Arcutis Announces Third Quarter 2021 Financial Results and Provides Business Update

November 4, 2021

- Submitted New Drug Application (NDA) for roflumilast cream for the treatment of plaque psoriasis across the full spectrum of disease
- Initiated single pivotal Phase 3 trial of roflumilast foam in scalp and body psoriasis
- Enrolling pivotal Phase 3 trials of roflumilast cream in atopic dermatitis and roflumilast foam in seborrheic dermatitis
- Expanded patent portfolio with issuance of first pharmacokinetics patent covering both the cream and foam formulations of topical roflumilast
- Strong financial position with approximately $370 million in cash, cash equivalents, and marketable securities, providing cash runway well into 2023

WESTLAKE VILLAGE, Calif., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions, today reported financial results for the quarter ended September 30, 2021, and provided a business update.

“The submission of our first NDA for roflumilast cream represents a pivotal milestone for the Arcutis team and for the millions of individuals struggling with plaque psoriasis. It also demonstrates Arcutis' progress to simplify complex disease management and solve the most persistent challenges of treating chronic inflammatory diseases of the skin,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “With our proven, experienced team, our strong financial position, and our expanded intellectual property estate, we continue to invest in our ability to maximize the potential of our medicines for patients, dermatologists, and shareholders. We look forward to a transformative 2022 for Arcutis, with a potential launch in plaque psoriasis and three additional Phase 3 clinical data readouts anticipated.”

Pipeline Updates

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

- In late September, Arcutis submitted an NDA for plaque psoriasis to the U.S. Food and Drug Administration (FDA), supported by the positive results from two pivotal Phase 3 clinical trials (DERMIS-1 and DERMIS-2).
- Patient enrollment continues in the pivotal Phase 3 trials in patients with atopic dermatitis (INTEGUMENT-1, INTEGUMENT-2, and INTEGUMENT-PED), with topline data anticipated in the second half of 2022.

Roflumilast foam - an alternative 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 July, Arcutis announced the initiation of a single pivotal Phase 3 trial for the treatment of seborrheic dermatitis, with topline data anticipated in the second or third quarter of 2022. If positive, the Company expects the data to be sufficient basis for an NDA.
- In August, 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.

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

- In July, the Company announced the termination of the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment for vitiligo, after analyses of the previously announced Phase 2 chronic hand eczema study pointed to inadequate local drug delivery to the skin.
- 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

- Formulation and preclinical efforts are continuing.

Recent Corporate Highlights

- The U.S. Patent and Trademark Office issued Arcutis a new patent on the pharmacokinetics properties of topical roflumilast for improving delivery and extending half-life
- In preparation for commercial launch, the Company finalized commercial supply agreements across the roflumilast cream primary manufacturing network
- Keith Leonard was appointed to Arcutis' Board of Directors. Mr. Leonard brings over 25 years of commercial, operational, and international leadership experience, including as a sitting chair of a publicly listed biotechnology company and as former CEO of two public biotech companies.
- Bruce Binkowitz, Ph.D., joined the Company as Vice President of Biometrics. Dr. Binkowitz brings over 30 years of drug development experience at Shionogi and Merck across many therapeutic areas.

Third Quarter 2021 Summary Financial Results

Cash, cash equivalents, restricted cash, and marketable securities were $368.8 million as of September 30, 2021, compared to $286.0 million as of December 31, 2020. Arcutis believes that its current cash, cash equivalents, and marketable securities will be sufficient to fund its operations well into 2023.

Research and development (R&D) expenses for the quarter ended September 30, 2021 were $40.6 million compared to $32.7 million for the corresponding period in 2020. R&D expenses for the nine months ended September 30, 2021 were $93.0 million compared to $87.9 million for the corresponding period in 2020. The year-over-year increase for the quarter ended September 30, 2021 was primarily due to higher headcount and professional services expenses. The year-over-year increase for the nine months ended September 30, 2021 was primarily due to higher headcount and professional services expenses, mostly offset by the completion of several clinical studies.

General and administrative (G&A) expenses for the quarter ended September 30, 2021 were $16.5 million compared to $5.6 million for the corresponding period in 2020. G&A expenses for the nine months ended September 30, 2021 were $42.2 million compared to $14.6 million for the corresponding period in 2020. These year-over-year increases were primarily due to higher headcount and professional services expenses.

Net loss was $57.0 million, or $1.14 per basic and diluted share, for the quarter ended September 30, 2021 compared to $38.2 million, or $1.01 per basic and diluted share, for the corresponding period in 2020. Net loss was $135.0 million, or $2.75 per basic and diluted share, for the nine months ended September 30, 2021 compared to $101.6 million, or $3.06 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 submission filed 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 data events anticipated during 2021/2022; and the Company's belief that its current cash, cash equivalents, and marketable securities, including the net proceeds from its recent financing, will be sufficient to fund its operations well into 2023. 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, 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 16, 2021, 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)

	September 30, 2021	December 31, 2020

	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,778	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	315,492	219,359
Prepaid expenses and other current assets	12,958	6,843
Total current assets	381,770	292,826
Property and equipment, net	2,045	2,016
Operating lease right-of-use asset	3,115	3,349
Other assets	78	78
Total assets	$ 387,008	$ 298,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,871	$ 7,140
Accrued liabilities	13,881	15,462
Operating lease liability	306	—
Total current liabilities	19,058	22,602
Operating lease liability, noncurrent	4,924	4,964
Other long-term liabilities	31	82
Total liabilities	24,013	27,648
Stockholders' equity:		
Common stock	5	4
Additional paid-in capital	699,988	472,569
Accumulated other comprehensive loss	(18)	(2)
Accumulated deficit	(336,980)	(201,950)
Total stockholders' equity	362,995	270,621
Total liabilities and stockholders' equity	$ 387,008	$ 298,269

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 40,604	$ 32,743	$ 93,000	$ 87,934
General and administrative	16,474	5,560	42,243	14,647
Total operating expenses	57,078	38,303	135,243	102,581
Loss from operations	(57,078)	(38,303)	(135,243)	(102,581)
Other income, net	98	99	213	952
Net loss	$ (56,980)	$ (38,204)	$ (135,030)	$ (101,629)
Per share information:				
Net loss per share, basic and diluted	$ (1.14)	$ (1.01)	$ (2.75)	$ (3.06)
Weighted-average shares used in computing net loss per share, basic and diluted	50,097,851	37,748,454	49,136,768	33,214,005