

**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): October 19, 2023

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

Delaware  
(State or other jurisdiction  
of incorporation)

001-39186  
(Commission  
File Number)

81-2974255  
(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 2.02 Results of Operations and Financial Condition.**

Arcutis Biotherapeutics, Inc. (the “Company”) is disclosing certain preliminary financial results as of and for the three months ended September 30, 2023.

While the Company has not finalized its full financial results as of and for the quarter ended September 30, 2023, the Company expects to report that for the three months ended September 30, 2023, the Company generated total revenues of approximately \$38.1 million, which comprised net product revenue of approximately \$8.1 million and other revenue of \$30.0 million. Net product revenue was driven by demand growth for ZORYVE and sequential improvement in gross-to-net revenue compared to the prior quarter. Gross-to-net percentage for the three months ended September 30, 2023 was in the low 70 percent range. Other revenue comprised an upfront payment of \$30.0 million under the Company’s License Agreement entered into with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd., a wholly owned subsidiary of Huadong Medicine Co., Ltd., on August 10, 2023. In addition, the Company expects to report it had approximately \$228.1 million of cash, cash equivalents, restricted cash and marketable securities as of September 30, 2023. During the quarter, the Company continued its selective pursuit of partners to commercialize products in the United States outside of dermatology offices, including in the primary care setting, and to develop and commercialize products in Japan and other territories outside of the United States, Greater China and Southeast Asia. In addition, the Company implemented steps to drive efficiencies and enhance its financial flexibility, including headcount reductions, to align with its previously announced pipeline reprioritization. The Company continues to evaluate and explore opportunities for further efficiencies and cost savings.

These amounts are preliminary, have not been audited and are subject to change pending completion of the Company’s unaudited financial statements for the quarter ended September 30, 2023. Additional information and disclosures would be required for a more complete understanding of the Company’s financial position and results of operations as of and for the quarter ended September 30, 2023.

The Company’s independent registered public accounting firm has not audited, reviewed, compiled, or applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, the Company’s independent registered public accounting firm does not express an opinion or any other form of assurance with respect thereto. It is possible that the Company or its independent registered public accounting firm may identify items that require the Company to make adjustments to the financial information set forth above. Accordingly, undue reliance should not be placed on these preliminary estimates.

The information contained in Item 2.02 is furnished to and not filed with the Securities and Exchange Commission, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended (the “Securities Act”), or the Securities Exchange Act of 1934, as amended (the “Exchange Act”), regardless of any general incorporation language in any such filing or document, except as shall be expressly set forth by specific reference in such filing.

**Cautionary Statement Regarding Forward-Looking Statements**

This Current Report on Form 8-K contains certain “forward-looking” statements as that term is defined by Section 27A of the Securities Act and Section 21E of the Exchange Act. Statements that are predictive in nature, that depend on or relate to future events or conditions, or that include words such as “believes”, “anticipates”, “expects”, “may”, “will”, “would,” “should”, “estimates”, “could”, “intends”, “plans” or other similar expressions are forward-looking statements, including the Company’s preliminary financial results as of and for the three months ended September 30, 2023 and its continued pursuit of partners. These forward-looking statements are based on the Company’s current assumptions, expectations and beliefs and are subject to numerous risks, including, among other things, those set forth under the caption “Risk Factors” in the Company’s most recent filings with the Securities and Exchange Commission, uncertainties, assumptions and changes in circumstances that may cause the Company’s actual results, performance or achievements to differ materially from those expressed or implied in any forward-looking statement. The Company cautions investors not to place undue reliance on the forward-looking statements contained in this Current Report on Form 8-K.

---

Further information on these and other factors that could affect the Company's financial results and the forward-looking statements in this Current Report on Form 8-K is included in the Company's filings with the Securities and Exchange Commission, including, among others, the Company's Annual Report on Form 10-K for the year ended December 31, 2022, particularly under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Company undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

**Item 8.01 Other Events.**

On October 19, 2023, the Company posted an updated corporate presentation to the investor section of the Company's website. The updated corporate presentation includes information regarding, among others, (i) recent U.S. Food and Drug Administration approval of the Company's supplemental new drug application to expand the indication of ZORYVE (roflumilast) cream 0.3% for the topical treatment of plaque psoriasis, including psoriasis in intertriginous areas (e.g., groin or axillae), to children ages 6 to 11 years of age; and (ii) recently announced positive data from the Company's pivotal "INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis in PEDiatric patients" (INTEGUMENT-PED) trial and long-term "INterventional Trial EvaluatinG roflUMilast cream for the treatmENt of aTopic dermatitis Open Label Extension" (INTEGUMENT-OLE) study. 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 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 the presentation in this Current Report on Form 8-K, 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Company Presentation dated October 19, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**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: October 19, 2023

By: /s/ Todd Franklin Watanabe  
Todd Franklin Watanabe  
Chief Executive Officer



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; current and 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.

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.

For further information with respect to Arcutis, we refer you to our most recent annual report on Form 10-K, as amended, and our most recent quarterly report on Form 10-Q, filed with the SEC. In addition, we are subject to the information and reporting requirements of the Securities Exchange Act of 1934 and, accordingly, we file periodic reports, current reports, proxy statements and other information with the SEC. These periodic reports, current reports, proxy statements and other information are available for review at the SEC's website at <http://www.sec.gov>.

