Arcutis Announces Second Quarter 2021 Financial Results and Provides Business Update

August 5, 2021

- Anticipates submission of a New Drug Application (NDA) for topical roflumilast cream as a potential treatment for plaque psoriasis late in the third quarter or early in the fourth quarter of 2021
- Initiated single pivotal Phase 3 trial of topical roflumilast foam in seborrheic dermatitis, a disease that affects more than 10 million people in the U.S.
- Anticipates initiation of single pivotal Phase 3 trial of topical roflumilast foam in scalp psoriasis in Q3 2021
- Enrolling pivotal Phase 3 trials of topical roflumilast cream in atopic dermatitis
- Strong financial position with over $400 million in cash, cash equivalents, and marketable securities providing cash runway well into 2023

WESTLAKE VILLAGE, Calif., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations to address the urgent needs of patients living with immune-mediated dermatological diseases and conditions, or immuno-dermatology, today reported financial results for the quarter ended June 30, 2021, and provided a business update.

“We are on track to submit our plaque psoriasis NDA to the FDA soon, based on the strongly positive pivotal Phase 3 results reported in February. We have also initiated, or are on the cusp of initiating, three more Phase 3 programs of topical roflumilast, with multiple top-line readouts in 2022,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “We continue to add top talent to our team, as our strong financial position allows us to build out key capabilities to ensure we are ready to launch topical roflumilast, pending FDA approval, and to maximize the potential of our medicines for patients, dermatologists, and shareholders. The significant progress made at Arcutis in the first half of 2021 positions us well for an exciting next 18 months.”

Pipeline Updates

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

- Arcutis anticipates submitting an NDA for plaque psoriasis to the U.S. Food and Drug Administration (FDA) late in the third quarter or early in the fourth quarter of 2021, based on 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 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.
- The Company anticipates initiating a single pivotal Phase 3 trial for the treatment of scalp and body psoriasis in Q3 2021, 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 May, Arcutis announced that the Phase 2 study of ARQ-252 in chronic hand eczema did not meet its primary endpoint of Investigator Global Assessment (IGA) of clear or almost clear at week 12. Further analyses of the study pointed toward inadequate local drug delivery to the skin as a key driver of the lack of efficacy. Importantly, no safety or tolerability issues were seen.
- In July, the Company announced the termination of the Phase 2a clinical trial evaluating ARQ-252 as a potential treatment for vitiligo, based on the aforementioned analyses of the Phase 2 chronic hand eczema study.
- 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

- Sue-Jean Lin was appointed to Arcutis' Board of Directors
- Raj Madan was appointed Senior Vice President and Chief Digital and Information Officer
- Greg Sukay joined the Company as Vice President of Manufacturing and Process Technologies

Second Quarter 2021 Summary Financial Results

Cash, cash equivalents, restricted cash, and marketable securities were $410.9 million as of June 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 June 30, 2021 were $30.8 million compared to $30.0 million for the corresponding period in 2020. R&D expenses for the six months ended June 30, 2021 were $52.4 million compared to $55.2 million for the corresponding period in 2020. The year-over-year increase for the quarter ended June 30, 2021 was primarily due to increased clinical costs for the Phase 3 studies of topical roflumilast in atopic dermatitis, seborrheic dermatitis, and scalp psoriasis and the Phase 2 study of ARQ-252 in vitiligo, mostly offset by completion of the Phase 3 studies of roflumilast cream in plaque psoriasis and Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis. The year-over-year decrease for the six months ended June 30, 2021 was primarily due to the completion of the Phase 3 studies of roflumilast cream in plaque psoriasis and Phase 2 studies of roflumilast foam in seborrheic dermatitis and scalp psoriasis, offset partially by increased clinical costs for the Phase 3 studies of topical roflumilast in atopic dermatitis, seborrheic dermatitis, and scalp psoriasis, and the Phase 2 study of ARQ-252 in vitiligo.

General and administrative (G&A) expenses for the quarter ended June 30, 2021 were $11.3 million compared to $5.6 million for the corresponding period in 2020. G&A expenses for the six months ended June 30, 2021 were $25.8 million compared to $9.1 million for the corresponding period in 2020. These year-over-year increases were primarily due to higher headcount and professional services costs. First half 2021 G&A expenses were also impacted by a one-time $5.3 million non-cash charge for modifications to previously granted stock awards in connection with an officer's retirement.

Net loss was $42.0 million, or $0.84 per basic and diluted share, for the quarter ended June 30, 2021 compared to $35.4 million, or $0.94 per basic and diluted share, for the corresponding period in 2020. Net loss was $78.1 million, or $1.60 per basic and diluted share, for the six months ended June 30, 2021 compared to $63.4 million, or $2.05 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 seven clinical programs for a range of inflammatory dermatological conditions, with our first NDA submission anticipated late in the third quarter or early in the fourth quarter of 2021 and three more Phase 3 clinical data readouts anticipated over the next 18 months. The company's lead product candidate, 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 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.

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, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 89,128	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	320,236	219,359
Prepaid expenses and other current assets	16,648	6,843
Total current assets	427,554	292,826
Property and equipment, net	2,069	2,016
Operating lease right-of-use asset	3,191	3,349
Other assets	78	78
Total assets	$ 432,892	$ 298,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,676	$ 7,140
Accrued liabilities	10,565	15,462
Operating lease liability	106	—
Total current liabilities	13,347	22,602
Operating lease liability, noncurrent	5,032	4,964
Other long-term liabilities	25	82
Total liabilities	18,404	27,648
Stockholders' equity:		
Common stock	5	4
Additional paid-in capital	694,519	472,569
Accumulated other comprehensive loss	(36)	(2)
Accumulated deficit	(280,000)	(201,950)
Total stockholders' equity	414,488	270,621
Total liabilities and stockholders' equity	$ 432,892	$ 298,269

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 30,765	$ 30,009	$ 52,396	$ 55,191
General and administrative	11,315	5,618	25,769	9,087
Total operating expenses	42,080	35,627	78,165	64,278
Loss from operations	(42,080)	(35,627)	(78,165)	(64,278)
Other income, net	72	215	115	853
Net loss	$ (42,008)	$ (35,412)	$ (78,050)	$ (63,425)
Per share information:				
Net loss per share, basic and diluted	$ (0.84)	$ (0.94)	$ (1.60)	$ (2.05)
Weighted-average shares used in computing net loss per share, basic and diluted	50,000,716	37,587,330	48,648,262	30,921,866