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): July 29, 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 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

On July 29, 2022, Arcutis Biotherapeutics, Inc. (the "Company") commenced a drawdown of the tranche B-1 term loan of $50.0 million and tranche B-2 term loan of $75.0 million (collectively, the “Tranche B Term Loans”) available under its previously disclosed loan and security agreement (the “Loan Agreement”) with SLR Investment Corp. ("SLR"). As previously disclosed, the availability of the Tranche B Term Loans was subject to the delivery to SLR of satisfactory evidence of the approval by the U.S. Food and Drug Administration (the "FDA") of roflumilast cream for an indication relating to the treatment of patients with plaque psoriasis. On July 29, 2022, the Company announced that the FDA approved ZORYVE™ (roflumilast) cream 0.3% for the treatment of plaque psoriasis, including in intertriginous areas, in people 12 years of age or older. With such approval, the Company commenced a drawdown of the Tranche B Term Loans and intends to use the proceeds of the Tranche B Term Loans to continue clinical development activities and commercialization efforts for ZORYVE and for other working capital and general corporate purposes. The Tranche B Term Loans are scheduled to mature on January 1, 2027, if not repaid sooner.

The above descriptions of the Loan Agreement and certain of the terms of the Tranche B Term Loans are not complete and are qualified in their entirety by reference to the full text of the Loan Agreement, a copy of which is filed as Exhibit 10.33 to the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 22, 2022, as amended.

Item 8.01 Other Events

FDA Approval

On July 29, 2022, the Company issued a press release announcing that the FDA approved ZORYVE™ (roflumilast) cream 0.3% for the treatment of plaque psoriasis, including in intertriginous areas, in people 12 years of age or older (the "FDA Approval"). ZORYVE – a once-daily, steroid-free cream in a safe and well-tolerated, patient-friendly formulation – is formulated to simplify disease management for people living with plaque psoriasis. The Company intends to make ZORYVE widely available via key wholesaler and national dermatology pharmacy channels as a new treatment option by mid-August 2022. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Corporate Presentation

On August 1, 2022, the Company posted an updated corporate presentation to include information regarding the FDA Approval of ZORYVE™ (roflumilast) cream to the investor section of the Company’s website. A copy of this presentation is filed as Exhibit 99.2 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.

Forward Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statement. These statements are based on the Company’s current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential for ZORYVE to simplify disease management for care of plaque psoriasis, the Company’s expected timing and plan to commercially launch ZORYVE by mid-August 2022 and the Company's intended use of the proceeds of the Tranche B Term Loans. These statements are subject to 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. Risks and uncertainties that may cause actual results to differ include risks inherent in the Company's business, conditions limiting the Company's ability to access additional capital under its debt financing agreement, the impact of competition and other important factors discussed in the “Risk Factors” section of the Company's Form 10-K filed with U.S. Securities and Exchange Commission ("SEC") on February 22, 2022, as amended, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements. The Company undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes

available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Arcutis Biotherapeutics, Inc.
99.2	Company presentation dated August 1, 2022.
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: August 2, 2022

By: /s/ Scott Burrows
Scott Burrows
Chief Financial Officer

FOR IMMEDIATE RELEASE

FDA APPROVES ARCUTIS' ZORYVE™ (ROFLUMILAST) CREAM 0.3% FOR THE TREATMENT OF PLAQUE PSORIASIS IN INDIVIDUALS AGE 12 AND OLDER

- *First and only topical PDE4 inhibitor approved for the treatment of plaque psoriasis, including intertriginous psoriasis*
- *Approved for once-daily treatment in mild, moderate, and severe plaque psoriasis with no limitations on duration of use*
- *Established efficacy – provides rapid clearance of plaques and reduction of itch in all affected areas of the body*
- *Safe and very well-tolerated, steroid-free cream with minimal application site reactions*
- *Commercial product expected to be available by mid-August*
- *Management will host conference call on Monday, August 1 at 8:30 a.m. EDT*
- *Arcutis expects to draw an additional $125 million from the Company's debt facility with SLR Capital Partners*

WESTLAKE VILLAGE, Calif., July 29, 2022 – Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, announced today that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for ZORYVE (roflumilast) cream 0.3% for the treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age or older. The first and only topical phosphodiesterase-4 (PDE4) inhibitor approved for the treatment of plaque psoriasis, ZORYVE provides rapid clearance of psoriasis plaques and reduces itch in all affected areas of the body. ZORYVE — a once-daily, steroid-free cream in a safe and well tolerated, patient-friendly formulation — is uniquely formulated to simplify disease management for people living with plaque psoriasis.

“Today Arcutis has reached a major milestone, with our ability to offer this next generation topical PDE4 inhibitor to both adults and adolescents with plaque psoriasis. ZORYVE's combination of efficacy, safety, and tolerability, coupled with our proprietary HydroARQ Technology formulation, is designed to fit into patients’ everyday lives with no restrictions on duration of use,” said Frank Watanabe, President and CEO of Arcutis. “Additionally, ZORYVE has been shown to rapidly clear plaques and reduce itch across all areas of the body. ZORYVE is the only topical for which data focused on the treatment of intertriginous plaques — a common area affected by plaque psoriasis — have been specifically generated. This FDA approval is the fruition of our efforts, and we are excited to launch ZORYVE, with expected product availability by mid-August.”

Topical therapies remain the primary treatment option for the vast majority of individuals with plaque psoriasis, a common immune-mediated skin disease that affects approximately nine million people in the U.S. and is the most frequent type of psoriasis occurring in both adults and adolescents. Severity can range between mild, moderate, and severe, with itch being the most burdensome and frequently reported symptom.

While the disease may affect any area of the body, plaques in certain areas, like the face, elbows and knees, genitalia, and intertriginous areas (areas of skin-to-skin contact), present unique treatment challenges. As a result, individuals with psoriasis are often prescribed multiple topical medications for different areas, which makes for a complicated treatment regimen.

“In multiple clinical trials, ZORYVE was proven to be safe and effective, with improvements in disease clearance in hard-to-treat areas like knees and elbows, as well as in sensitive areas such as the face, genitalia, and intertriginous areas. ZORYVE is very well tolerated, which is an important consideration for treating a chronic skin disease such as plaque psoriasis,” said Mark Lebwohl M.D., FAAD, principal investigator and Dean for Clinical Therapeutics and Chairman Emeritus of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai. “With this FDA approval, adults and adolescents with psoriasis and their dermatologists have a new steroid-free treatment option for use on all affected areas of the body.”

ZORYVE features HydroARQ Technology™, a proprietary drug delivery formulation that creates a non-greasy moisturizing cream that spreads easily and absorbs quickly.

“Plaque psoriasis is a challenging disease and finding the right treatment option can be complicated, especially if individuals have to use multiple treatments for different parts of their

body. We welcome a new treatment option that can make a meaningful difference for adults and adolescents with plaque psoriasis," says Leah M. Howard, President and CEO of the National Psoriasis Foundation. "Our hope is that new treatments translate into improved outcomes and help alleviate the burdens of chronic disease for people impacted by psoriasis."