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

# Our Strategy to Build the Preeminent Immuno-Dermatology Company



## Filling the innovation gap

in the dermatology drug sector



## Elevating the standard of care

to simplify disease management and optimize drug efficacy, safety, and tolerability



## Developing potential best-in-class

and innovative topical dermatology therapies against **validated biological targets**



## World-class leadership team

>50 FDA-approved products



## Rapidly advancing

a **broad, innovative pipeline** with strong IP protection for clinical assets

FDA = U.S. Food and Drug Administration; IP = intellectual property

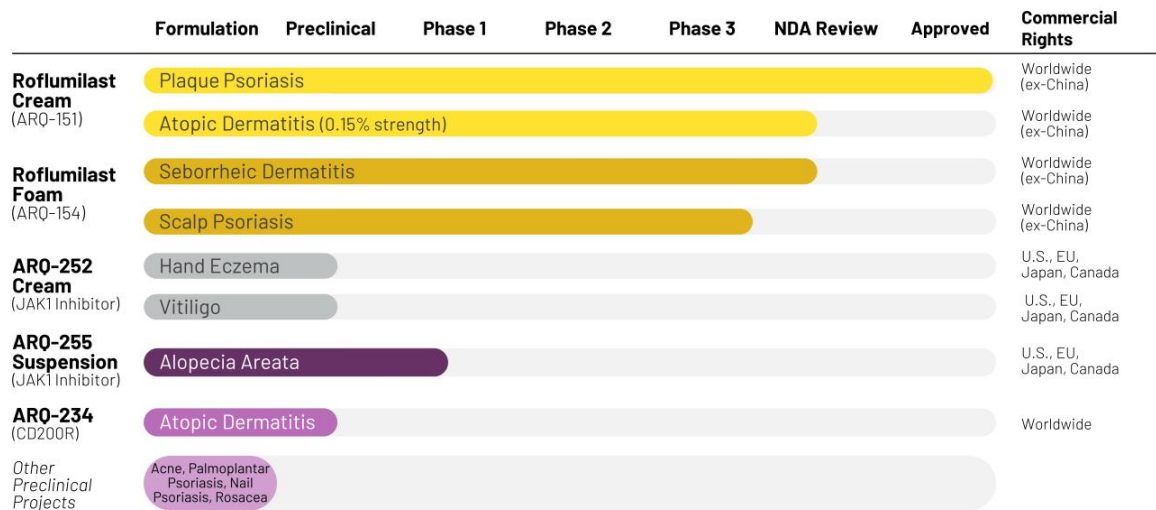
# Recent Business Updates – Laying the Groundwork for Long-Term Growth

- ✓ ZORYVE® (roflumilast) cream 0.3% launch building momentum with ~100,000 TRx launch-to-date; new Chief Commercial Officer on-board
- ✓ \$8.1 million in ZORYVE net product revenues for Q3 2023, reflecting sequential demand growth and a GTN % in the low 70s; \$38.1 million in total revenues for the quarter with Huadong upfront
- ✓ Filed sNDA for roflumilast cream 0.15% in atopic dermatitis down to age of 6; expect Q3 '24 approval and potential launch
- ✓ Announced positive results from INTEGUMENT-OLE showing durable and improving efficacy in atopic dermatitis
- ✓ Announced positive results in atopic dermatitis from INTEGUMENT-PED trial with roflumilast cream 0.05% in children ages 2-5
- ✓ Strengthened capital position with Huadong outlicense, ~\$228 million cash<sup>1</sup> as of 9/30/23

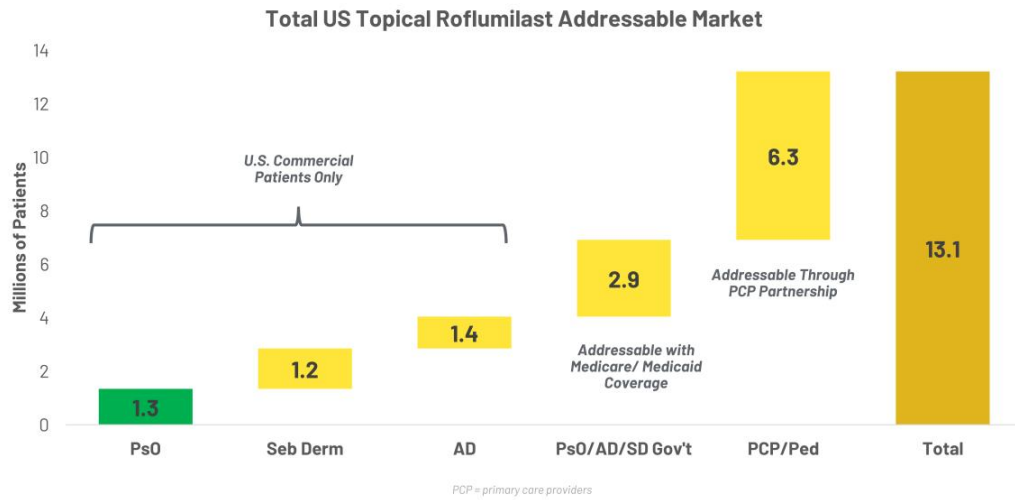
TRx = total prescriptions; GTN = gross-to-net; sNDA = supplemental New Drug Application; <sup>1</sup>Cash, Restricted Cash, Cash Equivalents, and Marketable Securities as of September 30, 2023. This slide contains preliminary financial information for the three months ended September 30, 2023. This information is based upon our estimates and is subject to the completion of our financial closing procedures. Our actual results may differ from these estimates due to the completion of our financial closing procedures and final adjustments and other developments that may arise between now and the time our final quarterly financial statements are completed. There can be no assurances that these estimates will be realized, and estimates are subject to risks and uncertainties, many of which are not within our control.



# Broad and Deep Pipeline Continues to Progress



# Topical Roflumilast: Total Patient Opportunity Potential to Grow ~10X



# Arcutis Enjoys Strong IP Protection

<b>19</b>	<b>Issued U.S. and foreign patents relating to topical roflumilast formulations</b>	<b>1</b>	Pending U.S. patent applications on novel restorative effect of the roflumilast cream vehicle
<b>3</b>	<b>Issued U.S. patents for method of treatment using topical roflumilast</b>	<b>1</b>	Pending U.S. patent application on use of a critical ingredient in topical roflumilast formulations
<b>3</b>	<b>Issued foreign patents for use of a critical ingredient in topical roflumilast formulations</b>	<b>3</b>	Pending U.S. patent applications for the Deep Dermal Drug Delivery (4D) Technology underlying ARQ-255
<b>1</b>	<b>Issued U.S. patent on anti-fungal properties of roflumilast</b>	<b>1</b>	Issued U.S. patent for novel JAK1 inhibitor formulation (ARQ-252)



