expenses.

General and administrative (G&A) expenses for the quarter ended June 30, 2022 were $27.6 million compared to $11.3 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 $67.4 million, or $1.31 per basic and diluted share, for the quarter ended June 30, 2022 compared to $42.0 million, or $0.84 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 including plaque psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis 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; expectations with regard to the timing of clinical trial results and regulatory events anticipated during 2022; the anticipated successful commercial launch of ZORYVE in plaquepsoriasis; 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, expenses and success of our 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.

Contacts:

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

Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com

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

	June 30,	December 31,

	2022	2021
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,512	$ 96,449
Restricted cash	1,233	1,542
Marketable securities	220,657	290,610
Prepaid expenses and other current assets	12,024	14,172
Total current assets	295,426	402,773
Property and equipment, net	2,078	2,261
Operating lease right-of-use asset	2,882	3,040
Other assets	78	78
Total assets	$ 300,464	$ 408,152
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,437	$ 7,353
Accrued liabilities	18,463	25,540
Operating lease liability	582	433
Total current liabilities	27,482	33,326
Operating lease liability, noncurrent	4,450	4,774
Long-term debt, net	73,138	72,350
Other long-term liabilities	12	25
Total liabilities	105,082	110,475
Stockholders' equity:		
Common stock	5	5
Additional paid-in capital	736,665	706,233
Accumulated other comprehensive loss	(1,252)	(255)
Accumulated deficit	(540,036)	(408,306)
Total stockholders' equity	195,382	297,677
Total liabilities and stockholders' equity	$ 300,464	$ 408,152

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 38,205	$ 30,765	$ 78,827	$ 52,396
General and administrative	27,622	11,315	49,628	25,769
Total operating expenses	65,827	42,080	128,455	78,165
Loss from operations	(65,827)	(42,080)	(128,455)	(78,165)
Other income (expense):				
Other income, net	421	72	563	115
Interest expense	(2,000)	—	(3,838)	—
Total other income (expense)	(1,579)	72	$ (3,275)	$ 115
Net loss	$ (67,406)	$ (42,008)	$ (131,730)	$ (78,050)
Per share information:				
Net loss per share, basic and diluted	$ (1.31)	$ (0.84)	$ (2.58)	$ (1.60)
Weighted-average shares used in computing net loss per share, basic and diluted	51,422,386	50,000,716	50,970,465	48,648,262