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): **February 4, 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 8.01 (Other Events).

Dermata Therapeutics, Inc. (the "Company") has submitted requests to the U.S. Food and Drug Administration (the "FDA") for the waiver of the requirements to complete a 90-day dermal minipig study and a standard dermal pharmacokinetic study prior to holding an End of Phase 2 meeting with the FDA for the Company's DMT310 acne program. While the Company has already planned and budgeted to conduct both studies, the Company submitted the requests for waiver because DMT310 has been used in clinical trials by over 170 human patients exhibiting an acceptable safety and tolerability profile. Further, the Company was given approval by the FDA to use DMT310 in the Company's ongoing 180 human patient Phase 2 study for the treatment of rosacea. Typically, the FDA requires the 90-day dermal minipig study to be conducted prior to filing an Investigational New Drug application and proceeding to trials in humans for a topical dermatology development product candidate. However, due in part to DMT310's historical safety profile and the Company's ability to reference the FDA's Botanical Drug Development Guidance for Industry for certain aspects of the development of DMT310, the FDA allowed DMT310 to proceed directly into human trials without first completing this 90-day dermal minipig study. Considering the human safety data collected from DMT310 clinical trials and the historical safety data collected to date, the Company believes the FDA may grant the waiver request with respect to the 90-day dermal minipig study. If the FDA grants the waiver request with respect to conducting a 90-day dermal minipig study, the Company believes it would provide a cost savings of approximately $600,000 in development costs. Alternatively, the FDA may waive the Company's requirement to complete the 90-day dermal minipig study prior to initiating the Phase 3 acne program, but still require the study be completed prior to a New Drug Application submission.

The Company has also submitted a request to the FDA for the waiver of the requirement to conduct the standard dermal pharmacokinetic study. The Company submitted this request for waiver based on the human tolerability and safety profile of DMT310 observed to date. If the FDA grants both waiver requests, the Company plans to immediately request an End of Phase 2 meeting with the FDA and begin the process to initiate the Company's Phase 3 acne program in the second half of 2022. If the FDA grants the Company's waiver request only with respect to the 90-day dermal minipig study, the Company believes it can still complete the standard dermal pharmacokinetic study and initiate the Phase 3 program in 2022, as planned. If the FDA grants the waiver request only with respect to the standard dermal pharmacokinetic study, or denies both of waiver requests, the Company may be forced to delay the start of its Phase 3 program into 2023 due to supply chain constraints relating to the acquisition of the required minipigs used in the 90-day dermal minipig study.

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: February 4, 2022

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