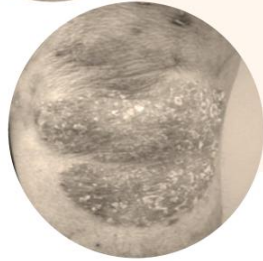
<sup>1</sup>As of 9/31/23; PK = pharmacokinetics; PDE4 = phosphodiesterase 4; JAK = Janus Kinase

# Plaque Psoriasis - Significant Unmet Needs in Treatment Paradigm



**~9M**

individuals in the U.S. affected



**>90%**

of U.S. patients treated with topical drugs

Past topical therapies have **numerous shortcomings**

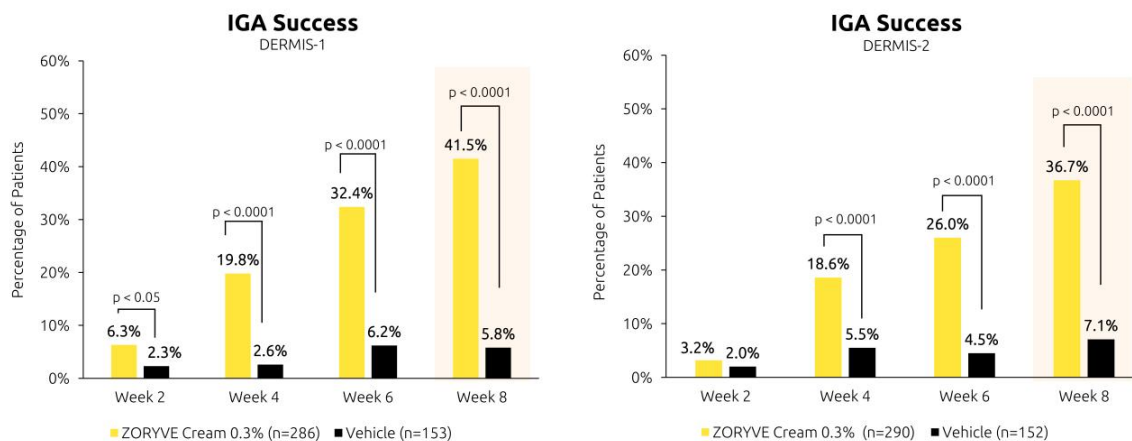
Physicians and patients forced to trade-off between efficacy and safety/tolerability

**81%**

of patients wish they had more topical treatment alternatives to steroids<sup>1</sup>

<sup>1</sup> Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals, March 2022

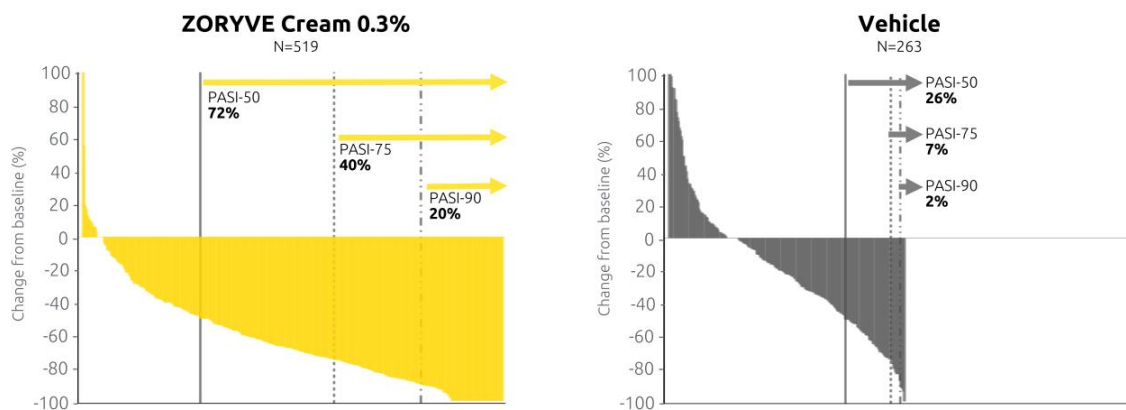
# Rapid, Robust Efficacy on IGA Success in Both Phase 3 DERMIS Trials in Plaque Psoriasis



IGA = Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; ITT Population  
 Statistical analysis based on multiple imputation; Week 2, 4, and 6 consistent with label

# ZORYVE Delivered Clinically Meaningful Response in 3 out of 4 Patients

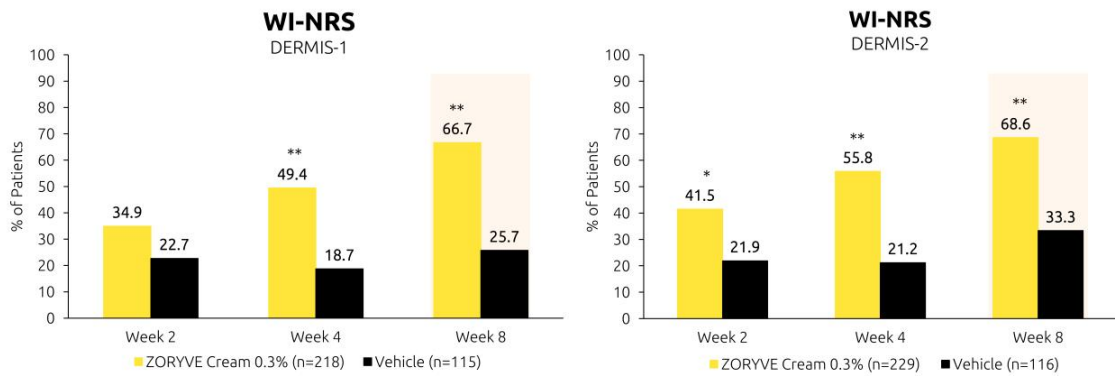
% Change in PASI Total Score at Week 8 - Pooled DERMIS Trials



PASI = Psoriasis Area and Severity Index

# Rapid Reduction of Itch in DERMIS-1 and DERMIS-2

Proportion of patients who achieved a  $\geq 4$ -point improvement in WI-NRS from baseline score of  $\geq 4$



