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): June 6, 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, Suite 300
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 8.01. Other Events.

On June 6, 2022, Arcutis Biotherapeutics, Inc. (the "Company") announced positive topline results from its "STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis" ("STRATUM") pivotal Phase 3 trial investigating roflumilast foam 0.3% as a potential treatment for adolescents and adults with moderate to severe seborrheic dermatitis. The trial was a Phase 3, randomized, parallel group, double-blind, vehicle-controlled trial in which subjects ages nine years and older with moderate to severe seborrheic dermatitis received eight weeks of (i) roflumilast foam 0.3% once daily or (ii) vehicle once daily. STRATUM enrolled 457 subjects.

Results from the eight-week treatment period demonstrated statistically significant improvements compared to the matching vehicle. On the study's primary endpoint of percentage of patients achieving Investigator Global Assessment ("IGA") success, which was defined as an IGA score of "clear" or "almost clear" plus a 2-grade improvement from baseline at week eight, 80.1% of patients treated with roflumilast foam 0.3% achieved IGA success, compared to 59.2% of patients treated with vehicle ($p < 0.0001$).

Roflumilast foam 0.3% also demonstrated statistically significant improvements compared to vehicle on key secondary endpoints, including IGA success at week four, an IGA score of zero at week eight and reductions in itch as measured by the Worst Itch-Numerical Rating Scale. For example, 50.7% of patients treated with roflumilast foam 0.3% achieved an IGA score of clear at week eight, compared to 28.2% of patients treated with vehicle ($p < 0.0001$).

Roflumilast foam 0.3% was well-tolerated, with rates of treatment-emergent adverse events ("TEAEs") low and similar to vehicle, with most TEAEs assessed as mild to moderate in severity. Of the subjects treated with roflumilast foam 0.3% in the trial, 276 (91% of subjects) completed the full eight weeks. There were few discontinuations due to adverse events in both the roflumilast foam 0.3% group and the vehicle group, with two subjects treated with roflumilast foam 0.3% (0.7% of subjects treated with roflumilast foam 0.3%) and three subjects in the vehicle group (2.0% of subjects in the vehicle group) discontinuing the trial due to an adverse event. There were no treatment-related serious adverse events.

On June 6, 2022, the Company issued a press release relating to its topline results from its STRATUM pivotal Phase 3 trial investigating roflumilast foam 0.3% as a potential treatment for adolescents and adults with moderate to severe seborrheic dermatitis. On June 6, 2022, the Company also provided a presentation relating to these topline results by posting an additional presentation to the investor section of the Company's website. Copies of the press release and presentation are filed as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information contained in the slides is summary information that is intended to be considered in the context of the more complete information included in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such update may be made through the filing of other reports or documents with the SEC.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Arcutis Biotherapeutics, Inc., dated June 6, 2022.
99.2	Company presentation of Arcutis Biotherapeutics, Inc., dated June 6, 2022.
104	Cover Page Interactive Data File, formatted in 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.

Date: June 9, 2022 By: /s/ Scott Burrows
Scott Burrows
Chief Financial Officer

Arcutis Announces Positive Topline Results from STRATUM Pivotal Phase 3 Trial of Roflumilast Foam 0.3% in Seborrheic Dermatitis

June 6, 2022

- Study met its primary endpoint with 80.1% of individuals treated with roflumilast foam achieving Investigator Global Assessment (IGA) Success compared to 59.2% of patients treated with vehicle (P<0.0001)
- More than 50% of patients treated with roflumilast foam achieved an IGA score of clear at week eight
- Roflumilast foam was well-tolerated with a favorable safety and tolerability profile
- Data further support the potential of roflumilast foam as a best-in-class, once-daily, non-steroidal topical treatment for seborrheic dermatitis
- New drug application (NDA) submission anticipated in 1H of 2023
- Company to host a conference call today at 8:30 a.m. EDT

WESTLAKE VILLAGE, Calif., June 06, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced positive topline results from the STRATUM pivotal Phase 3 trial investigating roflumilast foam as a potential treatment for adolescents and adults with moderate to severe seborrheic dermatitis. Roflumilast foam 0.3%, an investigational once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor being developed to treat inflammatory dermatoses, particularly in hair-bearing areas of the body such as the scalp, demonstrated significant improvements based on IGA Success and other endpoints.

