

“Arcutis is building a pioneering company dedicated to revolutionizing treatments for patients with serious diseases of the skin.”

— Frank Watanabe, President and CEO



Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin.

The company’s management team, which includes the industry’s leading topical drug formulator and three dermatologists on staff, has deep experience in dermatology and proven expertise in clinical development, product development, commercialization, finance, and operations. Collectively, the Arcutis executive team has developed or commercialized more than 50 FDA-approved products.

The Opportunity for Dermatology Drug Development

Current standards of care to treat many serious skin diseases are outdated, having remained unchanged for decades, and carry significant treatment limitations, resulting in poor outcomes that can have a negative impact on patient quality of life. Industry consolidation and subsequent disinvestment in R&D by large pharmaceutical players have strangled recent innovation in dermatology drug development. The result is a stagnant innovation pipeline in dermatology with remaining players mostly reformulating older drugs, repackaging them, and charging premium prices, as opposed to identifying novel molecules or mechanisms of action that address dermatologist’s and patients’ problems.

Arcutis was created to fill the innovation void with a focus on elevating the standard of care through innovative therapies that simplify disease management for physicians and eliminate the need to compromise between drug safety, efficacy, and tolerability for patients.

Arcutis Fast Facts

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Founded
2016

Headquarters
Westlake Village, CA

Therapeutic Class
Dermatology

Initial Indications
Psoriasis, atopic dermatitis, and seborrheic dermatitis

Lead Candidate
Topical roflumilast (ARQ-151/154)

Pivotal Trial
Phase 3 trials (DERMIS-1 and -2) for topical roflumilast cream

Market Opportunity* (U.S.)
Plaque psoriasis: 2.0 million
Atopic dermatitis: 1.0 million
Seborrheic dermatitis: 1.7 million
Scalp psoriasis: 850,000

**Figures represent number of patients treated with topical therapies by dermatologists*

Clinical Development Program and Pipeline

Arcutis is rapidly advancing a robust pipeline including four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The pipeline includes best-in-class molecules that are the products of scientific advances in the understanding of key immunology targets such as phosphodiesterase-4 (PDE4) and Janus kinase type 1 (JAK1) and their role in the inflammation that drives many dermatological conditions.

Arcutis' pipeline addresses large segments of the dermatology market including topical roflumilast cream (ARQ-151) for plaque psoriasis and atopic dermatitis; topical roflumilast foam (ARQ-154) for seborrheic dermatitis and scalp psoriasis; ARQ-252 cream (JAK 1 inhibitor) for hand eczema and vitiligo; and ARQ-255, an alternative topical formulation of ARQ-252 for alopecia areata. The lead candidate, roflumilast cream, is a highly potent, PDE-4 inhibitor currently in Phase 3 development for plaque psoriasis. Topline data are expected in the first half of 2021. Roflumilast cream demonstrated statistically significant improvement over a matching vehicle on key efficacy endpoints in a Phase 2b clinical trial in chronic plaque psoriasis, highlighting its potential as a once-daily, non-steroidal chronic topical therapy for this patient population. Arcutis also plans to report topline results from a Phase 2 proof-of-concept study of roflumilast foam in patients with seborrheic dermatitis early in fourth quarter of 2020, and topline results from a Phase 2b study of roflumilast foam in patients with scalp psoriasis in the fourth quarter of 2020.

Management Team

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Frank Watanabe
President and Chief Executive Officer

Patrick Burnett, M.D., Ph.D., FAAD
Chief Medical Officer

John W. Smither
Chief Financial Officer

David W. Osborne, Ph.D.
Chief Technical Officer

Kenneth A. Lock
Chief Commercial Officer

Patricia A. Turney
Senior Vice President, Manufacturing

Keith L. Klein
General Counsel

Investors & Media Contact

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Pipeline at a Glance

		Preclinical	Phase 1	Phase 2	Phase 3
Topical Roflumilast Cream (ARQ-151) Cream (PDE4i)	Plaque Psoriasis	●●●●●●●●	●●●●●●●●	●●●●●●●●	●●●●
	Atopic Dermatitis	●●●●●●●●	●●●●●●●●	●●●●	
Topical Roflumilast Foam (ARQ-154) Foam (PDE4i)	Seborrheic Dermatitis	●●●●●●●●	●●●●●●●●	●●●●	
	Scalp Psoriasis	●●●●●●●●	●●●●●●●●	●●●●	
ARQ-252 (JAK1i)	Hand Eczema	●●●●●●●●	●●●●●●●●	●●●●	
	Vitiligo	●●●●●●●●	●●●●●●●●		
ARQ-255 (JAK1i)	Alopecia Areata	●●●●			