**Robust reduction in itch occurs early and consistently improves through Week 8**

\*P < 0.001; \*\*P < 0.0001; Evaluated in a subset of the intent-to-treat population of patients with WI-NRS pruritus score  $\geq 4$  at baseline; WI-NRS: Worst Itch Numeric Rating Scale  
Statistical analysis based on multiple imputation

# ZORYVE Ps0 Launch Continues to Strengthen

~ 100,000 TRx Launch-to-date



Data Source: ZORYVE - IDVIA SMART Rapid data through week ending 9/29/23





~80% Commercial Coverage in the U.S.;  
>90% Lives Covered Without PA



**Total US Commercial Market = 165 million lives**

**Covered Commercial Lives = >130 million**

**Positive Halo Building on Prescriber Confidence with Coverage**

PA = prior authorization; Source: MMIT

# Progress Towards Sustained ZORYVE Growth

## Commercial Success



### Drive Prescriber Awareness and Use

- ~8,500 unique writers since launch



### Patient Engagement and Positive Experience

- Refills building nicely each quarter
- Live with focused connected TV campaign in Q3



### Broad, High-Quality Access

- ~132 million commercial lives covered
- >90% of coverage without a PA

## Investing to Fuel the Next Leg of this Launch

# Atopic Dermatitis: Compelling Opportunity for Roflumilast Cream



## Very large, established market

- ~26 million individuals in U.S. affected
- 12% prevalence in children<sup>2</sup>
- Need for safe/effective therapy



## Significant unmet need

for safe, effective non-steroidal therapy suitable for chronic use

## Roflumilast Cream

### Atopic Dermatitis Profile

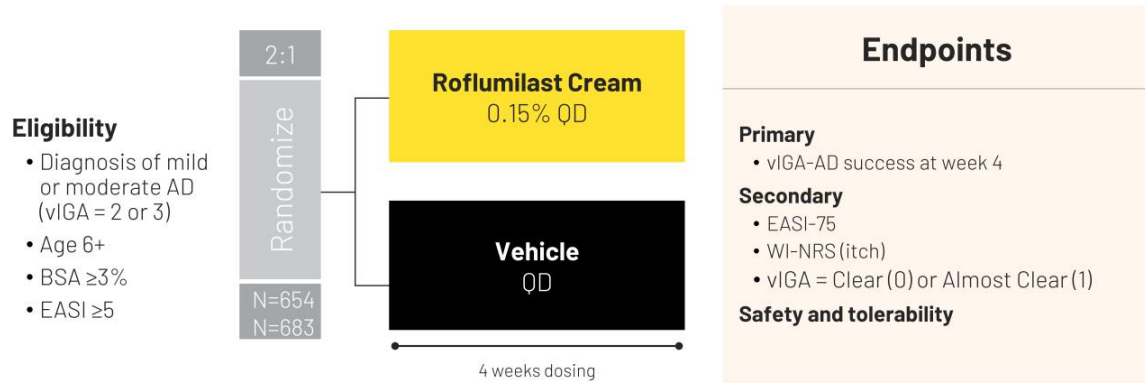
Closely aligned with needs of:

1. Physicians
2. Patients
3. Parents
4. Payors

<sup>2</sup>Silverberg, JI, Dermatol Clin 35 (2017) 283-289

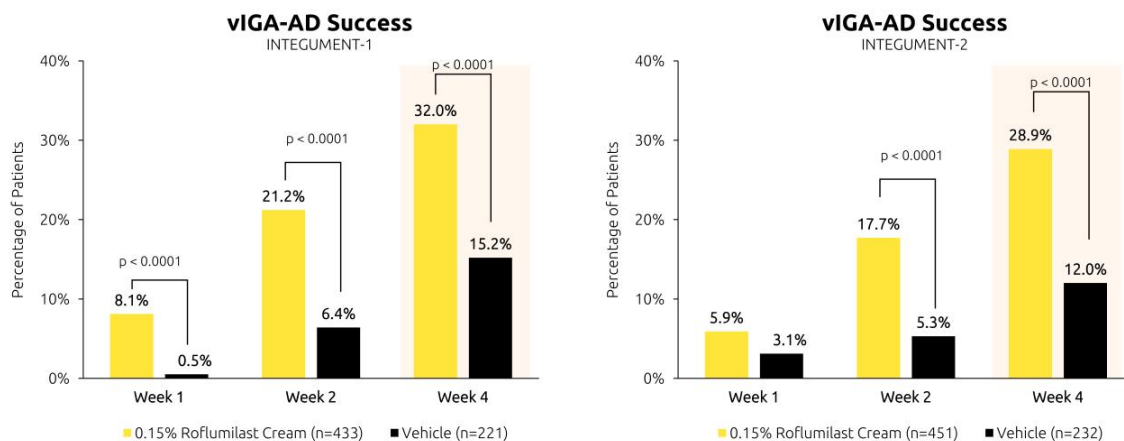
# INTEGUMENT-1 & -2 Phase 3 Atopic Derm Trials

Randomized, Double-blind, Vehicle-controlled, Multicenter Trials  
(Two identical, parallel Phase 3 trials)



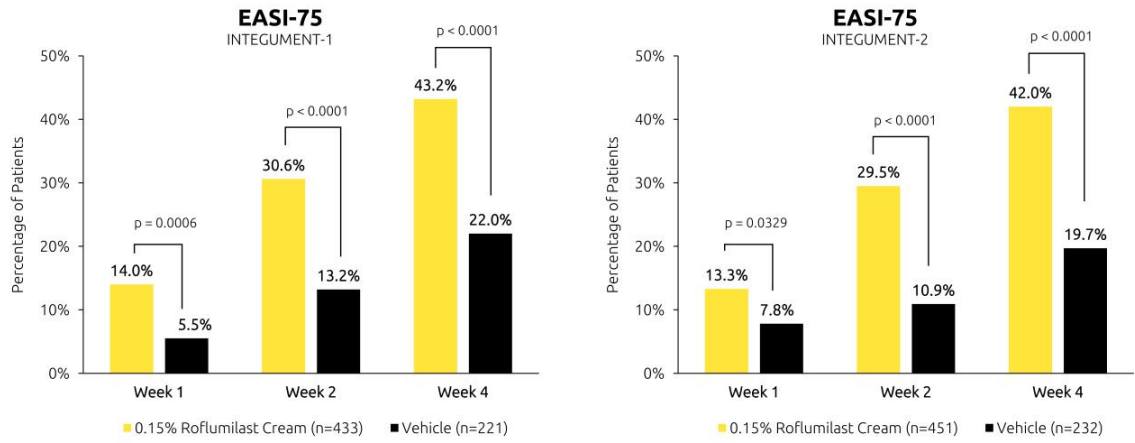
vIGA - Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; BSA = body surface area; EASI = eczema area severity index; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day dosing

