

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2023

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-40739

DERMATA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

86-3218736

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification Number)

3525 Del Mar Heights Rd., #322, San Diego, CA

92130

(Address of Principal Executive Offices)

(Zip Code)

858-800-2543

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to Section 240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Capital Market on June 30, 2023, was approximately \$4.8 million.

As of March 18, 2024, the number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, was 6,660,840.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement for the 2024 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference in Part III of this Form 10-K.

**DERMATA THERAPEUTICS, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023**

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as “may,” “can,” “anticipate,” “assume,” “should,” “indicate,” “would,” “believe,” “contemplate,” “expect,” “seek,” “estimate,” “continue,” “plan,” “point to,” “project,” “predict,” “could,” “intend,” “target,” “potential” and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history;
- the expectation that we will incur significant operating losses for the foreseeable future and will need significant additional capital;
- our current and future capital requirements to support our development and commercialization efforts for our product candidates and our ability to satisfy our capital needs;
- our dependence on our product candidates, which are still in preclinical or early stages of clinical development;
- our ability to acquire sufficient quantities of raw material needed to manufacture our drug product;
- our, or that of our third-party manufacturers, ability to manufacture cGMP quantities of our product candidates as required for pre-clinical and clinical trials and, subsequently, our ability to manufacture commercial quantities of our product candidates;
- our ability to complete required clinical trials for our product candidates and obtain approval from the FDA or other regulatory agencies in different jurisdictions;
- our lack of a sales and marketing organization and our ability to commercialize our product candidates if we obtain regulatory approval;
- our dependence on third-parties to manufacture our product candidates;
- our reliance on third-party CROs to conduct our clinical trials;
- our ability to maintain or protect the validity of our intellectual property;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support organizational and business growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in such forward-looking statements. Please see “Part I—Item 1A—Risk Factors” for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

## PART I

### ITEM 1. BUSINESS

All references in this report to “Dermata,” the “Company,” “we,” “us,” or “our” mean Dermata Therapeutics, Inc. and its subsidiaries unless stated otherwise or the context otherwise indicates.

#### Overview

We are a late-stage medical dermatology company focused on identifying, developing, and commercializing innovative pharmaceutical product candidates for the treatment of medical and aesthetic skin conditions and diseases we believe represent significant market opportunities.

Dermatological diseases such as acne vulgaris (or acne), psoriasis vulgaris (or psoriasis), hyperhidrosis, and various aesthetic indications, affect millions of people worldwide each year which may negatively impact their quality of life and emotional well-being. While there are multiple current treatment options for these indications on the market, we believe that most have significant drawbacks, including underwhelming efficacy, cumbersome application regimens and varying negative side effects, all of which we believe lead to decreased patient compliance. A majority of these indications are first treated with topical therapy, however, many patients frequently switch treatments or discontinue treatment altogether due to patient dissatisfaction. This is primarily due to slow and modest response rates, early onset of negative side effects, daily application schedules and long duration of therapy. Given the limitations with current topical therapies, we believe there is a significant opportunity to address the needs of frustrated patients searching for topical products that satisfy their dermatological and lifestyle needs.

Our two product candidates, DMT310 and DMT410, both incorporate our proprietary, multifaceted, *Spongilla* technology to topically treat a variety of dermatological conditions. Our *Spongilla* technology is derived from a naturally grown freshwater sponge, *Spongilla lacustris* or *Spongilla*, which is processed into a powder that is mixed with a fluidizing agent immediately prior to application to form an easily applicable paste. *Spongilla* is a unique freshwater sponge that only grows in commercial quantities in select regions of the world and under specific environmental conditions, all of which give it its distinctive anti-microbial, anti-inflammatory, and mechanical properties. The combination of these environmental conditions, the proprietary harvesting protocols developed with our exclusive supplier, and our post-harvest processing procedures produce a pharmaceutical product candidate that optimizes the mechanical components as well as the chemical components of the sponge to create a product candidate with multiple mechanisms of action for the treatment of inflammatory skin conditions and aesthetic applications.

We believe our *Spongilla* technology platform will enable us to develop and formulate singular and combination products that are able to target the topical delivery of chemical compounds into the dermis for a variety of dermatology indications. We believe the combination of *Spongilla*'s mechanical and chemical components (which we believe have demonstrated, *in-vitro*, anti-microbial and anti-inflammatory properties), add to the versatility of our *Spongilla* technology platform's effectiveness as a singular product, in the treatment of a wide variety of medical skin diseases like acne and psoriasis. We also believe the mechanical properties of our *Spongilla* technology allows for the intradermal delivery of a variety of large molecules, like botulinum toxins, monoclonal antibodies, or dermal fillers, to target treatment sites, through topical application without the need for needles.

Our lead product candidate, DMT310, is intended to utilize our *Spongilla* technology for once weekly treatment of a variety of skin diseases, with our initial focus being the treatment of acne vulgaris, which has a U.S. market size of approximately 50 million patients. We have recently initiated a Phase 3 program of DMT310 in moderate-to-severe acne and began enrolling patients in the first of two identical studies in December of 2023. Both studies will be double blinded, randomized, placebo controlled, and enroll about 550 patients, age 9 years or older across sites in the United States and Latin America. The primary endpoints include absolute reduction in inflammatory and noninflammatory lesions and the improvement in investigators global assessment (IGA) of acne, which are the same endpoints used in our Phase 2b study of DMT310 for moderate-to-severe acne. Patients will be treated once a week for 12 weeks with either DMT310 or placebo and will be evaluated monthly. We expect to have top-line results from the first Phase 3 study in the first quarter of 2025. Previously DMT310 has shown its ability to treat the multiple causes of acne in a Phase 2b study where we initially saw a 45% reduction in inflammatory lesions after four treatments, with DMT310 achieving statistically significant improvements at all time points for all three primary endpoints throughout the study (reduction in inflammatory lesions, reduction in non-inflammatory lesions, and improvement in IGA). In addition, based on the multiple mechanisms of action and anti-inflammatory effect seen with the DMT310 acne trial, we completed a Phase 1b proof of concept, or POC, trial in psoriasis where we saw encouraging results warranting further investigation.

DMT310 consists of two grams of powder processed from the naturally grown freshwater sponge, *Spongilla lacustris*. The patient mixes the powder with a fluidizing agent (hydrogen peroxide) immediately prior to application by the patient to form an easy-to-apply paste. The paste is applied similar to a mud mask and is left on the skin for approximately ten to fifteen minutes, after which time it is washed off with water. Due to the unique combination of DMT310's mechanical components and chemical components, and based on our Phase 2 acne data, we believe patients will only need to apply DMT310 once-weekly to produce a desired treatment effect. The mechanical components of the *Spongilla* powder consist of many microscopic siliceous, needle-like spicules that, when massaged into the skin, penetrate the stratum corneum (the skin's outermost protective layer) and create microchannels into the dermis where pro-inflammatory cytokines and bacteria reside. We believe that the penetration of the spicules also leads to the opening of microchannels, which allow oxygen to enter pilosebaceous glands, helping to kill *C. acnes*, which grow in an anaerobic (without oxygen) environment (*C. acnes* is the bacteria that cause inflammatory lesions in acne patients). The spicules also cause rejuvenation of the top layer of dead skin, thereby increasing collagen production. Additionally, we believe the newly created microchannels provide a conduit for DMT310's naturally occurring chemical compounds to be delivered to the dermis and pilosebaceous glands, helping to kill the *C. acnes* and fight inflammation. In addition to these anti-microbial compounds, DMT310 also appears to have anti-inflammatory chemical compounds, as demonstrated in *in vitro* experiments, that inhibit inflammation through the reduction of *C.acnes* stimulated IL-8 production and by inhibiting IL-17A and IL-17F expression in human cell lines. Also, during *in vitro* studies of DMT310's organic compounds, we observed the inhibition of the lipogenesis of sebocytes, which may translate to a reduction in sebum (an oily and waxy substance produced by the human body's sebaceous glands) production and the oiliness of the skin in patients, which was observed by a number of clinical investigators in our Phase 2 acne studies. We believe the combination of these biological and mechanical effects could be important factors in treating multiple inflammatory skin diseases, as seen in our clinical trials.

Our second product candidate utilizing our *Spongilla* technology is DMT410, our combination treatment. DMT410 is intended to consist of one treatment of our proprietary sponge powder followed by one topical application of botulinum toxin for delivery into the dermis. Currently, botulinum toxin is only approved to be delivered to the dermis by intradermal injections, which can be painful for the patient and time-consuming for the physician. However, we believe DMT410's ability to topically deliver botulinum toxin into the dermis could have similar levels of efficacy to existing delivery techniques, with fewer tolerability issues, and a quicker application time, possibly replacing the need for intradermal injections. We first tested DMT410 in a Phase 1 POC trial of axillary hyperhidrosis patients, which saw 80% of patients achieve a reduction in gravimetric sweat production greater than 50% four weeks after a single treatment. With almost 40% of the hyperhidrosis market currently being treated with intradermal injections of botulinum toxin, we believe there could be significant opportunity for DMT410 to break into this market and replace intradermal injections of botulinum toxin. Based on DMT410's ability to effectively deliver botulinum toxin to the dermis as observed in the Phase 1 axillary hyperhidrosis trial, we also conducted a Phase 1 POC trial of DMT410 for the treatment of multiple aesthetic skin conditions, including reduction of pore size, sebum production, and fine lines, among others. In November 2021, we announced top-line results from this trial, where we saw promising data that we believe warrants further investigation of DMT410. We are currently in the process of discussing partnering opportunities with botulinum toxin companies to move the DMT410 program into Phase 2 studies.

#### Application of DMT310



**Image 1: The *Spongilla* is processed into a fine powder and packaged into 2g pouches with a 6mL bottle of 3% H<sub>2</sub>O<sub>2</sub> (hydrogen peroxide). Once per week, patients mix the powder with hydrogen peroxide, and massage the mixture onto their skin; after 10-15 minutes the product is easily removed with water.**

We believe that the current medical and aesthetic dermatology landscape lacks innovative treatment options, mainly seeing the introduction of reformulations or combinations of old molecules. We believe this lack of innovation provides an ideal opportunity for us to change how patients treat their skin conditions. With our anticipated once weekly treatment schedule and product candidate derived from a natural source, we believe we can become a leader in the space that may improve patient compliance with minimal side effects and a rapid time to treatment effect, as seen in our multiple clinical trials in acne, psoriasis, hyperhidrosis and aesthetic conditions. If we can successfully develop our product candidates, receive FDA approval, develop a concentrated prescribing base of dermatologists, and utilize our management's prior experience, we believe we have the ability to build a commercial organization to develop and commercialize treatment options in our core areas of focus within the dermatology space.

## Our Clinical Development Pipeline and Product Candidates

Our clinical development pipeline currently consists of DMT310 and DMT410, each in development for multiple skin diseases and conditions. In the accompanying section we will describe each product candidate, its benefits, and our market strategy for each product candidate. The dates reflected in the below table and sections are estimates only, and there can be no assurances that the events included in the below table or sections will be completed on the anticipated timeline presented, or at all.

### *DMT310*

*Moderate-to-Severe Acne.* In December 2023, we began enrolling patients in the first of two Phase 3 clinical studies of DMT310 for the treatment of moderate-to-severe acne. Each study will be double blind, randomized, placebo controlled, and enroll about 550 patients, age 9 years or older across sites in the United States and Latin America. with the primary endpoints being the absolute reduction in inflammatory and noninflammatory lesions and the improvement in investigators global assessment (IGA) of acne as were used in our DMT310 Phase 2b acne study. Patients will be treated once a week for 12 weeks with either DMT310 or placebo and will be evaluated monthly. The first Phase 3 study is expected to have top-line results in the first quarter of 2025. In June 2020, we completed a randomized, double-blind, multicenter, placebo-controlled Phase 2b clinical trial of DMT310 for the once weekly treatment of moderate-to-severe acne. DMT310 showed statistically significant improvement versus placebo for all three endpoints (inflammatory lesion counts, non-inflammatory lesion counts, and IGA), after only four topical treatments and continued to statistically separate from placebo through the end of study at week 12. We believe these results from once weekly applications may favorably position DMT310 as a first-in-class product in the market for the treatment of moderate-to-severe acne.

*Mild-to-Moderate Psoriasis.* In October 2021, we completed a Phase 1b POC trial of DMT310 for the once weekly treatment of mild-to-moderate psoriasis. Plaque psoriasis is a chronic, inflammatory skin disease that comprises approximately 80% of the psoriasis market as of 2019, according to Fortune Business Insights Market Research Report, a majority of patients have mild-to-moderate disease which makes them less likely to receive an approved biologic treatment, that are only indicated for patients with moderate to severe disease, as a first line therapy. Due to the large population of patients who suffer from mild-to-moderate psoriasis, and lack of effective topical therapies for more mild disease, we believe there is a large unmet need for an effective topical product with limited side effects. Based on the data in our Phase 1b POC trial, the in-vitro data of DMT310's reduction of IL-17A and IL-17F, and the anti-inflammatory effects we observed in its Phase 2b trial for acne, we believe DMT310 may be used as a first-line therapy for patients suffering from mild-to-moderate psoriasis who are not candidates for biologic treatments. In October 2021, we announced top-line results from our Phase 1b POC trial of DMT310 for the treatment of 30 mild-to-moderate patients with psoriatic lesions covering between 2% to 30% of their body surface area. Patients were treated with DMT310 once a week for 12 weeks. Based on the efficacy, safety and tolerability profile observed in the POC trial, we initiated additional work to better inform our clinical trial design prior to moving into a larger Phase 2, placebo-controlled, clinical trial. We plan to continue development of DMT310 for the treatment of psoriasis upon the acquisition of additional financial resources to support such development.

*Moderate-to-Severe Rosacea.* On December 5, 2022, we announced topline results from our Phase 2 trial of once-weekly topical application of DMT310 for the treatment of moderate-to-severe rosacea. The data was supportive of DMT310 as a treatment for inflammatory skin diseases, but the rosacea study did not meet its primary endpoints. While some patients did achieve a meaningful change in their rosacea, with 36% of DMT310 patients meeting the criteria for a responder on the Investigator Global Assessment (IGA) score, DMT310 was not able to statistically separate from placebo with 23% of placebo patients meeting the criteria as a responder at Week 12. A treatment responder is defined as an IGA grade of 'clear' or 'almost clear' and at least a 2-grade improvement from baseline. Based on the foregoing, we have decided not to devote any further financial resources to the development of this indication for DMT310 at this time.

## DMT410

We are developing the second product candidate from our *Spongilla* platform, DMT410, for the topical treatment of skin diseases and aesthetic conditions typically treated with multiple injections of botulinum toxin. Currently, botulinum toxin must be injected multiple times to successfully deliver enough botulinum toxin to the desired treatment area. While injections are effective for many different diseases and aesthetic conditions, they limit botulinum toxin's use for additional conditions where injections, especially intradermal injections, are difficult, painful, or otherwise not viable. DMT410's combination treatment regimen uses one application of our unique *Spongilla* powder followed by one topical application of botulinum toxin. The *Spongilla* powder is mixed with a fluidizing agent and is massaged into a patient's treatment area by the treating physician to enhance spicule penetration to create microchannels into the dermis. After 10 to 15 minutes, the physician removes the *Spongilla* mask with water. The physician then expresses botulinum toxin from a syringe in precise amounts and onto the patient's skin. The botulinum toxin is then massaged into the treatment area to take advantage of the microchannels created by *Spongilla*'s spicules, which allows the botulinum toxin to penetrate the stratum corneum and enter the dermis. We believe this treatment application will enable the topical delivery of botulinum toxin into the dermis for the treatment of a variety of medical diseases, including for the treatment of hyperhidrosis, acne, and acne scars, as well as improving the skin's luminosity, brightness, and reducing pore size and count, fine lines, and sebum production. We believe DMT410's topical delivery of botulinum toxin can greatly increase market opportunities for botulinum toxin due DMT410's needle-free application, targeted intradermal delivery, thus potentially expanding the aesthetic market for botulinum toxin.

To date, we have completed an open-label Phase 1b POC clinical trial of DMT410 for the treatment of axillary hyperhidrosis and an open-label Phase 1b POC clinical trial in multiple aesthetic skin conditions. The Phase 1b POC trial for axillary hyperhidrosis consisted of 10 patients receiving one treatment of DMT410 to each axilla. Four weeks after one treatment with DMT410, patients exhibited a reduction in sweat production. The clinical endpoints for this trial included (i) percent of patients with greater than 50% reduction in gravimetrically measured sweat production from baseline, (ii) percent of patients with gravimetric sweat production less than 50mg, and (iii) percent change in gravimetric sweat production. Four weeks after one treatment with DMT410, 80% of patients experienced a decrease in gravimetric sweat production greater than 50%, 85% of patients recorded gravimetric sweat production of less than 50mg, and patients had an average decrease in gravimetric sweat production of 75% from baseline. We believe these results support that DMT410 may aid in the topical delivery of botulinum toxin into the dermis for a treatment effect similar to multiple intradermal injections of botulinum toxin. With DMT410, we believe botulinum toxin may be applied topically to penetrate the skin into the dermis without the need for multiple injections.

