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): **November 19, 2021**

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 7.01. Regulation FD.

On November 19, 2021, Dermata Therapeutics, Inc. (the "Company") issued a press release announcing positive efficacy and safety data from its Phase 1b proof of concept study evaluating a single treatment of one of the Company's lead product candidates, DMT410, to treat multiple aesthetic skin conditions. The Phase 1b data were also featured in a presentation at the American Society for Dermatologic Surgery 2021 Annual Meeting held November 19-21, 2021. A copy of the press release is attached hereto as Exhibit 99.1. The Company will also hold a webcast to discuss the data at 4:30 pm ET on November 19, 2021. After the webcast, a copy of the presentation will be available on the "Investors" page of the Company's website, www.dermatarx.com, under the "Company Info" tab.

Investors should note that the Company currently announces material information to its investors and others using filings with the Securities and Exchange Commission, press releases, public conference calls, webcasts or the Company's corporate website (www.dermatarx.com), including news and announcements regarding its financial performance, key personnel, its clinical development and its business strategy. The information on the Company's website is not, and shall not be deemed to be, a part hereof or incorporated into this or any of the Company's other filings with the SEC.

The information in this Current Report on Form 8-K under Item 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 (the "Exchange Act"), 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 Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On November 19, 2021, the Company announced efficacy and safety data from its Phase 1b proof of concept study evaluating a single treatment of one of the Company's lead product candidates, DMT410, to treat multiple aesthetic skin conditions.

The open-label, single-center study of 10 female patients receiving one treatment of DMT410, which consists of one topical application of*Spongilla* powder followed by one topical application of 64 units of OnabotulinumtoxinA (BOTOX®) to the upper face. Patients were observed at four weeks, eight weeks, 12 weeks, and 16 weeks to collect safety and efficacy data and track duration of effect.

The endpoints of the study included reduction in pore size, improvements in the Global Aesthetic Improvement scale, improvement in luminosity and brightness, reduction in sebum production, reduction in fine lines, and reduction of glabellar, forehead, and lateral canthal lines.

- Global Aesthetic Improvement (GAI) - the physician measured an improvement in patient's overall GAI at week 4 in 70% of patients, 80% of patients at week 8, and 60% of patients at week 12. GAI is measured on a 4-point scale, with at least a 1-point reduction being a 25% improvement. The mean improvement in GAI score from baseline was 0.8 at week 8.

- Pore size - the physician observed an improvement in pore size in 50% of patients at week 4, 60% of patients at week 8, and 50% of patients at week 12. An improvement in pore size is measured on a 4-point scale, with at least a 1-point reduction being a 25% decrease in pore size. The mean improvement in pore size from baseline was about 0.7 at week 8.

- Luminosity - the intensity of light area reflected on the skin, improved in 50% of patients at week 4, 90% of patients at week 8, and 90% of patients at week 12. The mean improvement of luminosity from baseline, on a scale of 0 to 10 points, peaked at 1.4 points of improvement at week 12.

- Brightness - a measurement of the combined uniformity of skin coloring and texture, improved in 30% of patients at week 4, 60% of patients at week 8, and 60% of patients at week 12. The mean improvement of brightness from baseline, on a scale of 0 to 10 points, peaked at 0.7 points of improvement at week 12.

- Upper facial lines - a measurement of the visible improvement of a patient's forehead, lateral canthal, and glabellar lines did not show clinically meaningful improvement. This result is consistent with the knowledge that botulinum toxin is only approved for injections into the muscle to treat these endpoints.

In terms of safety and tolerability, DMT410 was generally safe and well tolerated with no adverse events reported, no withdrawals due to treatment-related adverse events, and no potential distant spread of toxin reported.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which the Company operates and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or the Company's financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibits are furnished with this report:

Exhibit No.	Description
99.1	Press Release, dated November 19, 2021, issued by Dermata Therapeutics, Inc. entitled "Dermata Announces Positive Results from DMT410 Phase 1b Proof of Concept Study for Aesthetic Skin Conditions."
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: November 19, 2021

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

Dermata Announces Positive Results from DMT410 Phase 1b Proof of Concept Study for Aesthetic Skin Conditions

- Observed improvements in pore size, luminosity, brightness, and overall aesthetic appearance -

- Duration of effect lasted approximately 3 months -

- No potential distant spread of toxin observed -

SAN DIEGO, CA, November 19, 2021 -- Dermata Therapeutics, Inc. ("Dermata," or the "Company") (Nasdaq: DRMA), a clinical-stage biotechnology company focused on the treatment of medical and aesthetic skin conditions, today announced positive efficacy and safety data from its Phase 1b proof of concept study evaluating a single treatment of DMT410 to treat multiple aesthetic skin conditions. This data was presented at The American Society for Dermatologic Surgery 2021 Annual Meeting held today through November 21, 2021.

Dermata will be hosting a virtual investor event via live webcast later today at 4:30 pm ET. The live webcast may be accessed via the "Investors" section of Dermata's website or by clicking the following link.

