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): September 29, 2020

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)

2945 Townsgate Road, Suite 110
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 September 29, 2020, Arcutis Biotherapeutics, Inc. (the "Company") announced positive topline results from its completed Phase 2 study of ARQ-154 in seborrheic dermatitis. The study was a multi-center, multi-national, double-blind, vehicle-controlled study in which 226 adults with moderate-to-severe seborrheic dermatitis received 8 weeks of (i) 0.3% ARQ-154 topical foam once daily, or (ii) matching vehicle once daily.

Results from the eight-week treatment period demonstrated statistically significant improvement compared to the matching vehicle on key efficacy endpoints. On the primary efficacy endpoint of percentage of patients achieving an Investigator's Global Assessment, or IGA, score of "clear" or "almost clear" PLUS a 2-grade improvement from baseline at week 8, 73.8% of patients treated with ARQ-154 achieved "clear" or "almost clear", compared to 40.9% of patients treated with vehicle ($p < 0.0001$). ARQ-154 separated from vehicle with statistical significance on the primary efficacy endpoint and multiple secondary endpoints as early as week 2, the first visit after baseline. ARQ-154 also statistically separated from vehicle in reduction of itch as measured by Worst Itch-Numerical Rating Scale, or WI-NRS, with 64.6% of patients with substantial itching (baseline WI-NRS > 4) treated with ARQ-154 experiencing at least a 4-point reduction in their WI-NRS score at week 8, compared to 34.0% of patients treated with vehicle ($p = 0.0007$). Other secondary endpoints included overall assessment of erythema and overall assessment of scaling.

ARQ-154 was well-tolerated by the patient population, with rates of application site adverse events, treatment-related adverse events and discontinuations due to adverse events low and similar to vehicle. Two out of 154 patients (1.3%) treated with ARQ-154 discontinued the study due to an adverse event, compared to one out of 72 (1.4%) treated with vehicle. Two patients missed the IGA score assessment at week 8 due to concerns arising from COVID-19. As a result, the intent-to-treat and modified intent-to-treat populations differed by two patients, with the results above reflecting the modified intent-to-treat.

On September 29, 2020, the Company provided a corporate presentation relating to its topline results from its completed Phase 2 study of ARQ-154 in seborrheic dermatitis by posting an additional corporate presentation to the investor section of the Company's website. A copy of this presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K and is 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

Exhibit No.	Description
99.1	Company presentation dated September 29, 2020.

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: September 29, 2020

By: /s/ John W. Smither
John W. Smither
Chief Financial Officer

ARCUTIS
BIOTHERAPEUTICS

Seborrheic Dermatitis

September 2020

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, 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 relate data, our ability to obtain and maintain regulatory approval, the potential therapeutic benefits and economic value of our product candidates, competitive position, ind 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 succes 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 ARQ-151 and ARQ-154; 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 applic 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 ou 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 potenti 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 intellect property protection; our dependence on third party manufacturers; the success of competing therapies that are or may become available; our ability to attract and reta key scientific or management personnel; our ability to identify additional product candidates with significant commercial potential consistent with our commercial objecti 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 pre 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 materiall 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 inform on these and other factors that could affect these forward-looking statements is contained in our our Form 10-Q filed with U.S. Securities and Exchange Commission (SEC) August 11, 2020, 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 for 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 m 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 degre uncertainty and risk.

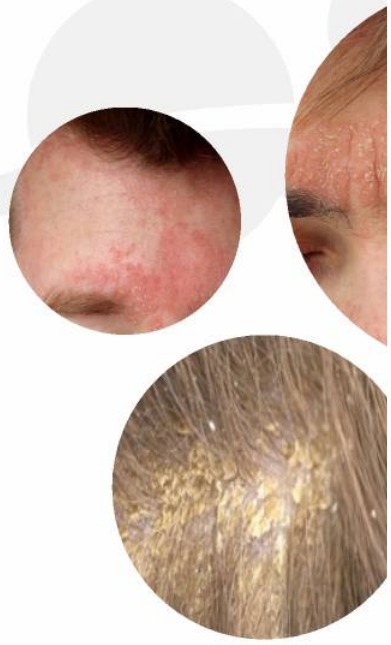
Seborrheic Dermatitis Phase 2 Data Call

Frank Watanabe

President & CEO

Seborrheic Dermatitis (Seb Derm)

- Common, chronic inflammatory skin disease
- Affects 10M people in the U.S.
- Appears as itchy red patches covered by greasy, flaking scales on the scalp, face & chest



Negative Impact on Quality of Life (QoL)

Seb derm can have a significant, negative influence on QoL

Psychological Distress
Oily skin and flakiness in visible areas causes psychological distress

Women Express Particular Self-Consciousness
Limits clothing choices (no black), hairstyle (due to Rx shampoos), and make-up

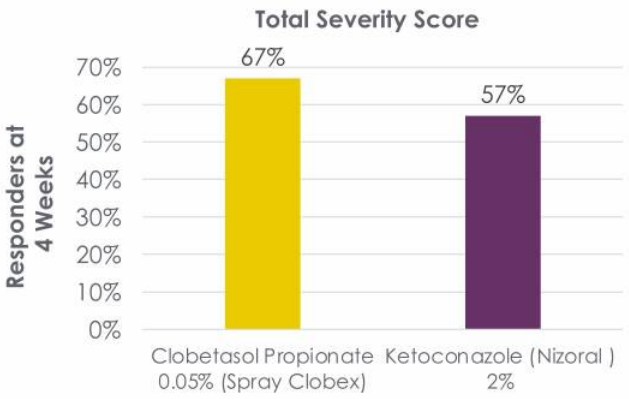
Significant QoL Impact
QoL impacted by all symptoms: erythema, flaking, oily skin, and pruritus[1]