Arcutis intends to make ZORYVE widely available via key wholesaler and national dermatology pharmacy channels as a new treatment option by mid-August, and the Company is dedicated to affordable access to therapy. The ZORYVE Direct patient support program will help commercially insured individuals with plaque psoriasis get access and start ZORYVE treatment as prescribed by their healthcare provider quickly and easily by helping them navigate the payer process, lowering the out-of-pocket cost for eligible patients, and offering programs that support staying on therapy.[†] Arcutis will also offer the Arcutis Cares patient assistance program (PAP) – the first of its kind for a topical psoriasis treatment – that will provide ZORYVE at no cost for financially eligible patients who are uninsured or underinsured.[‡]

With this approval, Arcutis has access to, and plans to draw, an additional $125 million tranche as part of the Company's non-dilutive financing agreement with SLR Capital Partners. Combined with the Company's cash, cash equivalents, restricted cash, and marketable securities as of June 30, 2022, this additional $125 million will provide for capital resources of over $400 million to support the launch and commercialization efforts for ZORYVE, as well as continue to advance the Company's pipeline development initiatives.

Management will host a conference call on Monday, August 1 at 8:30 a.m. EDT. Dial-in information for conference participants may be obtained by registering for the event here. A live webcast of the call and presentation material will be available on the "Events" section of the Company's Investor website. An archived version of the webcast will be available on the Arcutis website after the call.

ZORYVE Clinical Data

The approval is based on comprehensive results from the pivotal DERMIS-1 and DERMIS-2 (trials of P**DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque psorias**IS** One and Two) Phase 3 studies. In these trials, significantly more patients treated with ZORYVE achieved Investigator Global Assessment (IGA) success at Week 8 compared to vehicle (42% in DERMIS-1 and 37% in DERMIS-2 with ZORYVE compared to 6% in DERMIS-1 and 7% in DERMIS-2 with vehicle (P<0.0001 in both studies)). IGA success is defined as an IGA score of clear (0) or almost clear (1), plus a ≥2-grade IGA score improvement from baseline.

ZORYVE improved the severity and impact of itch, as early as Week 2. Two-thirds of patients with a Worst Itch-Numerical Rating Score (WI-NRS) of 4 or higher at baseline achieved a ≥ 4-point reduction in itch at Week 8 with ZORYVE (67% vs. 26% in DERMIS-1 and 69% vs. 33% in DERMIS-2 at Week 8 (P<0.0001)).

ZORYVE is the only topical for which efficacy has been specifically demonstrated in the treatment of intertriginous psoriasis, as measured by Intertriginous IGA (I-IGA) Success (72% vs. 14% in DERMIS-1 and 68% vs. 17% in DERMIS-2 at Week 8 (P<0.0001)).

In both trials, ZORYVE was very well-tolerated with a favorable safety and tolerability profile. The most common adverse reactions reported in DERMIS-1 and -2 (≥1%of subjects treated with ZORYVE for 8 weeks), and for which the rate exceeded the rate for vehicle-treated patients, included diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Of 239 individuals who continued treatment with ZORYVE for at least 52 weeks in an open-label long-term safety trial, 45% were evaluated as an IGA of “Clear” or “Almost Clear” at Week 52.

ZORYVE also demonstrated statistically significant improvements over vehicle on key secondary endpoints, including Psoriasis Area Severity Index-75 (PASI-75), and patient perceptions of signs and symptoms, such as itching, pain, and scaling, as measured by the Psoriasis Symptoms Diary (PSD). In both studies, ZORYVE improved overall signs and symptoms of psoriasis at Weeks 4 and 8 compared to vehicle.

Dr. Lebwohl reports receiving grant support and consulting fees from Arcutis Biotherapeutics.

About Psoriasis

Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately nine million people in the United States. The majority of individuals with psoriasis develop “plaques,” or raised, red areas of skin covered with a silver or white layer of dead skin cells. The plaques’ clinical presentation may have more grayish, purplish, or brownish tones in people with darker skin tones. Psoriatic plaques are often itchy and sometimes painful and can appear on any area of the body. Plaques in certain anatomical areas present unique treatment challenges, including the face, elbows and knees, scalp, and intertriginous areas (where two skin areas may touch or rub together.)

INDICATION

ZORYVE is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full Prescribing Information.

About Arcutis

Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis harnesses our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis' dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including plaque psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

Forward-Looking Statements

Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential for ZORYVE to simplify disease management for care of plaque psoriasis; the Company's expected timing and plan to commercially launch ZORYVE by mid-August; and the Company's plan to draw down on its loan agreement. These statements are subject to 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. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, conditions limiting our ability to access additional capital under our debt financing agreement, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as amended, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Contacts:

Media

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asheldon@arcutis.com

Investors

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

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† *Uninsured patients and patients with government insurance are not eligible for the ZORYVE Direct savings program; Other terms and restrictions apply

‡ Subject to financial eligibility requirements. Other terms and restrictions apply

Exhibit 99.2

ARCUTIS
BIOTHERAPEUTICS

Bioscience applied to the skin.

Corporate Overview

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.

2022: A Transformational Year for Arcutis Continues

- FDA approval of ZORYVE (roflumilast) in plaque psoriasis and imminent launch is the realization of our efforts to bring meaningful innovation to address the unmet needs of patients with immune-mediated skin diseases
- Topical roflumilast is a unique "pipeline-in-a-product" opportunity across four development programs
- We remain confident in continuing our track record of Phase 3 successes in subsequent pivotal readouts in atopic dermatitis and scalp and body psoriasis later this year
- We will further strengthen our balance sheet by drawing an additional $125 million from our debt facility; enables robust launch investment for ZORYVE and continued pipeline advancement