We also completed an open-label, ten (10) patient, Phase 1b POC trial of DMT410 for the treatment of multiple aesthetic skin conditions (pore size, Global Aesthetic Improvement, brightness, luminosity, sebum production, fine lines under the eye, glabellar lines, forehead lines, and lateral canthal lines) and announced topline results in November 2021. In our Phase 1b POC trial of DMT410, patients received one treatment of DMT410 and were evaluated every four weeks for a total duration of 16 weeks to determine DMT410's safety and tolerability profile, effectiveness, and its duration of treatment effect. We announced top-line results in November 2021, where we observed an improvement in many of the trial's endpoints. At week 8, 80% of patients had at least a 25% improvement in their Global Aesthetic and 60% of patients had a 25% improvement in pore size. Also at week 8, 90% of patients had at least a one-point improvement in luminosity and 60% of patients had at least a one-point improvement in brightness. These physicians graded results were supported by objective analysis provided by Canfield Scientific's VISIA and PRIMOS visual analysis camera systems. Based on these results, we continue to actively discuss partnership opportunities with botulinum toxin companies to continue development of DMT410 in a larger placebo-controlled Phase 2 trial where we can study multiple doses of botulinum toxin applied to the entire face. We believe these results, combined with our results in hyperhidrosis, clearly demonstrate how DMT410's combination regimen could greatly expand the potential indications for botulinum toxins for aesthetic skin conditions, as well as other dermatologic skin diseases such as hyperhidrosis, acne, or acne scars.

There can be no assurance that DMT310 or DMT410 will receive FDA approval for any of the foregoing indications.

## Our Strategy

We plan on in-licensing, developing and commercializing differentiated medical and aesthetic dermatology product candidates for the treatment of various skin diseases and conditions, which we believe have significant unmet needs in the market. The key components of this strategy are as follows:

- *Complete development and regulatory approval of DMT310 for acne.* We initiated the first of two Phase 3 clinical studies of DMT310 for the treatment of acne in December 2023. We expect to receive top-line results from the first study in the first quarter of 2025. In 2025, we plan on initiating the second DMT310 Phase 3 clinical study followed by a long-term extension study. We also plan to initiate the FDA required dermal carcinogenicity studies in rats and the repeat dose dermal toxicity study in minipigs. Assuming positive results from the Phase 3 program, we plan on submitting a New Drug Application to FDA approximately 6 months after completion of the trials.
- *Explore mutually beneficial partnership opportunities for our DMT410 program in hyperhidrosis and aesthetic skin conditions.* We have received top-line results from two Phase 1b POC trials of DMT410 in both axillary hyperhidrosis and for the treatment of multiple aesthetic skin conditions using our *Spongilla* technology for the topical application of OnabotulinumtoxinA (brand name BOTOX®). We believe these trials provide further evidence of the ability for DMT410 to topically deliver any botulinum toxin into the dermis for skin conditions and diseases. Based on the results of DMT410 in hyperhidrosis and aesthetics, we are currently discussing partnership opportunities with multiple botulinum toxin companies to further develop DMT410 for the topical treatment of skin diseases and aesthetic skin conditions.
- *Complete a Phase 2 trial of DMT310 for the treatment of psoriasis.* In October 2021, we announced top-line results of our Phase 1b POC trial in patients with mild-to-moderate psoriasis. We believe the results of this POC study warrant further development of DMT310 for the treatment of psoriasis. If successfully developed and commercialized, we believe DMT310 would be the first once weekly topical product available to treat psoriasis. The DMT310 program for psoriasis is currently on hold with further advancement subject to obtaining additional financing and/or a strategic partner.
- *Acquire or in-license additional dermatology programs to our portfolio that complement our current product candidates.* We continuously evaluate potential partnering opportunities that will bolster our current product candidate portfolio and provide substantial value to our organization. We intend to focus on early to mid-stage development product candidates to generate clinical data and potentially move to later stages of development and ultimately on to commercialization.
- *Maximize the value of our portfolio by commercializing our product candidates in territories where we can do so effectively and partner for other territories to help us reach new markets.* We plan to maximize the territories where our product candidates could be sold by partnering with established companies in new territories outside of the U.S. market for development and potential commercialization, if possible.
- *Further strengthen our intellectual property portfolio, path to new chemical entity, or NCE, exclusivity, raw material supply and advance our regulatory filings.* We plan to continue to strengthen our IP portfolio for DMT310 and DMT410, seek NCE exclusivity for DMT310, maintain our exclusive supply agreement for our raw material requirements, and continue to protect our proprietary information. We believe these activities will be our primary competitive advantages if our product candidates receive regulatory approval.

The dates reflected in the foregoing are estimates only, and there can be no assurances that the events included will be completed on the anticipated timeline presented, or at all. Further, there can be no assurance that we will be successful in the development of DMT310 or DMT410, or any other product candidate we may develop in the future, or that DMT310 or DMT410, or any other product candidate we may develop in the future, will receive FDA approval for any indication.

## Dermatology Market Overview

We are currently focused on the medical and aesthetic dermatology markets, which include multiple common and undertreated skin diseases and conditions such as acne, psoriasis, hyperhidrosis, and multiple aesthetic conditions, some with no currently approved products, including the reduction of fine lines, pore size, sebum production and improvement in luminosity and overall skin quality. We believe these diseases and conditions cause significant negative impacts on patients' quality of life, including physical and emotional trauma and social stigmatism, causing patients to constantly seek better treatment options to help alleviate their conditions. We also believe these markets have not experienced the same level of development and advances as other markets, as there have been few innovative topical products recently approved other than reformulations or combinations of existing compounds. We believe our product candidates will be well situated within the market and offer the innovative solutions to the underserved medical and aesthetic dermatology markets.



The U.S. medical dermatology market has experienced significant growth in recent years based on the new treatment options and greater patient access to care. Based on current market data, the U.S. medical dermatology market (excluding biologics) was valued at over \$16 billion dollars in prescription pharmaceutical sales in 2020.

The American Society of Plastic Surgeons estimates that over 15.4 million cosmetic procedures were performed in the U.S. in 2016, of which about 7 million used botulinum toxin. There are many factors that continue to drive growth in the aesthetics dermatology market such as greater patient acceptance, including from an increase in younger patients, and the discretionary cash that patients are willing to spend on aesthetic care. We also believe patients have a growing willingness to pay out-of-pocket for effective skin treatments to achieve their desired personal aesthetic look, which further supports the demand and pricing in those markets.

Based on the foregoing, we believe the dermatology market, both aesthetic and medical, offer a low-cost commercialization opportunity compared to many other prescription-based specialty markets, due to the relatively small number of specialists in the dermatology field. According to the American Academy of Dermatology, in 2020 there were approximately 18,000 dermatologists in the U.S., and we plan to target a subset of these dermatologists, who are larger prescribers of competitive products and who treat a large percentage of patients with our approved indications. We believe the combination of prescription based and cash-pay based product lines is an attractive business opportunity, as it incorporates multiple aspects of the dermatology market that move independent of the greater healthcare market.

## **Background of Our *Spongilla* Technology**

### *Spongilla Lacustris Overview*

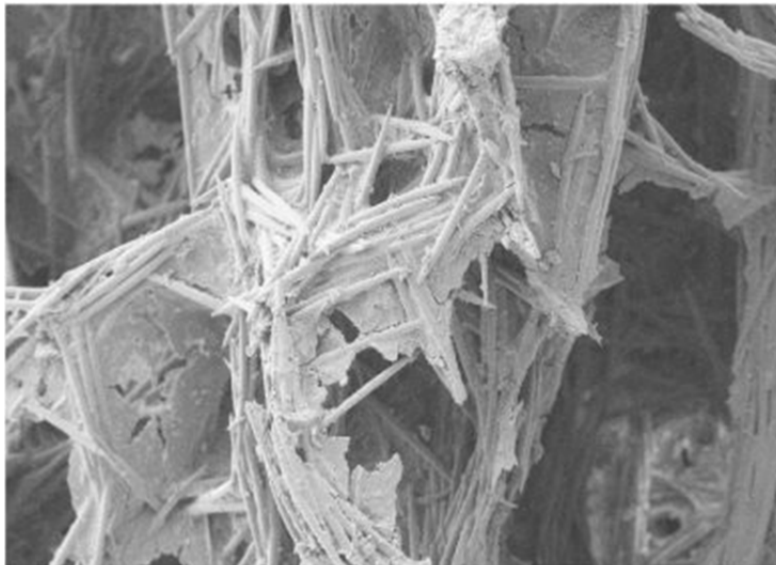
*Spongilla lacustris*, or *Spongilla*, is a freshwater sponge from the *Spongillidea* family that grows in freshwater rivers and lakes in commercial quantities in select regions of the world. It becomes dormant during the winter months and regrows each year to growth forms ranging from encrusting, to digitate, to branched, depending on its habitat's growth conditions. While it grows in many parts of the northern hemisphere, there are only certain locations where it grows in the quantities and of the quality to viably support a commercial pharmaceutical product. One such location is the Volga River in central Russia, where we have signed an exclusive supply agreement with one of the larger known suppliers of *Spongilla* raw material for DMT310, which we believe provides us with a reliable source of our supply of *Spongilla* raw material for the foreseeable future. Traditionally, locals would harvest small amounts of *Spongilla* for its perceived medicinal properties and use it as a folk medicine to treat a variety of inflammatory conditions, including arthritis. Over the last 21 years, our exclusive supplier has refined its harvesting methods and procedures and is now capable of supplying a high-quality raw material. Our supplier has the capacity to collect and process large quantities of *Spongilla* per year. We believe our supplier will be able to supply a raw material in the quantities and of the quality necessary to support our clinical and commercial needs.

The traditional use of *Spongilla* in Russia has provided a large amount of safety data. In 2003, the Russian Ministry of Health indicated that *Spongilla* has been used by over one million people per year, with few reported safety issues. In 2017, we submitted this safety information, along with various other publications and non-clinical studies, in an Investigational New Drug, or IND, application to the FDA's Division of Dermatology and Dental Products with reference to the FDA's Botanical Drug Development Guidance for Industry, or Botanical Guidance. This submission enabled the FDA to approve our IND for DMT310, allowing us to proceed directly into a Phase 2 clinical trial in patients due in part to historical human exposure. In 2023, the FDA also confirmed that DMT310 would be filed under a new drug application (NDA). While we are still required to complete certain non-clinical and pharmacokinetic studies prior to filing an NDA, we were able to strategically conserve resources while gathering human clinical efficacy and safety data prior to completing such work.

### *Spongilla's Multiple Mechanism of Actions*

The unique properties of *Spongilla lacustris* not only allows us to reference the FDA's Botanical Guidance, but also helps ensure the sustainable regrowth of sufficient supply of raw material each year. While *Spongilla* is technically a part of the animal kingdom, it grows and acts more similarly to a plant in that it can completely regenerate every year, even in harsh environmental conditions. In addition to causing a regrowth of the sponge each year, the harsh environmental conditions the sponge lives in helps contribute to our *Spongilla* technologies' multiple mechanisms of actions. Based on knowledge gained from over 21 years of harvesting *Spongilla*, our supplier has learned the necessary environmental conditions and *Spongilla* characteristics that must be present for optimal raw material harvest and to ensure the raw material contains the necessary properties for an effective pharmaceutical product. These properties include both mechanical and chemical components that are a naturally occurring part of the sponge raw material and contribute to our *Spongilla* technology's mechanisms of action in the treatment of skin diseases and conditions.

The mechanical components of DMT310 come from the *Spongilla*'s skeletal structure, which is made up of siliceous spicules that are bound together by organic material, as seen in Image 2 below. These spicules are smooth, rod-like shapes which come to a point on each end, and if the *Spongilla* is harvested under certain proprietary environmental conditions, the spicules can average between 150-300 micrometers in length and about 10-15 micrometers in diameter. While there are other types of freshwater and marine sponges, many of their spicules can be covered in barbs or hooks which we believe would get stuck in the skin or contain spicules that are blunt on each end, making skin penetration difficult.



**Image 2: Siliceous Spicules Present in *Spongilla***

After harvesting and further processing in the U.S., the form and size of our spicules make them the ideal mechanism to penetrate the stratum corneum, the skin's barrier, and temporarily create a micro-channel into the dermis without penetrating into subcutaneous tissue, where the larger blood vessels are located. These newly created microchannels temporarily open the skin's barrier to allow for the targeted delivery of large and small chemical compounds into the dermis. Most topically applied products currently contain various penetration enhancers that help force the active molecule through the stratum corneum and into the dermis, such as Dimethyl Sulfoxide (DMSO). However, DMSO is only able to help smaller molecules penetrate and is usually unable to aid larger molecules, such as botulinum toxin, in topical delivery. These penetration enhancers can also cause unwanted side effects such as dry skin or garlic like taste, breath, and body odor. We believe our *Spongilla* technology is differentiated by enabling the delivery of both small and large molecules through topical application with less irritation and side effects than other topically applied products.

In addition to creating many microchannels in the skin, we believe the penetration of the spicules can open closed comedones, allowing oxygen into the anaerobic environment of the clogged pilosebaceous glands, where *C.acnes* and other bacteria survive. Lastly, we believe the spicules promote collagen production within the skin which accelerates the skin's rejuvenation period, thus bringing refreshed skin to the surface at a quicker rate than the skin's normal turnover cycle. Typically, the skin takes between three to four weeks to bring a new layer to the surface, while we believe our *Spongilla* technology may allow this process to complete in less than one week. We believe this decreases the time to treat inflammatory skin diseases and conditions while also enhancing the look of a patient's skin.

Our *Spongilla* technology also contains multiple active chemical compounds that we believe may aid in our product candidates' treatment of multiple dermatology skin diseases and conditions. We believe part of *Spongilla*'s natural defense mechanism is the creation of organic material to fight off natural enemies present in the water in which it grows. This organic material binds its spicules together to form the skeletal structure of the sponge. Based on multiple in-vitro studies, we believe the organic compounds within the sponge, when separated from the spicules, have both anti-inflammatory and antimicrobial properties. We have observed anti-inflammatory activity including reduction of *C. acnes*, stimulated IL-8 production, and the downregulation of the production of IL-17A and IL-17F in human cell lines. Additionally, in our in-vitro studies, we observed the inhibition of lipogenesis of sebocytes, which may translate to a reduction in sebum production and oiliness of the skin in patients.

While we believe each of the mechanical or chemical components of our *Spongilla* technology may be beneficial in treating various diseases, we believe the impact of each mechanism may be greatly enhanced when combined with the other. The large number spicules contained in each treatment create many microchannels through the stratum corneum, allowing for sufficient penetration and delivery of the chemical components into the treatment area to fight inflammation and kill bacteria.

#### *FDA Botanical Drug Development Guidance for Industry*

Most currently approved topical dermatology products are reviewed solely by the FDA's Office of Dermatology and Dental Products and follow a standard approval pathway. However, due to our lead product candidate, DMT310, being derived from a natural source, it will be reviewed by the FDA Office of Dermatology and Dental Products with input from the FDA Botanical Review Division. While *Spongilla* is not a botanical, the FDA has allowed us to reference the Botanical Guidance for raw material quality control and batch to batch consistency through development and into commercialization. We believe our ability to reference the Botanical Guidance and receive input from the Botanical Review Division on DMT310 provides us with key advantages in DMT310's regulatory pathway to approval, if achieved. These advantages include being able to move into human clinical studies upon the FDA's acknowledged receipt of our IND letter and subsequent study may proceed, saving us substantial financial resources to achieve human clinical data. Additionally, while we believe that our sponge contains multiple active chemical compounds, based on our regulatory analysis of the feedback from the FDA and the Botanical Guidance, we believe we are only required to provide identifiable and quantifiable active components to show quality control and batch to batch consistency. We believe this will make it more difficult for potential competitors to replicate DMT310 due to their inability to know every component of our product candidate and to show their product is similar in its composition. Thus, we believe a competitor with a similar product or product candidate would have to follow all the manufacturing, development, and regulatory steps we must complete for approval. However, there can be no assurance that we successfully navigate the development of DMT310 or that DMT310 will receive FDA approval.