Perception of Poor Hygiene
Patients are perceived as "dirty," causes negative impact on self-esteem

QoL is Key Driver for Rx
High patient QoL burden motivates dermatologists to treat seb derm

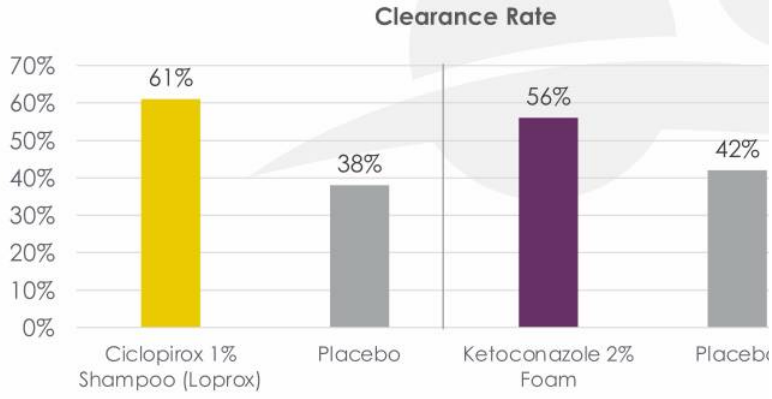
Szepietowski JC, Reich A, Wesołowska-Szepietowska E, Baran E. National quality of life in dermatology group. 2009

Efficacy Benchmarks



n= 326

- Total severity score (TSS) ≥2 defined as sum of erythema, loose desquamation, and adherent desquamation at 4 weeks[1]
- Moderate-to-severe scalp SD (IGA of 3 or 4 on a 5-point scale)
- TEAEs: 5%



n= 183

- Responders equals none or slight (0-1 scores) at 4 weeks[2]

n= 1,162

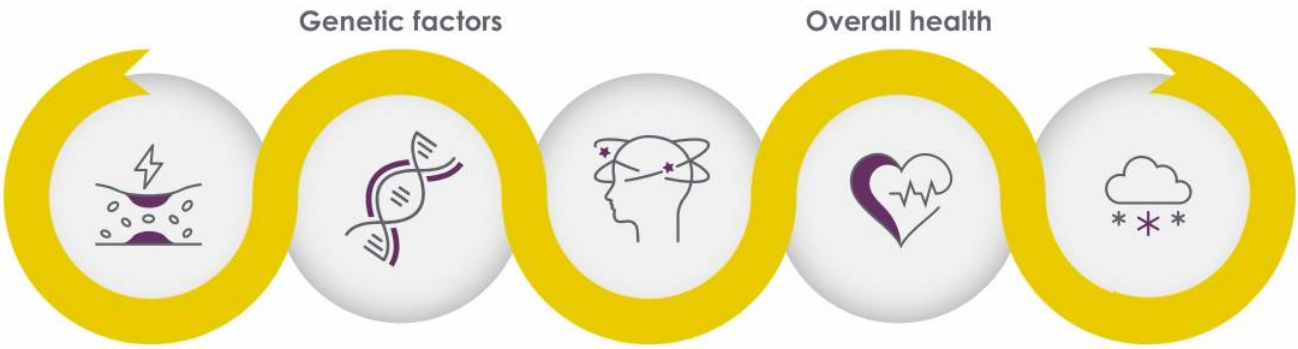
- IGA score of 0 or 1 at 4 we equals treatment success
- Placebo rate: 42%
- Predominantly mild subjec
- TEAEs: 14%

References: 1. 2011 (Ortonne, JP – Galderma funded) 2. 2004 (Abeck, D) 3. 2007 (Elewski, BE)

Patrick Burnett, M.D., Ph.D., FAAD

Chief Medical Officer

Seb Derm Contributing Factors



Particular yeast that lives on all human skin

Emotional or physical stress, such as lack of sleep

Climate (usually worse in cold weather)

Limitations of Current Seb Derm Treatments

Topical Anti-Fungals

- Often used as first-line therapy
- Often ineffective for long-term remission

Topical steroids

- Increased risk of glaucoma and cataracts
- No chronic high-potency steroid use beyond 2-4 weeks
- Skin atrophy concerns since skin on face and scalp is thin

