

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): August 10, 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 August 10, 2023, Dermata Therapeutics, Inc. (the “Company”) issued a press release disclosing certain information regarding its results of operations for the quarter ended June 30, 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	<a href="#">Press Release, dated August 10, 2023, issued by Dermata Therapeutics, Inc. entitled “Dermata Therapeutics Provides Corporate Update and Reports Second Quarter 2023 Financial Results.”</a>
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: August 10, 2023

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



## Dermata Therapeutics Provides Corporate Update and Reports Second Quarter 2023 Financial Results

- Raised an aggregate of \$6.8 million in gross proceeds from two financings completed in 1H 2023 -
- Received positive feedback on its End of Phase 2 meeting package from FDA in June 2023 -
- Phase 3 STAR-1 study is projected to start enrolling patients in the 2H 2023 -

**SAN DIEGO, CA, August 10, 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 second quarter ended June 30, 2023.

“The second quarter was another crucial period for our team where we successfully raised additional capital to extend our runway into the second quarter of 2024 and we received positive feedback from FDA on our End of Phase 2 meeting package. We are excited that FDA agreed that our Phase 3 clinical study design appeared acceptable to support filing a new drug application and we have submitted amendments to the Phase 3 protocols to include some additional safety testing as recommended by FDA,” said Gerry Proehl, Dermata’s Chairman, President, and Chief Executive Officer. “We are currently completing the manufacturing of the drug product and placebo batches for the Phase 3 clinical trials in anticipation of final agreement with FDA to initiate the Phase 3 clinical program,” concluded Mr. Proehl.

### Corporate Highlights

- **Dermata successfully closed a \$1.8 million offering in May 2023 priced at-the-market under Nasdaq rules.** The Company closed a registered direct offering of an aggregate of 800,877 shares of the Company’s common stock (or pre-funded warrants in lieu thereof) and accompanying warrants to purchase up to 800,877 shares of common stock at a combined offering price of \$2.285 per share of common stock (or pre-funded warrant in lieu thereof) and accompanying warrant, for aggregate gross proceeds of \$1.8 million, before deducting the placement agent’s fees and other offering expenses payable by the Company.
- **FDA provided responses to the Company’s End of Phase 2 Meeting Package in June 2023.** The Company received responses from FDA on the Company’s End of Phase 2 meeting package including an agreement that (1) the Company’s nonclinical program appears reasonable to support Phase 3 clinical trials, (2) the overall Phase 3 clinical development program appears acceptable to support filing a New Drug Application (NDA), (3) the three co-primary endpoints and secondary endpoints proposed in the Phase 3 clinical trial protocols are acceptable, and (4) the completed and planned nonclinical studies would be sufficient to support the submission of an NDA. Additionally, at the recommendation of FDA, the Company has agreed to include additional safety evaluations (laboratory measurements, electrocardiograms, and an extension study) in the Phase 3 clinical program and the Company has submitted final amended protocols to FDA.

### Anticipated Upcoming Milestones

- **Initiate DMT310 Phase 3 Program in Moderate-to-Severe Acne.** After receiving responses from FDA on the amended Phase 3 clinical trial protocols, the Company intends to initiate its DMT310 Phase 3 STAR-1 study in 2H 2023. STAR-1 will be the first of two Phase 3 clinical studies the Company will need to complete prior to filing an 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 pursue partnership discussions for its DMT410 program for the topical delivery of botulinum toxin.

### Second Quarter 2023 Financial Results

As of June 30, 2023, Dermata had \$8.4 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 \$5.7 million net proceeds from the financing that closed in March 2023 and May 2023, offset by \$3.5 million of cash used in operations for the six months ended June 30, 2023. Dermata expects its current cash resources are sufficient to fund operations into the second quarter of 2024.

Research and development expenses were \$0.8 million for the quarter ended June 30, 2023, compared to \$1.6 million for the quarter ended June 30, 2022. The decrease in research and development expenses was due to decreased clinical expenses, offset by increased non-clinical and chemicals, manufacturing, and controls expenses for the DMT310 program.

General and administrative expenses were \$0.9 million for the quarter ended June 30, 2023, compared to \$1.1 million for the quarter ended June 30, 2022, resulting from decreases in payments for 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/>.

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## 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; 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.

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**DERMATA THERAPEUTICS, INC.**  
Balance Sheets

	<u>June 30, 2023</u> (unaudited)	<u>December 31, 2022</u>
<i>In 000's</i>		
<b>Assets</b>		
Cash and cash equivalents	\$ 8,439	\$ 6,241
Prepaid expenses and other current assets	274	703
Total assets	<u>8,713</u>	<u>6,944</u>
<b>Liabilities</b>		
Accounts payable	438	496
Accrued liabilities	245	426
Total liabilities	<u>683</u>	<u>922</u>
<b>Equity</b>	8,030	6,022
<b>Total liabilities and equity</b>	<u>\$ 8,713</u>	<u>\$ 6,944</u>

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**DERMATA THERAPEUTICS, INC.**  
Statements of Operations

*In 000's, except share and per share data*

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>	<b>2023</b>	<b>2022</b>
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
<b>Operating expenses</b>				
Research and development <sup>(1)</sup>	\$ 839	\$ 1,613	\$ 2,032	\$ 3,208
General and administrative <sup>(1)</sup>	893	1,118	1,979	2,308
Total operating expenses	1,732	2,731	4,010	5,516
Loss from operations	(1,732)	(2,731)	(4,010)	(5,516)
Interest income, net	(31)	-	(69)	-
<b>Net loss</b>	<b>\$ (1,701)</b>	<b>\$ (2,731)</b>	<b>\$ (3,942)</b>	<b>\$ (5,516)</b>
Net loss per common share, basic and diluted	\$ (0.63)	\$ (3.90)	\$ (2.13)	\$ (9.02)
Weighted average common shares outstanding, basic and diluted	2,704,987	699,679	1,850,167	611,344

<sup>(1)</sup> Includes the following stock-based compensation expense:

Research and development	\$ 48	\$ 53	\$ 97	\$ 109
General and administrative	\$ 83	\$ 208	\$ 166	\$ 366

**Investors:**

Sean Proehl

Senior Director, Legal and Business Development

[info@dermatarx.com](mailto:info@dermatarx.com)