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

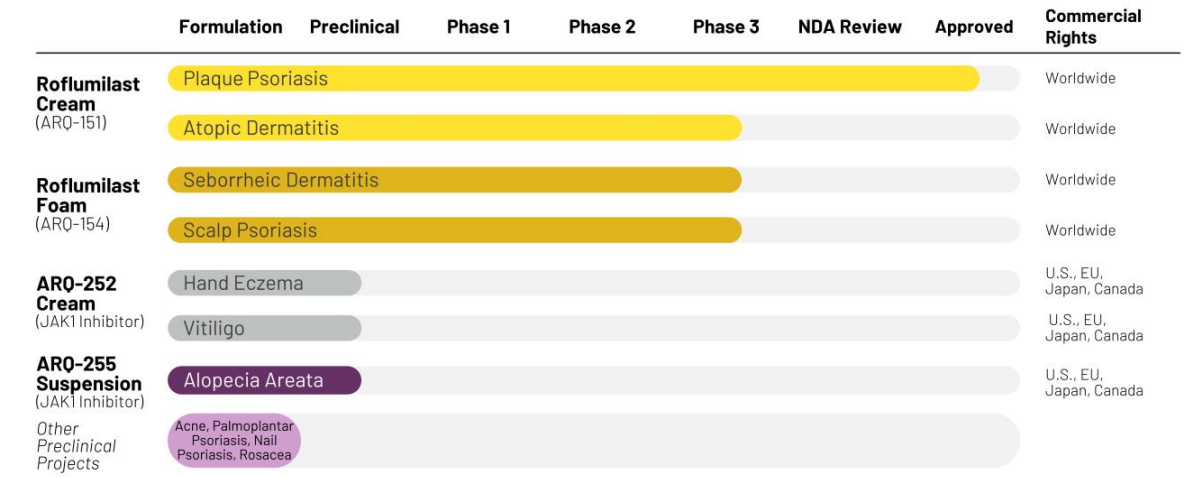
Rapidly advancing

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

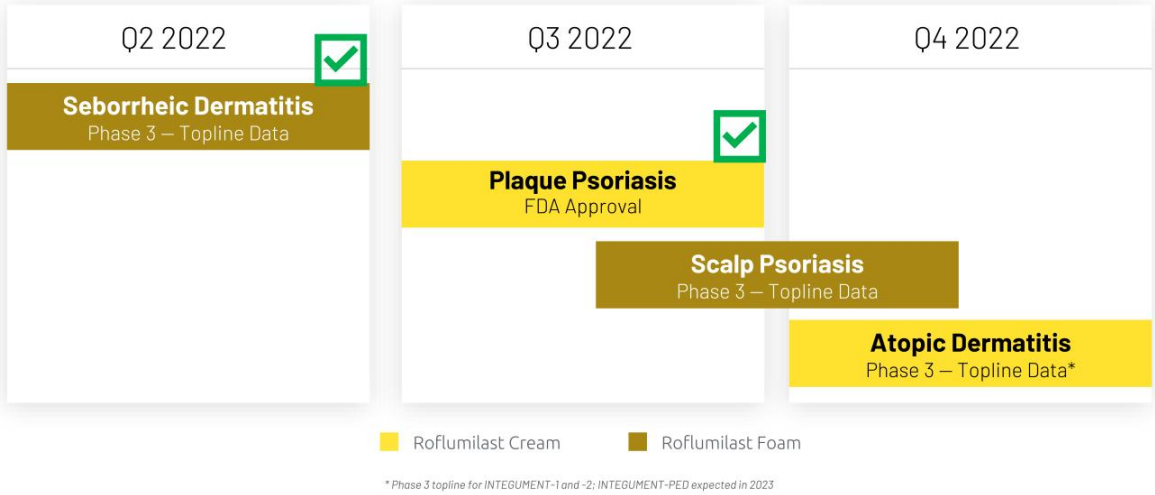
FDA = U.S. Food and Drug Administration; IP = intellectual property

Broad and Deep Pipeline

Multiple "Pipeline in a Molecule" Opportunities



Continued Execution Against Our Four Transformational Catalysts in 2022



** 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

ZORYVE (zor-eev) - Next Generation PDE4 Inhibitor Approved for Treatment of Plaque Psoriasis in Ages 12+

PDE4 = phosphodiesterase-4

Established, rapid efficacy

Significant clearance of plaques + itch in all affected areas of the body

Uniquely broad label

Once-daily treatment in mild, moderate, & severe plaque psoriasis, *including intertriginous psoriasis*

Very well-tolerated, steroid-free cream

Minimal adverse application site reactions; coupled with our proprietary HydroARQ™ technology

Efficacy & safety suitable for long-term use

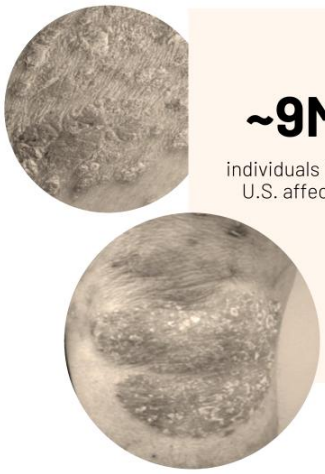
No boxed warnings/limitations on duration of use

Arcutis Enjoys Strong IP Protection[1]

11 **Issued U.S. and foreign patents on topical roflumilast cream and foam formulations**	**1** Pending U.S. patent application on novel restorative effect of the roflumilast cream vehicle
1 **Issued U.S. patent on topical roflumilast PK profile (plus 3 pending)**	**1** Pending U.S. patent application for method of use on a critical ingredient in the topical roflumilast formulations
1 **Issued foreign patent for use of a critical ingredient in topical roflumilast formulations**	**2** Pending U.S. patent applications for the Deep Dermal Drug Delivery (4D) Technology underlying ARQ-255
1 Pending U.S. patent application on anti-fungal properties of PDE4 inhibitors	**1** Pending U.S. patent application for novel JAK1 inhibitor formulation (ARQ-252)

[1]*As of 6/1/22; 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[1]

[1] *Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals, March 2022*

ZORYVE Cream – FDA-Approved U.S. Label in Psoriasis

Once-daily treatment in mild, moderate, & severe plaque psoriasis

ZORYVE™
(roflumilast) cream 0.3%

ZORYVE™ (roflumilast) cream, for topical use
Initial U.S. Approval: 2011

----------INDICATIONS AND USAGE----------
ZORYVE is a phosphodiesterase 4 inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. (1)

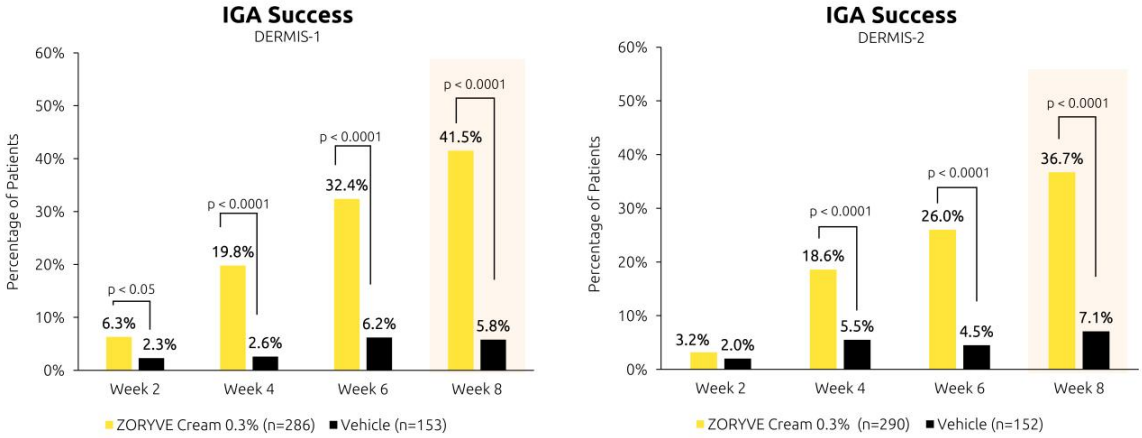
---------- DOSAGE AND ADMINISTRATION ----------
- Apply once daily to affected areas. (2)
- For topical use only. (2)
- Not for ophthalmic, oral, or intravaginal use. (2)

---------- DOSAGE FORMS AND STRENGTHS ----------
Cream, 0.3%: 3 mg of roflumilast per gram in 60-gram tubes. (3)

- Indication for treatment of intertriginous areas
- Indication for ages 12+
- Itch data (WI-NRS) included in label

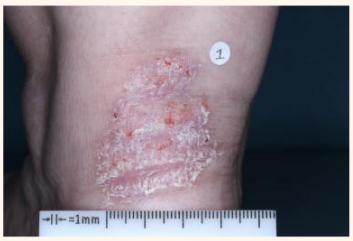
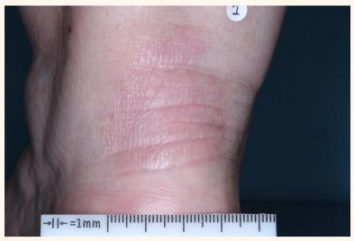
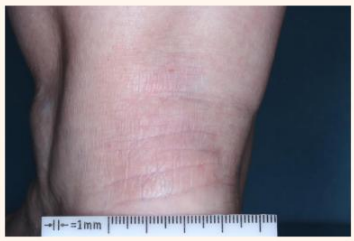
WI-NRS: Worst Itch Numeric Rating Scale