The study met the primary endpoint with 80.1% of individuals treated with roflumilast foam achieving 'IGA Success' compared to 59.2% of patients treated with vehicle (P<0.0001) at week eight. IGA Success was defined as an IGA score of clear or almost clear plus a ≥2 grade improvement from baseline. Improvement with roflumilast foam was seen early, with roflumilast separating statistically from vehicle on IGA Success at week two. In addition, more than 50% of patients treated with roflumilast foam achieved an IGA score of clear at week eight. Roflumilast foam also demonstrated statistically significant improvements compared to vehicle on key secondary endpoints, including itch, scaling, and redness (erythema).

"Despite the prevalence and impact on quality of life of seborrheic dermatitis, there remains significant unmet need for new options to treat this condition, with individuals today left to manage their symptoms with multiple treatments and complex application routines," said Dr. Zoe Draelos, study investigator, dermatologist in High Point, North Carolina, and President, Dermatology Consulting Services, PLLC. "As both a trial investigator and a clinician, I am excited by these results because they demonstrate the potential for roflumilast foam to be a well-tolerated, easy-to-use, steroid-free treatment option for adults and adolescents with moderate to severe seborrheic dermatitis."

Roflumilast foam was well-tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar between active treatment and vehicle, with most TEAEs assessed as mild to moderate severity. There were no treatment-related Serious Adverse Events (SAEs). Overall, the most common adverse events in the study population (over 1%) included COVID-19, urinary tract infection, nasopharyngitis, and nausea. Over 90% of patients who were randomized to roflumilast foam in the study completed the full eight weeks, and there were few discontinuations due to adverse events (0.7% and 2.0% in the roflumilast foam and vehicle groups, respectively).

"We are excited that investigational roflumilast foam demonstrated strong topline results in our pivotal Phase 3 trial, consistent with previously reported data. These results move us one step closer to providing a new treatment option for the millions of people suffering from seborrheic dermatitis," said Patrick Burnett MD, PhD, FAAD, Chief Medical Officer at Arcutis. "We will now prepare an NDA for roflumilast foam for the treatment of seborrheic dermatitis to submit to the U.S. Food and Drug Administration (FDA)."

Arcutis announced in January 2021 that, based on feedback received from the FDA, the Company believes the single STRATUM study, if positive, would be sufficient basis for an NDA for roflumilast foam in dermatitis. Arcutis plans to submit an NDA in the first half of 2023. If roflumilast foam is approved by the FDA, the Company plans to leverage its existing commercial infrastructure to bring the product to market.

Management will host a conference call today at 8:30 a.m. EDT to discuss these results. To access the call, please dial (833) 614-1393 (domestic) or (914) 987-7114 (international) and provide the conference ID# 7384524. A live webcast of the call will also be available on the "Events" section of the Company's Investor website. An archived replay of the webcast will be available on the Arcutis website following the call.

About STRATUM

The STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis (STRATUM) is a Phase 3, parallel group, double blind, vehicle-controlled study of the safety and efficacy of roflumilast foam 0.3% administered once-daily. A total of 457 subjects ages nine and older with moderate to severe seborrheic dermatitis were enrolled in the study and were randomized 2:1 roflumilast foam to vehicle. The primary endpoint of the study was the proportion of subjects achieving IGA Success, defined as an IGA score of clear or almost clear plus a ≥2 grade improvement at week 8.

About Seborrheic Dermatitis

Seborrheic dermatitis affects more than 10 million people in the U.S., and is a common, chronic or recurrent inflammatory skin disease that causes red patches covered with large, greasy, flaking yellow-gray scales, and persistent itch. Seborrheic dermatitis occurs most often in areas of the body with

oil-producing (sebaceous) glands, including the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back.

