

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 28, 2022**

Dermata Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction
of Incorporation)

001-40739

(Commission
File Number)

86-3218736

(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 2.02 Results of Operations and Financial Condition.

Dermata Therapeutics, Inc. (the “Company”) issued a press release on March 28, 2022, disclosing financial information and operating metrics for the fiscal year ended December 31, 2021, and providing a corporate update. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD.

See “Item 2.02 Results of Operation and Financial Condition” above.

The information in this Current Report on Form 8-K under Items 2.02 and 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, 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 Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release of Dermata Therapeutics, Inc. issued March 28, 2022
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 28, 2022

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



Dermata Therapeutics Provides Corporate Update and Reports Full Year 2021 Financial Results

DMT310 Phase 2 rosacea trial is over two-thirds enrolled with topline results expected in H2 2022

DMT310 Phase 2 psoriasis trial to start H1 2022, with topline results expected in H1 2023

DMT310 Phase 3 moderate-to-severe acne trials planned for H1 2023

SAN DIEGO, CA, March 28, 2022 – Dermata Therapeutics, Inc. (Nasdaq: DRMA; DRMAW) (“Dermata” or the “Company”), a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin conditions, today highlighted recent corporate progress and reported financial results for the year ended December 31, 2021.

“We continue to make excellent progress with the clinical programs for DMT310, our once weekly topical product derived from a naturally sourced freshwater sponge. In October 2021, we announced positive results from a Phase 1b proof of concept clinical trial in mild-to-moderate psoriasis patients. In November 2021, we initiated a Phase 2 trial in moderate-to-severe rosacea patients, where we believe DMT310’s anti-inflammatory properties can demonstrate a clinical effect on the inflammatory lesions of rosacea, similar to the clinical effects we have seen in our Phase 2 acne studies. We expect to complete enrollment for this Phase 2 trial in moderate-to-severe rosacea in the first half of 2022 and expect to announce topline results in the second half of 2022,” commented Gerry Proehl, Dermata’s Chairman, President, and Chief Executive Officer. “Additionally, we now have FDA guidance on the trials and trial designs required for an End of Phase 2 meeting with the FDA for moderate-to-severe acne, which we believe we can leverage for our other DMT310 clinical programs,” concluded Mr. Proehl.

“For DMT410, our combination product with botulinum toxin Type A, we completed a Phase 1b study in facial aesthetics with demonstrated improvements in several aesthetic measures that we believe continue to have a high unmet need. Successfully delivering botulinum toxin to the dermis through topical administration has been a target for many years and we believe DMT410 has demonstrated an ability to do just that,” stated Chris Nardo, Ph.D., Dermata’s Senior Vice President of Development. “With a topical application of DMT410, we were able to see a reduction in the number and size of pores, a reduction in fine lines, and a reduction in sebum production. In addition, the investigator graded most patients as improved in luminosity, brightness, and overall aesthetic appearance,” concluded Dr. Nardo.

Corporate Highlights

- **In November 2021, Dermata initiated a DMT310 Phase 2 trial in moderate-to-severe rosacea.** On November 15, 2021, the Company enrolled its first patient in a Phase 2 rosacea trial. As of March 28, 2022, the trial is more than two-thirds enrolled, with the last patient expected to be enrolled in the first half of 2022, with topline results expected in the second half of 2022. The trial is double-blinded, randomized, placebo-controlled with approximately 180 patients expected to be enrolled at 20 clinical sites in the United States. The co-primary endpoints are absolute reduction in inflammatory lesion count and Investigator Global Assessment (IGA), which will be graded on a 5-point scale (0-4). To be considered a responder, a patient needs to have at least a 2-grade reduction and an IGA score of 0 or 1.
- **In November 2021, Dermata successfully completed a Phase 1b proof of concept trial of DMT410 in facial aesthetics with compelling results.** In the trial, DMT410 showed a reduction in the size and number of pores and a reduction in fine lines as shown by facial photography. The Company also measured a reduction in sebum production. In addition, the clinical investigator observed improvements in luminosity, brightness, and patient’s overall facial aesthetic. The Company intends to seek to partner with a botulinum toxin company prior to moving into Phase 2.
- **FDA provided the Company with clarity on the trial requirements and trial designs required prior to holding an End of Phase 2 meeting with the FDA for the DMT310 Phase 3 acne studies.** In February 2022, the Company received feedback from the FDA on the non-clinical studies and Pharmacokinetic study required to be completed prior to an End of Phase 2 meeting with the FDA. The Company expects to complete these required studies by the end of 2022 and request an End of Phase 2 meeting with the FDA in Q1 2023.

