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): March 27, 2025

DERMATA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-40739**	**86-3218736**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

3525 Del Mar Heights Rd., #322, San Diego, CA	**92130**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code: **(858) 800-2543**

N/A
(Former name or former address, if changed since last report.)

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 Instruction 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**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.0001 per share	DRMA	The Nasdaq Capital Market
Warrants, exercisable for one share of Common Stock	DRMAW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1 933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01. Regulation FD Disclosure.

On March 27, 2025, Dermata Therapeutics, Inc. (the "Company") issued a press release announcing topline results from the Company's first pivotal Phase 3 Spongilla Treatment for Acne Research (STAR-1) trial of XYNGARI™, a novel, once-weekly, topical product candidate for the treatment of moderate-to-severe acne. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01. Other Events.

On March 27, 2025, the Company announced topline results from the Company's first pivotal Phase 3 trial of XYNGARI™, a novel, once-weekly, topical product candidate for the treatment of moderate-to-severe acne. The XYNGARI™ Phase 3 Spongilla Treatment for Acne Research (STAR-1) trial met all primary endpoints by achieving a statistically significant difference when compared with placebo after 12 weeks of once weekly treatments with XYNGARI™. XYNGARI™ appeared to be safe and well tolerated by patients with minimal treatment related adverse events and no serious adverse events attributed to treatment.

XYNGARI™ Phase 3 STAR-1 Clinical Study Design

The XYNGARI™ Phase 3 STAR-1 clinical study evaluated the efficacy, safety, and tolerability of XYNGARI™ in patients with moderate-to-severe facial acne. The STAR-1 study was a randomized (2:1), double-blind, and placebo-controlled study which enrolled 520 patients with moderate-to-severe acne, ages 9 years and older in the United States and Latin America. The primary endpoints include the mean change from baseline in inflammatory and noninflammatory lesion counts and the Investigator Global Assessment (IGA) treatment response. IGA is measured on a 5-point scale (0-4), with a treatment response defined as at least a 2-point improvement from baseline and an IGA score of 0 (clear) or 1 (almost clear). Patients were treated once-a-week for 12 weeks with either XYNGARI™ or placebo and were evaluated monthly. The STAR-1 study is the first of two pivotal Phase 3 studies, with the second Phase 3 study to be followed by an extension study. If positive, the results of the Phase 3 program would be used to support the filing of a new drug application with the U.S. Food and Drug Administration ("FDA").

XYNGARI™ Phase 3 STAR-1 Efficacy Results

In an intent to treat analysis, the Company saw statistically significant differences in IGA treatment success, inflammatory lesion count and non-inflammatory lesion count at Week 12 (study end) when compared to placebo.

Investigator Global Assessment: Patients achieving a 2-point reduction AND score of 0 or 1 ("clear" or "almost clear")

	Week 12
XYNGARI™ (n=342)	29.4%
Placebo (n=178)	15.2%
p-value	$p < 0.001$

Mean change from baseline in inflammatory lesion count

	Week 12
XYNGARI™ (n=342)	-16.8
Placebo (n=178)	-13.1
p-value	$p < 0.001$

Mean change from baseline in non-inflammatory lesion count

	Week 12
XYNGARI™ (n=342)	-17.3
Placebo (n=178)	-12.4
p-value	$p < 0.001$

Based on the foregoing results, the Company plans to initiate the second XYNAGRI™ Phase 3 STAR-2 trial in the second half of 2025, which will be followed by an open-label extension study. If the STAR-2 study produces positive results, the Phase 3 program is anticipated to help support the filing of a new drug application with the FDA.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 27, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DERMATA THERAPEUTICS, INC.

Dated: March 27, 2025

By: */s/ Gerald T. Proehl*
Name: Gerald T. Proehl
Title: Chief Executive Officer

BREAKING: Dermata's XYNGARI™ Phase 3 Trial Topline Data Meets All Primary Endpoints

- XYNGARI™ achieved its primary endpoints, demonstrating highly statistically significant and clinically meaningful improvement in acne -

- XYNGARI™ is the first once-weekly topical product candidate to demonstrate clinical benefit in a Phase 3 clinical trial for moderate-to-severe acne -

- Over 30 million acne patients seek treatment in the U.S. each year -

SAN DIEGO, CA, March 27, 2025 – Dermata Therapeutics, Inc. (Nasdaq: DRMA, DRMAW) ("Dermata" or the "Company"), a late-stage biotechnology company focusing on the treatment of medical skin diseases and aesthetic applications, today announced positive topline results from the Company's first pivotal Phase 3 trial of XYNGARI™, a novel, once-weekly, topical product candidate for the treatment of moderate-to-severe acne. XYNGARI™ also appeared to be safe and well tolerated by patients with minimal treatment related adverse events and no serious adverse events attributed to treatment.

The XYNGARI™ Phase 3 **S**pongilla **T**reatment for **A**cne **R**esearch (STAR-1) trial met all three primary endpoints by achieving a statistically significant difference when compared with placebo after 12 weeks of once weekly treatments with XYNGARI™.

"I believe having a once-weekly, topical product with a strong efficacy and safety profile, like XYNGARI™, would be a great addition to a dermatologist's arsenal for treating acne," commented Dr. Sunil Dhawan, MD, FAAD, FACP, clinical investigator at the Center for Dermatology Clinical Research, Inc., a participating site in the STAR-1 trial. "All FDA approved topical acne products are required to be applied at least once or twice a day, which may reduce patient compliance, so I believe having a once-weekly topical acne product like XYNGARI™ could lead to improved patient compliance," concluded Dr. Dhawan.