About Topical Roflumilast Foam

Roflumilast foam is a once-daily topical foam formulation of roflumilast, a highly potent and selective PDE4 inhibitor, which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis. Roflumilast has been approved by the U.S. FDA for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Arcutis has also submitted an NDA for a closely related cream formulation of topical roflumilast for the treatment of plaque psoriasis, with a Prescription Drug User Fee Act (PDUFA) action date of July 29, 2022. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators; it has been implicated in a wide range of inflammatory diseases including psoriasis, atopic dermatitis, and COPD.

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, with one NDA under review with the FDA in plaque psoriasis, one Phase 3 clinical trial now completed in 2022 in seborrheic dermatitis, and two additional Phase 3 clinical data readouts anticipated by the end of the year in atopic dermatitis and scalp and body psoriasis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains "forward-looking" statements, including, among others, statements regarding the potential for roflumilast foam to be approved for the treatment of adults and adolescents with seborrheic dermatitis, the potential to use roflumilast foam over a long period of time, or chronically, the potential to use roflumilast foam anywhere on the body, including the face and scalp, anticipated submission of the NDA and the potential for roflumilast to advance the standard of care in seborrheic dermatitis and other inflammatory dermatological conditions. 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 22, 2022, as amended on March 3, 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.

Contacts:
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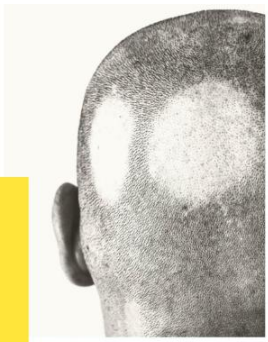
asheldon@arcutis.com

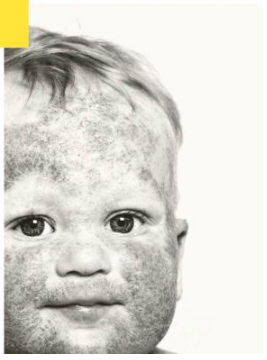
Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com

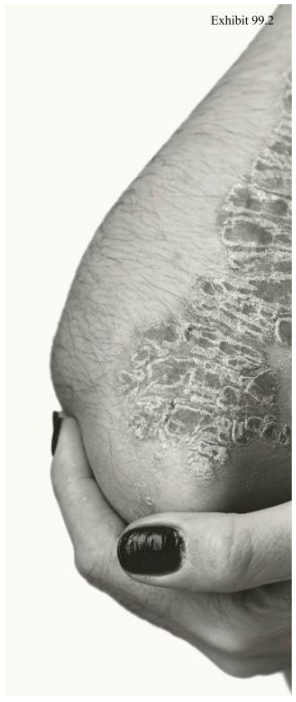
Exhibit 99.2

STRATUM
Phase 3 Seborrheic Dermatitis Topline Data Presentation

June 2022







ARCUTIS BIOTHERAPEUTICS

Bioscience applied to the skin.

Legal Disclaimers

This presentation and the accompanying oral presentation contain "forward-looking" statements that are based on our management's beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, current and future commercialization activities, timing and success of our ongoing and planned clinical trials and related data, the timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, industry environment, and potential market opportunities.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics, including our lead product candidates roflumilast cream and roflumilast foam; the progress of patient enrollment and dosing in our clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates; the potential for data from our clinical trials to support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations, development and commercialization of our product candidates; the timing of and our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates, and our ability to serve those markets; our commercialization, marketing and manufacturing capabilities and strategy; future agreements with third parties in connection with the commercialization of our product candidates; our expectations regarding our ability to obtain and maintain intellectual property protection; our dependence on third party manufacturers; the success of competing therapies that are or may become available; our ability to attract and retain key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objectives; and our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Further information on these and other factors that could affect these forward-looking statements is contained in our our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, and other reports filed with the SEC from time to time.

You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

All product and company names are trademarks™ or registered® trademarks of their respective holders.