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



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

Significant and Rapid Clearance of Plaques in DERMIS Phase 3 Studies

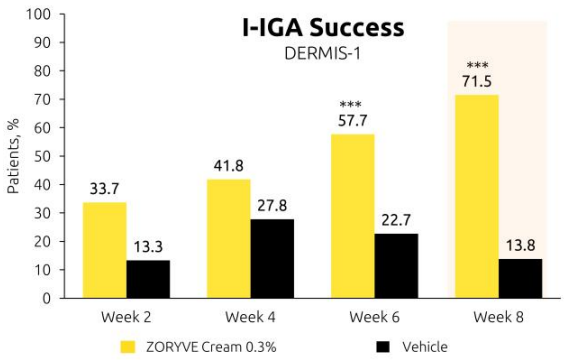
Baseline (Heel)	Week 4	Week 8
		
IGA = 2	IGA = 0	IGA = 0

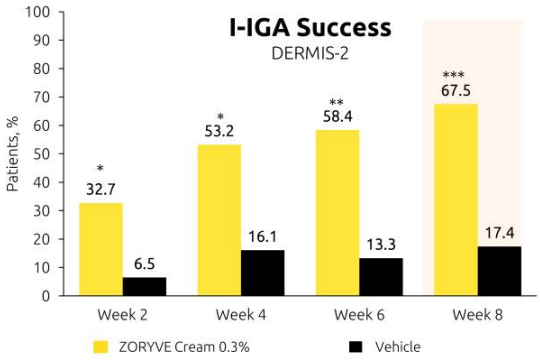
Demonstrated efficacy in tough-to-treat areas (knees/elbows) + intertriginous/sensitive areas

Individual patient results may vary

Demonstrated Efficacy and Favorable Safety and Tolerability in Treating Intertriginous Plaques

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



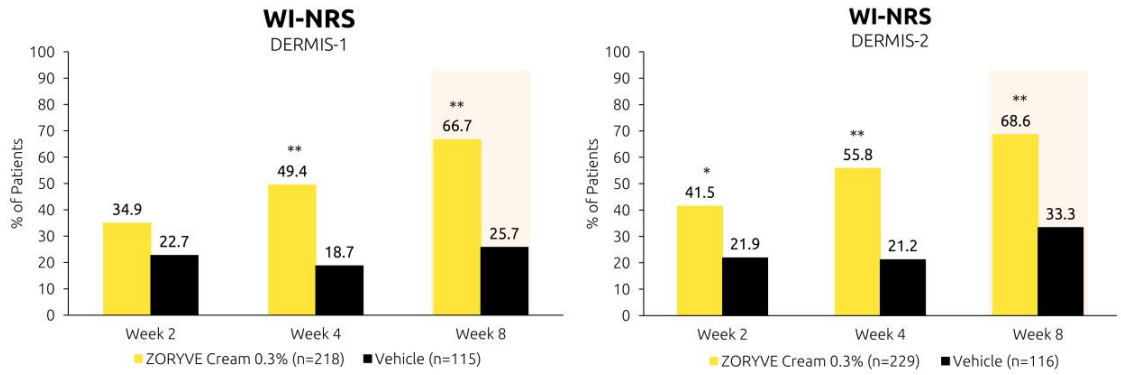


Survey Suggests ~2 in 3 Patients Have Exhibited Psoriasis in Intertriginous Areas[1]

**P<0.01; **P<0.001; ***P<=0.0001; I-IGA-intent-to-treat population: patients with intertriginous area involvement with severity of the intertriginous lesions at least mild (I-IGA ≥2) at baseline. Statistical analysis based on multiple imputation; Week 2, 4, and 6 consistent with label; I-IGA, Intertriginous-Investigator's Global Assessment. [1]Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals. March 2022*

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

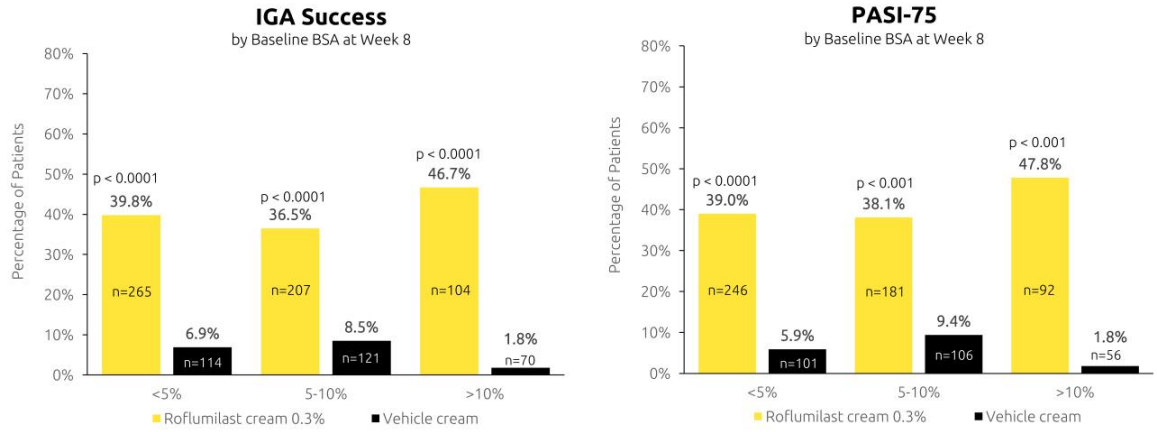
Proportion of patients who achieved a ≥4-point improvement in WI-NRS from baseline score of ≥4



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 ≥4 at baseline; WI-NRS: Worst Itch Numeric Rating Scale*
Statistical analysis based on multiple imputation

New Data Presented at AAD: Consistent Clearance Regardless of Baseline Disease Severity



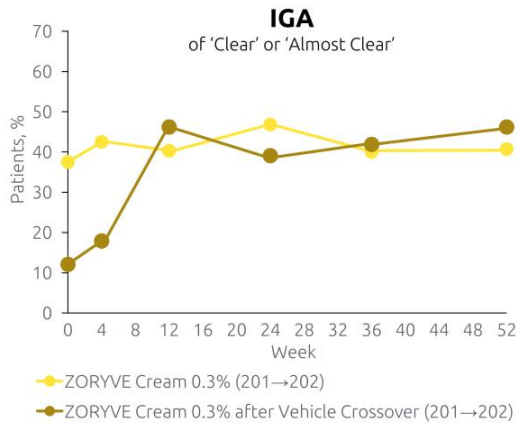
IGA Success = Clear or Almost Clear IGA status plus ≥2-grade improvement from baseline. PASI = Psoriasis Area and Severity Index; PASI-75 = ≥75% PASI improvement from baseline; Data are based on pooled data from DERMIS-1 and DERMIS-2. IGA results are from observed data from the Intent-to-treat population; Presented at American Academy Of Dermatology (AAD) Annual Meeting, March 25-29, 2022, Boston, MA, USA.

