Arcutis Announces First Quarter 2021 Financial Results and Provides Business Update

May 4, 2021

- New Drug Application (NDA) submission for topical roflumilast cream as a potential treatment for plaque psoriasis anticipated in the second half of 2021
- Positive Phase 3 results for topical roflumilast cream in plaque psoriasis announced in February
- Advancing topical roflumilast foam into Phase 3 development for the treatment of scalp psoriasis with a single pivotal trial
- Progressing topical roflumilast foam into Phase 3 development in seborrheic dermatitis with a single pivotal trial
- Pivotal Phase 3 trials of topical roflumilast cream in atopic dermatitis initiated in January
- Phase 1/2b study of ARQ-252 in chronic hand eczema did not meet its primary endpoint
- Strong financial position with over $440 million in cash, cash equivalents and marketable securities providing cash runway well into 2023

WESTLAKE VILLAGE, Calif., May 04, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today reported financial results for the quarter ended March 31, 2021, and provided a business update.

“Building on the foundation of last year’s strong execution, the first quarter of 2021 was highly productive for Arcutis,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “With the positive pivotal Phase 3 results in plaque psoriasis reported in February, we are on track to submit an NDA to the FDA in the second half of 2021 for topical roflumilast cream as a potential once daily topical treatment for plaque psoriasis. The robust Phase 3 data also reinforce our optimism for the multiple additional on-going development efforts with topical roflumilast cream and foam. We are also delighted that we were able to reach agreement with the FDA to advance roflumilast foam into Phase 3 development with a single pivotal study in scalp psoriasis.”

Mr. Watanabe continued: “We are disappointed with the recent results of the ARQ-252 Phase 1/2b study in chronic hand eczema, a difficult disease to treat, and are undertaking further analyses to understand the data. Looking forward, we believe 2021 will be a transformational year for Arcutis as we have begun our plaque psoriasis commercialization efforts in earnest, and continue to rapidly advance an innovative and differentiated late-stage pipeline of potential best-in-class topical dermatology therapies.”

Pipeline Updates

ARQ-151 (topical 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.

- Reported positive results from the two pivotal Phase 3 clinical trials (DERMIS-1 and DERMIS-2) in patients with plaque psoriasis; NDA submission to U.S. Food and Drug Administration (FDA) anticipated in the second half of 2021.
- Pivotal Phase 3 trials in patients with atopic dermatitis (INTEGUMENT-1, INTEGUMENT-2, and INTEGUMENT-PED) have been initiated, with topline data anticipated in the second half of 2022.

ARQ-154 (topical roflumilast foam) - an alternative topical foam formulation of 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.

- Following a recent End-of-Phase 2 meeting with the FDA, the Company is advancing roflumilast foam into Phase 3 development for the treatment of scalp psoriasis in a single pivotal trial, with topline data anticipated in the second half of 2022.
- After a previous FDA End-of-Phase 2 meeting early in Q1, announced advancement of roflumilast foam into Phase 3 development for the treatment of seborrheic dermatitis in a single pivotal trial, with topline data anticipated in the second or third quarter of 2022.

ARQ-252 - a potent and highly selective topical small molecule inhibitor of Janus kinase type 1 (JAK1), being developed as a potential treatment for chronic hand eczema and other inflammatory dermatoses.

- 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. In the study, none of the ARQ-252 arms achieved statistical significance versus vehicle. Further analyses of the data are underway. ARQ-252 was generally safe and well-tolerated.
- Initiated a Phase 2a clinical trial evaluating ARQ-252 as a potential treatment for vitiligo with topline data anticipated in the second half of 2023.

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 underway.

Recent Corporate Highlights

- Scott Burrows, previously Vice President of Finance, was appointed Senior Vice President and Chief Financial Officer, following the retirement of John Smither
- Courtney Barton joined the Company as Vice President, Chief Compliance Officer, and Chief of Staff
- Corey Padovano joined the Company as Vice President of Sales
- Sean Brugger joined the Company as Executive Director of Field Medical Affairs
- Completed underwritten public offering of common stock in February 2021 with gross proceeds of $221.4 million and net proceeds of $207.5 million

First Quarter 2021 Summary Financial Results

Cash, cash equivalents, restricted cash and marketable securities were $446.5 million as of March 31, 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 March 31, 2021 were $21.6 million compared to $25.2 million for the corresponding period in 2020. The year-over-year decrease was primarily due to the completion of our 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 our Phase 3 studies of roflumilast cream in atopic dermatitis and Phase 2 studies of ARQ-252 in hand eczema and vitiligo, as well as increased product development expenses.

General and administrative (G&A) expenses for the quarter ended March 31, 2021 were $14.5 million compared to $3.5 million for the corresponding period in 2020. The year-over-year increase was primarily due to higher headcount and professional services costs, as well as 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 $36.0 million, or $0.76 per basic and diluted share, for the quarter ended March 31, 2021 compared to $28.0 million, or $1.15 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 late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis' robust pipeline includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The company's lead product candidate, topical roflumilast, has the potential to revitalize 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.

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

	March 31, 2021	December 31, 2020
	(Unaudited)	

ASSETS		
Current assets:		
Cash and cash equivalents	$ 288,690	$ 65,082
Restricted cash	1,542	1,542
Marketable securities	156,237	219,359
Prepaid expenses and other current assets	19,506	6,843
Total current assets	465,975	292,826
Property and equipment, net	2,094	2,016
Operating lease right-of-use asset	3,269	3,349
Other assets	78	78
Total assets	$ 471,416	$ 298,269
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,146	$ 7,140
Accrued liabilities	12,168	15,462
Total current liabilities	15,314	22,602
Operating lease liability, noncurrent	5,050	4,964
Other long-term liabilities	58	82
Total liabilities	20,422	27,648
Stockholders' equity:		
Common stock	5	4
Additional paid-in capital	688,939	472,569
Accumulated other comprehensive income (loss)	42	(2)
Accumulated deficit	(237,992)	(201,950)
Total stockholders' equity	450,994	270,621
Total liabilities, convertible preferred stock and stockholders' equity	$ 471,416	$ 298,269

ARCUTIS BIOTHERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	**2020**
	(unaudited)	
Operating expenses:		
Research and development	$ 21,631	$ 25,182
General and administrative	14,454	3,469
Total operating expenses	36,085	28,651
Loss from operations	(36,085)	(28,651)
Other income, net	43	638
Net loss	$ (36,042)	$ (28,013)
Per share information:		
Net loss per share, basic and diluted	$ (0.76)	$ (1.15)
Weighted-average shares used in computing net loss per share, basic and diluted	47,280,769	24,256,402