Today's Speakers

Frank Watanabe
President & CEO

Patrick Burnett, MD, PhD, FAAD
Chief Medical Officer

Zoe Diana Draelos, MD, FAAD
Principal Investigator & President, Dermatology Consulting Services, PLLC

Ken Lock
Chief Commercial Officer

Speakers & Agenda

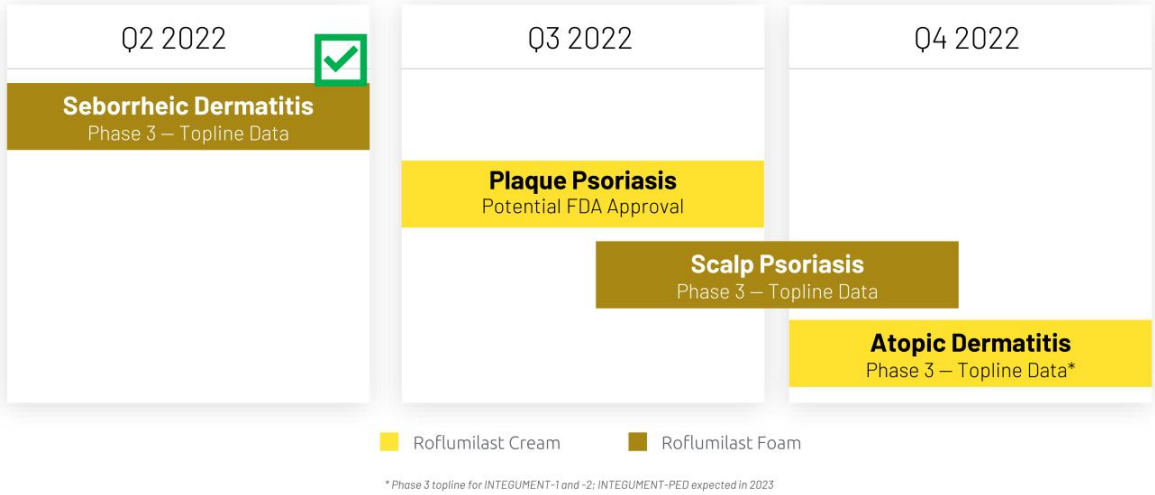
Frank Watanabe
President and CEO

Arcutis Overview
Seborrheic Dermatitis Disease State Education
Clinical Results
Commercial Opportunity
Q&A

2022: A Transformational Year for Arcutis

- Topical roflumilast offers a differentiated clinical profile, targeting three distinct disease areas each with >2 million topically treated patients today in U.S. Dermatology offices
- We are increasingly excited about the clinical profile and the underappreciated opportunity of roflumilast foam in seborrheic dermatitis
- We are progressing our commercial launch preparations in advance of our July PDUFA date for roflumilast cream in plaque psoriasis
- We remain confident in replicating our track record of Phase 3 success in subsequent pivotal readouts in atopic dermatitis and scalp and body psoriasis later this year

First of Four Potential Transformational Catalysts



** Phase 3 topline for INTEGUMENT-1 and -2; INTEGUMENT-PED expected in 2023*

Topical Roflumilast Opportunity: ~7 million Dermatologist-Treated Patients in the U.S. Alone

	Psoriasis	Atopic Dermatitis	Seborrheic Dermatitis
Prevalence	~9M	~26M	~10M
Topical Rx treated in Derm Setting	**2.0M** *(mild-moderate-severe)*	**2.6M** *(mild-to-moderate)*	**2.2M** *(moderate-to-severe)*
Topically treated outside Derm	~1.2M *(mild-moderate-severe)*	~4.1M *(mild-to-moderate)*	~1.0M *(moderate-to-severe)*

Significant incremental opportunity

to access the millions of U.S. patients Rx treated by other specialties (e.g., PCPs or pediatricians) via partnership

Rx = Prescription; PCP = primary care physician

Topical Roflumilast – A Differentiated & Transformational Clinical Profile

- Efficacy results on par with steroid / vitamin D combinations
- Non-steroidal with ability to use chronically, anywhere on the body
- No boxed warnings anticipated
- Favorable local tolerability

~3.5K

Individuals evaluated with topical roflumilast across clinical programs

Speakers & Agenda

Zoe Diana Draelos, MD, FAAD
Principal Investigator & President, Dermatology Consulting Services, PLLC