ZORYVE – Safe and Very Well-Tolerated

	DERMIS-1 and -2	
Adverse Reactions Reported in >=1% of Subjects for 8 Weeks [n (%)]	**ZORYVE** *(n=576)*	**Vehicle** *(n=305)*
Diarrhea	18 (3.1)	0 (0.0)
Headache	14 (2.4)	3 (1.0)
Insomnia	8 (1.4)	2 (0.7)
Nausea	7 (1.2)	1 (0.3)
Application site pain	6 (1.0)	1 (0.3)
Upper respiratory tract infection	6 (1.0)	1 (0.3)
Urinary tract infection	6 (1.0)	2 (0.7)

Data are presented for safety population

Durability of Response Maintained: Phase 2 Long-Term Data in Plaque Psoriasis

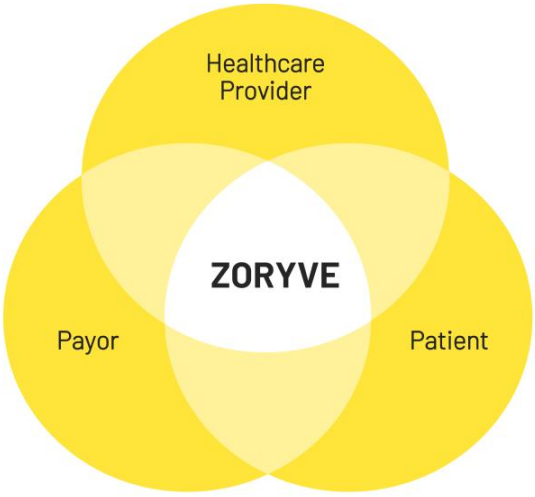


In 594 subjects who continued ZORYVE for up to 64 weeks in OLE trials, the adverse reaction profile was similar to that of vehicle-controlled vehicles

- **Durable efficacy over 52-64 weeks**
  - *Comparable to DERMIS-1/-2 8-week efficacy*
  - *Median duration of IGA of Clear or Almost Clear = 37 weeks*
- **73.5% of patients completed 52-64 weeks of treatment**
  - *Only 0.9% discontinued due to lack of efficacy*
  - *Only 3.9% discontinued due to any adverse event*

Observed data from ARQ-151-202 study; IGA = Investigator's Global Assessment; OLE = open label extension

ZORYVE: Designed to Simplify the Treatment of Psoriasis



ZORYVE Cream's Label in Psoriasis is Recognition of Our Differentiated Profile

In Label	DUOBRII®	ENSTILAR®	Wynzora®	VTAMA™	ZORYVE™
Intertriginous efficacy	⊖	⊖	⊖	⊖	⊕
Approved down to age 12	⊖	☑	⊖	⊖	⊕
Itch efficacy data	⊖	⊖	☑	⊖	⊕
Lack of warnings or precautions	⊖	⊖	⊖	☑	⊕
No limitations on duration of use	☑	⊖	⊖	☑	⊕

Comparison based on FDA-approved labels for referenced products. No head-to-head trials between these products have been conducted.

DUOBRII® : halobetasol propionate and tazarotene; ENSTILAR® : calcipotriene and betamethasone dipropionate; Wynzora® : calcipotriene and betamethasone dipropionate; VTAMA™ : tapinarof

ZORYVE - Patient-Friendly Formulation That Effectively Delivers Highly Potent PDE4

- Once-daily dosing
- Steroid-free
- Uniquely featuring HydroARQ Technology
  - Non-greasy, moisturizing cream
  - Spreads easily, absorbs quickly
  - No sensitizing excipients or irritants (e.g. propylene glycol, ethanol)

Patient Dynamics Are Favorable Towards Trial

~2M

Psoriasis patients currently Rx treated topically by U.S. dermatologists

Minimal behavioral change required to activate utilization

- 90% of U.S. patients treated with topicals

Highly dynamic market facilitates start/switch

- Steroids limited to short duration – frequent need to switch

Sparse competitive landscape for innovative topical therapies

- Synergy in activating non-steroidal market with two innovative topicals launching

Rx = prescription

Strong Patient Interest and Engagement in Innovation

9 in 10
Patients

- Wish there were more effective topical treatment options
- Wish topical treatments were a once daily application
- Wish they could use a single topical therapy anywhere on their body
- Are interested in trying a new topical treatment for their psoriasis

2 in 3
Patients have exhibited psoriasis in intertriginous areas

9 in 10
Intertriginous patients would be more adherent if a single topical could be used everywhere on the body

Source: Skin Insights: Uncovering Psoriasis survey of >500 adults who use topicals, March 2022

Our Access Strategy Remains Unchanged: Unlocking Broad, High-Quality Access to ZORYVE

Responsible pricing

Designed to obtain broad and rapid coverage

Reduced prescriber burden

Key to maximizing volume opportunity

Rapid follow-on indications

Allow for portfolio volumes across multiple indications

WAC Price of $825 Optimizes for Our Access Objectives, Helps More Patients, & Maximizes Total Franchise Value

Our Access/Coverage Goals

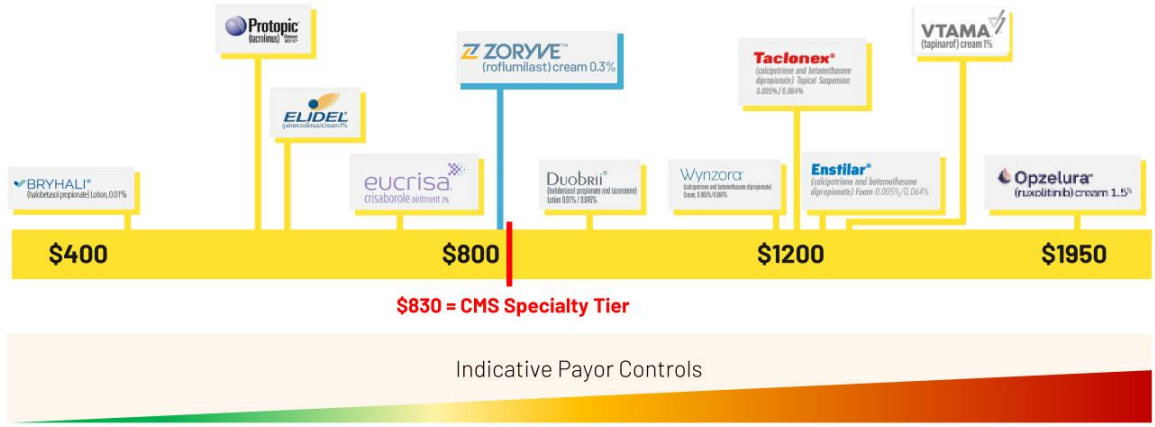
- High-quality coverage for patients
- Faster formulary consideration/adoption
- Preservation of gross-to-net
- Optimizing for volume & franchise value

Topical Roflumilast

- Highly innovative
- Effective, safe, well-tolerated
- Potential 1st line treatment option
- Potential follow-on indications in AD & Seb Derm with varied patient mix

$825/tube

List Prices of Select Branded Topicals



Source: Analysource – 7/15/22

Patients Will be Supported via ZORYVE Direct

ZORYVE direct

Patient access support made easy

Savings Program*

Commercially insured patients with ZORYVE coverage	Commercially insured patients without ZORYVE coverage
$25	**$75**

For Financially Eligible Patients who are Uninsured or Underinsured, Arcutis Will Also Offer the Arcutis Cares™ Patient Assistance Program

**Uninsured patients and patients with government insurance are not eligible for the ZORYVE Direct savings program; Other terms and restrictions apply*

ZORYVE Launch Readiness

- Sales force fully hired; detailing begins today
- Product expected in channel in < 2 weeks
- Broad sampling program ready to activate
- ZORYVE Direct patient support active