# Rapid, Robust Efficacy on IGA Success Observed in Both Phase 3 Atopic Dermatitis Trials



vIGA = Validated Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; ITT Population  
 Statistical analysis based on multiple imputation

# Over 40% of Patients Achieved EASI-75 at Week 4



EASI-75 = 75% improvement from baseline

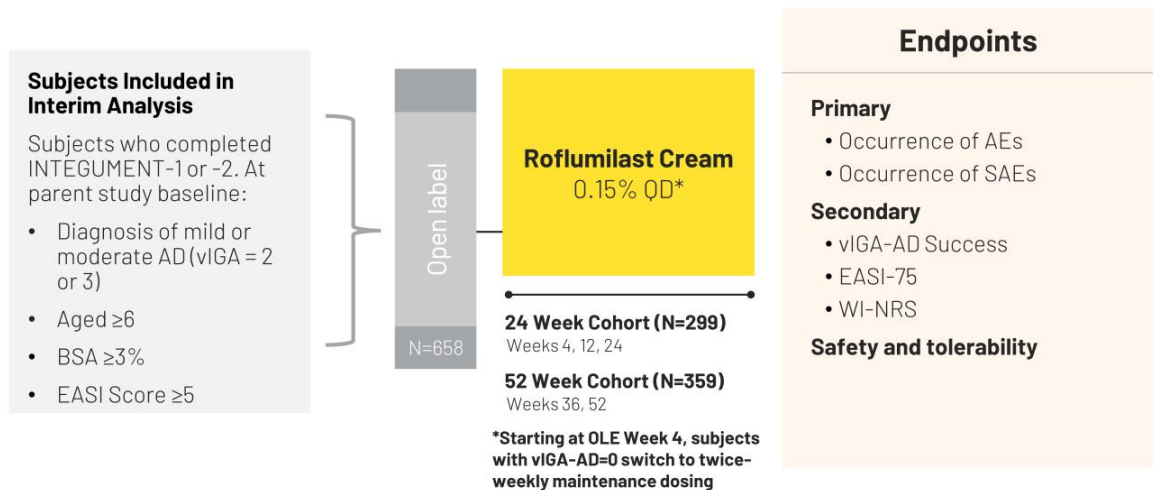
## Roflumilast Cream Was Well-Tolerated in Phase 3 Trials

Subjects (%)	INTEGUMENT-1		INTEGUMENT-2	
	Roflumilast 0.15% (n=433)	Vehicle (n=221)	Roflumilast 0.15% (n=452)	Vehicle (n=230)
Subjects with any TEAE	92 (21.2%)	35 (15.8%)	102 (22.6%)	30 (13.0%)
Subjects with any Treatment-Related TEAE	27 (6.2%)	4 (1.8%)	26 (5.8%)	8 (3.5%)
Subjects with any SAE	4 (0.9%)	0	4 (0.9%)	0
Subjects with treatment-related SAE	0	0	2 (0.4%)	0
Subjects who discontinued Study due to AE	6 (1.4%)	3 (1.4%)	8 (1.8%)	2 (0.9%)

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

# INTEGUMENT-OLE Phase 3 Atopic Dermatitis Trial

Open Label, Long-Term, Multicenter Trial





# Long-Term Safety and Tolerability Profile Consistent With INTEGUMENT-1 & -2 in AD

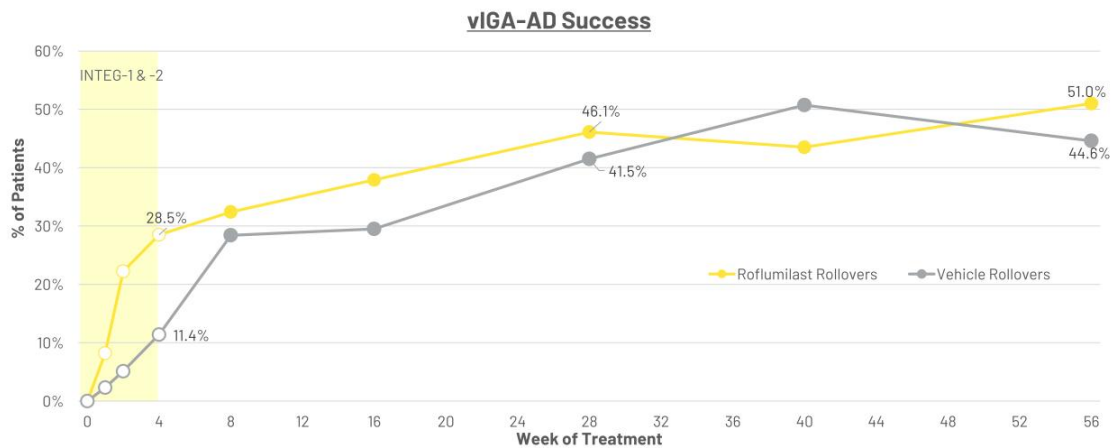
Subjects (%)	Overall (n=657)
Subjects with any TEAE	241 (36.7%)
Subjects with any Treatment-Related TEAE	31 (4.7%)
Subjects with any SAE	8 (1.2%)
Treatment-related SAE	0
Subjects who discontinued Study due to AE	21 (3.2%)