Arcutis Overview
Seborrheic Dermatitis Disease State Education
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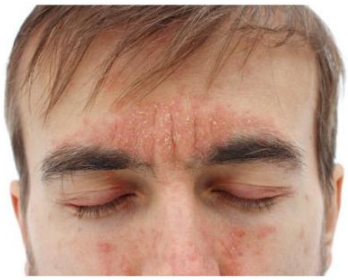
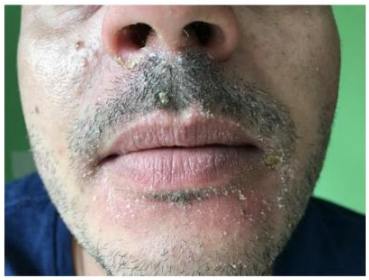
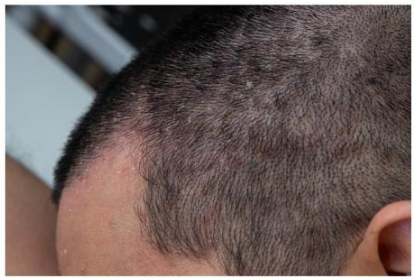
Commercial Opportunity
Q&A

Seborrheic Dermatitis – Significant Unmet Needs in Current Treatment Paradigm







Speakers & Agenda

Patrick Burnett,
MD, PhD, FAAD
Chief Medical Officer

Zoe Diana Draelos,
MD, FAAD

Arcutis Overview
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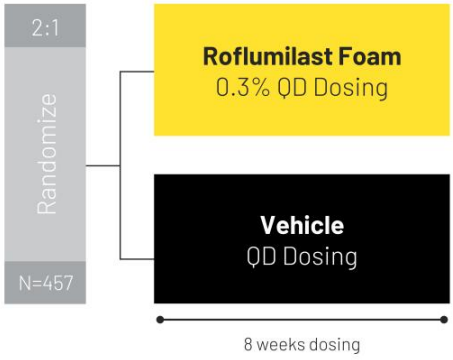
STRATUM Phase 3 Trial in Seborrheic Dermatitis

Randomized, Double-blind, Vehicle-controlled Multicenter Study

Eligibility

- Diagnosis of at least moderate seborrheic dermatitis (IGA ≥3)
- Age 9+
- Up to 20% BSA



Endpoints

Primary

- IGA success at week 8

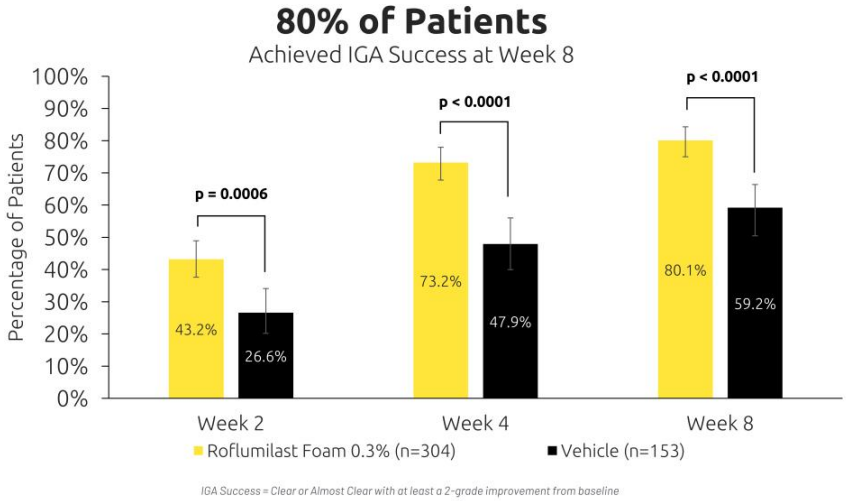
Secondary

- IGA success at week 2 and 4
- IGA score of 0 at week 8
- Overall assessment of erythema/scaling
- WI-NRS (itch)