"We are incredibly excited about these Phase 3 clinical trial results for XYNGARI™, which we believe reinforce its potential as a unique acne treatment, distinct from any existing product on the market," said Gerry Proehl, Chairman, President, and Chief Executive Officer of Dermata. "The highly statistically significant efficacy data not only confirms the results of our Phase 2b acne study but also strengthens our confidence about the upcoming XYNGARI™ Phase 3 STAR-2 trial, set to launch in the second half of 2025. With these positive Phase 3 clinical trial results, we are eager to advance discussions with potential partners interested in securing future rights to XYNGARI™," Mr. Proehl added.

XYNGARI™ Phase 3 STAR-1 Clinical Study Design

The XYNGARI™ Phase 3 STAR-1 clinical study evaluated the efficacy, safety, and tolerability of XYNGARI™ in patients with moderate-to-severe facial acne. The STAR-1 study was a randomized (2:1), double-blind, and placebo-controlled study which enrolled 520 patients with moderate-to-severe acne, ages 9 years and older in the United States and Latin America. The primary endpoints include the mean change from baseline in inflammatory and noninflammatory lesion counts and the Investigator Global Assessment (IGA) treatment response. IGA is measured on a 5-point scale (0-4), with a treatment response defined as at least a 2-point improvement from baseline and an IGA score of 0 (clear) or 1 (almost clear). Patients were treated once-a-week for 12 weeks with either XYNGARI™ or placebo and were evaluated monthly. The STAR-1 study is the first of two pivotal Phase 3 studies, with the second Phase 3 study to be followed by an extension study. If positive, the results of the Phase 3 program would be used to support the filing of a new drug application with the U.S. Food and Drug Administration.

XYNGARI™ Phase 3 STAR-1 Topline Efficacy Results

In an intent to treat analysis, Dermata saw statistically significant differences in IGA treatment success, inflammatory lesion count and non-inflammatory lesion count at Week 12 (study end) when compared to placebo.

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Placebo (n=178)	-12.4
p-value	$p < 0.001$

“We wish to thank the study subjects and investigators for their participation in our study, as we could not have had this success without them,” states Christopher Nardo, Ph.D., Chief Development Officer of Dermata. “The clinical response observed in our XYNGARI™ Phase 3 STAR-1 trial gives us confidence that XYNGARI™, if approved, could alter the current treatment paradigm in acne by providing patients with a novel, natural, once-weekly treatment option with minimal side effects and potentially quicker time to treatment effect.”

Based on these results, Dermata plans to initiate the second XYNAGRI™ Phase 3 STAR-2 trial in the second half of 2025, which will be followed by an open-label extension study. If the STAR-2 study produces positive results, the Phase 3 program will help support the filing of a new drug application with the U.S. Food and Drug Administration.

About XYNGARI™ (formerly DMT310)

XYNGARI™ is a novel, once-weekly, topical product candidate derived from a freshwater sponge being developed for the treatment of multiple skin diseases. XYNGARI™ has multiple mechanisms of action that include mechanical components and chemical compounds to help treat inflammatory skin diseases, like acne. After processing, the sponge powder contains precisely sized and shaped silica spicules that upon application may help exfoliate the skin, promote collagen production, open closed comedones (creating an aerobic environment to help kill *C. acne* bacteria), and create microchannels to facilitate penetration of the sponge's naturally occurring chemical compounds. These chemical compounds have been shown, in-vitro, to have both antimicrobial and anti-inflammatory properties, which may play a significant role in the treatment of inflammatory skin diseases.

About Acne Vulgaris

Over 30 million acne patients in the U.S. seek treatment each year, with about 85% of U.S. teenagers experiencing some form of acne, and some individuals suffering from acne well into their 30s, 40s, and beyond. Acne is characterized by areas of scaly red skin, non-inflammatory blackheads and whiteheads, inflammatory papules and pustules, and occasionally cysts and scarring, which can present on the face, neck, chest, back, shoulders, and upper arms. While not life-threatening, acne can cause significant trauma for those suffering from it due to social stigmas, substantial risk of permanent facial scarring, lowered self-esteem, and social withdrawal.

About Dermata Therapeutics

Dermata Therapeutics is a late-stage biotechnology company focusing on the treatment of medical skin diseases and aesthetic applications. The Company's lead product candidate, XYNGARI™, is currently in Phase 3 and is the Company's first product candidate being developed from its *Spongilla* technology platform. XYNGARI™ is a once-weekly, topical product candidate derived from a naturally sourced freshwater sponge with multiple unique mechanisms of action. In addition to acne, XYNGARI™ is being studied for the treatment of psoriasis and rosacea. The Company's second product candidate, DMT410, uses its XYNGARI™ product candidate as a new method for needle-free intradermal delivery of botulinum toxin for the treatment of multiple aesthetic applications and medical skin diseases. Dermata is headquartered in San Diego, California. For more information, please visit http://www.dermatarx.com/.

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: expectations with regard to the potential market acceptance of any of the Company's product candidates; timing of trials and data events, including the initiation of a Phase 3 STAR-2 trial and extension study; expectations with regard to the timing and/or results or responses from meetings with regulatory bodies, including the FDA; expectations with regard to the timing of a New Drug Application with the FDA; the success, cost, funds available, and timing of its product candidate XYNGARI™ development activities and ongoing and planned clinical trials; and whether the results of XYNGARI™ will lead to future product development, partnerships, or approvals. 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, 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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