Arcutis Announces Third Quarter 2020 Financial Results and Provides Business Update

November 5, 2020

- Pivotal Phase 3 data in plaque psoriasis anticipated in first quarter of 2021
- Pivotal Phase 3 trials in atopic dermatitis anticipated to begin in late 2020 or early 2021
- Recent positive Phase 2 data in seborrheic dermatitis supports pipeline advancement in indication that impacts 10 million patients in the U.S.
- Strong financial position with over $300 million in cash, cash equivalents and marketable securities including the proceeds from our recent equity offering, providing cash runway into 2022

WESTLAKE VILLAGE, Calif., Nov. 05, 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 September 30, 2020, and provided a business update.

"Arcutis is rapidly advancing an innovative and differentiated late-stage pipeline of potential best-in-class topical dermatology therapies, with five important clinical data readouts anticipated by mid-2021," said Frank Watanabe, Arcutis' President and Chief Executive Officer. "We expect to report topline data from our pivotal Phase 3 trials evaluating roflumilast cream as a potential once daily topical treatment for plaque psoriasis in the first quarter of next year and, if positive, anticipate submission of our New Drug Application to the U.S. Food and Drug Administration (FDA) by the end of 2021. If approved, we believe roflumilast cream has the potential to eliminate the need for dermatologists and patients to compromise between efficacy and safety. Our focus on addressing the gap in dermatology drug development currently includes 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.

- Completed enrollment in the two on-going pivotal Phase 3 clinical trials (DERMIS-1 and-2) in patients with plaque psoriasis, with topline data anticipated in the first quarter 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. In July, the Company announced positive preliminary efficacy and safety data for the first patient cohort from this study.
- Results from the positive Phase 1/2a trial of ARQ-151 for the treatment of chronic plaque psoriasis were published in the Journal of Drugs in Dermatology.
- Based on FDA feedback from an End-of-Phase 2 meeting, the Company expects to begin pivotal Phase 3 trials of ARQ-151 in patients with atopic dermatitis in late 2020 or early 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.

- Reported positive topline data from Phase 2 clinical trial in seborrheic dermatitis, supporting pipeline advancement in an indication that impacts 10 million patients in the U.S.
- Ongoing Phase 2b study in scalp psoriasis has completed enrollment, with topline data anticipated by the end 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.

- Completed enrollment of the ongoing Phase 1/2b study in chronic hand eczema, with topline data anticipated by mid-2021.
- The Company anticipates initiating a Phase 2a study in vitiligo in late 2020 or early 2021.

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

- Bethany Dudek joined the Company as Vice President, Quality
- Completed underwritten public offering and concurrent private placement of common stock with gross proceeds of $135 million.

Third Quarter 2020 Summary Financial Results

Cash, cash equivalents and marketable securities were $189.7 million as of September 30, 2020, compared to $101.3 million as of December 31, 2019. Arcutis believes that its current cash, cash equivalents and marketable securities at over $300 million, including the $128.4 million net proceeds from our recent financing, will be sufficient to fund its operations into 2022.

Research and development (R&D) expenses for the quarter ended September 30, 2020 were $32.7 million compared to $12.3 million for the corresponding period in 2019. R&D expenses for the nine months ended September 30, 2020 were $87.9 million compared to $25.8 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 September 30, 2020 were $5.6 million compared to $2.3 million for the corresponding period in 2019. G&A expenses for the nine months ended September 30, 2020 were $14.6 million compared to $4.4 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 $38.2 million, or $1.01 per basic and diluted share, for the quarter ended September 30, 2020 compared to $14.5 million, or $7.56 per basic and diluted share, for the corresponding period in 2019. Net loss was $101.6 million, or $3.06 per basic and diluted share, for the nine months ended September 30, 2020 compared to $29.4 million, or $16.60 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 become 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 and initiation of clinical trials 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 into 2022. 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 November 5, 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)

	September 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,707	$ 63,336
Marketable securities	144,005	37,929
Prepaid expenses and other current assets	4,409	5,209
Total current assets	194,121	106,474
Property, plant, and equipment, net	322	227
Operating lease right-of-use asset	3,492	264
Other assets	78	47
Total assets	$ 198,013	$ 107,012
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 5,039	$ 1,405

Accrued liabilities	16,083	3,654
Operating lease liability	32	178
Total current liabilities	21,154	5,237
Operating lease liability, noncurrent	3,675	129
Other long-term liabilities	113	184
Total liabilities	24,942	5,550
Convertible preferred stock	—	166,491
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	4	—
Additional paid-in capital	340,964	1,244
Accumulated other comprehensive income (loss)	4	(1)
Accumulated deficit	(167,901)	(66,272)
Total stockholders' equity (deficit)	173,071	(65,029)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 198,013	$ 107,012

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 32,743	$ 12,348	$ 87,934	$ 25,765
General and administrative	5,560	2,300	14,647	4,373
Total operating expenses	38,303	14,648	102,581	30,138
Loss from operations	(38,303)	(14,648)	(102,581)	(30,138)
Other income, net	99	168	952	710
Net loss	$ (38,204)	$ (14,480)	$ (101,629)	$ (29,428)
Per share information:				
Net loss per share, basic and diluted	$ (1.01)	$ (7.56)	$ (3.06)	$ (16.60)
Weighted-average shares used in computing net loss per share, basic and diluted	37,748,454	1,915,601	33,214,005	1,773,025