UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 8, 2022

ARCUTIS BIOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39186**	**81-2974255**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

3027 Townsgate Road, Suite300
Westlake Village, CA 91361
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (805) 418-5006

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**ARQT**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2022, Arcutis Biotherapeutics, Inc. (the "Company" or "Arcutis") issued a press release relating to its financial results for the quarter ended September 30, 2022. The full text of the press release is furnished herewith as Exhibit 99.1.

The information in this Item 2.02 of this Form 8-K and the Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release November 8, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ARCUTIS BIOTHERAPEUTICS, INC.

November 8, 2022

By: /s/ Scott L. Burrows

Scott L. Burrows

Chief Financial Officer

Arcutis Announces Third Quarter 2022 Financial Results and Provides Business Update

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- Launched ZORYVE® (roflumilast) cream 0.3% for the treatment of plaque psoriasis in adolescents and adults in mid-August, achieving net revenues of $0.7 million for the third quarter
- ZORYVE now covered by one of the top pharmacy benefit managers and a large national health plan
- Announced positive topline results from pivotal Phase 3 trial of roflumilast foam in scalp and body psoriasis
- Completed enrollment in INTEGUMENT-1 and INTEGUMENT-2, the two pivotal Phase 3 trials in subjects with atopic dermatitis six years of age and older, with topline data expected by year end
- Completed acquisition of Ducentis BioTherapeutics Ltd. (Ducentis), adding to the Company's pipeline a potential best-in-class and highly complementary preclinical asset in moderate-to-severe atopic dermatitis
- Strong financial position with approximately $480 million in cash, cash equivalents, and marketable securities

Westlake Village, CA, November 8, 2022 – Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today reported financial results for the quarter ended September 30, 2022, and provided a business update.

“This quarter represented a transformational period for Arcutis, with the FDA approval and launch of ZORYVE delivering on our promise to bring meaningful innovation to patients, physicians, and shareholders, and cementing our commitment to access and affordability. Furthermore, the acquisition of Ducentis extends our continued evolution into the preeminent immuno-dermatology company,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “Our launch of ZORYVE in plaque psoriasis continues to accelerate, and we believe it will be a foundational driver of growth for Arcutis that will be further buoyed by each additional topical roflumilast development program we advance towards potential commercialization. We are well funded, affording us the flexibility to properly invest in the ZORYVE launch, and also to progress our early pipeline assets like ARQ-255 into the clinic.”

Program Updates / Key Milestones

ZORYVE (roflumilast cream) - a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor in a once-daily cream formulation, approved in the U.S. for the treatment of plaque psoriasis and under development for atopic dermatitis

- In August 2022, Arcutis launched ZORYVE, with patient demand and prescriber awareness accelerating. Effective November 2022, ZORYVE is now covered by one of the top pharmacy benefit managers and a large national health plan. Feedback from physicians and patients has been extremely positive and the Company anticipates continued demand growth as formulary coverage builds. In July 2022, ZORYVE was approved for the once-daily treatment of mild, moderate, and severe plaque psoriasis, including intertriginous psoriasis, in individuals 12 years of age and older.

- In August 2022, Arcutis announced the completion of enrollment in INTEGUMENT-1 and INTEGUMENT-2, the two pivotal Phase 3 trials for the treatment of atopic dermatitis in subjects six years of age or older. Patient enrollment continues in INTEGUMENT-PED, the third pivotal Phase 3 trial in patients aged two to five years old. Topline data from each of INTEGUMENT-1 and INTEGUMENT-2, in subjects six years of age or older, are anticipated by the end of 2022. Topline data from INTEGUMENT-PED are expected in 2023.

- In September 2022, the *Journal of the American Medical Association* (JAMA) published the positive results from the pivotal DERMIS-1 and DERMIS-2 Phase 3 trials in plaque psoriasis.

Roflumilast foam - a once-daily foam 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 and body psoriasis

- In June 2022, Arcutis announced positive topline results from the STRATUM pivotal Phase 3 trial for the treatment of moderate-to-severe seborrheic dermatitis. The Company anticipates submitting an NDA to the FDA in the first quarter of 2023. These STRATUM Phase 3 positive results were recently presented at the European Academy of Dermatology and Venereology (EADV) Congress in September 2022.
- In September 2022, Arcutis announced positive topline results from the ARRECTOR pivotal Phase 3 trial for the treatment of scalp and body psoriasis. The Company expects the data to be sufficient basis for a supplemental New Drug Application (sNDA) that will be submitted following the potential approval of roflumilast foam for seborrheic dermatitis.

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

- 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

- The Company continues its Investigational New Drug application (IND)-enabling efforts, and expects to enter the clinic in 2022.

Recent Corporate Highlights

- In September 2022, the Company announced the acquisition of Ducentis, aligning to its strategy and leveraging the Company's deep dermatology and biologics expertise. The lead preclinical asset, ARQ-234, was immediately integrated in the Company's R&D portfolio, and offers a potential best-in-class profile in moderate-to-severe atopic dermatitis, and is highly complementary to roflumilast cream in that indication. The Company is excited by the promise and recent biologic validation of checkpoint agonism as an emerging strategy for the treatment of atopic dermatitis, and the potential differentiation of ARQ-234.

