

**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 20, 2025

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
*(IRS Employer
Identification No.)*

3525 Del Mar Heights Rd., #322, San Diego, CA
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: **(858) 800-2543**

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 (see General Instruction A.2. below):

- ☐ 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 7.01. Regulation FD Disclosure.

On May 20, 2025, Dermata Therapeutics, Inc. (the "Company") announced that it has initiated the manufacturing of the drug product for the XYNGARI[™] Phase 3 STAR-2 trial ("STAR-2") and expects the STAR-2 trial to commence in the fourth quarter of 2025, which the Company believes would enable the publication of topline trial results from the STAR-2 trial in first half of 2027. Patients from the STAR-2 trial will be allowed to rollover into a 9-month extension study to gather further safety and efficacy data to support a potential new drug application ("NDA") for XYNGARI[™] with the U.S. Food and Drug Administration. Based on the Company's view of the clinical trial pathway for XYNGARI[™], the Company anticipates the completion of this extension study by the end of the fourth quarter 2027 with a potential NDA filing in first half of 2028.

Item 8.01. Other Events.

The information provided above under Item 7.01 is incorporated by reference into this Item 8.01.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as "aims," "anticipates," "believes," "could," "expects," estimates," "intends," "may," "plans," "potential," "projects," "should," "will," and "would," or similar references to future periods. Examples of forward-looking statements in this Current Report on Form 8-K include, without limitation, statements regarding 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 to be completed on schedule, if at all; timing and ability to generate clinical data; expectations with regard to the nature of any clinical data; 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 XYNGARI™ development activities and ongoing and planned clinical trials; and whether the results of any ongoing or planned clinical trials of XYNGARI™ will lead to future product development. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in or implied by the forward-looking statements, see the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission as well as discussions of potential risks, uncertainties and other important factors in any subsequent Company filings with the Securities and Exchange Commission. All information in this Current Report on Form 8-K is as of the date of the filing; the Company undertakes no duty to update this information unless required by law.

SIGNATURES

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 21, 2025

By: /s/ Gerald T. Proehl

Name: Gerald T. Proehl

Title: Chief Executive Officer