Anticipated Upcoming Milestones

- **DMT310 Phase 2 trial in mild-to-moderate psoriasis.** Based on the clinical results seen in its Phase 1b trial, the Company plans on initiating a DMT310 Phase 2 study in mild-to-moderate psoriasis in the first half of 2022, with topline results expected in the first half of 2023. The trial will be double-blinded, randomized, placebo-controlled which is anticipated to enroll approximately 150 mild-to-moderate psoriasis patients at clinical sites in the United States.
- **DMT310 Phase 3 trials in moderate-to-severe acne.** After the End of Phase 2 meeting with FDA planned for the first quarter of 2023, the Company plans to initiate the two Phase 3 trials in the first half of 2023. Results from these two trials are expected in the second half of 2024, with an intended filing of the NDA approximately 6 months after completion of the trials.

Full Year 2021 Financial Results

As of December 31, 2021, Dermata had \$10.8 million in cash, compared to \$0.5 million as of December 31, 2020. Dermata received net proceeds of \$15.4 million from the sale of its common stock and warrants in its initial public offering which closed in August 2021, proceeds which are expected to fund operations into the fourth quarter of 2022.

Research and development expenses were \$3.5 million for the year ended December 31, 2021, compared to \$1.6 million for the year ended December 31, 2020. The increase in research and development expenses was due to increased clinical trial and non-clinical expenses and manufacturing costs, as well as increases in salaries, benefits, and stock-based compensation expense. Stock-based compensation expense attributable to research and development totaled \$0.4 million for the year ended December 31, 2021.

General and administrative expenses were \$4.4 million for the year ended December 31, 2021, compared to \$1.6 million for the year ended December 31, 2020. The increase in general and administrative expenses was due to increased professional fees, insurance costs, and salaries, benefits, and stock-based compensation expense. Stock-based compensation expense attributable to general and administrative totaled \$1.6 million for the year ended December 31, 2021.

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 the 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 is currently under clinical development for the treatment of acne, psoriasis, and rosacea. 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 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 data events; expectations with regard to any potential partnership opportunities for the Company's product candidates; the Company's expectations with regard to current cash 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 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.
(Formerly Dermata Therapeutics, LLC)
Balance Sheets

	December 31, 2021	December 31, 2020
Assets		
Cash	\$ 10,798,806	\$ 530,400
Other current assets	825,134	75,053
Total assets	11,623,940	605,453
Liabilities		
Accounts payable	515,245	104,276
Accrued liabilities	1,001,591	133,477
Convertible notes	-	2,989,479
Debt	-	556,160
Total liabilities	1,516,836	3,783,392
Equity (deficit)	10,107,104	(3,177,939)
Total liabilities and equity	\$ 11,623,940	\$ 605,453

DERMATA THERAPEUTICS, INC.
(Formerly Dermata Therapeutics, LLC)
Statements of Operations

	Years Ended December 31,	
	2021	2020
Operating expenses		
Research and development (1)	\$ 3,459,340	\$ 1,607,819
General and administrative (1)	4,397,524	1,565,034
Total operating expenses	7,856,864	3,172,853
Loss from operations	(7,856,864)	(3,172,853)
Interest expense, net	45,613	63,677
Net loss	\$ (7,902,477)	\$ (3,236,530)
Deemed dividend upon redemption of 5,221,156 shares of Series 1c preferred stock	\$ 269,038	\$ -
Deemed dividend upon the amendment of terms of the Series 1d convertible preferred stock	\$ 2,293,199	\$ -
Net loss attributable to common stockholders	\$ (10,464,714)	\$ (3,236,530)
Net loss per common share, basic and diluted	\$ (2.43)	\$ (1.69)
Weighted average common shares outstanding, basic and diluted	4,302,232	1,911,009
(1) Includes the following stock-based compensation expense		
Research and development	\$ 354,201	\$ -
General and administrative	\$ 1,551,207	\$ -

Investors:
Sean Prochl
Senior Director, Legal and Business Development
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