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Dermata Therapeutics Announces Strategic Pivot to Over-the-Counter Skin Care Treatments

SAN DIEGO, CA / [ACCESS Newswire](#) / September 10, 2025 / Dermata Therapeutics, Inc. (Nasdaq:DRMA)(Nasdaq:DRMAW) ("Dermata" or the "Company"), a science-driven leader in dermatologic solutions, today announced a bold strategic pivot to prioritize the development and distribution of over-the-counter (OTC) pharmaceutical dermatology focused products that can be sold directly to consumers. This decision was informed by the knowledge gained while developing the Company's *Spongilla* technology as well as current market dynamics. The Company believes this transition represents a significant landmark in the Company's mission to deliver patients with safe, effective, and consumer-friendly dermatology products.

For over a decade, Dermata has focused on researching and developing innovative treatments for patients worldwide, including XYNGARI™, a once-weekly topical product for the treatment of moderate-to-severe acne utilizing the Company's proprietary *Spongilla* technology. In March 2025, the Company announced that XYNGARI™ achieved statistically significant results in the Company's US Food and Drug Administration (FDA) Phase 3 *Spongilla* Treatment Acne Research clinical study (STAR-1) for the treatment of moderate-to-severe acne. Following the completion of the STAR-1 trial and in light of the growing capital requirements, extended regulatory timeline, and everchanging dermatology insurance landscape for prescription drug development, the Company's management, in agreement with its board of directors, has decided to shift the Company's strategic focus toward developing and distributing OTC pharmaceutical dermatology products.

The Company believes this repositioning through leveraging FDA's OTC monograph pathway, may accelerate Dermata's path to commercialization, reduce its regulatory burden, and give it access to a broader customer base not limited by insurance coverage. This pivot is designed to address a growing demand for high-quality, scientifically proven OTC pharmaceutical products that empower consumers to manage their skin health independently. Dermata intends to leverage its knowledge in research, development, and regulatory compliance to deliver a robust portfolio of OTC product offerings, aimed at meeting the needs of patients suffering from various diseases, disorders, and conditions of the skin like acne, psoriasis, and seborrheic dermatitis.

Dermata plans to initially develop a once weekly acne kit that utilizes an approved OTC monograph active ingredient along with its *Spongilla* technology, to reach the almost 50 million US patients with acne. The Company plans to launch this initial acne kit in the middle of 2026 with additional product candidates anticipated to follow.

"We see a tremendous opportunity to make healthcare more accessible and more affordable for patients by providing safe and effective OTC solutions directly to consumers," said Gerry Proehl, Chairman, President, and CEO of Dermata. "After a thorough review of the

everchanging dynamics in the prescription acne market, we felt patients would be better served by leveraging our pharmaceutical expertise with a consumer-centric approach, ensuring individuals have access to trusted OTC pharmaceutical products for their skin care needs. After assessing commercial opportunities in the skin care market, we believe there is growing demand for safe and effective OTC pharmaceutical products that are backed by trusted dermatological research. Our conversations with many dermatologists, practitioners, and payers made it clear to us that there is a growing trend for more patients to first utilize OTC treatments for many skin conditions prior to trying prescription medications. We aim to provide patients with products that are natural, by incorporating our *Spongilla* technology and know-how, with FDA listed OTC pharmaceutical ingredients to offer differentiated skin care solutions patients want to use. We have begun the development and pre-commercialization process and expect to be ready to launch our acne kit in the middle of 2026," continued Mr. Proehl. "Our entire team is reinvigorated by this new direction to better serve patients on an accelerated timeline, and we truly believe this strategic pivot is in the best interests of patients, Dermata, and Dermata investors alike," concluded Mr. Proehl.

"We are excited to embark on this new chapter, which aligns with our overall mission of providing patients with access to efficacious and safe treatment options," said Dr. Christopher Nardo, Dermata's Chief Development Officer. "Our team has extensive experience in developing differentiated pharmaceutical products that work, and patients want to use. Therefore, we look forward to leveraging this clinical experience to make an impact in the OTC marketplace. We will apply the clinical knowledge we've gained over the last ten years to design safe and effective products which are also accessible and affordable as OTC products. We believe this development strategy will offer unique treatments for patients suffering from various skin diseases and conditions," concluded Dr. Nardo.

Dermata remains committed to its core values of innovation, quality, and patient care. As part of the Company's strategic shift into the OTC marketplace, it has withdrawn its investigational new drug application for XYNGARI™ with FDA. The Company believes this strategic decision will provide greater flexibility to leverage the many novel features and benefits of its *Spongilla* technology in a variety of skin care products for the OTC marketplace. The Company plans to provide regular updates on the progress of this strategic shift and its upcoming OTC product launches, with the first product launch planned for mid-2026.

Management Recording - Available [Here](#)

Dermata management has recorded a short presentation to further discuss this strategic pivot. To listen to this recording, please click [here](#). Questions for management can be submitted to cmastriola@dermatarx.com. The recording will be accessible for listening post event date with a link published to the Dermata Therapeutics website once available.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are based on the Company's current beliefs and expectations and new risks may emerge from time to time. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but are not limited to, statements related to: Dermata's shift to prioritize OTC dermatology products; the anticipated benefits of the strategic shift; the anticipated benefits of Dermata's strategic

shift, including acceleration of its path to commercialization, reduction of regulatory burdens, and expansion into broader consumer markets; the expected timing and success of any planned or future OTC product launches; and other factors described in the Company's filings with the Securities and Exchange Commission. These forward-looking statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug development, approval and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to Dermata's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Dermata undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

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