Safety and tolerability

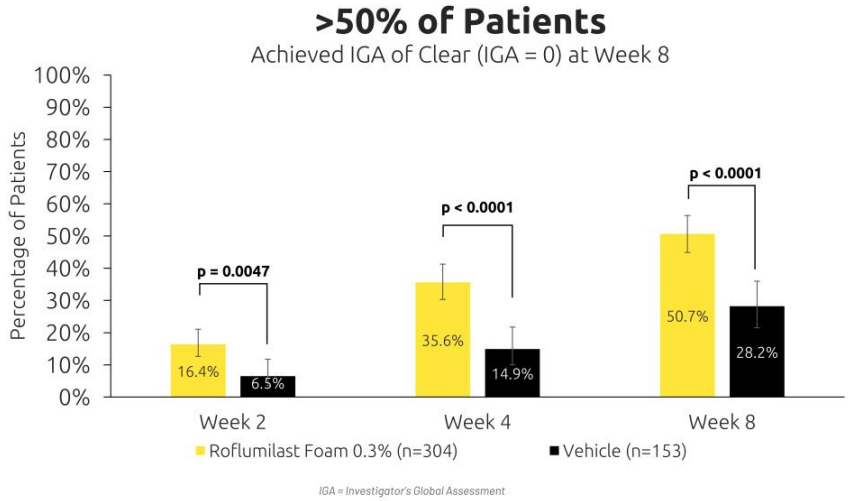
IGA = Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day; BSA = body surface area

Rapid and Robust Results on IGA Success in Pivotal Phase 3 STRATUM Trial



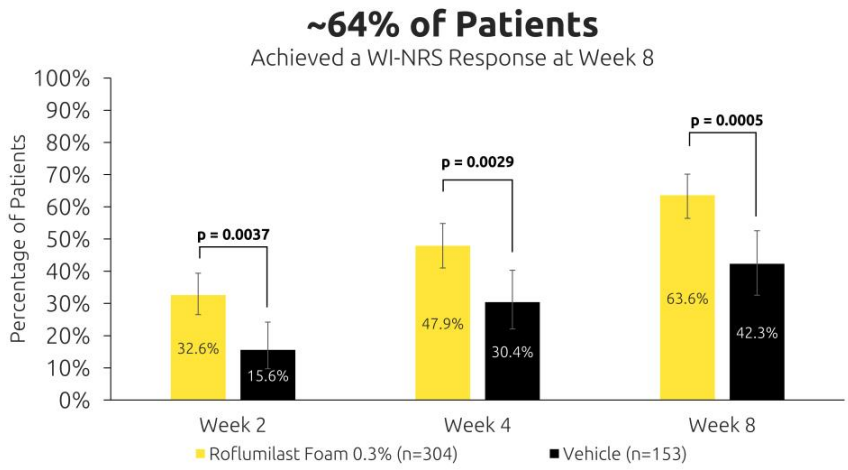
IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline

Over 50% of Patients Achieved IGA of Clear at Week 8



IGA = Investigator's Global Assessment

Robust Itch Response in Phase 3



WI-NRS: Worst Itch Numeric Rating Scale; WI-NRS response = 4 point reduction in WI-NRS in patients with WI-NRS > 4 at baseline

Roflumilast Foam Was Well-Tolerated in Phase 3

Subjects (%)	Roflumilast 0.3% (n=304)	Vehicle (n=153)	Overall (n=457)
Subjects with any TEAE	70 (23.0%)	33 (21.6%)	103 (22.5%)
Subjects with any Treatment-Related TEAE	8 (2.6%)	5 (3.3%)	13 (2.8%)
Subjects with any SAE	1 (0.3%)	0	1 (0.2%)
Treatment-related SAE	0	0	0
Subjects who discontinued Study Drug due to AE	2 (0.7%)	3 (2.0%)	5 (1.1%)
Subjects who discontinued Study due to AE	2 (0.7%)	3 (2.0%)	5 (1.1%)

AE: adverse event; SAE: serious adverse event; TEAE: treatment-emergent adverse event

Most Common Treatment Emergent Adverse Events (>1.0% in Any Group)