Non-steroidals

- Perceived lack of efficacy and/or tolerability

No single product appropriate for both scalp and face/body

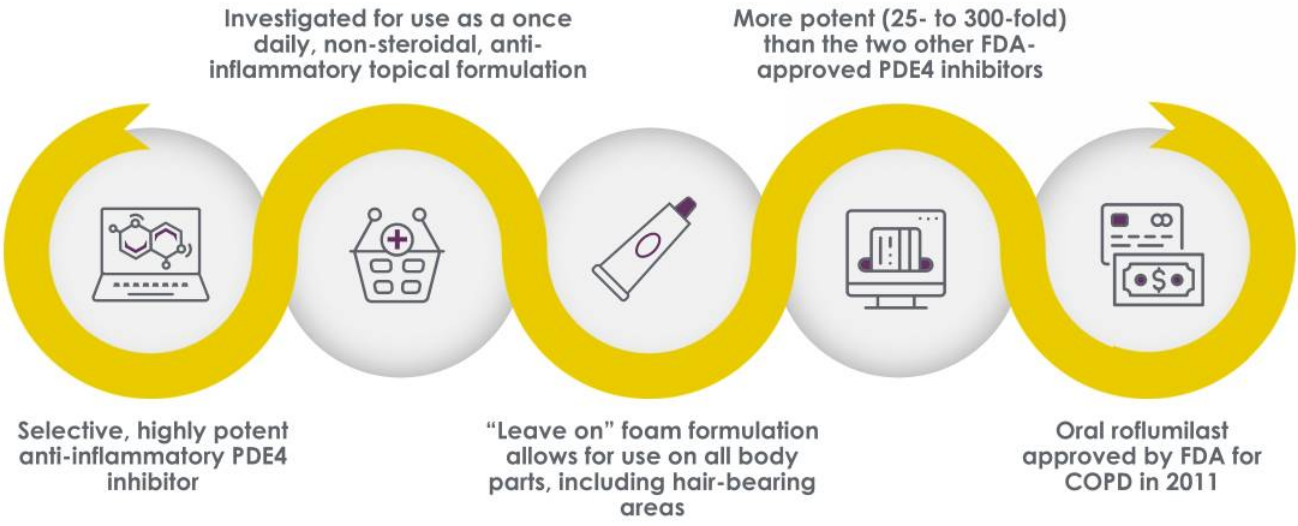
- Many patients use 3-5 products
- Time management challenge and complexity
- Reduces patient compliance
- Increases time / expense (multiple co-pc

Rx shampoos

- Usage usually 2x/week for up to 4 weeks
- Texture of vehicle can mess up hair styles and dry out hair
- Perceived unpleasant smell

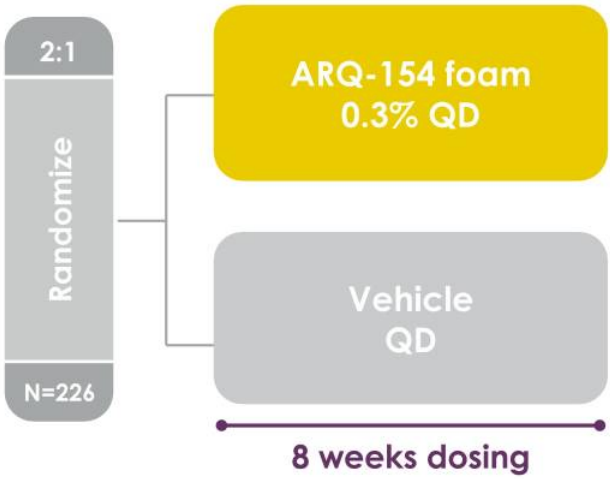
Topical Roflumilast Foam

Roflumilast foam offers a highly differentiated clinical profile



Phase 2 Study of Roflumilast Foam in Seb Derm

Eligibility
- Diagnosis of at least moderate seb derm
- Aged ≥18 y
- ≤20% BSA



Endpoints

Primary
- IGA success at week 8

Secondary
- Overall assessment of erythema
- Overall assessment of scaling
- WI-NRS

Exploratory
- Scalpdex
- DLQI
- BSA

Safety and tolerability

[a]IGA success was defined as IGA score of 0 or 1 (clear or almost clear) with at least a two-grade improvement from baseline.
BSA, body surface area; DLQI, dermatology life quality index; IGA, investigator global assessment; QD, once daily; WI-NRS, worst itch numeric rating scale.
NCT04091646. https://clinicaltrials.gov/ct2/show/NCT04091646. Accessed July 20, 2020.

Study Populations

	ARQ-154 0.3%	Vehicle	Overall
ITT	154 (100%)	72 (100%)	226 (100%)
Safety Population	154 (100%)	72 (100%)	226 (100%)
mITT*	153 (99.4%)	71 (98.6%)	224 (99.1%)
PRU4	125 (81.2%)	59 (81.9%)	184 (81.4%)
PRU2	141 (91.6%)	68 (94.4%)	209 (92.5%)

* Excludes 2 subjects: One roflumilast subject (31003) who was enrolled Mar 6, then withdrew consent due to the fear of contracting COVID-1 (informed site May 1), with no post-baseline visits, and one vehicle subject (17006) who missed week 8 IGA due to COVID, but did not discontii due to COVID, and came back for the week 9

ITT = all randomized subjects
Safety population = all subjects who are enrolled and received at least 1 confirmed dose of IP
mITT = all randomized subjects with the exception of subjects who missed the week 8 IGA assessment specifically due to COVID-19 disruption
PRU4 population = subset of the ITT population and includes subjects with WI-NRS pruritus score ≥4 at Baseline
PRU2 population = subset of the ITT population and includes subjects with WI-NRS pruritus score ≥ 2at Baseline

