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 21, 2024**

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)	(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 2.02. Results of Operations and Financial Condition.

On March 21, 2024, Dermata Therapeutics, Inc. (the "Company") issued a press release disclosing certain information regarding its results of operations for the fiscal year ended December 31, 2023. A copy of the press release is furnished under Item 2.02 as Exhibit 99.1.

The information included in this Item 2.02, and Exhibit 99.1 to this Current Report on Form 8-K, shall not be deemed "filed" for the purposes of or otherwise subject to the liabilities under Section 18 of the Securities Exchange Act of 1934 as amended (the "Exchange Act"). Unless expressly incorporated into a filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act made after the date hereof, the information contained in this Item 2.02 and Exhibit 99.1 hereto shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 7.01. Regulation FD Disclosure.

See "Item 2.02 Results of Operations and Financial Condition" above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 21, 2024, issued by Dermata Therapeutics, Inc. entitled "Dermata Therapeutics Provides Corporate Update and Reports Full Year 2023 Financial Results."
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: March 21, 2024

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

Dermata Therapeutics Provides Corporate Update and Reports Full Year 2023 Financial Results

- Initiated enrollment of DMT310 Phase 3 Spongilla Treatment of Acne Research (STAR-1) clinical trial in Q4 2023 -

- Raised $9.1 million in gross proceeds from three financings completed in 2023 -

- Received issuance of Japanese patent for DMT410 for the treatment of hyperhidrosis -

SAN DIEGO, CA, March 21, 2024 – Dermata Therapeutics, Inc. (Nasdaq: DRMA; DRMAW) ("Dermata," or the "Company"), a late-stage biotechnology company focused on the treatment of medical and aesthetic skin diseases and conditions, today highlighted recent corporate progress and reported financial results for the full year ended December 31, 2023.

"It is an enormous accomplishment for our team to have successfully initiated the first of two DMT310 Phase 3 clinical studies in acne," commented Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "We feel confident that based on the positive data observed in our DMT310 Phase 2b acne study that we have powered and designed the Phase 3 clinical studies to sufficiently detect a statistically significant difference in the primary endpoints of once weekly treatments of DMT310 when compared with placebo," continued Mr. Proehl. "We look forward to potentially completing enrollment of STAR-1 by the end of 2024 and we expect to receive topline results from STAR-1 in the first quarter of 2025," concluded Mr. Proehl.

Corporate Highlights

- **Dermata reached agreement with FDA to initiate the DMT310 Phase 3 clinical program.** After submission of amended protocols to FDA and FDA's agreement that Dermata's chemistry, manufacturing, and controls were sufficient to support initiation of the Phase 3 program, Dermata reached final agreement with FDA to proceed with the DMT310 Phase 3 clinical program in acne.

- **Dermata initiated the DMT310 Phase 3 STAR-1 clinical trial.** In December 2023, Dermata began enrolling patients in the STAR-1 clinical trial. The trial will examine the efficacy, safety, and tolerability of once weekly treatments of DMT310 for moderate-to-severe acne. Dermata plans to enroll approximately 550 acne patients who will be followed for 12 weeks. STAR-1 will be the first of two Phase 3 clinical trials, with the second Phase 3 trial followed by an extension study.

Anticipated Upcoming Milestones

- **Complete DMT310 Phase 3 STAR-1 clinical trial in moderate-to-severe acne.** Based on enrollment projections, Dermata expects to receive topline results from STAR-1 in the first quarter of 2025. STAR-1 will be the first of two Phase 3 clinical studies the Company will need to complete prior to filing a new drug application (NDA). If the Phase 3 program is successful, the Company intends to submit an NDA to FDA seeking regulatory approval of DMT310 for the treatment of moderate-to-severe acne.

- **DMT410 Partnership Discussions.** The Company continues to make progress on partnership discussions for its DMT410 program for the topical delivery of botulinum toxin. DMT410 is the Company's combination treatment regimen that uses the unique mechanical features of the Company's *Spongilla* technology to facilitate the intradermal delivery of botulinum toxin by topical application rather than through multiple injections with a needle. The Company has successfully completed proof-of-concept Phase 1 clinical trials using DMT410 in combination with BOTOX® for the treatment of primary axillary hyperhidrosis and for the treatment of multiple aesthetic skin conditions.