#### **Our Product Candidates**

##### *DMT310*

Our lead product candidate, DMT310, is a unique, once weekly, naturally derived topical product, first being developed for the treatment of moderate-to-severe acne vulgaris, or acne. It is derived from freshwater *Spongilla lacustris*, or *Spongilla*, which grows under certain environmental conditions in select locations throughout the northern hemisphere. Our *Spongilla* raw material is harvested by our exclusive partner in Russia abiding by strict protocols based on our supplier's 21 years of experience and our expertise in an ideal pharmaceutical product. The result of these strict protocols is a consistent chemical structure that is reproducible year after year, which is critical in producing a material able to be used in a pharmaceutical product. After harvesting, the *Spongilla* is shipped to our manufacturing facility in the U.S. for further processing into a uniform powder before being packaged into sachets. Immediately prior to treatment the patient will mix the powder with a diluent (hydrogen peroxide) to form a paste, which the patient can then apply to the treatment area to treat the multiple facets of their disease. DMT310 utilizes the *Spongilla's* mechanical spicules to help resurface a patient's skin while also creating microchannels through the stratum corneum to allow the penetration of the *Spongilla's* naturally created organic compounds to help treat various skin diseases. We believe these organic compounds can travel through the newly created microchannels into the dermis and sebaceous glands where both inflammatory and non-inflammatory acne lesions originate. DMT310 targets treatment of the multiple facets of acne by combining the substantial mechanical and chemical activity of *Spongilla* into an easy to apply product that only needs to be applied once weekly. If approved by the FDA, we believe the combination of the mechanical and chemical properties of DMT310 has the potential for a more rapid time to treatment effect with fewer treatments, less side effects, and better tolerability than other currently marketed topical acne products.

##### *DMT310 for Treatment of Acne Vulgaris*

*Market Opportunity.* Acne is characterized by areas of scaly red skin, non-inflammatory blackheads and whiteheads, inflammatory lesions, papules, and pustules and occasionally cysts and scarring that occur on the face, neck, chest, back, shoulders, and upper arms. It affects approximately 50 million people in the U.S., with about 85% of teenagers experiencing some form of acne. The U.S. prescription acne market had approximately \$2.6 billion in prescription pharmaceutical sales in 2016 and is expected to reach approximately \$3.8 billion in 2026 according to GlobalData Inc. market data.

Most patients experience some form of acne during their teenage years and for some, their acne may diminish over time, or at least tends to decrease by age 25. There is, however, no way to predict how long it will take for acne to disappear entirely, with some individuals suffering from acne well into their 30s, 40s and beyond. While not life-threatening, acne causes significant trauma for those suffering from it due to social stigmas, substantial risk of permanent facial scarring, lowered self-esteem and social withdrawal. Therefore, we believe early and aggressive treatment with an effective once weekly product may lessen the overall long-term impact of this disease and may lead to an increase in a patient's quality of life.

Due to acne's negative impact on a patient's quality of life and negative impact on facial aesthetic, patients suffering from acne tend to be highly motivated to treat their acne and we believe willing to pay more out-of-pocket for higher priced and highly effective treatments. It is our belief that patients seeking an easy to use and effective topical product will tolerate less favorable reimbursement rates than for other prescription products for other indications, allowing for favorable pricing if we are able to eventually obtain approval for and successfully commercialize DMT310 for acne. Furthermore, if approved, we believe that DMT310's natural characteristics may allow us to expand our addressable acne market to include those patients who value using naturally derived products, such as DMT310.

The acne market can be broken into three separate classes based on the severity of the acne:

- Mild Acne: characterized by few papules or pustules; typically treated with over-the-counter products or topical prescription therapies.
- Moderate Acne: characterized by multiple papules and pustules with moderate inflammation; typically treated with a combination of oral and topical prescription therapies.
- Severe Acne: characterized by substantial papules and pustules, with many nodules and/or cysts and significant inflammation; currently treated with oral and topical combination treatments and photodynamic therapy as a third-line treatment option.

*Limitations of Current Standard of Care.* While current treatment options may be effective for some patients, there are many limitations and drawbacks of current acne products which cause poor patient compliance. All currently approved topical therapies for the treatment of acne must be applied once or twice a day to allow an accumulation of the active ingredient within the skin to effectively treat the disease. This requirement to apply multiple times per day becomes very onerous and time consuming for patients, causing many patients to fail to comply with the strict application regimen and/or skip multiple treatments. Proper use and application schedules are particularly important for topical acne products and poor patient adherence may lead to reduced treatment effect and ultimately discontinuation of treatment by the patient due to the lack of effect.

Many current acne products, such as retinoids that must be applied at least once or twice-a-day, may cause significant stinging, burning, and peeling after each application. These tolerability issues, which may start occurring after the first application, and the substantial discomfort they cause, lead many patients to discontinue the necessary daily application schedule or the use of the product altogether. It is well known that benzoyl peroxide, or BPO, leads to drying of the skin and that retinoids result in many local skin reactions including erythema, burning, and peeling, after the first treatment. It has been observed in the combination study of adapalene/BPO, where more than 20% of the subjects reported moderate or severe erythema and stinging/burning.

Lastly, most topical products have an unavoidable latency period of 6-8 weeks until patients have a definite improvement in their acne lesions. This means they may have to endure 30 to 60 applications before observing that their acne is improving (assuming a daily, or twice daily regimen), all while dealing with the burning, stinging, and peeling that may accompany these topical products. We believe that teenagers, who make up the largest segment of the acne market, become impatient with the lack of rapid perceived effect leading to premature discontinuation of treatment. The lack of rapid treatment effect, side effects, and onerous application schedules all greatly contribute to patient noncompliance issues and could ultimately lead to treatment failure for current topical therapies. We believe patients are more concerned with rapid efficacy outcomes and low side effects than costs, thus we believe patients will be more willing to pay higher out of pocket costs for a product that has these attributes.

*Our Solution for Moderate-to-Severe Acne.* If approved, we believe DMT310's once weekly application regimen and apparent rapid treatment effect will increase patient compliance, potentially increasing the likelihood of improved acne results. Using our multifaceted, once weekly *Spongilla* treatment technology, we are developing DMT310 to create a paradigm shift in how acne is treated by dermatologists by attempting to make DMT310 the preferred treatment option for all acne patients. We have designed DMT310 to treat the multiple factors of acne while also attempting to increase patient compliance.

If approved, we believe DMT310 has the potential to remedy many of the negative characteristics associated with current topical therapies for moderate-to-severe acne vulgaris, including cumbersome treatment regimens, negative side effects (including burning, stinging, itching or dryness, which may occur as early as the first treatment and continue daily thereafter), and delayed time to effectiveness (which may take up to eight weeks). DMT310 is designed to be applied only once a week, rather than once or twice a day. We believe a once weekly schedule may be conducive to high patient compliance as it is less onerous for the patient. In addition, in our Phase 2b acne trial, on average, patients experienced an approximately 45% reduction in inflammatory acne lesions after just four treatments, with continued improvement of up to 62% reduction of inflammatory lesions at 12 weeks. Further, approximately 90% of patients had no, or mild, tolerability issues at the end of the 12-week trial and no patients experienced any severe tolerability issues.

In addition, in our Phase 2b trial we observed that DMT310 started showing a statistically significant difference from placebo for all three endpoints after just four treatments while also having a rapid reduction on inflammatory and non-inflammatory lesions. We believe this rapid visible response encouraged patients to continue to comply with the once weekly application schedule leading to a continued reduction in their lesions until the end of trial at week 12. Thus, we believe that a topical product that only needs to be applied once weekly with a quicker time to perceived treatment effect and fewer tolerability issues has the opportunity to exhibit greater treatment success due to improved patient compliance leading to loyal and repeat users.

#### *DMT310 for the Treatment of Mild-to-Moderate Psoriasis*

We believe that DMT310 could also be an effective treatment for mild-to-moderate psoriasis based on the clinical data received from our recently completed Phase 1b POC trial and the in-vitro effect DMT310 has shown on the down regulation of IL-17A and IL-17F, as well as its ease of application to mild-to-moderate psoriatic lesions with smaller surface areas.

Psoriasis is characterized by “plaques,” or raised red areas of skin covered with a silver or white layer of dead skin cells referred to as “scales.” Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and the plaques are often itchy and sometimes painful. The psoriasis lesions are characterized by hyperproliferation of keratinocytes and a lymphocyte-rich infiltrate consisting primarily of T cells. In the dermis and epidermis, T lymphocytes interact with antigen-presenting cells and secrete Th1 and Th17 cytokines. These activated T cells and the inflammatory cytokines they secrete are believed to induce the skin lesions seen in psoriasis. In addition to the broad anti-inflammatory properties, we have observed in our clinical acne studies, DMT310’s ability exhibited in-vitro a dose dependent inhibition of both IL-17A and IL-17F, key cytokines implicated in the pathogenesis of psoriasis. Thus, DMT310 may provide a method to topically deliver targeted anti-inflammatory therapy directly to psoriatic lesions with good local tolerability in an easy to apply regimen.

*Market Opportunity.* Currently patients with mild-to-moderate disease are either underdiagnosed, undertreated or untreated. This leaves patients seeking new and effective treatment options. Psoriasis is a chronic, inflammatory skin disorder estimated to affect up to 3.2% of the world’s population with global sales of \$14.2 billion in 2020, which is projected to increase to \$27.5 billion by 2030. Plaque-type psoriasis is the most common form of psoriasis, occurring in more than 80-90% of cases of psoriasis with approximately 80% of patients experiencing the mild disease form and 20% experiencing moderate-to-severe form of the disease. In addition to the disfigurement caused by psoriatic lesions, patients also may experience pruritus, or itching, which can be particularly common and bothersome for patients. Not only does psoriasis cause direct clinical challenges, but patients also suffer a negative impact on their quality of life. Patients can suffer substantial psychological impacts from their disease, including, social stigmas, feelings of rejections and shame, discrimination in the workplace, and reduced productivity, among many others. These patients are commonly looking for a safe and effective product to treat their disease.

*Limitations of Current Standard of Care.* Most of the available therapies target moderate-to-severe disease, meaning that mild patients are undertreated with one in five not being happy with their current treatments. The treatments for mild psoriasis patients are mostly generic, but are often inadequate to control a patient’s disease. Mild psoriasis patients are first treated with topical therapies due to the reduced systemic exposure. However, patients often feel that topical treatments are one of the negative aspects of psoriasis, which we believe is partly due to the limited options available like, coal tar, retinoids, calcineurin inhibitors and corticosteroids. While topical steroids are a very common treatment, drawbacks include being able to be used only for a short period of time and are associated with Hypothalamic pituitary adrena axis suppression, skin atrophy (thinning), striae (stretch marks), and telangiectasia (spider veins), among other side effects. Furthermore, some of these side effects are irreversible, persisting even after therapy is discontinued. Consequently, high-potency topical steroids are not recommended for chronic use and physicians generally will not prescribe them for treatment on the face. Also, rebound is a known challenge with steroids, where after steroid discontinuation, the psoriasis returns even worse than it was before steroid treatment was initiated.

While biologic therapies, including drugs such as Enbrel, Cosentyx, Humira, and Stelara, are available for treatment of psoriasis, their use remains highly restricted to patients with moderate-to-severe disease. In the U.S., with less than 20% of patients having moderate-to-severe psoriasis, we believe a vast majority of the psoriasis market are left without long-term effective treatment options. While additional data has caused an uptake of biologics, they remain limited due to multiple factors, including being indicated only for use in moderate-to-severe patients, high costs, consequent reimbursement and access restrictions, frequent high patient co-pays, perceived risk of side effects, and patient fear of injection. Additionally, we believe there is room for topical products that treat mild psoriasis to be priced at a premium compared to other topical products for other inflammatory skin diseases like acne. This is based on fact that when comparing the cost of biologic therapy, which can cost \$50,000 per year, an effective and safe topical product for mild psoriasis could have a large impact on the market. Therefore, we believe physicians would be more likely to prescribe a topical product for psoriasis long before biologic treatment, and patients experiencing milder psoriasis would prefer using a topical product over a systemic treatment.

Non-biologic systemic therapy options for psoriasis exist, but their use is also limited due to unfavorable side effects. Apremilast (Otezla), an oral PDE4 inhibitor, generated more than \$1 billion in sales in all indications in 2019, but has only achieved a small patient share in psoriasis due to limitations on its use to moderate-to-severe patients, its modest symptomatic improvement, and frequent adverse events. We believe there is still a great need to bring to market a product that addresses mild-to-moderate psoriasis.

Due to the shortcomings of existing topical therapies and the lack of options providing robust symptomatic improvement with chronic treatment, especially in the last 25 years, we believe there remains a need for a safe, effective, and easily applicable topical treatment for chronic disease, that has a low risk of side effects, is well tolerated, and can be easily applied on all anatomical areas.

*Our solution for Mild-to-Moderate Psoriasis.* Similar to the needs of patients with acne, we believe patients suffering with psoriasis might comply better with a treatment that is easy to apply and requires less application time than current treatment options. DMT310, if approved, could be used as a first line therapy for patients with mild-to-moderate psoriasis. We believe the spicules within DMT310 will help break up the psoriatic lesions, while the anti-inflammatory components of DMT310 assist with the healing of the lesions. Due to the historical use of *Spongilla* and the human safety data collected to date in our clinical studies, we believe DMT310 may be suitable for long term treatment of chronic psoriasis due to its unique treatment effect and acceptable safety and tolerability profile.

In addition to the mechanical effects of DMT310, extracts of the organic material have shown in-vitro to have a dose dependent inhibition of IL-17A and IL-17F secretion. In the dermis and epidermis, T lymphocytes interact with antigen-presenting cells and secrete Th1 and Th17 cytokines, including interferon-gamma (IFN-g), interleukin (IL)-2, IL-17, IL-22, and tumor necrosis factor alpha (TNF- $\alpha$ ). These activated T cells and the inflammatory cytokines they secrete are believed to induce the skin lesions seen in psoriasis and be a fundamental contributor in the disease's immune pathway. We know that there are multiple approved IL-17A inhibitors on the market, such as secukinumab (Cosentyx®, Novartis) and ixekizumab (Taltz®, Eli Lilly and Co.), but these are both biologics and only indicated for patients with moderate-to-severe psoriasis who are candidates for systemic therapy. The limited patient population who are candidates for these biologic treatments is a small percentage of the overall psoriasis market. Therefore, a topical product that can inhibit the IL-17 pathway in the skin with minimal systemic exposure would be an ideal option for both physicians and patients.

Based on clinical and non-clinical data generated to date for DMT310, and anecdotal evidence of DMT310's effect on psoriatic lesions, we completed a Phase 1b, open label, POC study in mild-to-moderate psoriasis patients in October 2021. This trial included once weekly treatments of DMT310 for 12 weeks in 30 mild-to-moderate psoriasis patients with lesions covering 2% to 30% of their body surface area. The primary endpoints in this trial were the Physician's Global Assessment, which is a 6-point scale measuring the physician's assessment of psoriasis severity of the target lesion site, the Psoriasis Area Severity Index scale is also a 6-point scale measuring the psoriatic disease severity taking into account qualitative lesion characteristics (erythema, thickness, and scaling) and degree of surface area involvement and the Pruritus Visual Analog Scale consists of the patient's measurement of pruritus, or itch, in addition to normal tolerability and safety assessments. We announced top-line results in October 2021, and based on the efficacy, safety and tolerability profile seen in the POC trial we initiated additional work to better inform the clinical trial design prior to moving into a larger Phase 2, placebo-controlled, clinical trial upon the receipt of sufficient financial resources.