Subject Disposition

	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Completed	141 (91.6%)	67 (93.1%)	208 (92.0%)
Prematurely discontinued	13 (8.4%)	5 (6.9%)	18 (8.0%)
Reason for discontinuation			
Withdrawal by subject	4 (2.6%)	1 (1.4%)	5 (2.2%)
Sponsor decision	0	0	0
PI Decision	0	0	0
Non-compliance	0	0	0
Protocol violation	0	1 (1.4%)	1 (0.4%)
Lost to follow-up	6 (3.9%)	2 (2.8%)	8 (3.5%)
Adverse event	2 (1.3%)	1 (1.4%)	3 (1.3%)
Death	0	0	0
Pregnancy	0	0	0
Other	1 (0.6%)	0	1 (0.4%)

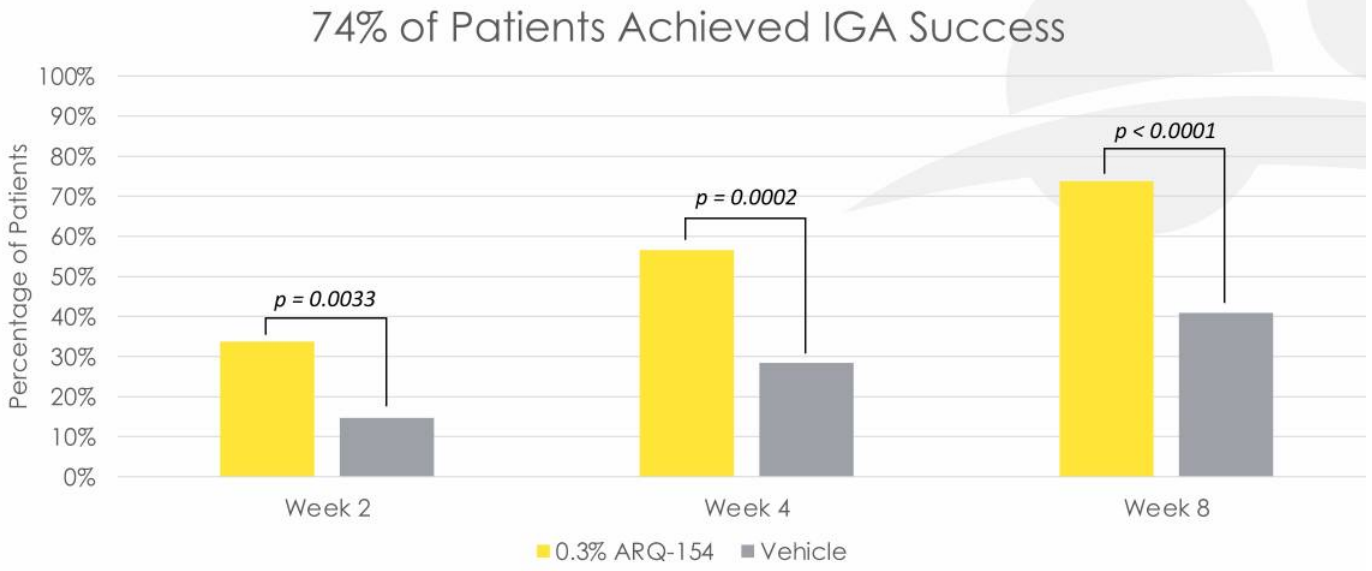
Demographics (Safety Population)

	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Age, mean (yrs)	45.3	44.2	44.9
Gender			
Male	76 (49.4%)	40 (55.6%)	116 (51.3%)
Female	78 (50.6%)	32 (44.4%)	110 (48.7%)
Ethnicity			
Hispanic or Latino	29 (18.8%)	16 (22.2%)	45 (19.9%)
Not Hispanic or Latino	125 (81.2%)	56 (77.8%)	181 (80.1%)
Race			
American-Indian or Alaskan Native	1 (0.6%)	0	1 (0.4%)
Asian	7 (4.5%)	1 (1.4%)	8 (3.5%)
Black or African-American	17 (11.0%)	6 (8.3%)	23 (10.2%)
Native Hawaiian or Other Pacific Islander	0	0	0
White	123 (79.9%)	62 (86.1%)	185 (81.9%)
Other	1 (0.6%)	2 (2.8%)	3 (1.3%)
More than one race	5 (3.2%)	1 (1.4%)	6 (2.7%)