## Most Common TEAEs by Preferred Term (≥ 2% overall)

Subjects, n (%) Preferred Term	Roflumilast cream 0.15% (N=657)
COVID-19	30 (4.6%)
Upper respiratory tract infection	21 (3.2%)
Nasopharyngitis	20 (3.0%)
Headache	18 (2.7%)

**No New Safety Signals Observed Up to 56 Weeks of Treatment**

# Durable & Improving Response on IGA Success Over Time

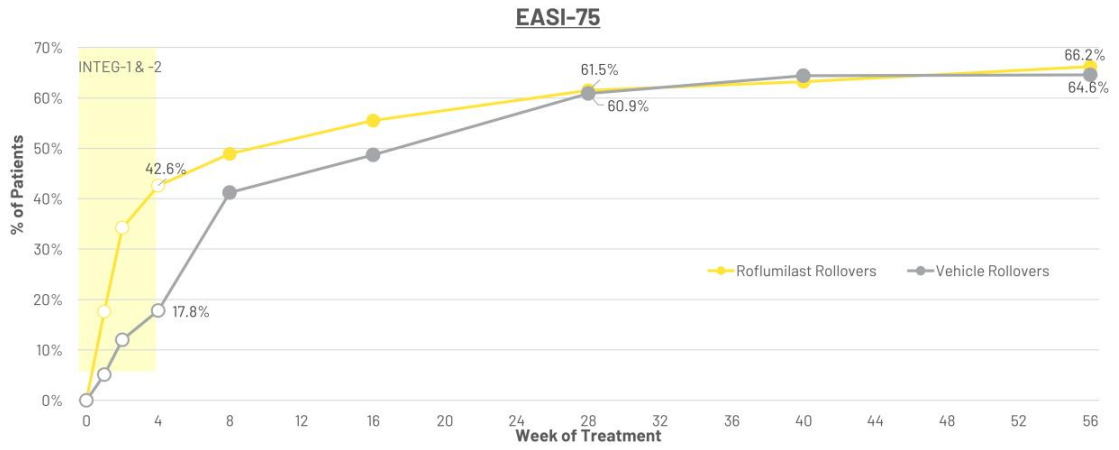


vIGA-AD success = achievement of IGA=0/1 plus 2-grade improvement from Parent Study Baseline. Observed cases.

At Week 4, Roflumilast Rollovers = n of 439, Vehicle Rollovers = n of 219. At Week 28, Roflumilast Rollovers = n of 319, Vehicle Rollovers = n of 159. At Week 56, Roflumilast Rollovers = n of 145, Vehicle Rollovers = n of 65.



# Durable & Improving Response on EASI-75 in INTEGUMENT-OLE Trial



75% EASI improvement from Parent Study Baseline, Observed Cases.

At Week 4, Roflumilast Rollovers = n of 439, Vehicle Rollovers = n of 219. At Week 28, Roflumilast Rollovers = n of 325, Vehicle Rollovers = n of 161. At Week 56, Roflumilast Rollovers = n of 145, Vehicle Rollovers = n of 65.



# First Large Trial to Demonstrate Maintenance Dosing

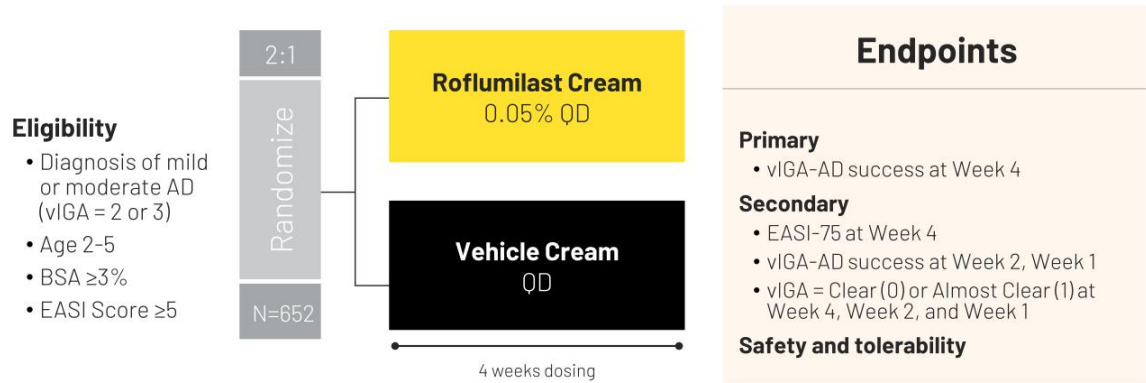
- Starting at Week 4 of INTEGUMENT-OLE, participants who achieved vIGA-AD score of clear (0) switched to twice weekly maintenance dosing
- Disease control was defined by maintaining twice weekly dosing with vIGA-AD score of clear (0) or almost clear (1)
- Participants were to resume once-daily dosing if signs or symptoms were not adequately controlled, or if they reached if vIGA-AD of mild (2)



**> 2/3** of these participants remained on twice weekly schedule for **> 50%** of their time in study

# INTEGUMENT-PED Phase 3 Atopic Dermatitis Trial

Parallel group, Double-blind, Vehicle-controlled, Multicenter Trial

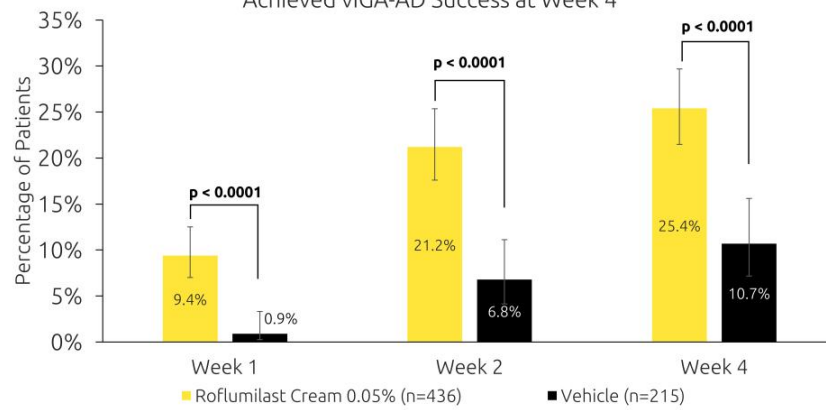


vIGA = Validated Investigator's Global Assessment; vIGA-AD Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; BSA = body surface area; EASI = eczema area severity index; QD = once a day dosing