- In September 2022, the Company announced the appointment of Neha Krishnamohan to its Board of Directors and as a member of the audit committee. Ms. Krishnamohan brings a depth of business, financial and investment experience, including deep knowledge of Arcutis' business having previously worked on the Company's initial public offering.

- In August 2022, the Company announced the initiation of Arcutis Cares, a patient assistance program (PAP) for financially qualified uninsured and underinsured patients, aligning to Arcutis' commitment to help patients access ZORYVE.

Third Quarter 2022 Summary Financial Results

Product revenues, net for the quarter ended September 30, 2022 related to sales of ZORYVE were $0.7 million. In addition to strong patient demand, about half of the net product revenues for the quarter related to wholesalers' inventory build at launch.

Cost of sales for the quarter ended September 30, 2022 were $0.3 million driven primarily by the amortization of a milestone payment to AstraZeneca.

Research and development (R&D) expenses for the quarter ended September 30, 2022 were $69.7 million compared to $40.6 million for the corresponding period in 2021. The year-over-year increase was primarily due to the approximately $30 million upfront expense for the Ducentis acquisition.

Selling, general, and administrative (G&A) expenses for the quarter ended September 30, 2022 were $35.5 million compared to $16.5 million for the corresponding period in 2021. The year-over-year increase was primarily due to higher headcount and professional services expenses related to the launch of ZORYVE.

Net loss was $107.7 million, or $1.89 per basic and diluted share, for the quarter ended September 30, 2022 compared to $57.0 million, or $1.14 per basic and diluted share, for the corresponding period in 2021. The Ducentis acquisition contributed $0.51 to the net loss per share in the third quarter of 2022.

Cash, cash equivalents, restricted cash, and marketable securities were $478.2 million as of September 30, 2022, compared to $388.6 million as of December 31, 2021. The year-over-year increase includes the $162 million in net proceeds from the August 2022 public offering, as well as the $125 million drawn from the existing debt facility with SLR Capital Partners upon the ZORYVE approval in plaque psoriasis. Net cash used in operating activities during the third quarter was $67.7 million.

Conference Call and Webcast

Arcutis management will host a conference call and webcast today at 5:00pm ET to discuss the financial results for the quarter and provide a business update. The webcast for this conference call may be accessed at the “Events” section of the Company’s website. The replay of the webcast will be available on the Arcutis website following the call.

About Arcutis

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 multiple clinical programs for a range of inflammatory dermatological conditions including plaque psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit https://www.arcutis.com or follow the company on LinkedIn, Facebook, 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; the development, approval and potential commercialization of Arcutis' product candidates; expectations with regard to the timing of and successful clinical trial results anticipated during 2022; the potential commercial success and growth of ZORYVE in plaque psoriasis; and the timing of regulatory filings for a number of dermatology indications for roflumilast in the U.S. and Canada. 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, the timing, expenses, and success of our commercialization efforts, including uncertainty of future commercial sales and related items that can impact net sales, 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 22, 2022 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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)

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,543	$ 96,449
Restricted cash	1,234	1,542
Trade receivable, net	2,431	—
Marketable securities	395,420	290,610
Inventories	4,307	—
Prepaid expenses and other current assets	11,784	14,172
Total current assets	496,719	402,773
Property and equipment, net	1,939	2,261
Intangible assets, net	7,375	—
Operating lease right-of-use asset	2,803	3,040
Other assets	78	78
Total assets	$ 508,914	$ 408,152
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,666	$ 7,353
Accrued liabilities	27,797	25,540
Operating lease liability	639	433
Total current liabilities	37,102	33,326
Operating lease liability, noncurrent	4,285	4,774
Long-term debt, net	196,753	72,350
Other long-term liabilities	—	25
Total liabilities	238,140	110,475
Stockholders' equity:		
Common stock	6	5
Additional paid-in capital	920,109	706,233
Accumulated other comprehensive loss	(1,596)	(255)
Accumulated deficit	(647,745)	(408,306)
Total stockholders' equity	270,774	297,677
Total liabilities and stockholders' equity	$ 508,914	$ 408,152

ARCUTIS BIOTHERAPEUTICS, INC.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Product revenue, net	$ 725	$ —	$ 725	$ —
Total revenues	725	—	725	—
Operating expenses:				
Cost of sales	269	—	269	—
Research and development	69,731	40,604	148,558	93,000
Selling, general, and administrative	35,473	16,474	85,101	42,243
Total operating expenses	105,473	57,078	233,928	135,243
Loss from operations	(104,748)	(57,078)	(233,203)	(135,243)
Other income (expense):				
Other income, net	1,938	98	2,501	213
Interest expense	(4,899)	—	(8,737)	—
Total other income (expense)	(2,961)	98	(6,236)	213
Net loss	$ (107,709)	$ (56,980)	$ (239,439)	$ (135,030)
Per share information:				
Net loss per share, basic and diluted	$ (1.89)	$ (1.14)	$ (4.52)	$ (2.75)
Weighted-average shares used in computing net loss per share, basic and diluted	57,091,743	50,097,851	53,028,962	49,136,768