Arcutis Announces Fourth Quarter and Full Year 2021 Financial Results and Provides Business Update

February 22, 2022

- Received U.S. Food and Drug Administration (FDA) acceptance of the New Drug Application (NDA) for roflumilast cream for the treatment of plaque psoriasis in adults and adolescents
- Completed enrollment of the sole pivotal Phase 3 trial of roflumilast foam in seborrheic dermatitis
- Enrolling pivotal Phase 3 trials of roflumilast cream in atopic dermatitis and roflumilast foam in scalp and body psoriasis
- Secured $225 million in non-dilutive debt financing from SLR Capital Partners, further strengthening the balance sheet at an attractive cost of capital and extending cash runway into 2024
- Strong financial position with more than $385 million in cash, cash equivalents, and marketable securities

WESTLAKE VILLAGE, Calif., Feb. 22, 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 and year ended December 31, 2021, and provided a business update.

"We executed exceptionally well in 2021, delivering strong Phase 3 plaque psoriasis data, initiating three additional Phase 3 programs, and commencing our commercialization efforts. We then capped off the year by receiving FDA acceptance of our NDA filing for roflumilast cream in plaque psoriasis and securing a $225 million non-dilutive loan facility to extend our cash runway into 2024," said Frank Watanabe, Arcutis' President and Chief Executive Officer. "We have strong momentum and expect that 2022 will be a transformational year for Arcutis, as we prepare for our first potential product launch in plaque psoriasis and progress our three additional Phase 3 topical roflumilast programs, as well as our early pipeline. With the strong team we have built and our financial flexibility enhanced, we can continue to appropriately invest in our mission to advance the treatment of chronic inflammatory skin diseases for patients and healthcare professionals."

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' NDA for plaque psoriasis in adults and adolescents and assigned a target action date of July 29, 2022.
- In December 2021, the Company announced the proprietary vehicle in roflumilast cream had comparable moisturizing properties as a commercially-marketed, ceramide-containing moisturizing cream in adults with mild eczema, providing additional support for ongoing pivotal studies of roflumilast cream in atopic dermatitis.
- 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. The Company intends to submit a supplemental New Drug Application (sNDA) for topical roflumilast cream for the treatment of atopic dermatitis patients aged six years or older in 2023 based on the results of INTEGUMENT-1 and -2. Due to the inherent challenges of enrolling young children in clinical trials, along with impacts on enrollment from COVID-19, Arcutis now expects topline data from INTEGUMENT-PED in 2023. The Company intends to submit a subsequent sNDA for the younger age cohort based on INTEGUMENT-PED following the potential initial atopic dermatitis approval in patients aged six years or older.

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 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 August 2021, Arcutis announced the initiation of a single pivotal Phase 3 trial for the treatment of scalp and body psoriasis, with topline data anticipated in the second half of 2022. If positive, the Company expects the data to be sufficient basis for an NDA 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 formulation and preclinical efforts.

Recent Corporate Highlights

- The Company secured a $225 million non-dilutive term loan facility from SLR Capital Partners in December 2021 at an attractive cost of capital, extending cash runway into 2024. Under the terms of the facility, $75 million was drawn at closing and an additional $125 million becomes available upon FDA approval of roflumilast cream in plaque psoriasis. An additional $25 million is also available if certain revenue milestones are achieved. The loan facility is interest-only for the entire five years, and is secured by the Company's assets.
- Mas Matsuda, Esq., joined the Company as General Counsel and Corporate Secretary, overseeing all legal and compliance matters for the Company. Mr. Matsuda brings over 20 years of legal experience, previously serving as General Counsel, Chief Compliance Officer, and Corporate Secretary at Halozyme Therapeutics, as well as positions of increasing responsibility at Amgen.

Fourth Quarter and Full Year 2021 Summary Financial Results

Cash, cash equivalents, restricted cash, and marketable securities were $388.6 million as of December 31, 2021, compared to $286.0 million as of December 31, 2020. 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 December 31, 2021 were $52.6 million compared to $27.4 million for the corresponding period in 2020. R&D expenses for the year ended December 31, 2021 were $145.6 million compared to $115.3 million for the corresponding period in 2020. The year-over-year increase for the quarter ended December 31, 2021 was primarily due to increased clinical and manufacturing costs related to the initiation of three additional Phase 3 topical roflumilast development programs. The year-over-year increase for the year ended December 31, 2021 was primarily due to higher headcount to manage our growing clinical programs, as well as increased professional services expenses.

General and administrative (G&A) expenses for the quarter ended December 31, 2021 were $18.7 million compared to $6.7 million for the corresponding period in 2020. G&A expenses for the year ended December 31, 2021 were $61.0 million compared to $21.3 million for the corresponding period in 2020. These year-over-year increases were primarily due to higher headcount and professional services expenses as we prepare for commercialization.

Net loss was $71.3 million, or $1.42 per basic and diluted share, for the quarter ended December 31, 2021 compared to $34.0 million, or $0.79 per basic and diluted share, for the corresponding period in 2020. Net loss was $206.4 million, or $4.18 per basic and diluted share, for the year ended December 31, 2021 compared to $135.7 million, or $3.80 per basic and diluted share, for the corresponding period in 2020.

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 www.arcutis.com or follow Arcutis 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 data 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)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,449	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	290,610	219,359
Prepaid expenses and other current assets	14,172	6,843
Total current assets	402,773	292,826
Property and equipment, net	2,261	2,016
Operating lease right-of-use asset	3,040	3,349
Other assets	78	78
Total assets	$ 408,152	$ 298,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,353	$ 7,140
Accrued liabilities	25,540	15,462
Operating lease liability	433	—
Total current liabilities	33,326	22,602
Operating lease liability, noncurrent	4,774	4,964
Long-term debt, net	72,350	—
Other long-term liabilities	25	82
Total liabilities	110,475	27,648
Stockholders' equity:		
Common stock	5	4
Additional paid-in capital	706,233	472,569
Accumulated other comprehensive loss	(255)	(2)
Accumulated deficit	(408,306)	(201,950)
Total stockholders' equity	297,677	270,621
Total liabilities and stockholders' equity	$ 408,152	$ 298,269

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	(unaudited)			
Operating expenses:				
Research and development	$ 52,558	$ 27,374	$ 145,558	$ 115,308
General and administrative	18,728	6,690	60,971	21,337
Total operating expenses	71,286	34,064	206,529	136,645
Loss from operations	(71,286)	(34,064)	(206,529)	(136,645)
Other income, net	(40)	15	173	967
Net loss	$ (71,326)	$ (34,049)	$ (206,356)	$ (135,678)
Per share information:				
Net loss per share, basic and diluted	$ (1.42)	$ (0.79)	$ (4.18)	$ (3.80)
Weighted-average shares used in computing net loss per share, basic and diluted	50,202,491	42,977,244	49,405,575	35,668,152