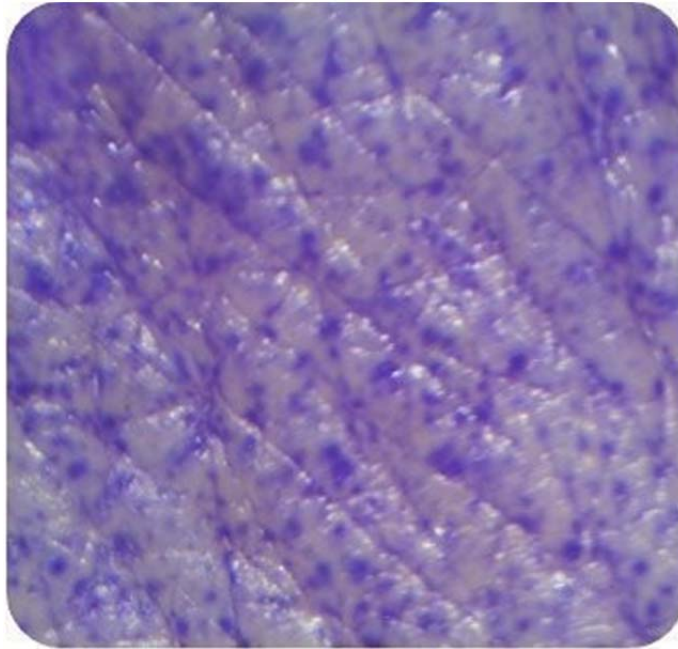
#### *DMT310 for the Treatment of Moderate-to-Severe Rosacea*

On December 5, 2022, we announced topline results from our Phase 2 trial of once-weekly topical application of DMT310 for the treatment of moderate-to-severe rosacea. The data was supportive of DMT310 as a treatment for inflammatory skin diseases, but the rosacea study did not meet its primary endpoints. While some patients did achieve a meaningful change in their rosacea, with 36% of DMT310 patients meeting the criteria for a responder on the Investigator Global Assessment (IGA) score, DMT310 was not able to statistically separate from placebo with 23% of placebo patients meeting the criteria as a responder at Week 12. A treatment responder is defined as an IGA grade of 'clear' or 'almost clear' and at least a 2-grade improvement from baseline. We believe that the 23% dropout rate in the DMT310 group may have contributed to the outcome of this study. After further assessment of the data, we believe DMT310 may not be tolerable for rosacea patients, who tend to have more sensitive skin.

Based on the foregoing, we have decided not to devote any further financial resources to development of this indication for DMT310, and we have determined not to pursue further development efforts regarding this indication for DM310. We will continue to focus our resources on our DMT310 program for acne based on the statistically significant results seen in our Phase 2b study.

### *DMT400 for the Topical Delivery of Macromolecules*

DMT400 is our combination treatment regimen that utilizes the unique mechanical features of our *Spongilla* technology to facilitate the intradermal delivery of macromolecules, such as botulinum toxin, monoclonal antibodies, dermal fillers, or vaccines, by topical application rather than with injections. These macromolecules are highly effective and approved for the treatment of multiple medical and aesthetic skin conditions and diseases, but currently are not approved in a topical form because the molecular structures are too large to penetrate the stratum corneum, the skin's outermost defense barrier. Thus, all current macromolecule treatment options for skin conditions and diseases must be injected, sometimes requiring numerous injections. We believe that DMT400's topical application regimen may provide patients with a topical treatment option for both medical and aesthetic dermatology conditions using products previously unavailable to them in a topical treatment.



**Image 3: Siliceous Spicules Microchannels**

DMT400 works by first topically applying our proprietary sponge powder to the treatment area wherein the mechanical spicules of the sponge penetrate the skin, thereby creating microchannels into the dermis as seen in Image 3 above. Unlike a derma roller or other microneedle technology, our unique spicules remain in the skin for one to two days allowing the microchannel to remain open rather than close up, as they would after using a derma roller. With the microchannel open for a longer period a macromolecule can be applied topically to the skin and is thus able to penetrate into the dermis. We believe this topical application of a macromolecule can be massaged into the newly created microchannels thereby facilitating the delivery of the macromolecule, through the microchannel and into the dermis, without the need for injections. This targeted delivery to the dermis rather than delivery to the systemic circulation, may decrease the systemic spread of these macromolecules thus potentially reducing side effects seen with injections, while increasing targeted application to where the disease resides.

### *DMT410 for the Treatment of Primary Axillary Hyperhidrosis*

We initially tested our DMT400 treatment with our DMT410 program, which consists of a topical application of our proprietary sponge powder followed by a topical application of botulinum toxin, a macromolecule. DMT410 was initially tested in a Phase 1b POC trial of ten (10) patients with primary axillary hyperhidrosis to determine if our sponge powder could successfully facilitate the intradermal delivery of botulinum toxin and potentially other macromolecules. Based on the results seen from this study we believe we were successful in delivering active botulinum toxin to the dermis for the treatment of primary axillary hyperhidrosis and potentially other skin conditions.

*Market Opportunity.* Hyperhidrosis is a life-altering disorder of excessive sweating out of proportion with thermoregulatory requirements. While many patients may exhibit this excessive sweating in response to specific triggers, such as emotional stress, others may exhibit symptoms spontaneously. Typically, the diagnosis of hyperhidrosis is based partly on subjective measures that measure how the excessive sweating affects a patient's quality of life. Physicians also gravimetrically measure the amount of sweat produced, though there is no standardized threshold which defines hyperhidrosis. It is believed to affect an estimated 15 million people in the U.S. alone. The U.S. prescription hyperhidrosis market had approximately \$66 million in prescription pharmaceutical sales in 2020, and is expected to reach approximately \$282 million in 2030, with almost 40% from injections of BOTOX, according to GlobalData Inc. market data. According to a 2016 update on the prevalence and severity of hyperhidrosis in the U.S., axillary (underarm) hyperhidrosis, is the most common form of the disorder. However, patients are affected by other forms like palmar (hands) and plantar (feet) hyperhidrosis, which we believe DMT410 may be able to treat and avoid the side effects seen in studies of poor administration of intradermal injections.

*Limitations of Current Standards of Care.* While the prevalence of hyperhidrosis is significant, treatment options are limited, and many come with unwanted side effects making patient acceptance low. Typical first line therapy is usually with aluminum chloride-based antiperspirants, but many have potential drawbacks. First, daily applications can be time consuming leading to poor compliance among patients. Second, many antiperspirants are irritating to the skin leading to treatment discontinuation. Lastly, topical aluminum chloride treatment has a transient duration of effect and requires frequent reapplication to maintain sweat control. More recently, topical anticholinergics have been investigated by companies such as Botanix Inc. (formerly developed by Fresh Tracks, Inc.) and Journey Medical Corporation (formerly developed by Dermira, Inc.), but we believe they tend to have the same side effects as systemic anticholinergics which are used off-label. These side effects include dry mouth, dry eyes, blurred vision, headache, urinary retention, among others. The unwanted side effects are often so intolerable that up to one third of patients are forced to withdraw from treatment. If topical or systemic treatments fail, then patients can get intradermal injections of botulinum toxin which has been shown to have a great treatment effect, but treatment is very technique driven, requiring a trained physician to administer the toxin to the thin layer of the dermis. Many times, poor treatment response with botulinum toxin is due to incorrect or insufficient dosing or incorrect administration. Patients may also experience injection site pain or discomfort, which may be accompanied by swelling and bruising. However, for the treatment of palmar hyperhidrosis with intradermal injections of botulinum toxin, the most notable adverse event is transient hand weakness, if administered incorrectly. As a last resort, patients may also seek surgery to treat their hyperhidrosis, if less invasive treatment options fail. While there are treatment options available for hyperhidrosis patients, only about half of affected individuals seek treatment due to social embarrassment associated with the diagnosis of the disease. We believe this leaves a wide gap in the market for a product that combines the efficacy of botulinum toxin with the safety and tolerability profile of topical therapies. We believe DMT410, if successfully commercialized, could address this underserved market opportunity.

*Our Solution for Primary Axillary Hyperhidrosis.* While primary axillary hyperhidrosis is idiopathic, the mechanism is thought to be neurogenic overactivity of the eccrine (sweat) glands in the affected area. Based on the summary basis for approval of BOTOX, we know that botulinum toxin type A has a clinical effect on hyperhidrosis, which acts by disrupting sympathetic stimulation to the eccrine glands resulting in considerably reduced axillary sweating from four to 12 months. Based on the package insert for BOTOX, intradermal injections of 50 units of BOTOX saw a greater than 50% decrease in axillary sweat production in 81% and 41% of patients treated with BOTOX or placebo, respectively, at four weeks. While intradermal injections of botulinum toxin appear to be very effective, the treatment requires multiple injections into each axilla, which is time consuming for the treating physician and administration is very technique sensitive due to the thin nature of the dermis. Additionally, given the nature of the target tissue being more sensitive, and the number of injections required, it is believed that injection site pain is a major cause for the lack of compliance. Thus, we believe a topical application regimen, capable of penetrating the stratum corneum to deliver botulinum toxin into the dermis, may be able to exhibit similar efficacy with greater compliance and adoption. In a Phase 1b POC study of DMT410 for the treatment of axillary hyperhidrosis, we saw a greater than 50% decrease in axillary sweat production in 80% of patients at week four. This result supports our belief that topical application of botulinum toxin via our *Spongilla* technology to the dermis could be a viable alternative to intradermal injections. If approved, DMT410 could eliminate the need for intradermal injections of botulinum toxin. Therefore, we believe DMT410 could potentially be a favorable treatment option for patients suffering with primary axillary hyperhidrosis. Additionally, we also believe that DMT410 may be an effective treatment for palmar or plantar hyperhidrosis due to DMT410's delivery of botulinum toxin to the dermis without the risk of distance spread of toxin to the muscle as with intradermal injections of botulinum toxin. DMT410 could limit the side effects seen with intradermal injections including hand weakness and administration pain. There can be no assurance that DMT410 will receive FDA approval for hyperhidrosis.



*DMT410 for the Treatment of Aesthetic Conditions* In addition to the use of DMT410 in the treatment of hyperhidrosis and other medical dermatology conditions such as acne, based on the data from our recent Phase 1b POC trial of DMT410 for the treatment of multiple aesthetic skin conditions such as pore size, sebum production, fine lines, luminosity, and brightness of the skin, we believe DMT410 has an opportunity to be used for the treatment of multiple aesthetic skin conditions. Botulinum toxin is known to treat a variety of aesthetic skin conditions, but to achieve these positive effects, the botulinum toxin needs to be delivered to the dermis rather than the muscle to have the desired effect. DMT410's uniquely sized spicules create microchannels through the stratum corneum and into the dermis that are large enough for botulinum toxin to be delivered to the dermis. However, the spicules are not long enough to reach the muscle layer, which limits the potential distant spread of toxin and potential side effects. Botulinum toxin acts by blocking the release of acetylcholine into the synaptic cleft, where it binds to a cholinergic receptor, thereby inhibiting sympathetic nerve function. This ability to inhibit cholinergic transmission makes it useful to treat indications with glandular hypersecretion, like sebum production or hyperhidrosis, which are partly caused by hyperactive sympathetic nerves. For aesthetic indications, since botulinum toxin must be delivered to the dermis, intradermal injections are typically required but can require numerous injections in order to cover the larger surface area to treat these aesthetic skin conditions as compared to targeted injections to the muscle. Intradermal injections can also be difficult to effectively administer and may be painful for patients. This tends to lead to poor adoption of this therapy, which is why we believe there are currently no approved aesthetic indications utilizing intradermal injections. Additionally, no topical formulations of a botulinum toxin have been approved, likely due to the size of the molecule and its difficulty in penetrating the stratum corneum to reach the dermis. Therefore, with no currently approved intradermal injections or topical applications methods of botulinum toxin for aesthetic skin conditions, we believe there is a large market opportunity for a product that can successfully deliver botulinum toxin by topical application into the dermis to improve a patient's aesthetic appearance. If approved, we believe DMT410 can address this market.

*Limitations of Standards of Care* While injections of botulinum toxin into the muscles have been approved for many years for aesthetic treatments such as the reduction of glabellar, lateral canthal or forehead lines, there are many other aesthetic skin conditions, such as enlarged pore size, excess sebum production, fine lines, decreased luminosity, and decreased brightness that botulinum toxin has been demonstrated to improve but a botulinum toxin product, whether via intradermal injections or topical application, has yet to be approved for these indications. This may be because these aesthetic indications typically require botulinum toxin to be delivered to the dermis rather than the muscle, which due to the thin nature of the dermis, can be more difficult than injecting into the muscle. Additionally, the areas of the face requiring intradermal injections are much more sensitive and thus can be more painful for patients. These intradermal aesthetic indications typically require a wider dispersion of botulinum toxin to be delivered to the dermis rather than the few injections into the muscle needed for the deeper facial lines. Some intradermal studies have required 25-30 intradermal injections in the face to deliver sufficient quantities of botulinum toxin to the dermis. With some patients having a fear of needles, a treatment that can avoid the use of needles would be desirable for this population. Additionally, topical application of botulinum toxin has been difficult due to the size of the molecule making it difficult for the botulinum toxin to penetrate the stratum corneum, resulting in many topical applications being ineffective and discontinued. An example is Revance's RT001 product which did not achieve the primary or other secondary endpoints in a Phase 3 trial for the treatment of crow's feet and therefore, Revance does not plan to continue development of this program at this time. Another botulinum toxin company, Allergan (now part of AbbVie), purchased a company in 2016 to pursue development of a topical botulinum toxin program. However, we believe Allergan has not conducted any studies with this program. We believe most botulinum toxin companies remain interested in developing a topical means of administering botulinum toxin that is less painful, easy to apply, provides wider coverage of toxin, and limits potential distant spread of toxin, but no product has yet been successfully developed.

*Our Solution for the Treatment of Aesthetic Skin Conditions* We believe a product candidate like DMT410, which may be able to successfully deliver botulinum toxin to the dermis covering a larger facial area than injections, would provide a new treatment option for a variety of aesthetic skin conditions, such as reduction in pore size, sebum production, and fine lines, and improvement in skin luminosity and brightness, thus potentially expanding the market for uses of botulinum toxin beyond injections into the muscle for treatment of deep lines. We believe DMT410 may be able to provide patients with a topical treatment option without the pain and discomfort typically associated with injections of botulinum toxin. Additionally, we believe administration will be easier and less time consuming for dermatologist, making it an additional value driven treatment option they can offer. While current botulinum toxins are approved for injections into the facial muscles to treat deeper wrinkles such as glabellar lines, lateral canthal lines and forehead lines, there remain many other aesthetic conditions of the face which could greatly benefit from an intradermal administration of botulinum toxin, especially via topical application. Certain aesthetic indications such as reduction in fine lines, pore size, and sebum production, and improvement in luminosity and brightness are typically not treated with injections into the muscles but need botulinum toxin to be delivered to the dermis to have the proper effect. With DMT410's uniquely sized spicules, we believe it can create numerous microchannels into the dermis allowing a pathway for the topical application of botulinum toxin. Once in the dermis botulinum toxin is able to act on reducing sebum production which in turn may reduce pore size and overall oiliness of the skin. Additionally, botulinum toxin has been demonstrated to have a beneficial effect on the mean volume and depth of facial lines giving the skin a smoother appearance. Therefore, we believe there may be a need for a product, such as DMT410, that can facilitate the topical application of botulinum toxin into the dermis, to treat a variety of these aesthetic skin conditions.

If approved, we believe DMT410 has the potential to expand the market for botulinum toxins' treatment to multiple additional aesthetic skin conditions. We believe DMT410 can be an effective product at delivering bioactive botulinum toxin with a topical application for treatment of pore size, sebum production, fine lines, luminosity, brightness, overall aesthetic appearance and possibly more. We recently completed a Phase 1b POC trial of DMT410 for the treatment of multiple aesthetic skin conditions where we examined improvements in pore size, sebum product, luminosity, brightness, and Global Aesthetic improvement after one treatment of DMT410. We believe this POC trial produced data which demonstrated that DMT410 was able to deliver botulinum toxin to the dermis and showed a reduction in pore size, reduce sebum production, improved luminosity, improved brightness, and improved the patients' Global Aesthetics. This study also produced no adverse events and provided acceptable tolerability data with only mild tolerability effects seen fifteen (15) minutes post treatment. We believe this data warrants further development of this program and we are currently seeking a partner who has a botulinum toxin they are looking to develop for aesthetic skin conditions which require delivery of botulinum toxin to the dermis. There can be no assurance that DMT410 will receive FDA approval for any aesthetic indication or that we will be able to find a partner for development.

### **Clinical Progress of our Lead Product Candidates**

#### *DMT310 Phase 3 Clinical Trial Program for Acne*

In December 2023, we initiated the DMT310 Phase 3 clinical program entitled Spongilla Treatment of Acne Research study (STAR). The DMT310 Phase 3 clinical program will include two Phase 3 clinical trials to evaluate the efficacy, safety, and tolerability of DMT310 in patients with moderate-to-severe facial acne. Each Phase 3 trial will be randomized (2:1), double-blind, placebo-controlled, and will enroll approximately 550 patients with moderate-to-severe acne, ages 9 years and older in the United States and Latin America. The primary endpoints are the mean change from baseline in inflammatory and noninflammatory lesion counts and the Investigator Global Assessment (IGA) treatment response rate. IGA is measured on a 5-point scale (0-4), with a treatment response defined as at least a 2-point improvement from baseline and an IGA score of 0 (clear) or 1 (almost clear). Patients will be treated once a week for 12 weeks with either DMT310 or placebo and will be evaluated monthly. STAR-1 is the first of two pivotal Phase 3 trials, with top-line results expected in the first quarter of 2025. Upon adequate financing, we will initiate the second Phase 3 clinical trial, STAR-2, which will be followed by a long-term extension study as required by FDA. If positive, the results from both Phase 3 clinical trials will be used to support the filing of an NDA with FDA.