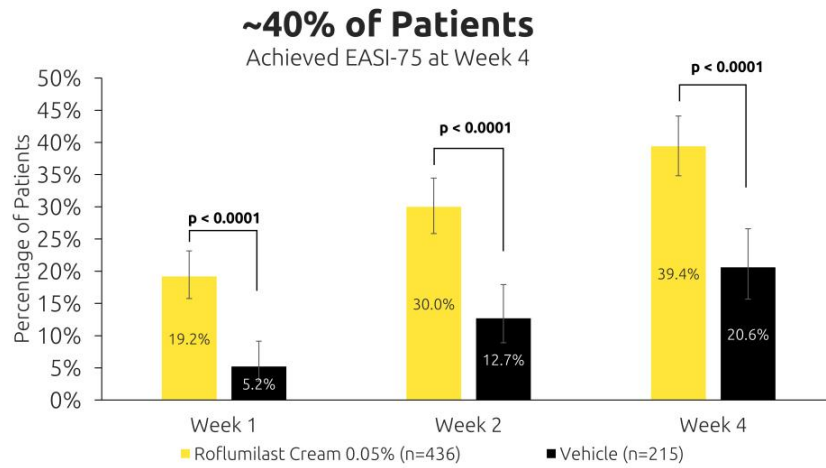
# Rapid, Robust Efficacy on IGA Success Observed, Consistent With INTEGUMENT-1 & -2

**~25% of Patients**

Achieved vIGA-AD Success at Week 4



# ~40% of Patients Achieved EASI-75 at Week 4



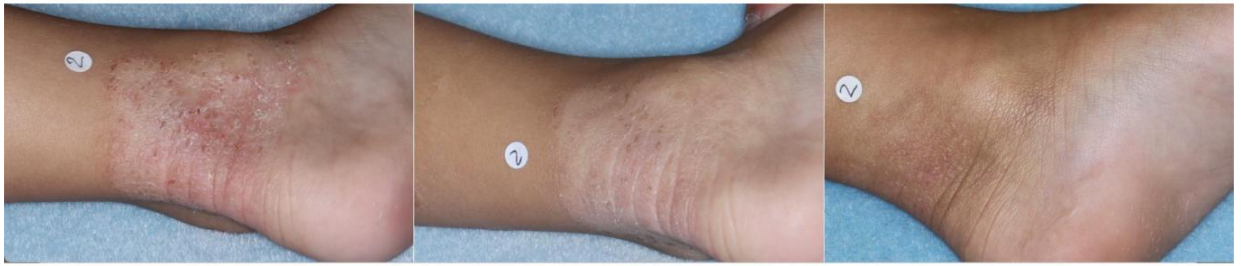
EASI-75 = 75% improvement from baseline

# Rapid Response to Treatment With Roflumilast Cream

Baseline  
vIGA-AD = 3

Week 1  
vIGA-AD = 1

Week 4  
vIGA-AD = 1



*Individual results may vary*



# Roflumilast Foam – Significant, Underappreciated Opportunity for Arcutis

## Scalp

- 40% of plaque psoriasis sufferers have scalp involvement
- Competitive differentiation in psoriasis

## Seb Derm

- As big a market as psoriasis, with no products promoted or in development



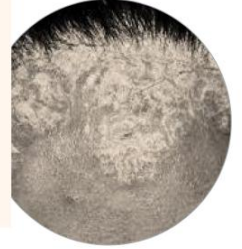
# Scalp Psoriasis - Roflumilast Foam May Address Unmet Needs

**~40%**

of Plaque Psoriasis sufferers have scalp involvement

## Roflumilast foam ideal for scalp and body psoriasis

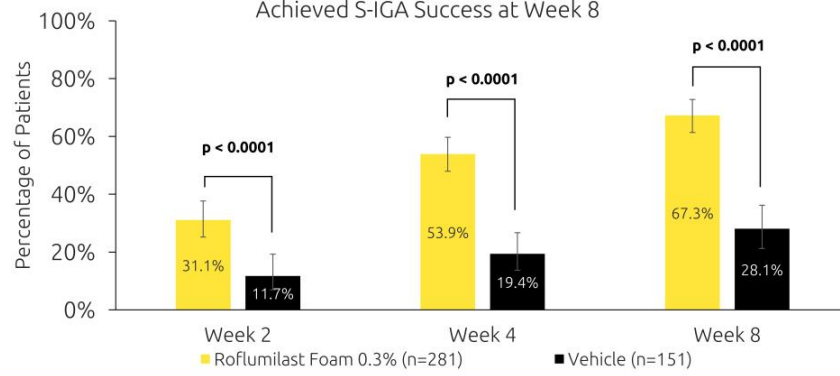
- Suitable for chronic use
- Foam is ideal for hair-bearing areas such as scalp, where cream, lotion, or ointment is not suitable
- Unlike most other options, single treatment for all areas of the body
- May be used near the eyes
- Rapid and robust impact on itch



# Robust Efficacy on Scalp IGA Success in Pivotal Phase 3 ARRECTOR Trial

**~2/3 of Patients**

Achieved S-IGA Success at Week 8



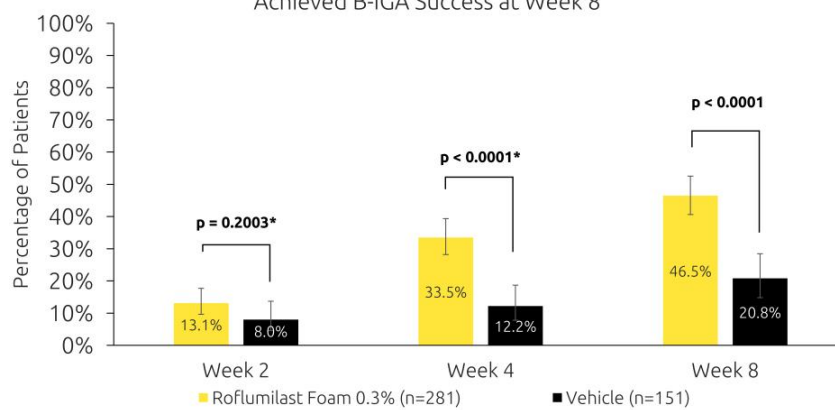
40% of Patients Achieved S-IGA of Clear at Week 8

