

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): **May 11, 2023**

Dermata Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or Other Jurisdiction of Incorporation)	<u>001-40739</u> (Commission File Number)	<u>86-3218736</u> (I.R.S. Employer Identification No.)
<u>3525 Del Mar Heights Rd., #322</u> <u>San Diego, CA</u> (Address of principal executive offices)		<u>92130</u> (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:

<u>Title of Each Class:</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on which Registered</u>
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 May 11, 2023, Dermata Therapeutics, Inc. (the “Company”) issued a press release disclosing certain information regarding its results of operations for the fiscal period ended March 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.

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated May 11, 2023, issued by Dermata Therapeutics, Inc. entitled “Dermata Therapeutics, Inc. Provides Corporate Update and Reports First Quarter 2023 Financial Results.”</u>
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: May 11, 2023

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



**Dermata Therapeutics Provides Corporate Update and Reports First Quarter
2023 Financial Results**

- Dermata raised \$5 million gross proceeds from a public offering in March 2023 –

- Dermata submitted an End of Phase 2 meeting package to FDA in April 2023 –

- FDA agreed that Dermata’s chemistry, manufacturing, and control (“CMC”) procedures support the initiation of Phase 3 studies of DMT310 for the treatment of acne -

SAN DIEGO, CA, May 11, 2023 – **Dermata Therapeutics**, Inc. (Nasdaq: DRMA; DRMAW) (“Dermata,” or the “Company”), a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin diseases and conditions, today highlighted recent corporate progress, and reported financial results for the first quarter ended March 31, 2023.

“We are very encouraged by FDA’s agreement that our current CMC procedures for DMT310 are adequate to support progressing DMT310 into our Phase 3 program in moderate-to-severe acne. This was a big hurdle for Dermata as DMT310 is a novel product candidate and potentially could be the first naturally-derived prescription product for the treatment of acne,” said Gerry Proehl, Dermata’s Chairman, President, and Chief Executive Officer. “We are also excited to have submitted our DMT310 End of Phase 2 meeting package to FDA, which will allow Dermata an opportunity to engage FDA in a discussion regarding our proposed Phase 3 clinical program for acne. We believe we have met all the requirements to move forward with our Phase 3 acne program and look forward to receiving FDA feedback by the end of June 2023,” continued Mr. Proehl. “Being able to initiate the DMT310 Phase 3 acne program will be a significant step for Dermata as I am confident we can build upon the positive results we saw in our DMT310 Phase 2b acne study,” concluded Mr. Proehl.

Corporate Highlights

- **Dermata successfully closed a \$5.0 million public offering priced at-the-market under Nasdaq rules.** Dermata closed a public offering of 1,618,123 shares of the Company’s common stock (or pre-funded warrants in lieu thereof) and accompanying Series A warrants to purchase up to 1,618,123 shares of common stock and Series B warrants to purchase up to 1,618,123 shares of common stock at a combined offering price of \$3.09 per share of common stock (or pre-funded warrant in lieu thereof) and accompanying warrants, for aggregate gross proceeds of \$5.0 million, before deducting the placement agent’s fees and other offering expenses payable by the Company.
- **FDA provided a response to the Company’s Type C Meeting Package.** The Company received a response from FDA on the Company’s Type C CMC meeting package indicating Dermata has provided documentation of its CMC procedures and controls sufficient to support the initiation of DMT310 Phase 3 clinical program for the treatment of acne.

Anticipated Upcoming Milestones

- **DMT310 End of Phase 2 Responses from FDA.** Dermata expects to receive FDA feedback to the Company's End of Phase 2 meeting package by the end of June 2023. Feedback from FDA will help guide Dermata's design of its DMT310 Phase 3 program in moderate-to-severe acne patients.
- **DMT310 Phase 3 Program in Moderate-to-Severe Acne.** After receiving responses from FDA on the End of Phase 2 meeting, the Company intends to initiate its DMT310 Phase 3 acne program in 2H 2023. If the Phase 3 program is successful, the Company intends to submit a New Drug Application to FDA seeking regulatory approval of DMT310 for the treatment of moderate-to-severe acne.
- **DMT410 Partnership Discussions.** Dermata continues partnership discussions surrounding its DMT410 program for the topical delivery of botulinum toxin.

First Quarter 2023 Financial Results

As of March 31, 2023, Dermata had \$8.8 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 \$4.2 million net proceeds from the March 2023 public offering, offset by \$1.6 million in cash used in operations for the first quarter of 2023. Dermata expects its current cash resources are sufficient to fund operations into the first quarter of 2024.

Research and development expenses were \$1.2 million for the quarter ended March 31, 2023, compared to \$1.6 million for the quarter ended March 31, 2022. The decrease in research and development expenses was due to decreased clinical expenses, offset by increased non-clinical and CMC expenses for the DMT310 program.

General and administrative expenses were \$1.1 million for the quarter ended March 31, 2023, compared to \$1.2 million for the quarter ended March 31, 2022, resulting from decreases in insurance policy premiums.

About Dermata Therapeutics

Dermata Therapeutics, Inc. is a clinical-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. 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; the uncertainties inherent in clinical trials; 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

<i>In 000's</i>	<u>March 31, 2023</u>	<u>December 31, 2022</u>
	(unaudited)	
Assets		
Cash and cash equivalents	\$ 8,767	\$ 6,241
Prepaid expenses and other current assets	528	703
Total assets	<u>9,295</u>	<u>6,944</u>
Liabilities		
Accounts payable	493	496
Accrued liabilities	714	426
Total liabilities	<u>1,207</u>	<u>922</u>
Equity	<u>8,088</u>	<u>6,022</u>
Total liabilities and equity	<u>\$ 9,296</u>	<u>\$ 6,944</u>

DERMATA THERAPEUTICS, INC.
Statements of Operations

<i>In 000's, except share and per share data</i>	Three Months Ended March 31,	
	2023	2022
	(unaudited)	(unaudited)
Operating expenses		
Research and development ⁽¹⁾	\$ 1,193	\$ 1,596
General and administrative ⁽¹⁾	<u>1,085</u>	<u>1,190</u>
Total operating expenses	<u>2,278</u>	<u>2,786</u>
Loss from operations	<u>(2,278)</u>	<u>(2,786)</u>
Interest income, net	<u>(38)</u>	<u>-</u>
Net loss	<u>\$ (2,240)</u>	<u>\$ (2,786)</u>
Net loss per common share, basic and diluted	<u>\$ (2.27)</u>	<u>\$ (5.35)</u>
Weighted average common shares outstanding, basic and diluted	<u>985,848</u>	<u>520,539</u>
⁽¹⁾ Includes the following stock-based compensation expense (in 000's)		
Research and development	\$ 48	\$ 55
General and administrative	\$ 83	\$ 158

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