#### *DMT310 Phase 2b Clinical Results for Acne*

In June 2020, we received results from our randomized, double-blind, placebo-controlled, Phase 2b clinical trial of once weekly treatments for twelve weeks of DMT310 for acne. We enrolled 181 moderate-to-severe acne patients at fourteen (14) sites across the U.S. Patients were required to be 12 years of age or older, have at least twenty (20) non-inflammatory lesions, twenty (20) inflammatory lesions, no more than two (2) nodules or cysts and be a moderate or severe (meaning a 3 or 4) on the IGA scale of acne. The IGA scale consists of a 5-point scale, 0-4, with 0 being clear, 1 being almost clear and 4 being severe acne as graded by the treating physician. Patients were randomly divided into two treatment groups, either to receive DMT310 or placebo. Patients were required to apply the product, whether DMT310 or placebo, to the entire face, once weekly for 12 weeks with the first two weeks of treatment applied in office under the supervision of trained study staff, then the remaining 10 weekly treatments were applied at home by the patient.

The primary clinical endpoints of the trial included the absolute reduction in inflammatory lesions from baseline. The secondary clinical endpoints included:

- the absolute reduction in non-inflammatory lesions from baseline;
- the IGA with a responder being a patient with a 2-grade change in IGA scale and being a 0 or 1 at study exit; and
- safety and tolerability.

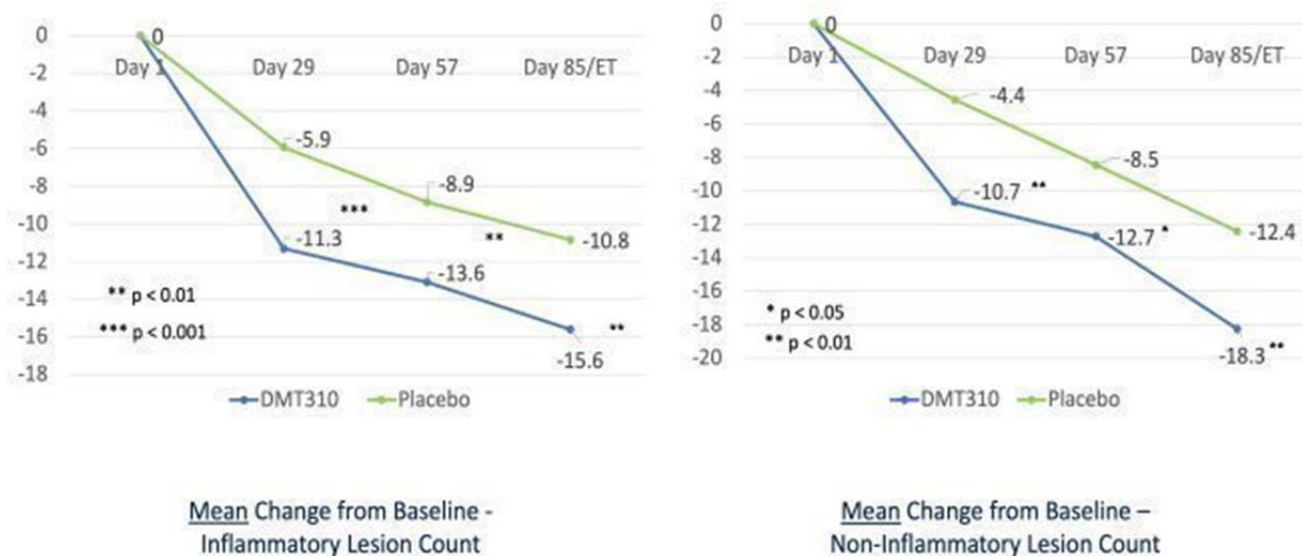
All statistical analyses and data shown for our Phase 2b study are on the intent-to-treat, or ITT, population. The ITT population included all randomized subjects in the group to which they were randomized, regardless of study drug received or if they completed the study. The ITT approach provides an unbiased comparison among the treatment groups.

The trial was completed in June 2020 and showed a statistically significant and we believe, a clinically meaningful effect for all efficacy endpoints of the trial, namely reduction in inflammatory and non-inflammatory lesions and IGA responders. Notably, the treatment effect for all efficacy endpoints was statistically significant at the four-week mark, after only four treatments, and continued to be statistically significant for week eight and week 12 when compared with placebo. Patients saw a rapid and sustained therapeutics treatment effect in percentage change in inflammatory lesions with a 45% reduction in inflammatory lesions at week four and reached 62% reduction in inflammatory lesions at week 12 compared to 24% and 42% reduction of inflammatory lesions for placebo at weeks four and 12, respectively. The effect on non-inflammatory lesions were also statistically significant after four weeks, with the therapeutic effect of an approximately 36% reduction in non-inflammatory lesions at week four reaching a therapeutic effect of 58% at 12 weeks, which was statistically significant when compared with placebo. In addition, both inflammatory and non-inflammatory percent reduction in lesion counts had P-values of less than 0.001 at week four and week 12 when compared to placebo.

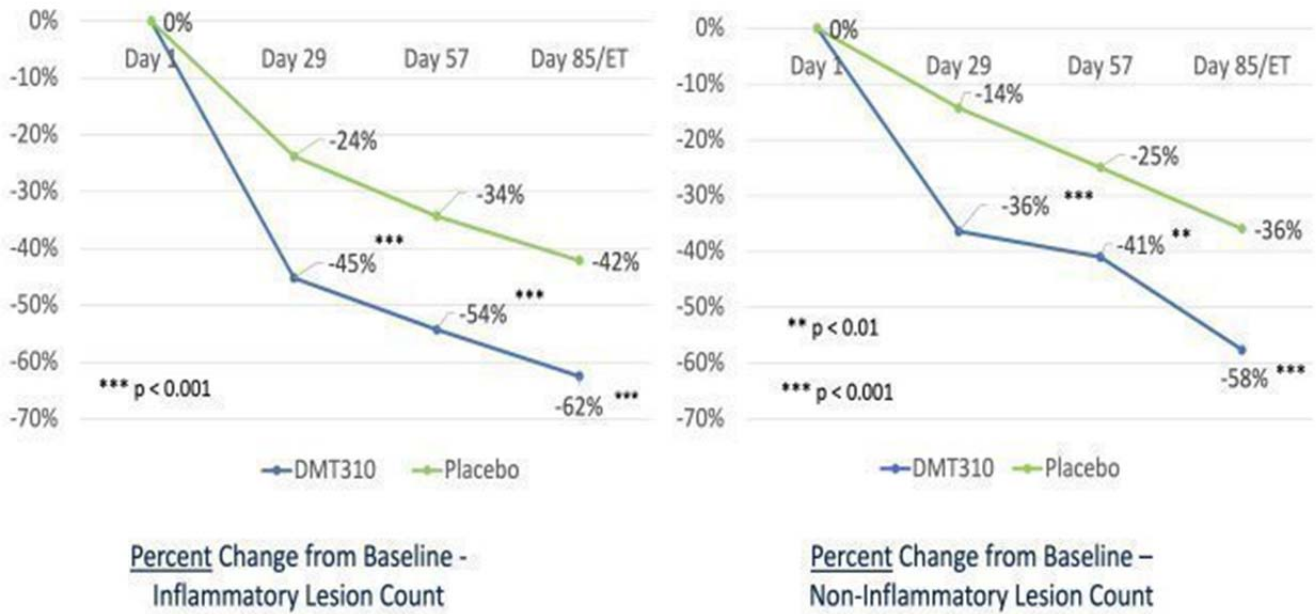
We also saw an early statistically significant separation in IGA with 15% of patients in the DMT310 group considered responders on the IGA scale, or who had an IGA score of 0, “clear,” or 1, “almost clear,” after only 4 treatments as compared with just over 2% of patients on placebo. This statistical separation continued for the remainder of the trial where at the completion of the trial, or week 12, 44% of patients in the DMT310 group, compared with 17% in the placebo group were IGA responders. This difference was statistically significant with a P-value of less than 0.001.

No reported drug-related severe adverse events were reported in the trial. The drug also appeared to be tolerable by a majority of patients with greater than 92% of patients experiencing no or mild tolerability with no severe dryness, scaling, erythema, or burning/stinging reported at week 12. Of those patients who did report tolerability issues, they also reported that the issues were usually transient and resolved quickly without intervention. Based on this data, after meeting with the FDA, we expect to proceed to Phase 3 clinical trials with the same clinical endpoints and the same formulation of DMT310 for moderate-to-severe acne.

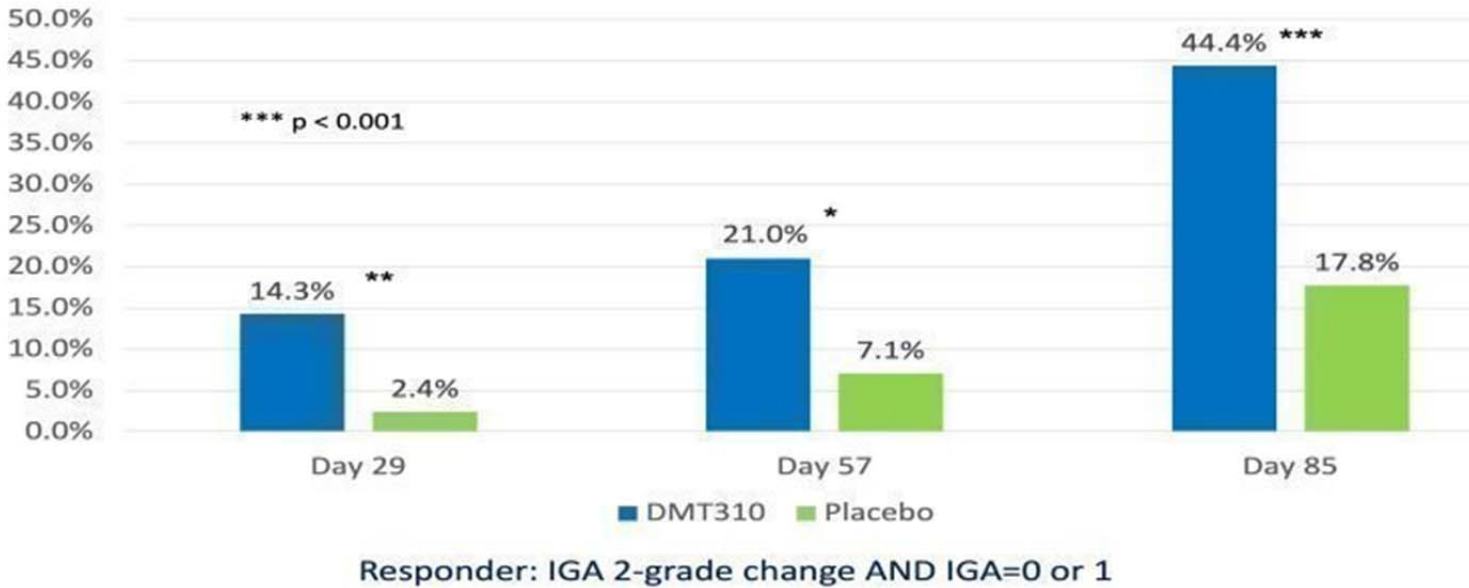
The following diagrams and tables show the absolute reduction of inflammatory and non-inflammatory lesions from baseline until the end of study, or week 12, for both DMT310 and placebo (Image 4), and percent reduction of inflammatory and non-inflammatory lesions from baseline until end of study, or week 12, for both DMT310 and Placebo (Image 5). Although reduction in non-inflammatory lesions was a secondary endpoint of this trial, it is a required metric for the Phase 3 acne studies necessary for FDA approval.



**Image 4: Mean reduction of inflammatory and non-inflammatory lesions from baseline until end of study, or week 12, for both DMT310 and Placebo**



**Image 5. Percent reduction of inflammatory and non-inflammatory lesions from baseline until end of study, or week 12, for both DMT310 and Placebo**



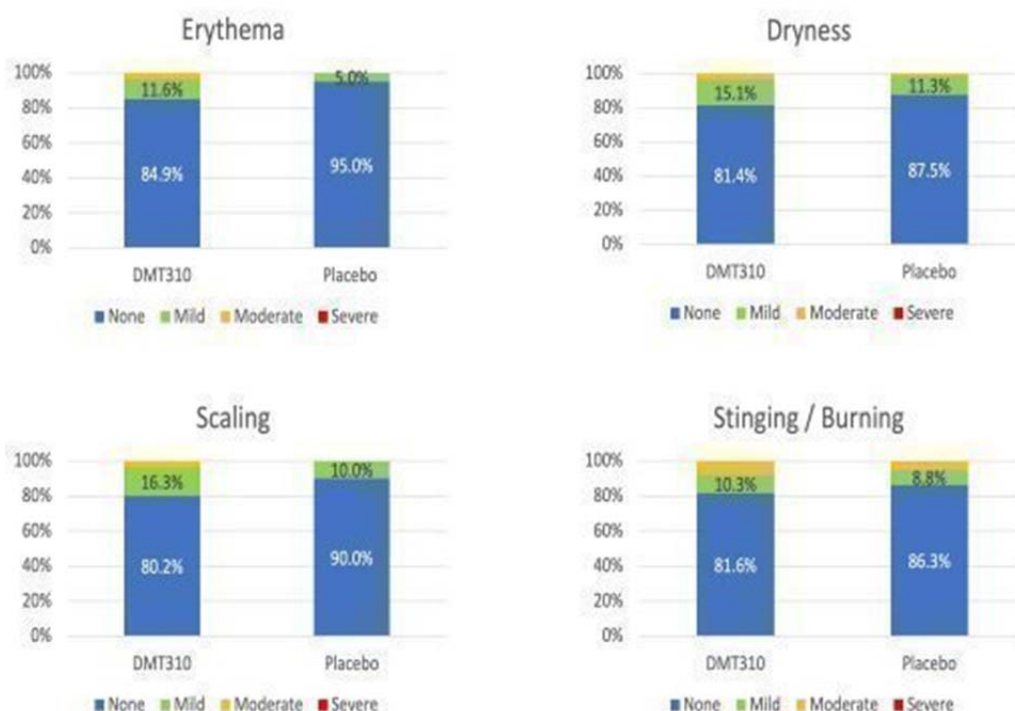
**Image 6. Investigator Global Assessment response rate at Day 29, or week 4, Day 57, or week 8 and Day 85, or week 12**

- (1) As used in the diagrams and table above, the reference to “P-value” (relative to placebo) means the probability of being wrong when asserting that a true difference exists between the results for the relevant patient group and the placebo group. For example, a “P-value” of less than 0.001 indicates that there is a less than one in 10,000 chance that the observed result in the treatment group and the observed result in the placebo group are the same. A “P-value” equal to or less than 0.05 means that a given difference is statistically significant.
- (2) “Success” is defined as an IGA score of “clear” or “almost clear” and a 2-grade change in IGA upon completion of the study.

Additionally, the safety and tolerability profile of DMT310 appeared to be acceptable with a small number of patients experiencing treatment emergent adverse events as seen in Image 7 below. In this Phase 2b trial, no subject receiving treatment with DMT310 experienced a severe local skin reaction at study end nor did any patient undergo a dose modification. Most tolerability issues were mild and resolved shortly after application without any rescue medication as seen in Image 8 below. Overall, DMT310 was generally safe and well tolerated by patients when applied once weekly for 12 weeks.