ZORYVE
(roflumilast) cream 0.3%
direct
Patient access support made easy

Strategic Parallels to Oral CGRPs

	Biohaven / Nurtec®	Arcutis / Topical Roflumilast
Chronic, symptomatic diseases	Migraine	Psoriasis / Atopic Derm / Seb Derm
Large, competitive markets with significant unmet need	~45 million Americans	~45 million Americans
Meaningful innovation to supplant outdated, generic standard of care	Triptans	Topical Steroids
Follow-on indications to expand opportunity	Acute → Preventive	Psoriasis → Atopic Derm + Seb Derm + Scalp Psoriasis

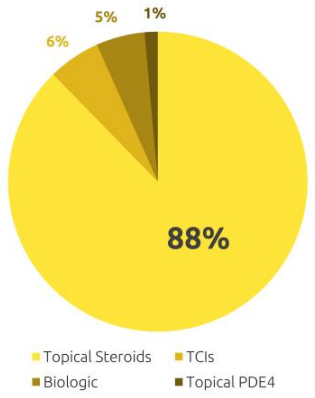
With the Right Product Profile and the Right Execution

First-time launches can be successful and drive significant value appreciation

CGRP = calcitonin gene-related peptide

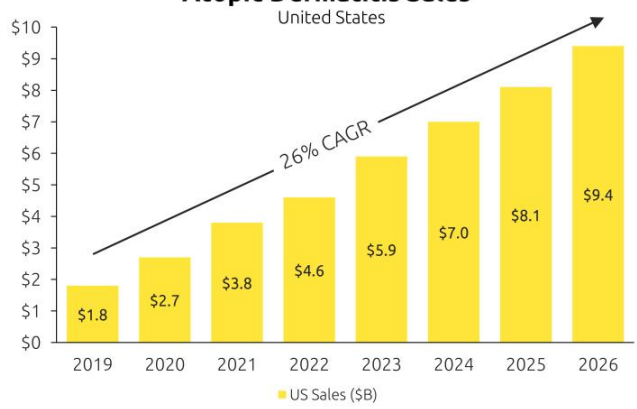
Significant Opportunity in Underserved, Rapidly Growing Atopic Dermatitis (AD) Market

Total 2021 TRx of ~26 Million[1]



[1]Source: IQVIA [Biologic = Dupixent; PDE4 = Eucrisa]; TCI = topical calcineurin inhibitor

Atopic Dermatitis Sales[2]



[2]Source: Evaluate Pharma; CAGR = compound annual growth rate

Atopic Dermatitis: Compelling Opportunity for Roflumilast Cream

Very large, established market

- ~26 million individuals in U.S. affected
- 12% prevalence in children → need for safe/effective therapy

Significant unmet needs
for safe, effective, and chronic use therapy

JAK class labeling
very favorable for roflumilast potential

Roflumilast Cream
Clinical Profile

Closely aligned with:

1. Physician
2. Payor
3. Patient
4. Parent

JAK = Janus kinase

Roflumilast Cream May Address Unmet Needs in Atopic Dermatitis

Efficacy

Robust Phase 2 efficacy across multiple endpoints

Validated Target

PDE4 inhibition validated in AD

Well-tolerated

- No application site reaction
- A favorable safety profile

Simple, easy-to-use

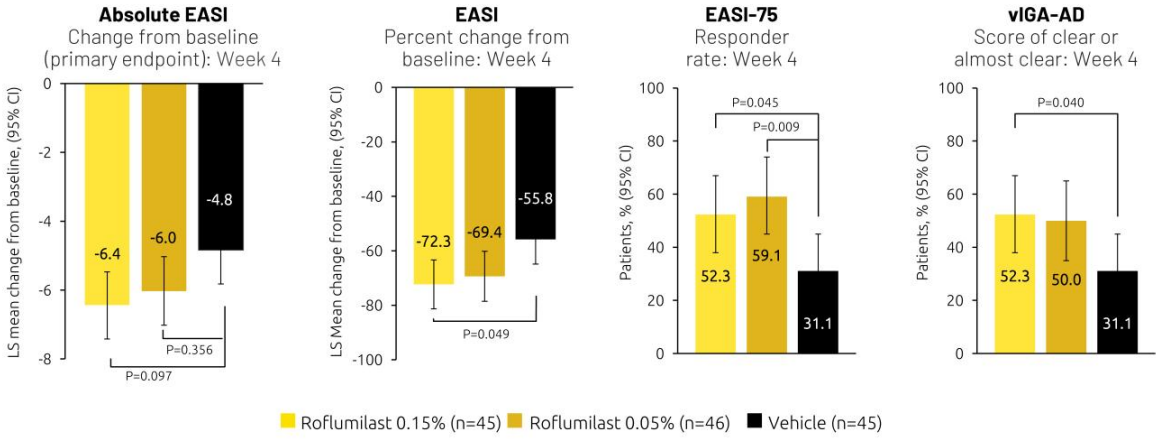
Once-a-day cream

Topline data expected by year-end 2022

INTEGUMENT-1 & -2

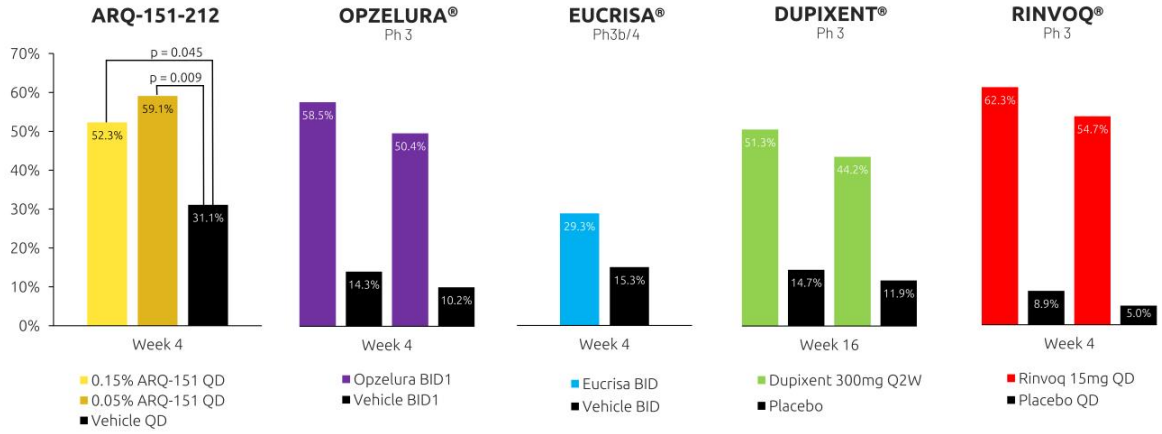
PDE4 = Phosphodiesterase 4

Consistent Evidence of Efficacy Results Across Endpoints in Phase 2 Proof of Concept



Data presented for intent-to-treat population.; EASI = eczema area severity index; vIGA-AD = validated investigator's global assessment – atopic dermatitis; LS = least squares; CI = confidence interval

Roflumilast Cream vs. Current Approved Treatments in Atopic Dermatitis [EASI-75 Responders]



Note: The results of this retrospective post-hoc cross-trial comparison may not be directly comparable, as they are not from a single head-to-head clinical trial. DUPIXENT & RINVOQ were studied in moderate-to-severe populations; QD = once a day dosing; BID = twice a day dosing; Q2W = once every two weeks dosing

