Arcutis Announces Second Quarter 2020 Financial Results and Provides Business Update

August 11, 2020

- Robust pipeline anticipated to deliver two Phase 3 and four Phase 2 data events in 2020 and 2021
- Arcutis currently expects no impact to its previously disclosed clinical timelines due to COVID-19
- Arcutis development programs address dermatological diseases impacting over 20 million patients in the U.S.
- Strong financial position with $224.0 million in cash, cash equivalents and marketable securities

WESTLAKE VILLAGE, Calif., Aug. 11, 2020 (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 June 30, 2020, and provided a business update.

“Arcutis is uniquely positioned to fill the innovation gap in the medical dermatology sector, and we anticipate six important clinical data readouts, including our pivotal Phase 3 clinical trials of topical roflumilast cream as a potential treatment for plaque psoriasis, between now and the end of 2021,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “Dermatologists and patients are desperate for new topical options to treat serious diseases of the skin. We are focused on elevating the standard of care for dermatological diseases and conditions through novel therapies that simplify disease management for physicians and eliminate the need for patients to compromise between drug safety, efficacy, and tolerability. We appreciate the strong support from investigators across our development programs, which currently include four product candidates in development for seven indications, with an addressable U.S. market of over 20 million patients.”

Pipeline Update

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.

- The *New England Journal of Medicine* published positive results from a Phase 2b trial, which demonstrated the compound significantly improves chronic plaque psoriasis.
- Topline data from two on-going Phase 3 clinical trials (DERMIS-1 and-2) in patients with plaque psoriasis is anticipated in the first half of 2021.
- On-going Phase 2 long-term safety study in plaque psoriasis has completed enrollment, with topline data anticipated in the first quarter of 2021.
- The Company expects to begin a Phase 2b study in atopic dermatitis in the second half of 2020, with topline data anticipated in the second half of 2021.

ARQ-154 (Topical roflumilast foam) - a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor in a foam formulation, 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 June, the Company completed enrollment in the on-going Phase 2 proof-of-concept study in seborrheic dermatitis, with topline data anticipated early in the fourth quarter of 2020.
- In July, the Company completed enrollment in the ongoing Phase 2b study in scalp psoriasis, with topline data anticipated in the fourth quarter of 2020.

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.

- In July, the Company initiated enrollment in the Phase 2b portion of the ongoing Phase 1/2b study in chronic hand eczema, with topline data anticipated in the second half of 2021.
- The Company anticipates initiating a Phase 2a study in vitiligo in the second half of 2020.

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

- Over the course of the second quarter, the Company announced that two senior executives had joined the Company:
- Jay Ramsinghani, Vice President of Commercial Strategy and Operations.
- Ayisha Jeter, Vice President of Market Access.

Second Quarter 2020 Summary Financial Results

Cash, cash equivalents and marketable securities were $224.0 million as of June 30, 2020, compared to $101.3 million as of December 31, 2019. Arcutis believes that its current cash, cash equivalents, and marketable securities will be sufficient to fund its operations through 2021.

Research and development (R&D) expenses for the quarter ended June 30, 2020 were $30.0 million compared to $7.2 million for the corresponding period in 2019. R&D expenses for the six months ended June 30, 2020 were $55.2 million compared to $13.4 million for the corresponding period in 2019. These year-over-year increases were primarily due to the initiation of multiple clinical trials during the last year.

General and administrative (G&A) expenses for the quarter ended June 30, 2020 were $5.6 million compared to $1.3 million for the corresponding period in 2019. G&A expenses for the six months ended June 30, 2020 were $9.1 million compared to $2.1 million for the corresponding period in 2019. These year-over-year increases were primarily due to higher headcount and professional services costs, including the costs associated with being a public company.

Net loss was $35.4 million, or $0.94 per basic and diluted share, for the quarter ended June 30, 2020 compared to $8.3 million, or $4.69 per basic and diluted share, for the corresponding period in 2019. Net loss was $63.4 million, or $2.05 per basic and diluted share, for the six months ended June 30, 2020 compared to $14.9 million, or $8.79 per basic and diluted share, for the corresponding period in 2019.

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 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 2020/2021; and the Company's belief that its current cash, cash equivalents and marketable securities will be sufficient to fund its operations through 2021. 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-Q filed with U.S. Securities and Exchange Commission (SEC) on August 11, 2020, 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, except share and par value)

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 171,546	$ 63,336
Marketable securities	52,429	37,929
Prepaid expenses and other current assets	4,060	5,209
Total current assets	228,035	106,474
Property, plant, and equipment, net	228	227
Operating lease right-of-use asset	3,629	264
Other assets	78	47
Total assets	$ 231,970	$ 107,012
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 8,253	$ 1,405
Accrued liabilities	10,948	3,654
Operating lease liability	80	178
Total current liabilities	19,281	5,237

Operating lease liability, noncurrent	3,610	129
Other long-term liabilities	156	184
Total liabilities	23,047	5,550
Convertible preferred stock	—	166,491
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	3	—
Additional paid-in capital	338,617	1,244
Accumulated other comprehensive income (loss)	—	(1)
Accumulated deficit	(129,697)	(66,272)
Total stockholders' equity (deficit)	208,923	(65,029)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 231,970	$ 107,012

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,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 30,009	$ 7,214	$ 55,191	$ 13,417
General and administrative	5,618	1,324	9,087	2,073
Total operating expenses	35,627	8,538	64,278	15,490
Loss from operations	(35,627)	(8,538)	(64,278)	(15,490)
Other income, net	215	248	853	542
Net loss	$ (35,412)	$ (8,290)	$ (63,425)	$ (14,948)
Per share information:				
Net loss per share, basic and diluted	$ (0.94)	$ (4.69)	$ (2.05)	$ (8.79)
Weighted-average shares used in computing net loss per share, basic and diluted	37,587,330	1,767,658	30,921,866	1,700,549