	<b>DMT310 (N=91) N (%)</b>	<b>Placebo (N=90) N (%)</b>
<b>System Organ Class Preferred Team</b>		
General disorders and administration site conditions .....	5(5.5)	2(2.2)
Application site erythema .....	4(4.4)	1(1.1)
Application site pruritus.....	2(2.2)	2(2.2)
Application site dryness.....	1(1.1)	0(0.0)
Application site exfoliation.....	1(1.1)	0(0.0)

**Image 7. Treatment Emergent Adverse Events**

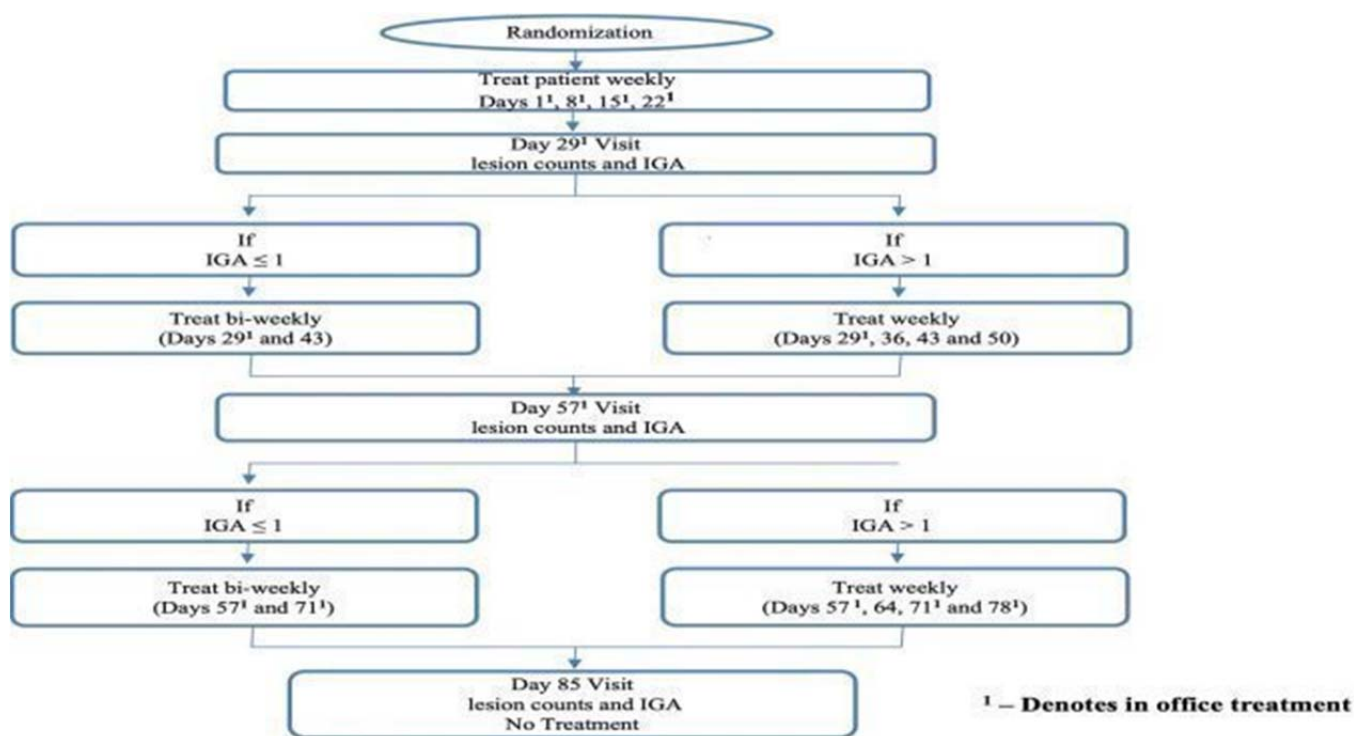


**Image 8. Local Tolerability**

*DMT310 Phase 2a Clinical Results for Acne*

In 2018 we conducted the first clinical trial of DMT310, a randomized, double-blind, 2x2 factorial, placebo-controlled, Phase 2a clinical trial of DMT310 for the treatment of acne. We enrolled 121 patients to evaluate the tolerability, safety, and efficacy of DMT310 mixed with 3% H<sub>2</sub>O<sub>2</sub> following 12 weeks of topical administration in male and female patients with moderate-to-severe facial acne. The study employed a 2x2 factorial design to assess the contribution of each component of the investigational product (i.e., *Spongilla lacustris* topical powder and 3% H<sub>2</sub>O<sub>2</sub> USP). This Phase 2a clinical trial employed the same clinical endpoints as our Phase 2b clinical trial of DMT310 for the treatment of acne, as discussed above.

Patients were randomly divided into one of four treatment groups, DMT310 + 3% H<sub>2</sub>O<sub>2</sub>, DMT310 + Water, Placebo + 3% H<sub>2</sub>O<sub>2</sub>, or Placebo + Water (control). The patients were required to apply the assigned study drug to their entire face up to once weekly for 12 weeks (84 days), beginning on Day 1 and through Day 78 (as applicable). During study center visits on Days 29 and 57, a determination was made for each patient, based on the Investigator’s Global Assessment (IGA) score, as to whether study drug application would continue once weekly or at a lower biweekly frequency (once every 2 weeks). Specifically, patients with an IGA > 1 at the Day 29 or Day 57 visits continued with once weekly study drug applications, while patients with an IGA 1 at these same visits were instructed to subsequently apply their assigned study drug biweekly (see Image 9 below for a presentation of the study drug application frequency algorithm).



**Image 9. Application Frequency Algorithm by Study Visit**

This Phase 2a trial showed statistically significant and clinically meaningful effects for its endpoint, absolute reduction in inflammatory lesions when comparing DMT310 + 3% H<sub>2</sub>O<sub>2</sub> and placebo + water (control) groups at both week 8 and week 12 or end of study. At week 12, DMT310 + 3% H<sub>2</sub>O<sub>2</sub> had a 16-lesion reduction from baseline while placebo + water had an 11 lesion reduction from baseline, with a p-value of less than 0.05. Across all the treatment groups, there was a mean decrease from baseline (i.e., improvement) in the inflammatory and non-inflammatory lesion counts at Days 15, 29, 57, and 85. However, there were no statistically significant differences between the DMT310 + 3% H<sub>2</sub>O<sub>2</sub> group versus the placebo + water (control) group for the mean changes from baseline in non-inflammatory lesion counts.

We did not observe a statistically significant difference between the DMT310 + 3% H<sub>2</sub>O<sub>2</sub> group and the placebo + water (control) group in the percentages of patients with IGA treatment success (IGA score of 1 or 0 and a 2-grade change) or patients with 1-grade or 2-grade improvements from baseline in IGA at any visit. At Day 85 in the DMT310 + 3% H<sub>2</sub>O<sub>2</sub>, DMT310 + water, placebo + 3% H<sub>2</sub>O<sub>2</sub>, and placebo + water groups, 29.6%, 20.0%, 27.6%, and 34.5% of patients had IGA treatment responders, respectively; 66.7%, 66.7%, 65.5%, and 55.2% of subjects had a 1-grade improvement from baseline in the IGA, respectively; and 37.0%, 20.0%, 27.6%, and 34.5% of subjects had a 2-grade improvement from baseline in the IGA, respectively.

*Analysis of Placebo:* After speaking with the clinical investigators in the trial, it was determined that the higher than normal placebo response in non-inflammatory lesions may have been partially due to the stickiness of the placebo, which required patient to scrub their face, resulting in exfoliation of the skin and removal of sebaceous plugs (whiteheads and blackheads), thereby reducing non-inflammatory lesion counts. We believe this caused a placebo response rate that was much higher than the placebo response rates seen in other topical Phase 2 acne trials. As a result of the inadequate placebo, we developed a new proprietary placebo formulation for our Phase 2b clinical trial.

*Once weekly vs. Biweekly Treatment Schedule:* Due to this being the first time DMT310 was studied in moderate-to-severe acne patients for 12 weeks, a conservative study design was chosen to ensure patient tolerability and safety while attempting to maintain efficacy. Therefore, we allowed IGA treatment responders (IGA score of 0 or 1) to move to a biweekly or every other week application schedule as discussed above. This resulted in 3 out of 27 patients in the DMT310 + 3% H<sub>2</sub>O<sub>2</sub> group and 0 out of 29 patients in the placebo + water group moving from an IGA score of 1 (treatment responder) at week 8 and regressing to an IGA score of 2 (treatment failure) at week 12. Therefore, our Phase 2b clinical trial of DMT310 in moderate-to-severe acne patients incorporated only once weekly applications for 12 weeks with no biweekly option.



No statistical or clinical difference was seen between the placebo + 3% H<sub>2</sub>O<sub>2</sub> and the placebo + water groups, which we believe indicates that 3% H<sub>2</sub>O<sub>2</sub> by itself does not have a treatment effect.

#### *DMT310 next steps for acne*

After receiving positive feedback and alignment with FDA from our End of Phase 2 meeting in June of 2023 we began enrolling patients in our DMT310 Phase 3 program in moderate-to-severe acne in December 2023.

The DMT310 Phase 3 program will include two, multi-center, placebo-controlled trials with identical clinical endpoints as our recent successful Phase 2b clinical trial of DMT310 for the treatment of moderate-to-severe acne. Once we receive top-line results from both Phase 3 studies, assuming positive results, we plan to file a new drug application, or NDA, with the FDA shortly thereafter. This Phase 3 program is intended to be designed to demonstrate the safety and efficacy of the treatment of DMT310 relative to placebo for the treatment of moderate-to-severe acne. Prior to, or in parallel with our planned Phase 3 program, we intend to continue conducting and complete the additional non-clinical studies necessary to support the filing of an NDA. We also intend to conduct a long-term safety study following the second Phase 3 clinical study. If DMT310 is approved for the treatment of acne, we believe DMT310 can eventually be an attractive prescription to over-the-counter switch, or Rx-to-OTC, target, which could provide a substantially larger sales opportunity. There can be no assurance that DMT310 will receive FDA approval for the treatment of acne.

#### *DMT310 Phase 1a Clinical Results for Psoriasis*

We completed a Phase 1a POC trial of DMT310 for the treatment of mild-to-moderate psoriasis. This was an open-label, multi-center, 12-week study in 30 mild-to-moderate psoriasis patients with psoriatic lesions covering between 2-30% of body surface area. The trial aimed at evaluating the tolerability, safety, and efficacy of once weekly treatments of DMT310, which consists of 2 grams of *Spongilla* powder mixed with 6 mL of 3% H<sub>2</sub>O<sub>2</sub>. One mild or moderate lesion was selected, and patients were required to apply DMT310 to the entire lesion, once weekly for 12 weeks with the first two weeks of treatment applied in office under the supervision of trained staff, then the remaining 10 weekly treatments were applied at home by the patient.

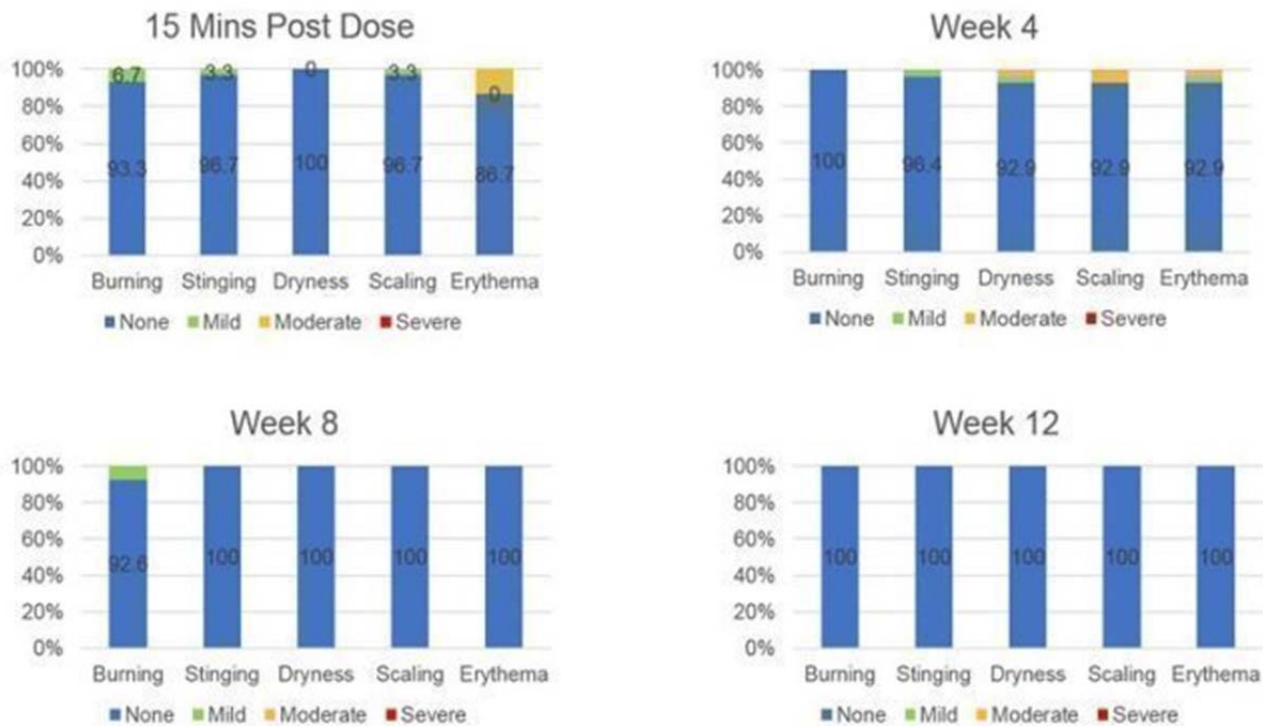
The endpoints in this study included:

- Physicians Global Assessment (PGA) of disease severity with success defined as absent or very mild disease, a score of 0 or 1 respectively on a 5-point scale, at the target lesion site.
- Psoriasis Area Severity Index (PASI) at the target lesion site defined as absent or mild, a score of 0 or 1 respectively, on a 6-point scale. This required each psoriatic sign of scaling, erythema, and plaque elevation to have a score of 0 or 1 for the subject to be considered a responder.
- Pruritus Visual Analog Scale (VAS) looking at the mean change and percent change from baseline in pruritus (itch).

All efficacy analyses were performed using the As-Treated population, which consists of all enrolled patients who received at least one dose of study medication and the per protocol population, which consists of all enrolled patients with no significant protocol violations during the study that would affect the efficacy analyses.

The trial was completed in August 2021 and showed an acceptable safety and tolerability profile that we believe is clinically meaningful and warrants further investigation of DMT310 as a potential treatment for mild-to-moderate psoriasis. DMT310 was able to achieve a PGA score of 0 or 1 for the target lesion in 29.6% of patients at week 8. DMT310 also demonstrated a total PASI score of 0 or 1 for the target lesion in 25.9% of patients at week 8. Notably, DMT310 demonstrated a 19.6% reduction from baseline in pruritus (itch) at week 8 with a peak reduction of 22.5%. We believe these findings from a POC trial are encouraging for the potential use of DMT310 as an easy to apply topical treatment for mild-to-moderate psoriasis with an acceptable safety and tolerability profile.

No reported drug-related severe adverse events were reported in the trial and only two treatment emergent adverse events were reported, both being application site pruritus. Additionally, the drug also appeared to be tolerated by a majority of patients. Of those patients who did report tolerability issues, they also reported that the issues were usually transient and resolved quickly without intervention.



**Image 10: Local Tolerability**

*DMT310 next steps for psoriasis*

We are pleased with data already seen in our Phase 1 POC trial, especially seeing a reduction in itch as that is one of the main complaints of patients suffering from psoriasis. We are in the process of designing a Phase 2 study of DMT310 for the treatment of psoriasis. The Phase 2 study will be a larger randomized, double-blind, placebo control study of DMT310 for the treatment of psoriasis. Based on the data from the Phase 1b proof of concept study we are considering adding additional arms to examine once versus twice weekly treatment, potentially enhancing the treatment effect seen in our Phase 1b trial. Additionally, due to the unique nature of psoriasis and the general thickness of psoriatic plaques, we may also examine increasing the application pressure and the length of application. We believe that the thicker psoriatic plaques may require a more intensive treatment compared to the application regimen for acne where there is no thickened skin. We believe DMT310 could be a first in class treatment option for psoriasis patients. The DMT310 program for psoriasis is currently on hold with further advancement subject to obtaining additional financing and/or a strategic partner. There can be no assurance that DMT310 will receive FDA approval for the treatment of psoriasis.

*DMT410 Phase 1b-Primary Axillary Hyperhidrosis*

In the first quarter of 2019, we completed a Phase 1b, open-label, POC trial of DMT410 for the treatment of moderate-to-severe primary axillary hyperhidrosis. In this study we treated ten (10) patients with one application of our proprietary sponge powder followed by one topical application of BOTOX, reconstituted per label, to each axilla. Patients were followed for 4 weeks after which time their sweat production was measured and compared with baseline measurements.

The endpoints for this trial included:

- percent of patients with less than 50% reduction in gravimetrically measured sweat production from baseline,
- percent of patients with gravimetric sweat production of greater than 50 mg, and
- percentage change in gravimetric sweat production.



After 4 weeks, 80% of patients saw a decrease in gravimetric sweat production greater than 50%, 85% of patients had gravimetric sweat production of less than 50mg, and patients had a 75% decrease in gravimetric sweat product from baseline. Based on this clinical data, we believe that we were able to deliver botulinum toxin into the dermis through topical application for the treatment of primary axillary hyperhidrosis. Treatment with DMT410 also had an acceptable safety and tolerability profile. We plan to partner with a botulinum toxin to run a larger Phase 2 study of DMT410 for axillary hyperhidrosis and possibly for palmar (hand) or plantar (foot) hyperhidrosis where there is currently no approved product. There can be no assurances that DMT410 will receive FDA approval for the treatment of hyperhidrosis.