Preferred Term	Roflumilast 0.3% (n=304)	Vehicle (n=153)	Overall (n=457)
COVID-19	11 (3.6%)	5 (3.3%)	16 (3.5%)
Urinary tract infection	4 (1.3%)	3 (2.0%)	7 (1.5%)
Nasopharyngitis	4 (1.3%)	1 (0.7%)	5 (1.1%)
Nausea*	5 (1.6%)	0	5 (1.1%)
Application site pain	1 (0.3%)	3 (2.0%)	4 (0.9%)
Sinusitis	0	2 (1.3%)	2 (0.4%)

*All graded as mild

Speakers & Agenda

Ken Lock
Chief Commercial Officer

Arcutis Overview
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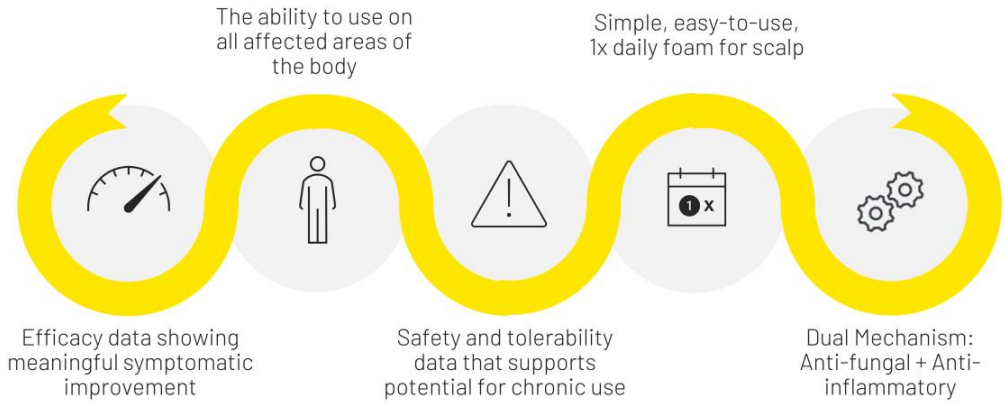
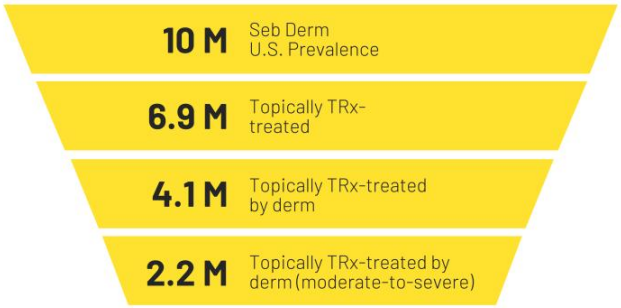
Roflumilast Foam Could Become Standard of Care in Seborrheic Dermatitis



Opportunity Comparable in Size to Psoriasis With No Products Promoted



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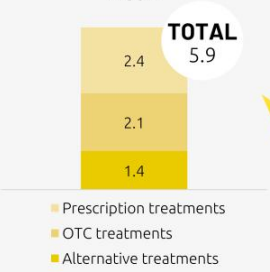
Average # of seborrheic dermatitis patients seen in a typical month

	Mild	Moderate	Severe
Patients receiving a prescription treatment 1st line[1]	71%	**92%**	**97%**

[1]*Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs; TRx = prescription*

Patients Are Dissatisfied with Complex and Onerous Treatment Regimens

Treatments Used Per Week[1], Mean



9 in 10 AGREE[1]

"I would be more likely to stick with a treatment plan if it meant using fewer treatments."

Patients ready for new options

"I am interested in trying new treatment options."

9 in 10
AGREE[1]

[1]*Harris Poll Seborrheic Dermatitis Survey (n>600 HCPs, n=300 patients), OTC = over the counter*

Thank You

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Chief Medical Officer

Ken Lock
Chief Commercial Officer

Arcutis Overview
Seborrheic Dermatitis Disease State Education
Clinical Results
Commercial Opportunity

Q&A