Baseline Characteristics (Safety Population

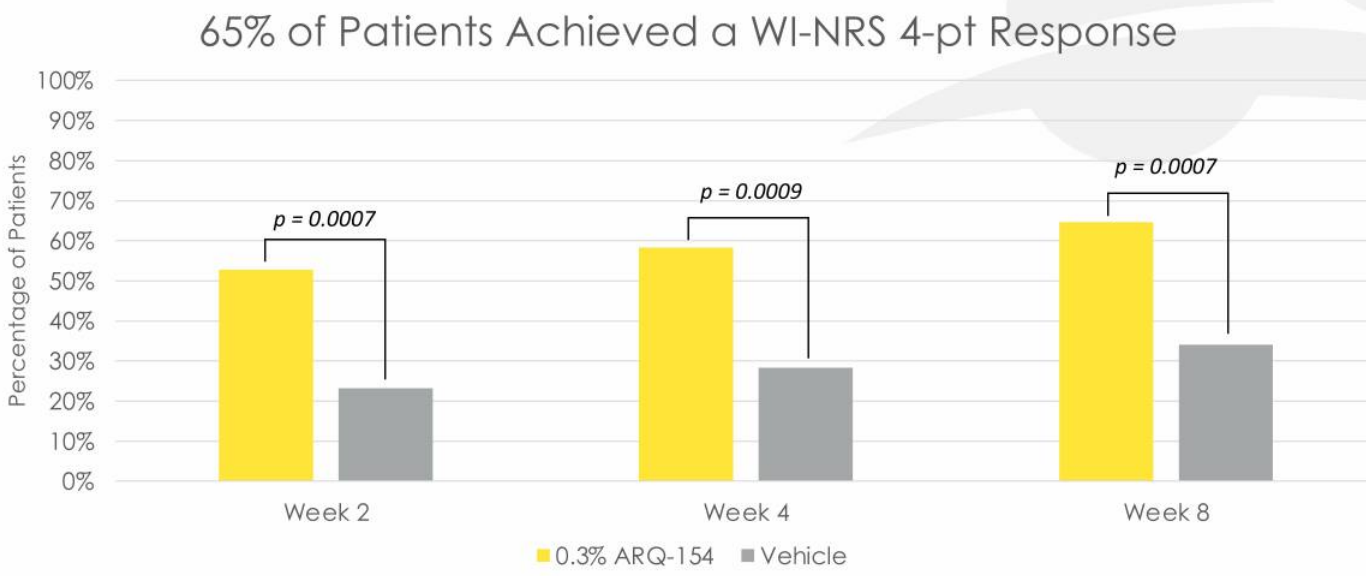
	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
BSA, mean (%)	3.3	3.0	3.2
Baseline IGA (0-4)			
3 – Moderate	141 (91.6%)	69 (95.8%)	210 (92.9%)
4 – Severe	13 (8.4%)	3 (4.2%)	16 (7.1%)
Baseline Erythema (0-3)			
2 – Moderate	135 (87.7%)	66 (91.7%)	201 (88.9%)
3 – Severe	19 (12.3%)	6 (8.3%)	25 (11.1%)
Baseline Scaling (0-3)			
2 – Moderate	130 (84.4%)	58 (80.6%)	188 (83.2%)
3 – Severe	24 (15.6%)	14 (19.4%)	38 (16.8%)
WINRS			
Mean	5.8 (2.66)	5.7 (2.33)	5.8 (2.56)
Median	6.0	6.0	6.0
≥4	125 (81.2%)	59 (81.9%)	184 (81.4%)
Facial involvement	100 (64.9%)	36 (50.0%)	136 (60.2%)

IGA Success at Each Visit (mITT)



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

WI-NRS 4-pt Response (PRU4 Population)



Low Rates of Adverse Events (Safety Population)

	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Subjects with any TEAE	37 (24.0%)	13 (18.1%)	50 (22.1%)
Subjects with any Tx-Related TEAE	3 (1.9%)	3 (4.2%)	6 (2.7%)
Subjects with any SAE	0	0	0
Subjects who discontinued Study Drug due to AE	2 (1.3%)	2 (2.8%)	4 (1.8%)
Subjects who discontinued Study due to AE	2 (1.3%)	1 (1.4%)	3 (1.3%)

Most Common TEAE's by Preferred Term ≥ 2% in any group

Preferred Term	ARQ-154 0.3% (N=154)	Vehicle (N=72)	Overall (N=226)
Contact Dermatitis	3 (2%)	2 (3%)	5 (2%)
Insomnia	3 (2%)	1 (1%)	4 (2%)
Nasopharyngitis	3 (2%)	0 (0%)	3 (1%)

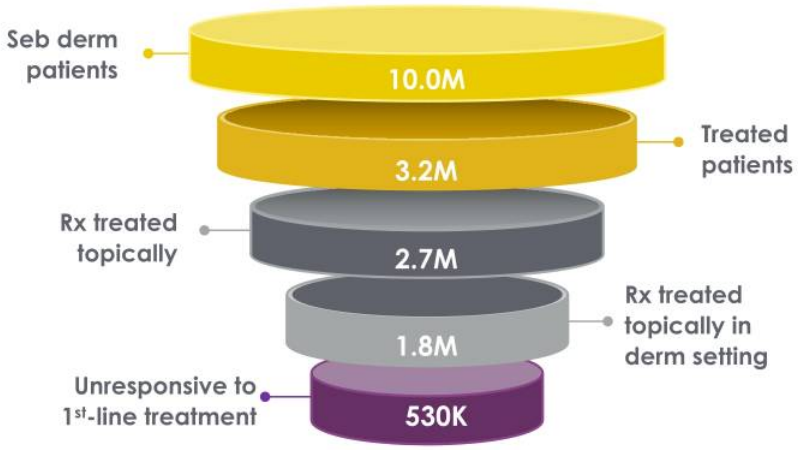
Dr. Matthew Zirwas, M.D.