#### *DMT410 Phase 1b— Aesthetic Conditions*

In November 2020, we enrolled our first patient in a Phase 1b open-label, POC trial of DMT410 for the treatment of upper facial lines along with multiple other aesthetic skin conditions that are affected by delivery of toxin to the dermis such as pore size, sebum production, brightness, luminosity, fine lines, and Global Aesthetic Improvement. Due to the fact that we do not own rights to a botulinum toxin product, we were required by the FDA to conduct this trial using an approved indication for BOTOX, upper facial lines, an approved dose for this indication (64 units of botulinum toxin) and an approved route of administration, which is typically injections into the muscle rather than the dermis. However, our primary interest was studying the clinical effect of DMT410 for the aesthetic skin conditions that require delivery of botulinum toxin to the dermis rather than the muscle. This is due to our belief that DMT410 only delivers botulinum toxin to the dermis and not the muscle, thus limiting the botulinum toxin's effect to aesthetic conditions which arise in the dermis like fine lines, pore size, sebum production, and others. With these constraints, we initiated the POC trial by enrolling ten (10) female patients, age 18 or older, each receiving one treatment of DMT410, consisting of one topical application of our proprietary sponge powder followed by one topical application for BOTOX, reconstituted per label, to the upper face. Patients were followed for sixteen (16) weeks to determine the achievement of our endpoints along with the duration of effect. We also collected safety and tolerability data. We received top-line data from this study in the November 2021, and believe that we achieved results in multiple aesthetic endpoints sufficient to warrant further investigation of DM410 for the treatment of various aesthetic skin conditions.

The endpoints for this trial were:

- Portion of patients achieving a grade of none or mild on the investigator's assessment of lateral canthal, forehead, and glabellar lines based on the Facial Wrinkle Scale (FWS), which consists of a 5-point scale with 0 being none and 1 being almost none. To be considered a responder, both the patient and physician had to agree on the score.
- Portion of patients achieving improvement on the physician's assessment of pore size improvement, based on the Global Aesthetic Improvement Scale (GAIS), which consists of a 5-point scale with 0 being no improvement, 1 being less than or equal to 25% improvement, 2 being a 26-50% improvement, 3 being a 51-75% improvement, and 4 being a 76-100% improvement.
- Mean and percent change from baseline in brightness based on the 10-point visual analog scale.
- Mean and percent change from baseline in luminosity based on the 10-point visual analog scale.
- Portion of patients achieving a two- grade improvement on the physician's assessment of FWS of fine lines under the eye.

The efficacy analysis was conducted on the ITT and Per Protocol (PP), meaning all patients completing the study without a major protocol violation, populations. In addition to the physician measured endpoints listed above, we also implemented 2-dimensional VISIA and 3-dimensional PRIMOS imaging technology from Canfield Scientific to provide objective analysis of many of the aesthetic endpoints.

Based on the assessment of forehead, lateral canthal, and glabellar lines, no patient was considered a responder in this study, while some patients did achieve at least a one-grade change throughout the course of the study. This result was not unexpected as BOTOX is only approved for injections into the muscle for these indications and we did not believe that we would see any potential distant spread of toxin outside of the dermis to the muscle. Seeing no potential distant spread of toxin was encouraging for us as it provides important safety data that while DMT410 can be applied over a larger treatment area than injections, it does not appear to travel beyond the dermis which may cause unwanted facial effects.

We believe the real potential of DMT410 lies in the aesthetic endpoints that can be affected by delivering BOTOX to the dermis rather than the muscles. These clinical endpoints include pore size, global aesthetic improvement, brightness, luminosity, and fine lines. The following table (Image 11) shows the improvements in pore size, or a decrease in overall pore size, with patients achieving at least a 25% improvement in pore size, for assessment of GAI, or the overall improvement in skin quality, the with patients achieving at least a 25% improvement in GAI, for assessment of brightness, or the skin's combined uniformity of color and texture, with patients having at least a 1-point improvement in brightness, and for assessment of luminosity, or the intensity of light area reflected off the face, with patients having at least a 1-point improvement in brightness.

Measure	Week 4 (N=10) N (%)	Week 8 (N=10) N (%)	Week 12 (N=2) N (%)	Week 16 (N=) N (%)
Physician Assessment of Pore Size	5 (50.0%)	6 (60.0%)	5 (50.0%)	4 (40%)
Global Aesthetic Improvement	7 (70.0%)	8 (80.0%)	6 (60.0%)	2 (20%)
Brightness	3 (30.0%)	6 (60.0%)	6 (60.0%)	4 (40%)
Luminosity	5 (50.0%)	9 (90.0%)	9 (90.0%)	6 (60%)

**Image 11: Aesthetic Endpoints**

In addition to the physician measured endpoints, we also utilized Canfield Scientific's 2-dimensional VISIA and 3-dimensional PRIMOS imaging technologies to gather additional objective data on some of the key endpoints. Based on the VISIA system patients saw a 14.1% reduction in pore count and a 14.3% reduction in pore area at week 4. Patients also saw a 16.5% reduction in wrinkle count and a 11.5% reduction in wrinkle area at week 4. Using the PRIMOS image analysis patients saw a percent decrease in mean line, which consist of the deeper facial lines, of 12.1% and a percent change in mean roughness, which consists of the superficial fine lines, of 6.5%. We believe the subjective effects seen by the treating physicians were further validated by the objective measures using Canfield camera systems.

No reported drug-related adverse events were reported in the trial. The drug appeared to be well tolerated by patients, with only mild stinging and erythema reported 15 minutes after treatment and no tolerability issues reported at week 4, 8, 12 or 16.

*DMT410 next steps for aesthetics*

We are very encouraged by the results from our Phase 1b POC trial of DMT410 for the treatment of multiple aesthetic skin conditions. This was designed to be a signal detection trial of DMT410 for the treatment of a variety of aesthetic skin conditions based on the clinical trial design constraints, including the limitation on the quantity of BOTOX that we were able to apply, the clinical endpoints that needed to be included, and the area of the face that could be treated. Even with these limitations we believe that we achieved results sufficient to warrant the continued development of this program as there remains no approved botulinum toxin, whether via injection or topical, to treat many of the endpoints in which we saw a treatment effect. We believe this is further supported by the fact that many of the endpoints saw an improvement by week eight (8) or twelve (12) and started to return towards baseline at week 16. This is consistent with the knowledge that BOTOX lasts for about three (3) months before the effect begins to fade. We believe that if we can conduct a larger Phase 2 clinical trial that consists of multiple doses of botulinum toxin, we will be able to find the optimal dose for the treatment of a variety of aesthetic skin conditions including pore size, sebum production, fine lines, luminosity, brightness, and overall aesthetic improvement. We know that botulinum toxin has shown efficacy of these endpoints but there has been very little research conducted on the optimal dose or administration procedure, likely due to challenges with intradermal injections and the lack of topical applications that can effectively deliver botulinum toxin to a large enough treatment area as required to treat many of these aesthetic skin conditions. We believe DMT410 can meet this need as shown by our Phase 1b data, so we are actively discussing partnership opportunities with botulinum toxin companies that may be interested in helping us further develop our DMT410 program for multiple aesthetic skin conditions. There can be no assurances that we are able to successfully negotiate a partnership with a botulinum toxin company or that DMT410 will receive FDA approval for the treatment of any aesthetic skin conditions.

## **Manufacturing**

We do not currently own or operate any manufacturing facilities and do not plan to own any in the near future. We have been relying on our third-party partners for the manufacture of our products used in pre-clinical studies and clinical trials and will likely continue to rely on these partners in the near term for the commercial manufacturing of our drug substance and drug product, if our drug product candidates are approved. Manufacturing of the active pharmaceutical ingredient, or API, for our product candidates requires a raw material that is derived from a natural source.

To date, we have obtained naturally sourced *Spongilla* raw material directly from our supplier based in Russia. In February 2020, we signed an exclusive supply agreement with this supplier of *Spongilla* raw material. Our supplier has over 21 years of experience collecting and processing *Spongilla* and has the capacity to collect and process large quantities of *Spongilla* per year. We believe our supplier is able to and will continue to be able to harvest sufficient quantities of raw material to fulfill our development and potential commercial needs, if a product candidate is approved using this raw material. We received multiple shipments of *Spongilla* raw material from our supplier during fiscal years 2022 and 2023 containing additional quantities of *Spongilla* raw material, which we believe will provide us with sufficient quantities of *Spongilla* to initiate and complete two Phase 3 studies in moderate-to-severe acne and support the filing of an NDA for DMT310 in acne in the event of successful completion of the two Phase 3 studies. However, we are exploring alternative manufacturing sources in order to ensure that we have access to sufficient manufacturing capacity to meet potential demand for any of our product candidates in a cost-efficient manner. See “*Business—Material Agreements— Supply Agreement between Dermata Therapeutics LLC and Reka-Farm LLC*” for more information regarding our supply of *Spongilla*.

Development and commercial quantities of any drug product candidates that we may develop will need to be harvested, manufactured in facilities, and processed in compliance with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We currently employ internal resources to manage our manufacturing contractors. The relevant manufacturers of our drug product candidates have advised us that they are in compliance with both current Good Laboratory Practices, or cGLP, and cGMP.

We have relied upon our complete supply chain while supporting both our Phase 1 and Phase 2 clinical supply requirements and we are confident that our manufacturers have the ability to scale our processes to support our Phase 3 clinical studies and future commercial commitments. Our suppliers and manufactures were specifically selected based on the capabilities of their organization, their compliance to regulations, their personnel and the type and capabilities of their equipment. Testing methods for each stage of the manufacturing process from acquisition of raw materials through production of finished drug product have been developed and satisfactorily qualified per the FDA’s phase appropriate regulations relating to clinical materials for human use. Analytical methods and operational procedures related to each stage of our production operations including product release will continue to evolve and be validated as part of our overall development plan for Phase 3 clinical supplies and commercial production.

## **Commercialization**

Given our stage of development, we do not currently have any internal sales, marketing, or distribution infrastructure or capabilities. If approved, we intend to commercialize DMT310, or any other product candidates that we may successfully develop, in the United States by building a specialized sales organization focused on dermatologists. We believe a scientifically oriented, customer-focused team of approximately 50-60 sales representatives would allow us to reach our targeted dermatologists in the U.S. with the highest potential for prescribing DMT310. In the future, we may develop and commercialize DMT310 for additional geographic regions, independently or with a strategic partner. If DMT310 is approved, and we are able to successfully commercialize it, we believe DMT310 can eventually become an attractive Rx-to-OTC switch target, which could provide a substantially larger addressable market and an expanded sales opportunity.

## **Competition**

The medical and aesthetic pharmaceutical industries in which we plan to operate are competitive and subject to changes in practice. While we believe that our unique natural technology, knowledge, experience and resources provide us with competitive advantages, we may face competition from many different sources with respect to our current programs or any other product candidates that we may seek to develop or commercialize in the future. Possible competitors may include pharmaceutical companies, academic and medical institutions, governmental agencies and public and private research institutions. These prospective competitors have the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers.

Many of our prospective competitors have substantially greater manufacturing, financial, research and development, personnel, and marketing resources than we do. Our prospective competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and foreign regulatory authorities. In addition to product development, testing, approval and promotion, other competitive factors in the pharmaceutical industry include industry consolidation, product quality and price, product technology, reputation, customer service and access to technical information. As a result, our prospective competitors may be able to develop competing or superior products and compete more aggressively and sustain their competitive advantage over a longer period of time than us. Our products may be rendered obsolete or may lack economic viability in the face of competition.

The key competitive factors affecting the success of DMT310, if approved, will likely be its efficacy, safety, convenience of administration and delivery, price, and the availability of reimbursement from government and other third-party payors. With respect to DMT310 for the treatment of moderate-to-severe acne, if approved, we will primarily be competing with therapies such as other topical products, oral products, in-office procedures, such as laser surgery, off-label drugs, over the counter medication and homeopathic remedies. With regards to DMT310 for the treatment of mild-to-moderate psoriasis, if approved, we will face competition from topical therapies, oral therapies, systemic therapies, photo therapies and homeopathic treatments. However, based on our clinical trials, we believe that DMT310 has multiple competitive advantages over current treatment alternatives with significantly less adverse side effects. Our main competition in these indications will be with products from Sun Pharmaceuticals Industries Ltd., Vyne Therapeutics, Inc, Sol-Gel Technologies Ltd., Arcutis Biotherapeutics, Inc., Almirall S.A., Galderma S.A., Pfizer Inc. See “*Business – Clinical Progress of our Lead Product Candidates*” for the results of our completed and ongoing clinical trials. While we are unaware of any potential similar competitive topical products to DMT310 for the treatment of acne and psoriasis, it is possible that such potentially similar competitive products are currently being developed.

We are also in early stages of clinical development for DMT410 for treating various medical and aesthetic skin conditions and diseases, and if we obtain marketing approval in the future, we will compete with traditional therapies, such as topical products, oral products, in-office procedures, such as botulinum toxin injections, off-label drugs, over the counter medication and homeopathic remedies, as well as additional new entrants to the applicable markets.

We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidate portfolio in our target commercial markets.

## **Intellectual Property**

### *Overview*

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for DMT310, DMT400, DMT410 and any of our future product candidates, medical devices, methodologies, assays, drug development technologies, harvesting procedures, know-how; to operate without infringing on or otherwise violating the proprietary rights of others; and to prevent others from infringing or otherwise violating our proprietary rights. Our strategy is to protect our proprietary position by, among other things, filing U.S. and foreign patent applications related to our product candidate and other proprietary technologies, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, trademarks, know-how, continuing technological innovations, exclusivity agreements, nondisclosure and confidentiality agreements, license agreements, assignment of inventions and potential in-licensing opportunities to develop and maintain our proprietary position.

### *Patent Portfolio*

Our patent estate consists of in-licensed and solely owned patent applications. Typically, we initially file U.S. provisional patent applications and then file applications directly or under the Patent Cooperation Treaty, or PCT, which is an international patent law treaty that provides a unified procedure for filing a single initial patent application to seek patent protection for an invention simultaneously in any one of the designated member jurisdictions and states, including in the U.S. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national phase applications filed at a later date. We currently have multiple patents and patent applications in our patent portfolio and continue to pursue and seek additional patent coverage of all our product candidates.

## **DMT310**

Our DMT310 portfolio includes two families, one in-licensed and one owned by Dermata. The in-licensed family includes patents and patent applications in-licensed from Villani, Inc. related to therapeutic compositions and methods for treating skin conditions. The in-licensed portfolio consists of one pending non-provisional U.S. patent application, two granted U.S. patents, and granted foreign patents in Australia, Brazil, Canada, France, Germany, Ireland, Italy, Mexico, Russia, Singapore, South Korea, Spain, Switzerland, and the United Kingdom. Additionally, the issued foreign patent in Japan, has lapsed and is no longer in force or valid. These in-licensed patents expired between 2022 and 2023 and did not receive any patent term adjustments or extensions. Based on the anticipated timing of any potential FDA approval of DMT310 for acne, the patents that expired in 2022 and 2023 are not material to our business, as we do not expect these patents to provide any protection for our product candidates and thus we have provided our licensor with a notice of abandonment for certain licensed patents. We expect our intellectual property portfolio to be protected by any potential NCE exclusivity for DMT310 and our other product candidates, the maintaining of our exclusive supply agreement for our raw material requirements, and our continued efforts to protect our proprietary information. We also have an additional Dermata owned family related to DMT310, with applications pending in the U.S., Australia, and Canada. This family refers to specific attributes of the DMT310 API and drug product as well as treatment related attributes for the treatment of acne based on the data received prior to its filing. Patents in this patent family, if granted, are expected to expire in 2039, absent any patent term adjustments or extensions.

## **DMT410**

Our DMT410 portfolio includes two families owned by Dermata. The first family consists of one issued patent in Japan, a pending non-provisional U.S. patent application, and seven pending foreign patent applications in Australia, Canada, China, the European Patent Office, Japan, Hong Kong, and South Korea. These patents/patent applications relate to compositions for the treatment of skin diseases using our proprietary sponge powder in combination with multiple types of botulinum toxin for both medical and aesthetic skin conditions and diseases. Patents in this patent family, if granted, are expected to expire in 2039, absent any patent term adjustments or extensions. The second family is related to certain of our clinical methods related to sponge powder and botulinum toxin. This second family consists of two pending US non-provisional applications and additional applications pending in Australia, Canada, the European Patent Office, Japan, and South Korea. Patents in this patent family, if granted are expected to expire in 2041, absent any patent term adjustments or extensions.

