Arcutis Highlights 2026 Strategic Priorities and Anticipated Milestones

January 12, 2026

- Continued strong growth of ZORYVE® (roflumilast) in 2026 with full-year net product sales guidance of $455–$470 million
- Advancement of ZORYVE indication-expansion strategy beginning with ongoing Phase 2 proof-of-concept trials in vitiligo and hidradenitis suppurativa
- Initiation of clinical development program for ARQ-234 in atopic dermatitis
- Transition to positive cash flows enables investment to both accelerate growth of ZORYVE franchise and advance pipeline

WESTLAKE VILLAGE, Calif., Jan. 12, 2026 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on immuno-dermatology, today announced its strategic priorities for 2026.

“2025 was a transformative year as we solidified ZORYVE’s position as an advanced targeted topical with the potential to redefine the standard of care for chronic inflammatory skin diseases,” said Frank Watanabe, president and chief executive officer of Arcutis. “In 2026, we will build on this momentum by driving ZORYVE growth across approved indications and investing in our commercial capabilities to accelerate the conversion from topical corticosteroids. At the same time, we will advance our innovative pipeline, including ZORYVE life cycle initiatives and ARQ-234, our biologic for atopic dermatitis. With strong operating leverage, we are well positioned to pursue new opportunities and reinforce our leadership in medical dermatology drug development and commercialization.”

2026 Strategic Priorities

Grow our core ZORYVE business as we establish ZORYVE as the foundational therapy for adults and children who need long-term therapeutic solutions for managing their plaque psoriasis, seborrheic dermatitis, and atopic dermatitis.

- Sustainable momentum of ZORYVE franchise with 2026 net product sales expected in the $455–$470 million range.
- Targeted ~20% expansion of dermatology sales force to optimize prescriber targeting and call frequency, deepening adoption of ZORYVE.

- Continued label expansion efforts to progress ZORYVE for the treatment of pediatric patients:
  - Expect to announce topline results from INTEGUMENT-INFANT Phase 2 study of ZORYVE cream 0.05% in infants age 3 months to less than 24 months in the first quarter of 2026 and submission of a supplemental New Drug Application (sNDA) in the third quarter of 2026.
  - U.S. Food and Drug Administration (FDA) review ongoing of sNDA for ZORYVE cream 0.3% for the treatment of plaque psoriasis in children ages 2-5; Prescription Drug User Fee Act (PDUFA) target action date set for June 29, 2026.

Expand the ZORYVE franchise into additional indications through strategic life cycle management beginning with proof-of-concept studies in vitiligo and hidradenitis suppurativa.

- Expect to report decision on program advancement for investigational ZORYVE foam 0.3% for the treatment of vitiligo in the fourth quarter of 2026.
- Expect to report decision on program advancement for investigational ZORYVE foam 0.3% for the treatment of hidradenitis suppurativa in the first quarter of 2027.

Build our pipeline by advancing innovative medicines for patients, leveraging industry-leading clinical development and commercialization capabilities that we have developed at Arcutis.

- Begin enrolling patients in the Phase 1 study of ARQ-234, a fusion protein that is a potent and highly selective checkpoint agonist of the CD200 receptor, being developed as a potential biologic treatment for atopic dermatitis, in the first quarter of 2026.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage 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 has a growing portfolio of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis’ unique dermatology development platform coupled with our dermatology expertise allows us to develop differentiated therapies against biologically validated targets, and has produced a robust pipeline for a range of inflammatory dermatological conditions. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

INDICATIONS
ZORYVE cream, 0.05%, is indicated for topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.

ZORYVE cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

ZORYVE cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION
ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.05% for pediatric patients with atopic dermatitis 2 to 5 years of age were upper respiratory tract infection (4.1%), diarrhea (2.5%), vomiting (2.1%), rhinitis (1.6%), conjunctivitis (1.4%), and headache (1.1%).

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.15% for patients with atopic dermatitis 6 years of age or older were headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

The most common adverse reactions reported (≥1%) for ZORYVE cream 0.3% for plaque psoriasis were diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

The most common adverse reactions reported (≥1%) for ZORYVE foam 0.3% for plaque psoriasis were headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions reported (≥1%) for ZORYVE foam 0.3% for seborrheic dermatitis were nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see full Prescribing Information for ZORYVE cream and full Prescribing Information for ZORYVE foam.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, statements contained in this press release regarding matters that are not historical facts are forward-looking statements. Such forward-looking statements include, but are not limited to, statements regarding the potential results of clinical trials and associated timelines, and statements regarding forward-looking financial results. These statements are based on the Company's current beliefs and expectations and 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, reimbursement and access to our products, the impact of competition, and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on February 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the Company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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