Full Year 2023 Financial Results

As of December 31, 2023, the Company had $7.4 million in cash and cash equivalents, compared to $6.2 million as of December 31, 2022. The increase in cash and cash equivalents resulted from $7.6 million net proceeds from three financings that closed in March 2023, May 2023, and November 2023, offset by $6.4 million of cash used in operations for the year ended December 31, 2023. The Company expects its current cash resources to be sufficient to fund operations into the third quarter of 2024.

Research and development expenses were $4.1 million for the year ended December 31, 2023, compared to $5.7 million for the year ended December 31, 2022. The decrease in research and development expense was the result of decreased clinical trial and non-clinical expenses during 2023, partially offset by increased chemistry, manufacturing, and controls, or CMC, expenses in preparation for the DMT310 Phase 3 program. Stock-based compensation attributable to research and development totaled $0.2 million for the years ended December 31, 2023, and 2022.

General and administrative expenses were $4.0 million for the years ended December 31, 2023, and 2022. Decreases in insurance and stock-based compensation expenses were offset by increased public company costs, including the expenses related to audit fees and shareholder meetings. Stock-based compensation attributable to general and administrative totaled $0.3 million for the year ended December 31, 2023, compared to $0.7 million for the year ended December 31, 2022.

About Dermata Therapeutics

Dermata Therapeutics, Inc. is a late-stage biotechnology company focusing on the treatment of medical and aesthetic skin diseases and conditions. The Company's lead product candidate, DMT310, is the Company’s first product candidate being developed from its *Spongilla* technology platform and is currently being evaluated in a Phase 3 program. DMT310 is a once-weekly topical product candidate derived from a naturally sourced freshwater sponge with multiple unique mechanisms of action. DMT310 has been studied for the treatment of acne, rosacea, and psoriasis. The Company's second product candidate, DMT410, uses its *Spongilla* technology as a new method for topical intradermal delivery of botulinum toxin for the treatment of hyperhidrosis and multiple aesthetic 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: expectations with regard to the timing of meetings and/or responses from submissions with regulatory bodies; expectations with regard to the timing of submission of an NDA; the uncertainties inherent in clinical trials including enrolling an adequate number of patients on time or be completed on schedule, if at all; timing and ability to generate clinical data; expectations with regard to any potential partnership opportunities for any of the Company's product candidates; the Company's expectations with regard to current cash and cash equivalents and the amount of time it will fund operations; the success, cost, and timing of its product candidates DMT310 and DMT410 development activities and ongoing and planned clinical trials; and whether the results of any ongoing or planned clinical trials of DMT310 or DMT410 will lead to future product development. 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.

DERMATA THERAPEUTICS, INC.
Balance Sheets

In thousands USD	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 7,438	$ 6,241
Prepaid expenses and other current assets	541	703
Total assets	7,979	6,944
Liabilities		
Accounts payable	866	497
Accrued liabilities	757	426
Total liabilities	1,623	923
Equity	6,356	6,021
Total liabilities and equity	$ 7,979	$ 6,944

DERMATA THERAPEUTICS, INC.
Statements of Operations

In thousands, except share and per share data	Years Ended December 31, 2023	2022
Operating expenses		
Research and development (1)	$ 4,070	$ 5,651
General and administrative (1)	3,972	4,023
Total operating expenses	8,042	9,674
Loss from operations	$ (8,042)	$ (9,674)
Interest income, net	247	63
Net loss	$ (7,795)	$ (9,611)
Net loss per common share, basic and diluted	$ (2.67)	$ (13.92)
Weighted average common shares outstanding, basic and diluted	2,924,398	690,666
(1) Includes the following stock-based compensation expense		
Research and development	$ 194	$ 218
General and administrative	$ 328	$ 712

Investors:
Sean Proehl
Associate General Counsel
info@dermatarx.com