S-IGA = Scalp Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline ITT Population

# Demonstrated Efficacy on Body IGA Success in ARRECTOR Trial, Consistent With DERMIS Trials

**~47% of Patients**

Achieved B-IGA Success at Week 8



B-IGA = Body Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline ITT Population; \* Nominal p-values

# Seborrheic Dermatitis – Significant Unmet Needs in Treatment Paradigm

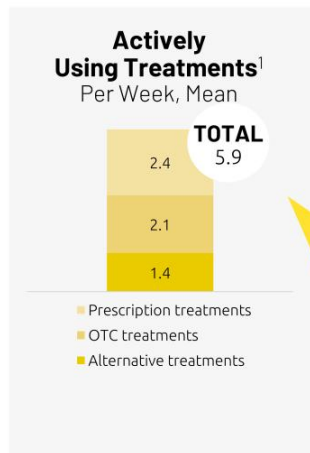
**~10  
million**

Individuals in the  
U.S. affected

- Itchy red patches covered by greasy / flaking scales on scalp, face, and chest
- Topicals dominate treatment, but options pose challenges:
  - Steroids pose safety issues, especially with chronic use
  - Proximity to eyes/thin skin on face exacerbates safety concerns
  - Topical antifungals offer only modest efficacy
  - Polypharmacy



# Seb Derm Patients Require Complex and Onerous Treatment Regimens



**9 in 10** AGREE<sup>1</sup>  
"I would be more likely to stick with a treatment plan if it meant using fewer treatments."

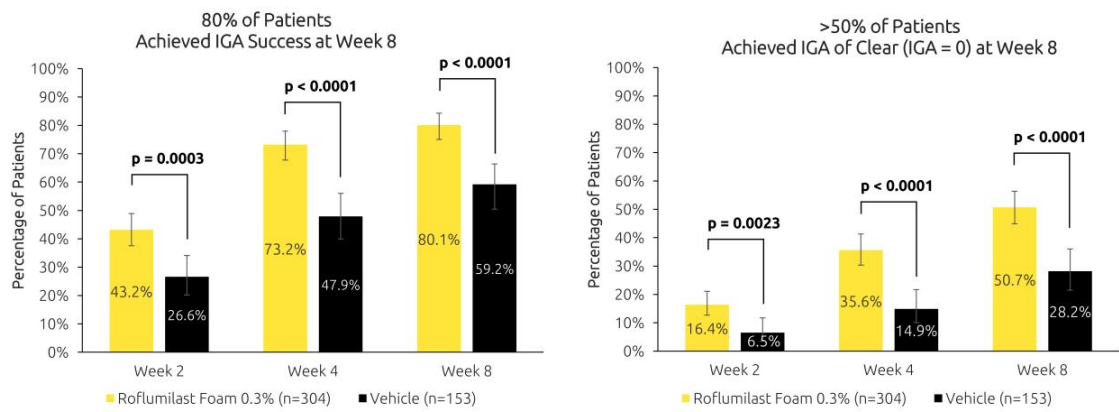
**Patients ready for new options**

“I am interested in trying new treatment options.”

**9 in 10** AGREE<sup>1</sup>

<sup>1</sup>Harris Pall Seborrheic Dermatitis Survey (n>600 HCPs, n=300 patients)  
OTC = over the counter; HCP = healthcare professional

# 80% of Patients Achieved IGA Success & 50% Completely Clear at 8 Weeks in Seb Derm Phase 3



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

# Alopecia Areata (AA) – Significant Unmet Needs

## **Autoimmune, chronic, and relapsing hair loss**

ranging from scattered patches to complete loss of hair

## **Significant psychosocial impact**

on self-esteem, body image, and/or self-confidence

## **Significant treatment gaps**

- Standard of care includes topical steroids or steroid injections
- Most development focused on oral/systemic therapies targeting more severe disease
- Topical therapy well-positioned for more common mild-to-moderate disease





# Barriers to Topical Drug Delivery to the Hair Bulb

## Drug delivery challenge

suggested by failure of topical JAKi approach, coupled with success of oral JAKs

## Inflammation in AA

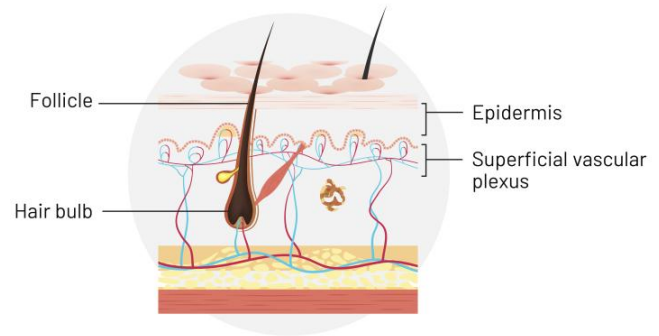
surrounds the hair bulb

## Challenges to topical treatment

- Depth of inflammation
- Dense vasculature

## ARQ-255

is designed to deliver drug to the site of inflammation deep in the hair follicle



Entered Clinic in December 2022 for ARQ-255

AA = alopecia areata

# Acquisition of Ducentis – Next Step Towards Evolution Into Preeminent Immuno-Dermatology Company



## Aligned to the Arcutis Strategy

(1) Atopic Derm (AD) is Large Market with High Unmet Need, (2) CD200R is a biologically-validated target, (3) ARQ-234 potentially best-in-class molecule



## Leverages Arcutis' Deep Dermatology & Biologics Expertise



## ARQ-234 Is Highly Complementary to Roflumilast Cream in AD



## Modest Investment to Acquire Biologic and Achieve Proof-of-Concept Against De-Risked Target in High-Value Indication