The Importance of Vehicle in AD Treatment – Restoring the Skin Barrier

In AD, the skin barrier function is compromised, and moisture is lost from skin
Moisturizing agents (emollients) are commonly used first-line therapies

Proprietary Vehicle Technology

Moisturizing

Non-lipid-extracting emulsifiers

Non-irritating

Roflumilast Cream

uniquely formulated as emollient, water-based cream without burning or stinging

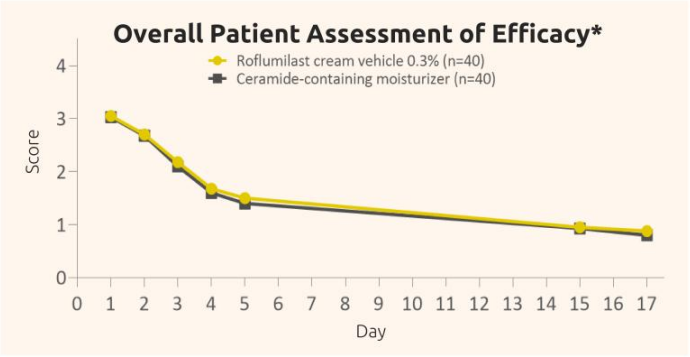
Optimized vehicle formulation may promote treatment adherence and therapeutic effect

Roflumilast Cream Vehicle Comparable to a Leading Commercial Moisturizer

Mild Eczema Trial

Vehicle for Roflumilast Cream *versus* Ceramide-Containing Moisturizing Cream

- N = 40
- Primary endpoint of TEWL showed no skin barrier damage for roflumilast vehicle at Day 15
- Mean TEWL similar between roflumilast vehicle and ceramide-containing moisturizer
- No adverse events / tolerability issues



Statistically Significant Improvements in Investigator and Patient-Assessed Moisturizing Properties

*TEWL = trans epidermal water loss; * Includes dryness, redness, roughness, irritation and others (Draelos et al RAD 2021 Poster)*

Favorable Safety and Tolerability Profile in Atopic Dermatitis

- **95% of subjects completed** Phase 2 study
- **Safety and tolerability** profile for roflumilast groups similar to vehicle
- **Treatment-related AEs** rare and balanced across study arms (all mild or moderate)
- **No evidence of local tolerability issues** (burning, stinging)
- **No evidence of side effects** typical of oral PDE4 inhibition (GI, psych, weight)

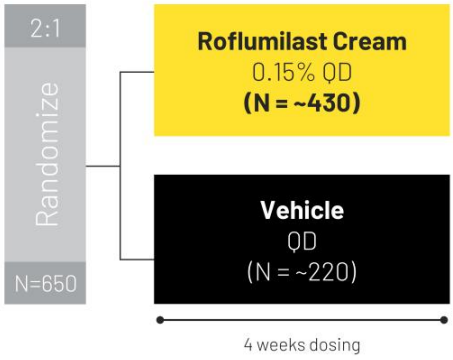
GI = gastrointestinal; PDE4 = Phosphodiesterase 4

INTEGUMENT-1 & -2 Phase 3 Atopic Derm Studies

Randomized, Double-blind, Vehicle-controlled, Multicenter Studies
(Two identical, parallel Phase 3 studies)

Eligibility

- Diagnosis of mild or moderate AD (vIGA-AD = 2 or 3)
- Age 6+
- BSA ≥3%
- EASI ≥5



Endpoints

Primary

- vIGA-AD success at week 4

Secondary

- EASI-75
- WI-NRS (itch)
- vIGA-AD = Clear (0) or Almost Clear (1)

Safety and tolerability

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; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day dosing;

INTEGUMENT Studies Designed for Broad Label in Mild-to-Moderate Atopic Dermatitis

INTEGUMENT-1, -2 and -PED each enrolling ~650 patients

- ~430 patients in each active arm compared to only ~45 in Phase 2
- Comprehensive safety database

>95% statistical power to detect IGA Success effect size seen in Phase 2

No upper limit on BSA

No expectation for limitation in duration of treatment

Statistical power on both primary and key secondary endpoints critical to ensuring a robust label

IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline.; BSA = body surface area;

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%

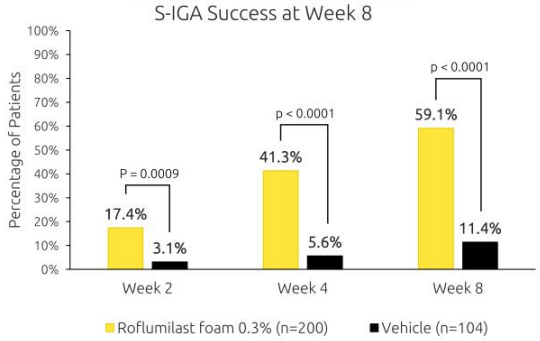
of Plaque Psoriasis sufferers have scalp involvement

Roflumilast foam ideal for scalp and body psoriasis

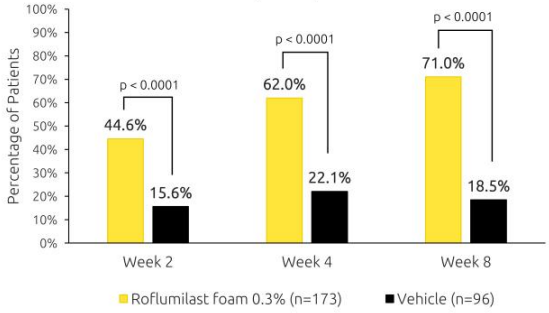
- Suitable for chronic use
- Foam is ideal for hair-bearing areas such as scalp, where cream, lotion, or ointment is not suitable
- Unlike most other options, single treatment for all areas of the body
- May be used near the eyes
- Rapid and robust impact on itch
- Topline expected late Q3 / early Q4 2022

Scalp Psoriasis - Rapid and Robust Impact on Key Efficacy Measures in Phase 2

~ 60% of Patients Achieved
S-IGA Success at Week 8



>70% of Patients Achieved
a SI-NRS 4-pt Response at Week 8



40.3% of patients on roflumilast foam achieved body IGA (B-IGA) success at week 8 versus 6.8% on vehicle

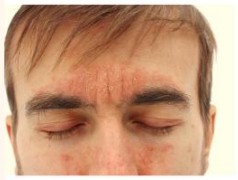
S-IGA = scalp investigator's global assessment; SI-NRS = scalp itch numeric rating scale; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline;

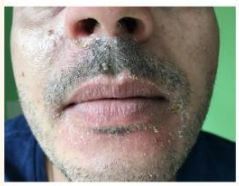
Seborrheic Dermatitis – Significant Unmet Needs in Treatment Paradigm