Founder of the Bexley Dermatology Research Clinic and Investigator in the Trial

Ken Lock

Chief Commercial Officer

Seb Derm Prevalence



Additional opportunities to drive value in Seb Derm:

- Market growth due to educationa efforts and promotional investme
- U.S. patients treated by other specialties (e.g., PCPs)
- Ex-US markets

In Derm Offices the Volume and Severity Is In-line with Psoriasis

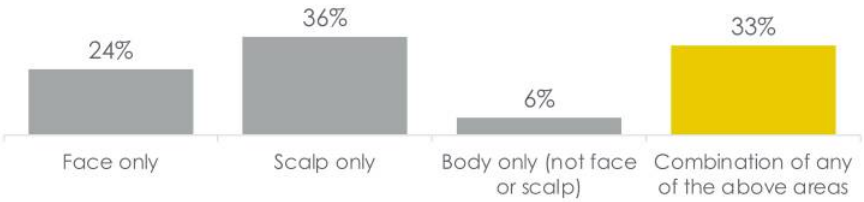
55 patients

average number o seborrheic dermat patients seen in a typical month

Severity of Seborrheic Dermatitis

41%	42%	17
Mild	Moderate	Sev

Symptoms Experienced in Each Area



From qualitative research and pilot interviews, most of the combinations HCPs are seeing ar **Face + Scalp**

Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

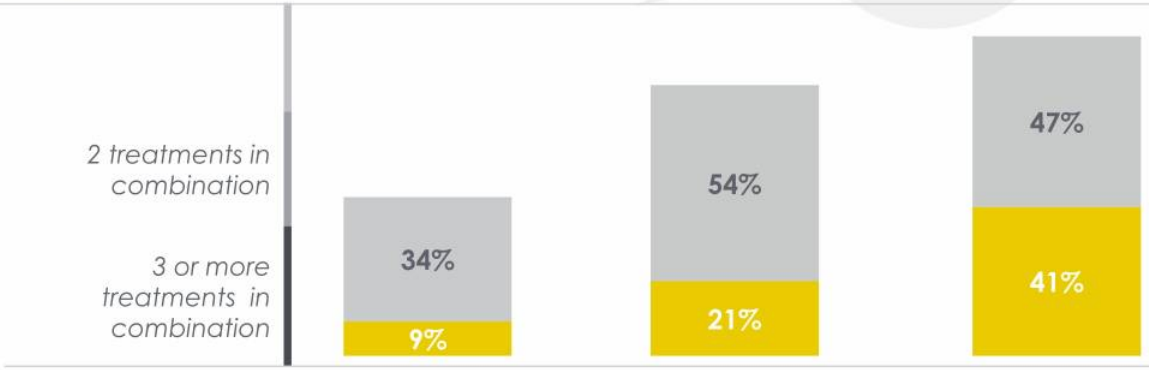
FDA Approved Seb Derm Treatment Optio

	Regimens	Side Effects	Approx List Price
LOCOID Solution *Hydrocortisone Butyrate 0.1%* Approved 1982	2-3x/ daily	Burning, itching, irritation, dryness, folliculitis (these reactions are listed in an approximate decreasing order of occurrence)	$65
LOPROX Shampoo *Ciclopirox 1%* Approved 1997	2x/ week for 4 weeks with a min of 3 days between applications	1% application site reaction 1% increased itching (n=626)	$55
XOLEGEL Gel *Ketoconazole 2%* Approved 2006	1x/ day for 2 weeks	4% application site burning (the most common treatment-related adverse reaction)	$970
EXTINA Foam *Ketoconazole 2%* Approved 2007	2x/ day	Burning: 10% Extina 10% vehicle	$785

* Data from USPIs of Select Products

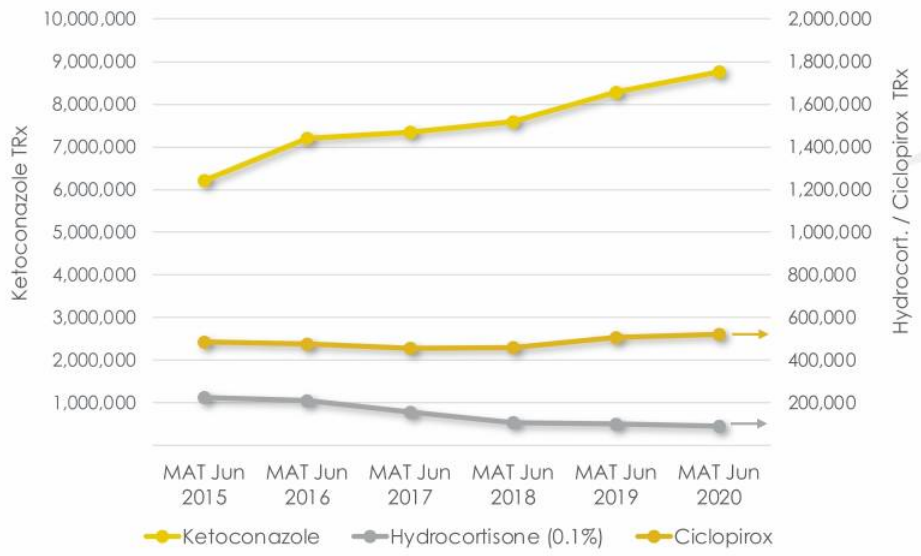
Most Patients Require 2 or More Products

