Arcutis Announces First Quarter 2020 Financial Results and Provides Business Update

May 12, 2020

- Multiple important Phase 3 and Phase 2 data events anticipated during 2020/2021
- Arcutis currently expects no impact to its previously disclosed clinical timelines due to COVID-19
- Strong financial position with $249.3 million in cash, cash equivalents and marketable securities

WESTLAKE VILLAGE, Calif., May 12, 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 March 31, 2020 and provided a business update.

"Despite the global challenges presented by COVID-19, Arcutis continued to make progress in executing upon our mission of addressing the gap we see in dermatology drug development by leveraging recent advances in inflammation and immunology," said Frank Watanabe, Arcutis' President and Chief Executive Officer. "Our priorities during these unprecedented times are first and foremost to safeguard the health and well-being of our trial participants, investigators, and employees; then to continue effective operations to support our clinical trial sites and to advance our pipeline of drug candidates; and to maintain the financial strength and stability afforded us by our recent successful initial public offering. Although some of our clinical sites have experienced disruptions as a result of COVID-19, at this time we do not expect delays to any of our previously disclosed clinical timelines, and we still expect to have six clinical data readouts over the next 18 months, including our pivotal Phase 3 clinical trials of topical roflumilast cream as a potential treatment for plaque psoriasis. We currently have four product candidates in development for seven indications, with an addressable U.S. market of over 20 million patients."

Pipeline Update

Topical roflumilast cream (ARQ-151) - 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 initiated two Phase 3 clinical trials (DERMIS-1 and -2) evaluating the compound in plaque psoriasis in January 2020, and anticipates announcing topline data in the first half of 2021. At the request of the U.S. Food and Drug Administration (FDA), in March the Company submitted a protocol amendment to include children ages 2 to 11 years old in these studies.
- In February, the Company announced the enrollment of the first patient in a Phase 3 open label extension study (DERMIS-OLE) of the compound in plaque psoriasis.
- On-going Phase 2 long-term safety study in plaque psoriasis has completed enrollment with topline data anticipated in the first half 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.

Topical roflumilast foam (ARQ-154) - 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.

- Arcutis initiated a Phase 2 proof-of-concept study in seborrheic dermatitis in December 2019 and anticipates announcing topline data in the second half of 2020.
- The Company initiated a Phase 2b study in scalp psoriasis in January 2020 with topline data anticipated in the fourth quarter of 2020 or first quarter of 2021.

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.

- Arcutis began enrollment in the safety cohort of a Phase 1/2b study in chronic hand eczema in April. Enrollment in the efficacy cohort of the study is anticipated to begin in the second half of 2020, with topline data expected 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

- In February, the Company closed on its Initial Public Offering, with net proceeds of approximately $167.2 million.
- The Company appointed two experienced biopharmaceutical leaders to its Board of Directors:

- Halley E. Gilbert, J.D., Director
- Joseph L. Turner, Director and Audit Committee Chair

- Over the course of the first quarter, the Company announced that three senior executives had joined the Company:
  - Patricia Turney, Senior Vice President of Operations
  - Heather Rowe Armstrong, Vice President of Investor Relations and Corporate Communications.
  - Kimberly Lathroum, Vice President of Marketing

First Quarter 2020 Summary Financial Results

Cash, cash equivalents and marketable securities were $249.3 million as of March 31, 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 March 31, 2020 were $25.2 million compared to $6.2 million for the corresponding period in 2019. The increase was primarily due to the initiation of multiple clinical trials during the last year.

General and administrative (G&A) expenses for the quarter ended March 31, 2020 were $3.5 million compared to $0.7 million for the corresponding period in 2019. The increase was due to higher headcount and professional services costs.

Net loss was $28.0 million, or $1.15 per basic and diluted share, for the first quarter of 2020 compared to $6.7 million, or $4.08 per basic and diluted share, for the first quarter of 2019.

About Arcutis - Bioscience, applied to the skin.

Arcutis 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. Arcutis exploits recent innovations in inflammation and immunology to develop potential best-in-class therapies against validated biological targets, leveraging our deep development, formulation and commercialization expertise to bring to market novel dermatology treatments, while maximizing our probability of technical success and financial resources. Arcutis is currently developing three novel compounds, including topical roflumilast cream (ARQ-151), topical roflumilast foam (ARQ-154), and ARQ-252 for multiple indications, including psoriasis, atopic dermatitis, seborrheic dermatitis, and eczema. For more information, please visit www.arcutis.com or follow the Company on LinkedIn.

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 to be filed with U.S. Securities and Exchange Commission (SEC) on May 12, 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)

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 190,893	$ 63,336
Marketable securities	58,426	37,929
Prepaid expenses and other current assets	4,559	5,209
Total current assets	253,878	106,474
Property, plant, and equipment, net	241	227
Operating lease right-of-use asset	226	264
Other assets	47	47
Total assets	$ 254,392	$ 107,012
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		

Accounts payable	$ 4,759	$ 1,405
Accrued liabilities	7,281	3,654
Operating lease liability	182	178
Total current liabilities	12,222	5,237
Operating lease liability, noncurrent	82	129
Other long-term liabilities	206	184
Total liabilities	12,510	5,550
Convertible preferred stock, $0.0001 par value; no shares and 48,787,898 shares authorized at March 31, 2020 and December 31, 2019, respectively; no shares and 24,385,388 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	—	166,491
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and no shares authorized at March 31, 2020 and December 31, 2019, respectively; no shares issued and outstanding at March 31, 2020 and December 31, 2019;	—	—
Common stock, $0.0001 par value; 300,000,000 and 65,820,000 shares authorized at March 31, 2020 and December 31, 2019, respectively; 38,154,550 and 2,879,763 shares issued at March 31, 2020 and December 31, 2019, respectively; 37,471,997 and 2,120,853 shares outstanding at March 31, 2020 and December 31, 2019, respectively	3	—
Additional paid-in capital	336,145	1,244
Accumulated other comprehensive income (loss)	19	(1)
Accumulated deficit	(94,285)	(66,272)
Total stockholders' equity (deficit)	241,882	(65,029)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 254,392	$ 107,012

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

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 25,182	$ 6,203
General and administrative	3,469	749
Total operating expenses	28,651	6,952
Loss from operations	(28,651)	(6,952)
Other income, net	638	294
Net loss	$ (28,013)	$ (6,658)
Per share information:		
Net loss per share, basic and diluted	$ (1.15)	$ (4.08)
Weighted-average shares used in computing net loss per share, basic and diluted	24,256,402	1,632,694