~10 million

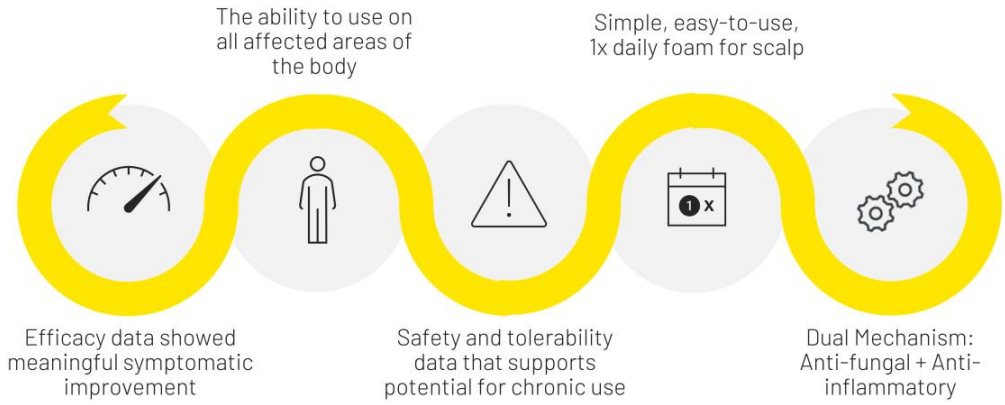
Individuals in the U.S. affected

- 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

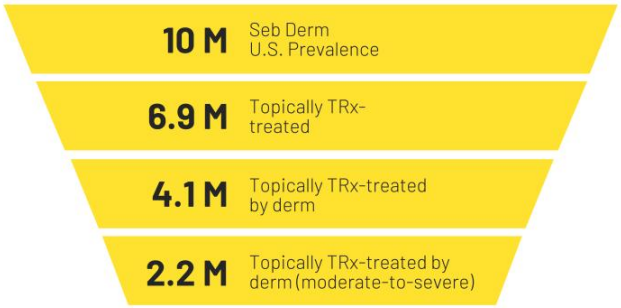




Roflumilast Foam Could Become Standard of Care in Seborrheic Dermatitis



Seborrheic Dermatitis: Opportunity Comparable in Size to Psoriasis



75

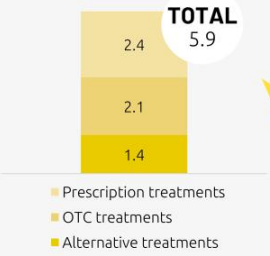
Average # of seborrheic dermatitis patients seen in a typical month

	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 Require Complex and Onerous Treatment Regimens

Actively Using Treatments[1]
Per Week, 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)*

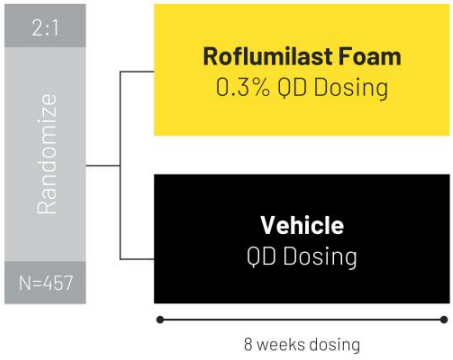
OTC = over the counter; HCP = healthcare professional

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

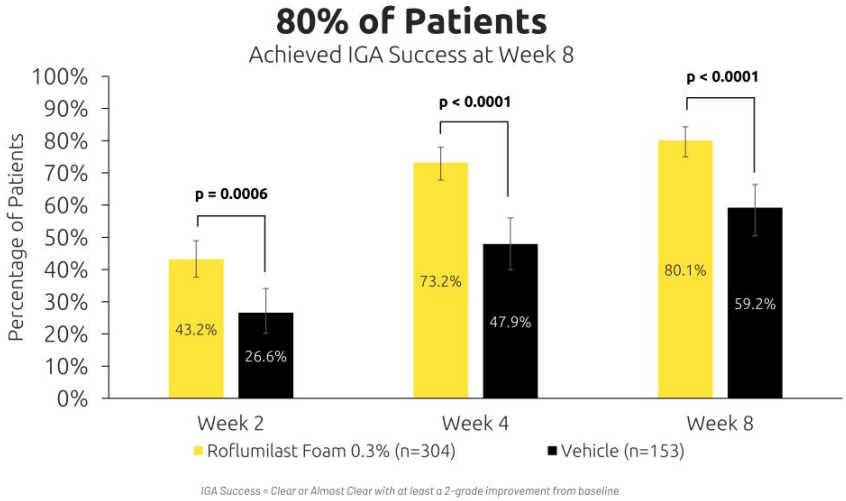
Secondary

- 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

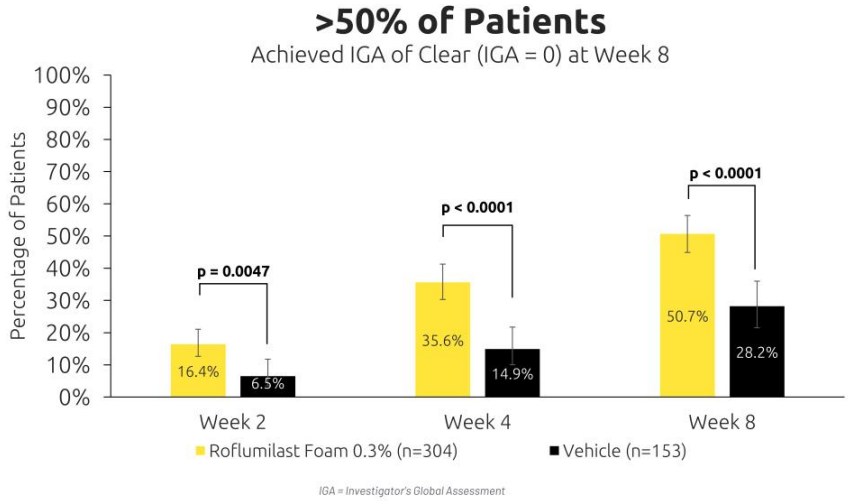
IGA = Investigator's Global Assessment; IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline; WI-NRS: Worst Itch Numeric Rating Scale; QD = once a day; BSA = body surface area

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



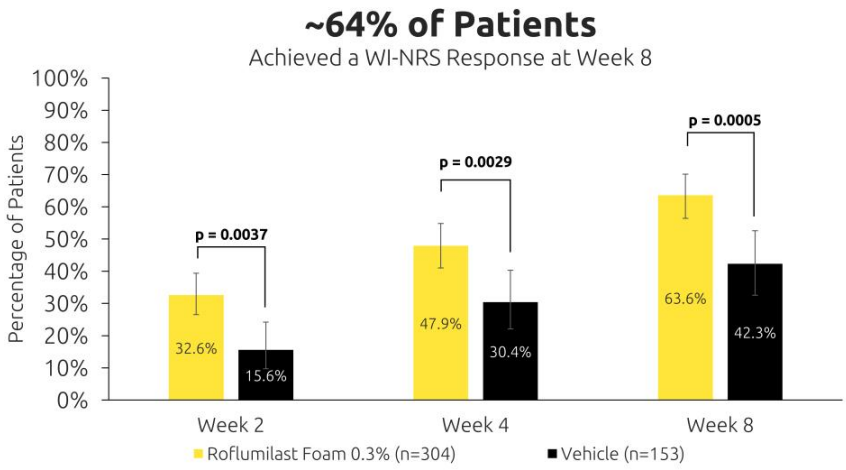
IGA Success = Clear or Almost Clear with at least a 2-grade improvement from baseline

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

Advancing Multiple Preclinical Programs in Dermatology

Candidate	Preclinical Program
ARQ-252 Cream (JAK1 Inhibitor)	• Chronic Hand Eczema • Vitiligo
ARQ-255 Suspension (JAK1 Inhibitor)	• Alopecia Areata
Other Preclinical Projects	• Acne • Palmoplantar Psoriasis • Nail Psoriasis • Rosacea

Strategic In-licensing / Business Development

- Best-in-class potential
- Validated targets
- Modality agnostic