	Mild	Moderate	Severe
% Patients getting 2 or more Treatments	43%	75%	88%



Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

TRx Trends for Approved Therapies



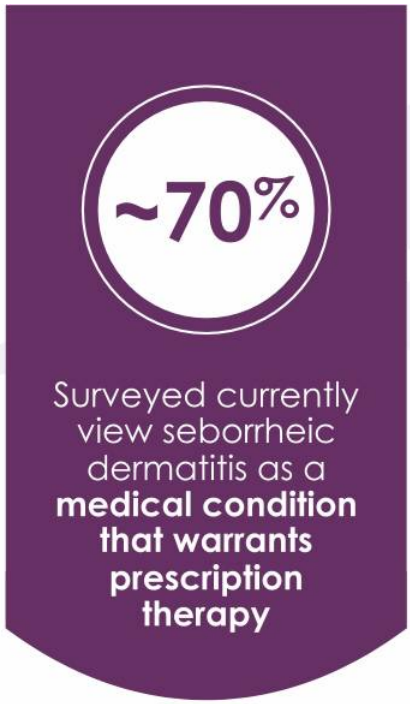
- There are >9M on-label T on an annual basis for FD Approved therapies
- Other off-label product are used (e.g. TCSs, TCI
- Ketoconazole is dominant therapy and utilization is growing

Source: IQVIA June 2020 Data

Payor Sentiment

Top National Pharmacy Benefit Managers and Health Plans representing over 80 million formulary lives were surveyed

- Seborrheic dermatitis is considered a **lower payer management priority** compared to conditions like psoriasis and atopic dermatitis
- Review of current medical policies of top National PBMs and Health Plans demonstrate Rx coverage and **benefit exclusions are rare**
- Payers expressed **minimal budget impact and superior efficacy** were the most likely ways for a brand product to avoid management in predominantly generic/OTC categories



Source: Arcutis Payer market research (August 2020, n=25)

High Interest in Roflumilast Foam

Dermatologist Likelihood to Prescribe Roflumilast Foam

Provides another possible option for these difficult-to-treat cases.(…) *The most important symptoms for most patients is the itching.*

Very, very excited that a PDE inhibitor would come to market especially in a ***foam vehicle and a non-steroidal****!"*

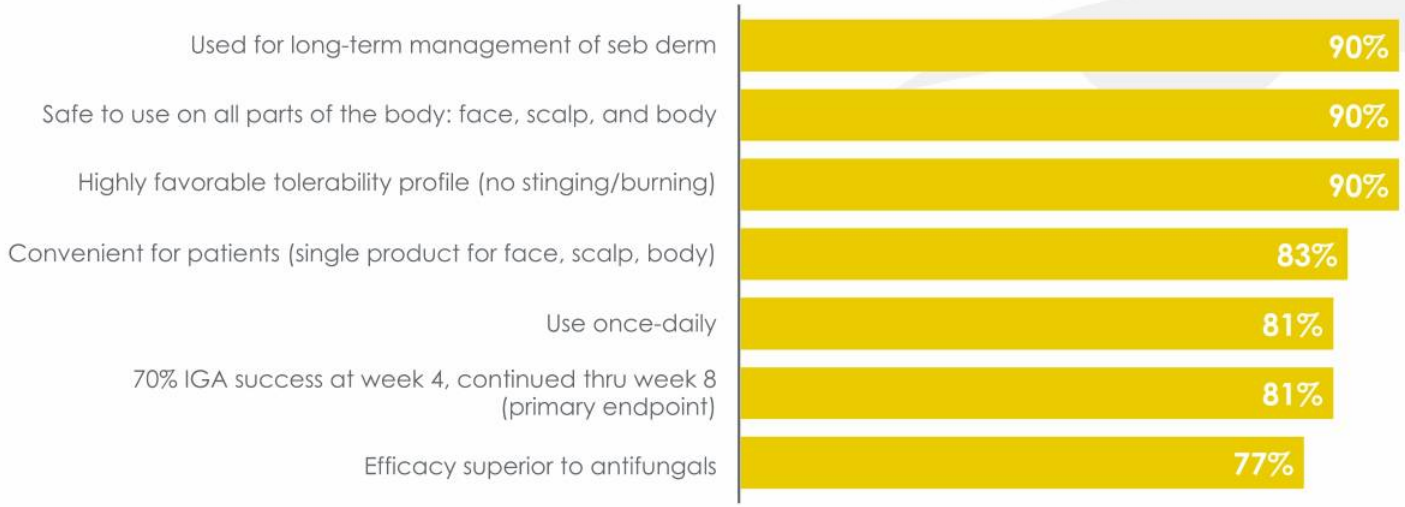
It sounds like an attractive optior as it is a foam and thus ***can be used on the scalp and face.*** *I als like that it does not have alcohol which may sting the skin. It's grea that it is not a topical steroid and the time frames listed for improvement are reasonable."*

Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

Most Compelling Aspects of Roflumilast Foa

Compelling Product Profile Statements

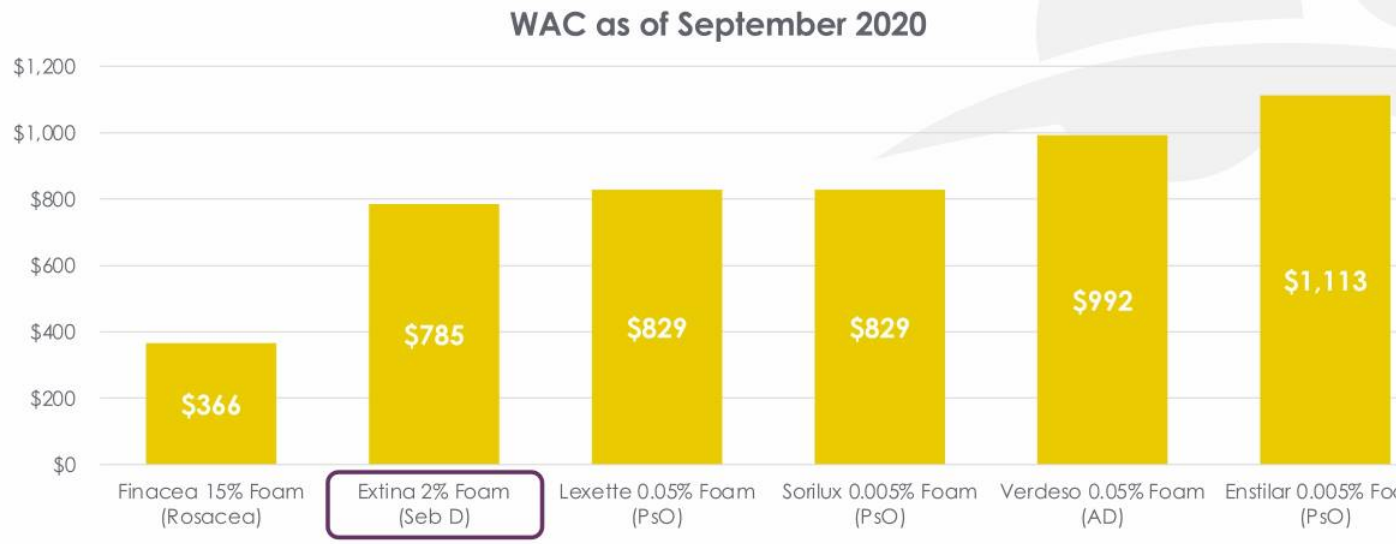
(top 2 – very/extremely compelling)



Arcutis Quantitative Seb Derm Research August 2020, n=100 Dermatology HCPs

Pricing of Current Foam Therapies

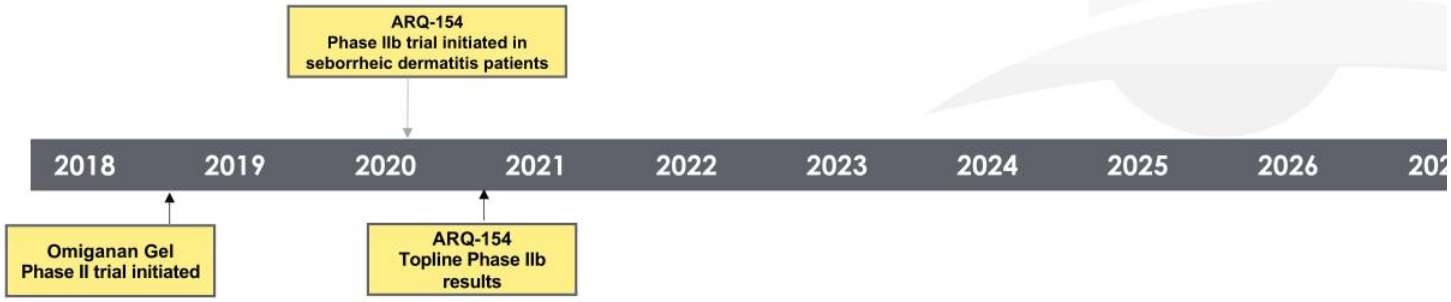
Ranges from ~$365 - $1100



Source: ProspectRx, September 2020

Seb Derm Competitive Pipeline

Development timeline for Seb Derm therapies



- 1.75% BID Gel
- Facial SD Only
- Mild to Moderate Pts
- Antifungal MOA

Source: Clintrials.gov Sept 2020 Seborrheic Dermatitis Trials

~5 Million Patients Currently Treated Topically by Dermatologists in US

US Patient Populations (Millions)

	Psoriasis	Atopic Dermatitis	Seborrheic Dermatiti
Prevalence	8.6	19.2	10.0
Rx treated	3.5	6.3	2.7
Topically treated	2.5	5.4	2.7
Rx treated in Derm Setting	2.8	1.2	1.8
Rx treated (Topically) in Derm Setting	**2.0**	**1.0**	**1.8**

Additional opportunities to unlock value of our molecules:

- U.S. patients treated by other specialties (e.g., PCPs or pediatricians)
- Ex-US markets

If Approved, Roflumilast Foam:

Novel Mechanism

- Will be first treatment in decades to offer a novel mechanism of action for the treatment of seb derm

"Best in Class"

- Has potential to be a "best in class" treatment for patients with seb derm

Convenience

- Will be an easy-to-use, once daily, single treatment option f both scalp and face/body

Suitability

- Will be suitable for use in hair-bearing areas (unlike creams), as well as face and around the eyes (unlike steroids)

The Potential of Roflumilast Foam

Current Treatments

- No single product works for scalp, face and body
- Most patients need an arsenal of products to manage disease
- Steroids not meant to be used chronically
- Shampoos can be drying

Roflumilast Foam

- Roflumilast can be used on all body areas, including hair-bearing
- Once-a-day roflumilast offers the convenience of a single product
- Has shown efficacy and is well tolerated – suitable for long-term us
- Dries quickly, is unscented and contains no drying ethanol

Thank You