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): **December 5, 2022**

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)	(I.R.S. Employer Identification No.)

3525 Del Mar Heights Rd., #322
San Diego, CA 92130
(Address of principal executive offices, including zip code)

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

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:

☐ 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 1933 (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.

On December 5, 2022, Dermata Therapeutics, Inc. (the "Company") issued a press release announcing the topline results from its Phase 2 trial of once-weekly topical application of DMT310 for the treatment of moderate-to-severe rosacea. 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. Results of Operations and Financial Condition.

On December 5, 2022, the Company announced topline results from its Phase 2 trial of once-weekly topical application of DMT310 for the treatment of moderate-to-severe rosacea.

The data was supportive of DMT310 as a treatment for inflammatory skin diseases, but rosacea study did not meet primary endpoints. DMT310 produced no serious adverse events related to treatment. The Company observed a 44% reduction in inflammatory lesion counts after just 4 treatments with DMT310, which is consistent with the 45% reduction in inflammatory lesion counts the Company saw in its DMT310 Phase 2b acne study. The Company believes that the above average dropout rate of 23% for patients treated with DMT310 seen in the Phase 2 rosacea study, versus 13% seen in the Phase 2b acne study, may explain the reduced treatment effect of DMT310 at Week 12. Some patients did achieve a meaningful change in their rosacea with 36% of DMT310 patients meeting the criteria for a responder on the Investigators Global Assessment scale at Week 12. However, DMT310 was not able to statistically separate from placebo with 23% of placebo patients meeting the criteria as a responder at Week 12. A treatment responder is defined as an IGA grade of 'clear' or 'almost clear' and at least a 2-grade improvement from baseline.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 5, 2022, issued by Dermata Therapeutics, Inc. entitled "Dermata Announces Topline Results from DMT310 Phase 2 Clinical Trial for the Treatment of Moderate-to-Severe Rosacea."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Signature

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: December 5, 2022

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

Dermata Announces Topline Results from DMT310 Phase 2 Clinical Trial for the Treatment of Moderate-to-Severe Rosacea

- Data supportive of DMT310 as a treatment for inflammatory skin diseases, but rosacea study did not meet primary endpoints –

- DMT310 produced no serious adverse events related to treatment –

- Dermata remains on track to request an End of Phase 2 meeting with the FDA for DMT310 for the treatment of acne in the first quarter of 2023 –

SAN DIEGO, CA, December 5, 2022 -- Dermata Therapeutics, Inc. ("Dermata" or the "Company") (Nasdaq: DRMA; DRMAW), a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions, today announced topline results from its Phase 2 trial of once-weekly topical application of DMT310 for the treatment of moderate-to-severe rosacea. DMT310 is Dermata's lead product candidate, with both mechanical and chemical mechanisms of action, with positive Phase 2 data in moderate-to-severe acne and Phase 1b data in mild-to-moderate psoriasis.

"While the final data were not what we had hoped for, we were encouraged to see a 44% reduction in inflammatory lesion counts after just 4 treatments with DMT310, which mirrors the 45% reduction in inflammatory lesion counts we saw in our DMT310 Phase 2b acne study," stated Christopher Nardo Ph.D., Dermata's Chief Development Officer. "We believe the above average dropout rate of 23% for patients treated with DMT310 seen in this rosacea study, versus 13% seen in the Phase 2b acne study, could explain the reduced treatment effect of DMT310 at Week 12. Rosacea is a complicated skin disease that affects patients with sensitive skin and the disease waxes and wanes with environmental and physiological exposures. Some patients did achieve a meaningful change in their rosacea with 36% of DMT310 patients meeting the criteria for a responder on the Investigators Global Assessment scale at Week 12. However, DMT310 was not able to statistically separate from placebo with 23% of placebo patients meeting the criteria as a responder at Week 12," continued Dr. Nardo. "A treatment responder is defined as an IGA grade of 'clear' or 'almost clear' and at least a 2-grade improvement from baseline. Lastly, we want to thank the patients and investigators who participated in this study."

"While we are disappointed with the results in rosacea, we are still encouraged by DMT310's treatment potential for acne, as we have seen a highly statistically significant treatment effect in our DMT310 Phase 2b moderate-to-severe acne study on all three co-primary endpoints at Week 12," stated Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "We will continue to evaluate the full data set to determine DMT310's potential as a treatment for moderate-to-severe rosacea. At this time, we will focus our efforts and resources on preparing for our End of Phase 2 meeting with the FDA for DMT310 in moderate-to-severe acne and initiation of the Phase 3 acne program in 2023," continued Mr. Proehl. "With each clinical study, we learn more about this product candidate and still believe in DMT310's potential as a unique, once-weekly treatment option for acne and other inflammatory skin diseases," concluded Mr. Proehl.

About DMT310

DMT310 is Dermata's lead product candidate and incorporates the Company's proprietary *Spongilla* technology to topically treat a variety of dermatological skin diseases and conditions. DMT310 is a multifactorial natural product candidate derived from *Spongilla lacustris*, a unique freshwater sponge that is harvested under specific environmental conditions and then processed into a powder. The powder is mixed with a fluidizing agent immediately prior to its once-weekly application. In addition to its mechanical components which create microchannels into the dermis and promote skin turnover, DMT310's organic components contain chemical compounds that when tested *in vitro* have shown a dose dependent inhibition of inflammatory mediators, which we believe play a role in a variety of skin diseases.

About Dermata Therapeutics

Dermata Therapeutics, Inc. is a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions. The Company's lead product candidate, DMT310, is its first product candidate being developed from its *Spongilla* technology platform. DMT310 has been studied in various skin diseases with statistically significant Phase 2b results in acne and clinically meaningful results in psoriasis and rosacea. Dermata's second product candidate, DMT410, uses its S*pongilla* technology as a new method for topical intradermal delivery of botulinum toxin for the treatment of multiple aesthetic and medical skin conditions. 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: the potential development and commercialization of DMT310; feedback from any meeting or meetings with the FDA; the ability of the Company's product candidates to achieve applicable endpoints in clinical trials; whether the interpretation of clinical results from studies of DMT310 will lead to future product development; the safety and tolerability profile of DMT310; the timing of when additional studies of DMT310 in rosacea may occur, if any; the design of any potential additional studies to be conducted; and whether the Company will have the ability to obtain adequate funding for future development of its product candidates. 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.

Investors:
Sean Proehl
Senior Director, Legal and Business Development
info@dermatarx.com