"We are excited to present the positive results from this proof of concept study of DMT410 showing our product candidate's ability to achieve topical administration of OnabotulinumtoxinA. During the trial, we saw results across multiple aesthetic endpoints that indicate DMT410's ability to provide targeted topical delivery of OnabotulinumtoxinA to the dermis," stated Christopher Nardo, Ph.D., Dermata's Senior Vice President of Development. "Patients demonstrated improvements in skin quality endpoints, such as brightness, luminosity, and reduction in pore size. Since we did not expect OnabotuliniumtoxinA to penetrate into the muscle, we saw minimal effect on the upper facial lines typically treated with injections of OnabotulinumtoxinA. Based on these data we believe that most of the toxin remained in the dermis limiting potential distant spread of toxin and its side effects."

DMT410 Phase 1b Aesthetic Study Design

The Phase 1b proof of concept study was an open-label, single-center study of 10 female patients receiving one treatment of DMT410, which consists of one topical application of *Spongilla* powder followed by one topical application of 64 units of OnabotulinumtoxinA (BOTOX®) to the upper face. Patients were observed at 4 weeks, 8 weeks, 12 weeks, and 16 weeks to collect safety and efficacy data and track duration of effect.

The endpoints of the study included reduction in pore size, improvements in the Global Aesthetic Improvement scale, improvement in luminosity and brightness, reduction in sebum production, reduction in fine lines, and reduction of glabellar, forehead, and lateral canthal lines.

DMT410 Phase 1b Aesthetic Study Results

DMT410 showed an improvement in the following key facial aesthetic measurements:

- Global Aesthetic Improvement (GAI) - the physician measured an improvement in patient's overall GAI at week 4 in 70% of patients, 80% of patients at week 8, and 60% of patients at week 12. GAI is measured on a 4-point scale, with at least a 1-point reduction being a 25% improvement. The mean improvement in GAI score from baseline was 0.8 at week 8.

- Pore size - the physician observed an improvement in pore size in 50% of patients at week 4, 60% of patients at week 8, and 50% of patients at week 12. An improvement in pore size is measured on a 4-point scale, with at least a 1-point reduction being a 25% decrease in pore size. The mean improvement in pore size from baseline was about 0.7 at week 8.

- Luminosity - the intensity of light area reflected on the skin, improved in 50% of patients at week 4, 90% of patients at week 8, and 90% of patients at week 12. The mean improvement of luminosity from baseline, on a scale of 0 to 10 points, peaked at 1.4 points of improvement at week 12.

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- Upper facial lines - a measurement of the visible improvement of a patient's forehead, lateral canthal, and glabellar lines did not show clinically meaningful improvement. This result is consistent with the knowledge that botulinum toxin is only approved for injections into the muscle to treat these endpoints.

In terms of safety and tolerability, DMT410 was generally safe and well tolerated with no adverse events reported, no withdrawals due to treatment-related adverse events, and no potential distant spread of toxin reported.

"We believe that DMT410's ability to achieve the topical delivery of botulinum toxin into the dermis increases the market opportunity for botulinum toxins as DMT410 would be complementary to injections of botulinum toxin into the muscles that treat forehead, lateral canthal, and glabellar lines," commented Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "We are pleased to have been selected to present these data at the American Society for Dermatological Surgery, and we look forward to our upcoming investor webcast to further discuss our findings."

About DMT410

DMT410 is Dermata's combination treatment regimen that uses the unique mechanical features of its*Spongilla* technology to facilitate the intradermal delivery of botulinum toxin by topical application rather than injection with a needle. The treatment consists of an initial topical application of Dermata's proprietary *Spongilla* powder to the treatment area where the spicules penetrate the stratum corneum creating microchannels into the dermis allowing for the topical application and penetration of botulinum toxin. Dermata is investigating DMT410 as a new method for topical intradermal delivery of botulinum toxin for the treatment of multiple aesthetic and medical skin conditions.

Conference Call

Dermata will host a conference call and a live webcast at 1:30 p.m. PT / 4:30 p.m. ET on November 19, 2021 to discuss the results. Individuals interested in listening to the conference call may do so by dialing (888) 506-0062 for domestic callers, or (973) 528-0011 for international callers and reference conference ID: 497530; or from the webcast link in the investor relations section of the company's website at: www.dermatarx.com. A replay of the call will be available until Friday, December 03, 2021. To access the replay, dial (877) 481-4010 or (919) 882-2331 and reference conference ID: 43543.

About Dermata

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 under clinical development for the treatment of acne, psoriasis, and rosacea. Dermata'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 and medical skin conditions. Dermata is headquartered in San Diego, California. For more information, please visit 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: the potential development and commercialization of product candidate DMT410 in aesthetic or medical skin conditions; the ability of the Company to find a partner with a botulinum toxin; the timing of when additional studies in DMT410 may occur, if any; the design of additional studies to be conducted; the safety and tolerability profile of DMT410; and the Company's ability to obtain funding for operations, development, and commercialization of DMT410. 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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