## **DMT400**

Our DMT400 portfolio includes three families owned by Dermata. The first family consists of pending applications in the U.S., Canada, and Japan covering our sponge powder in combination with many approved and development stage monoclonal antibodies for the treatment of skin diseases. Patents in this patent family, if granted, are expected to expire in 2039, absent any patent term adjustments or extensions. The second family consists of a pending applications in the U.S., Australia, Japan, and South Korea, covering compositions for the treatment of conditions by dermal fillers in combination with our proprietary sponge powder. Patents in this patent family, if granted, are expected to expire in 2040, absent any patent term adjustments or extensions. The third family consists of a pending PCT application filed in January of 2024, covering the compositions for the treatment of conditions by vaccines in combination with our proprietary sponge powder.

Although we believe our patent portfolio offers significant protection for DMT310, DMT410 and DMT400 and additional combination regimens, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents which claim chemical structures which were previously unknown. Accordingly, other parties may compete with us, for example, by independently developing or obtaining competing topical formulations that design around our patent claims, but which may contain the same or similar active ingredients, or by seeking to invalidate our patents.

The term of individual patents depends upon the laws of the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest priority date of filing of a non-provisional patent application. However, the term of United States patents may be extended for delays incurred due to compliance with the FDA, requirements or by delays encountered during prosecution that are caused by the United States Patent and Trademark Office, or the USPTO. For example, the Hatch-Waxman Act permits a patent term extension for FDA-approved drugs of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those product candidates. We intend to seek patent term extensions in any jurisdiction where these are available and where we also have a patent that may be eligible; however there is no guarantee that the applicable authorities, including the United State Patent and Trademark Office and United States FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

### *Other Intellectual Property*

In addition to patent protection, we also rely heavily on trade secrets, including unpatented know-how, technology innovation, technical specifications and assays and other proprietary information in attempting to develop and maintain our competitive advantage. We believe our ability to protect our unpatented know-how and trade secrets are as important if not more important than our patent portfolio due the complex nature and lack of expiration associated with such information.

We seek trademark protection in the United States and in certain other jurisdictions where available and when we deem appropriate. We currently have registrations for Dermata in the United States and multiple other jurisdictions. We intend to file applications for trademark registrations in connection with our therapeutic candidates in various jurisdictions, including the United States.

### **Material Agreements**

#### *License Agreement between Dermata Therapeutics, LLC and Villani, Inc.*

On March 31, 2017, we entered into a License Agreement (or, the License Agreement) with Villani, Inc. (or, Villani), whereby Villani has granted us an exclusive, sub-licensable, royalty-bearing license (or, the License) under the Licensed Patents (as defined in the License Agreement), to formulate, develop, seek regulatory approval for, make or sell products that contain *Spongilla lacustris* (alone or in combination with other active or inactive ingredients) for the treatment of diseases, disorders and conditions of the skin, including but not limited to acne, rosacea, psoriasis, atopic dermatitis, seborrheic dermatitis, actinic keratosis and eczema that were developed using certain licensed know-how (or, the Licensed Products). We are responsible for the development (including manufacturing, packaging, non-clinical studies, clinical trials and obtaining regulatory approval) and commercialization (including marketing, promotion, distribution, etc.) for all Licensed Products.

In partial consideration of the License, we forgave our outstanding loan to Villani in the amount of \$400,000 and agreed to make future milestone payments to Villani. The milestone payments due to Villani under the License Agreement have been amended to the amounts described below in connection with our entry into the Second License Amendment (as defined below).

The License Agreement may be terminated (i) by either party for material breach with 90 days written notice, or 30 days' notice if for material payment breach, if such material breach is not cured within such notice period, (ii) immediately upon written notice to either party if either party initiates a voluntary bankruptcy proceeding, dissolves or winds-up its business, (iii) immediately upon written notice to either party if either party becomes subject to involuntary bankruptcy proceedings, if such proceedings are not dismissed or stayed within 90 days.

The License Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies, and warranties.

On June 4, 2019, we entered into a License Amendment and Settlement Agreement (or the First License Amendment) with Villani. Pursuant to the First License Amendment, we made milestone payments to Villani in an aggregate amount of \$750,000, and in exchange for certain know-how, we issued to Villani 5,221,156 units of our Series 1c Preferred Units (which units were converted into shares of our Series 1c Preferred Stock in connection with our conversion into a Delaware corporation, which was equal to 5% of our total capitalization (on a fully-diluted basis) at the time of issuance). At the time of issuance, these units were valued at \$730,962. We subsequently cancelled the shares of Series 1c Preferred Stock issued to Villani pursuant to the Second License Amendment, as described below. Pursuant to the First License Amendment, we also agreed to make certain milestone payments to Villani, which rates were subsequently amended pursuant to the Second License Amendment, as discussed below. To date, the \$750,000 milestone payment made in connection with the First License Amendment is the total amount paid to Villani in connection with the License.

On July 30, 2021, we entered into a Second Amendment to the License and Settlement Agreement (or, the Second License Amendment), whereby, for the settlement of certain disputes arising under the First License Amendment, we agreed to exchange the shares of Series 1c Preferred Stock owned by Villani for an increase of milestone payments and royalty rates due to Villani under the License Agreement. The resulting royalty rates payable pursuant to the Second License Amendment are equal to single-digit percentages of net sales of Licensed Products and HMW Combination Products (as defined in the License Agreement), subject to certain adjustments as set forth in the Second License Amendment. Royalties are payable on a country-by-country and Licensed Product-by-Licensed Product basis, for the period of time from the effective date of the License Agreement until the later of (i) the expiration of the last to expire valid claim in such country (which is set to expire in 2023), (ii) the expiration of regulatory exclusivity for such Licensed Product in such country, and (iii) 15 years from the date of the first commercial sale of the Licensed Product in such country. Pursuant to the Second License Amendment, if we sublicense the License, we are obligated to pay to Villani a sublicense fee of between 10% and 30% of Sublicense Revenues (as defined in the License Agreement). Such future milestone payments due to Villani (all payable to Villani in cash or in equity, at the option of Villani) are in aggregate amounts of up to \$3.5 million in development milestones and \$37.0 million in sales milestones. We paid to Villani \$1.0 million upon the closing of our initial public offering.

### *Supply Agreement between the Company and Reka-Farm LLC*

On February 27, 2020, we entered into an exclusive Supply Agreement (or, the Supply Agreement) with Reka-Farm, LLC (or, Reka-Farm), whereby Reka-Farm will supply us with the *Spongilla* raw materials necessary for use in the development of our product candidates. The Supply Agreement has an indefinite term unless and until terminated. For the term of the Supply Agreement, Reka-Farm is prohibited from supplying *Spongilla* for development and sale of any other product outside of the Russian Federation, other than Cosmetic Products (as defined in the Supply Agreement).

Pursuant to the Supply Agreement, we shall provide Reka-Farm with two-year rolling forecasts of our *Spongilla* raw material requirements, and such forecasts shall be provided to Reka-Farm on a semi-annual basis, beginning on January 1, 2021 (each, a Forecast). Pursuant to the Supply Agreement, Reka-Farm has guaranteed its ability to supply us with the required amounts of *Spongilla* as specified in each Forecast for the first 12 months of each Forecast. All Forecasts are non-binding on us. If Reka-Farm is unable to supply us with *Spongilla* raw material in accordance with a Forecast, all available quantities of *Spongilla* then available to Reka-Farm shall be made available to us on a first priority basis until all amounts of *Spongilla* set forth in the Forecast are supplied.

Pursuant to the Supply Agreement, we pay a pre-negotiated price per kilogram for *Spongilla* supplied by Reka-Farm, and we are required to pay to Reka-Farm a royalty payment of less than one percent of the Net Sales (as defined in the Supply Agreement) of any products we develop containing *Spongilla* raw material supplied by Reka-Farm.

The Supply Agreement may be terminated (i) by either party for material breach with 90 days written notice, if such material breach is not cured within such notice period and (ii) by us for any reason or no reason upon 90 days written notice to Reka-Farm.

The Supply Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies, warranties, as well as certain quality requirements.

### ***Government Regulation***

Our activities and products are significantly regulated by a number of governmental entities, including the U.S. Food and Drug Administration, or FDA, in the United States and by comparable authorities in other countries. These entities regulate, among other things, the research, development, testing, safety, effectiveness, manufacturing, storage, distribution, labeling, documentation, advertising and sale of our products. We must obtain regulatory approval from the FDA and comparable authorities in other countries, as applicable, for our drug candidates before we can commercialize such drugs in the U.S. and foreign jurisdictions. Product development within this regulatory framework takes a number of years and involves the expenditure of substantial resources. Many drug candidates that initially appear promising ultimately do not reach the market because they are found to be unsafe or ineffective when tested. Our inability to commercialize a product would impair our ability to earn future revenues.

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

### ***Development of Drugs in the United States***

Products that we may develop or acquire in the future must be approved by the FDA before they may be legally marketed in the United States. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, and drug stability as well as carrying out non-human toxicology, pharmacology and drug metabolism studies that support subsequent clinical testing. These pre-clinical laboratory and animal tests are often performed under the FDA's Good Laboratory Practices regulations. A drug's sponsor must submit the result of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature and a proposed clinical protocol to the FDA as part of an IND application, which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. Similar filings are required in other countries.

### *Clinical Trials*

The clinical stage of development can generally be divided into three sequential phases that may overlap: Phase 1, Phase 2, and Phase 3 clinical trials. In Phase 1, generally, small numbers of healthy volunteers are initially exposed to single escalating doses and then multiple escalating doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action and general safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits, common short-term side effects and risks. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 3 trials are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects and are closely controlled and monitored. In addition to these Phase 1-3 trials, other trials may be conducted to gather additional safety, pharmacokinetic and pharmacodynamic information. Pharmaceutical products with active ingredients equal or similar to those already approved by the FDA often have more streamlined development programs than compounds entirely new to the agency, often skipping Phase 1 and 2 trials.

A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed studies, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards responsible for overseeing studies at particular sites and protecting human research study subjects. An independent institutional review board may also suspend or terminate a study once initiated. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that once begun, issues will not arise that could cause the trial to be suspended or terminated.

Post-approval studies, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. Sometimes, these studies are used to gain additional experience from the treatment of patients in the intended therapeutic condition. In certain instances, the FDA may mandate the performance of Phase 4 studies. In other situations, post-approval studies aim to gain additional indications for a medication or develop new dosage forms for a medication.

### *Chemistry, Controls and Manufacturing Development*

Concurrent with clinical trials, companies typically complete additional animal and laboratory studies, develop additional information about the chemistry and physical characteristics of the drug, and finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP") requirements. The manufacturing process must consistently produce quality batches of the drug, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life.

### *Disclosure of Clinical Trial Information*

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

### *Special Protocol Assessment*

The Federal Food, Drug, and Cosmetic Act directs the FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in a New Drug Application (NDA) or a Biologic Licensing Application (BLA). If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment (SPA). While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has latitude to change its assessment if certain exceptions apply. Exceptions include public health concerns emerging that were unrecognized at the time of the protocol assessment, identification of a substantial scientific issue essential to the safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.



### ***Review and Approval in the United States***

Following pivotal or Phase 3 trial completion, data are analyzed to determine safety and efficacy. Data are then filed with the FDA in an NDA or BLA, along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. In the United States, FDA approval of an NDA or BLA must be obtained before marketing a pharmaceutical product. The NDA or BLA must contain proof of safety, purity, potency, and efficacy, which entails extensive pre-clinical and clinical testing.

The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take several years to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current good manufacturing practice requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will act favorably or quickly in making such reviews and significant difficulties or costs may be encountered in our efforts to obtain FDA approvals. The FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or may condition the approval of the NDA or BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized. Further, the FDA may place conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan product designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to \$400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for our product candidates.

### ***FDA Botanical Drug Development Guidance for Industry***

Most currently approved topical dermatology products are reviewed solely by the FDA's Office of Dermatology and Dental Products and follow a standard approval pathway. However, due to our lead product candidate, DMT310, being derived from a natural source, it will be reviewed by the FDA Office of Dermatology and Dental Products with input from the FDA Botanical Review Division. While *Spongilla* is not a botanical, the FDA has allowed us to reference the Botanical Guidance for raw material quality control and batch to batch consistency through development and into commercialization. We believe our ability to reference the Botanical Guidance and receive input from the Botanical Review Division on DMT310 provides us with key advantages in DMT310's regulatory pathway to approval, if achieved. These advantages include being able to move into human clinical studies upon the FDA's acknowledged receipt of our IND letter and subsequent study may proceed, saving us substantial financial resources to achieve human clinical data. Additionally, while we believe that our sponge contains multiple active chemical compounds, based on our regulatory analysis of the feedback from the FDA and the Botanical Guidance, we believe we are only required to provide identifiable and quantifiable active components to show quality control and batch to batch consistency. We believe this will make it more difficult for a potential competitor to copy DMT310 and produce a similar product due to their inability to know every component of our product candidate. Thus, we believe a competitor with a similar product or product candidate would have to conduct all of the manufacturing, development, and regulatory steps we must complete for approval. However, there can be no assurance that we successfully navigate the development of DMT310 or that DMT310 will receive FDA approval.

## ***Special Regulatory Procedures***

*Fast track designation* — The FDA is required to facilitate the development and expedite the review of drugs and biologics that are intended for the treatment of a serious or life-threatening disease or condition and that demonstrate the potential to address unmet medical needs. Under the fast track program, the sponsor of a new drug or biologic candidate may request the FDA to designate the product for a specific indication as a fast track product, concurrent with or after the filing of the IND for the drug candidate. A drug that receives fast track designation is eligible for some or all of the following: (i) more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written communication from the FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for accelerated approval and priority review, if relevant criteria are met; and (iv) "Rolling Review," which means that a drug company can submit completed sections of its BLA or NDA for review by the FDA, rather than waiting until every section of the NDA or BLA is completed before the entire application can be reviewed. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA or BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if it believes that the designation is no longer supported by data emerging in the clinical trial process.

*Priority review* — Under FDA policies, a drug candidate may be eligible for priority review. The priority review program provides for expedited review of an NDA or BLA, typically within a six to eight month time frame from the time a complete application is accepted for filing. Products regulated by the FDA's Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. Products regulated by the FDA's Center for Biologics Evaluation and Research, or CBER, are eligible for priority review if they provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious or life-threatening disease. A fast track designated drug candidate could be eligible for priority review if supported by clinical data at the time of the BLA or NDA submission.

*Accelerated approval* — Under the law and the FDA's accelerated approval regulations, the FDA may approve a drug or biologic for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based on a surrogate endpoint that is reasonably likely to predict clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

*Breakthrough therapy designation* — The FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new drug candidate may request that the FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate.

## ***Pediatric Information***

Under the Pediatric Research Equity Act of 2003, an NDA, BLA or supplement to an NDA or BLA must contain data that are adequate to assess the safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Under the Food and Drug Administration Safety and Innovation Act, or FDASIA, the FDA has additional authority to take action against manufacturers not adhering to pediatric study requirements. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan drug designation.

### *U.S. Patent Term Restoration*

Depending upon the timing, duration, and specifics of the FDA approval of the use of our current and potential product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of the NDA or BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

### *Drug Development in Europe*

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the U.S., the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the U.S., the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

### *Review and Approval in the European Union*

In the European Union, approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure, and the decentralized procedure. We intend to determine which process we will follow, if any, in the future.

**Mutual Recognition Procedure:** An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state.

**Centralized Procedure:** This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other “innovative medicinal products with novel characteristics.” Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

**Decentralized Procedure:** The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, “clock stops” during the procedure.

### ***Post-Marketing Requirements***

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, and NDA and BLA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current good manufacturing practice and other laws. NDA and BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

### ***Other Regulatory Matters***

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent. The government may assert that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback law or related to off-label promotion constitutes a false or fraudulent claim for purposes of the federal false claims laws;
- the Federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members;
- the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act;
- The Lanham Act and federal antitrust laws; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, traceability, and storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and the Controlled Substances Import and Export Act.

Schedule I controlled substances are pharmaceutical products subject to specific regulations under the CSA, that establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. All parties responsible for the manufacturing, distribution and testing the drug in clinical studies must apply for and obtain a license from the DEA before they are permitted to perform these activities. Furthermore, these parties must have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All licensed facilities are required to renew their registrations annually if they intend to continue to work with our drug. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. We and our manufacturing vendors and clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

### ***Third-Party Payer Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any of our drug candidates that ultimately may obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payer has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payers.

The United States Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, the two-year spending law signed by the President of United States on February 9, 2018 includes a provision raising the manufacturer discount to 70% in 2019 in the Medicare Part D coverage gap, also known as the “donut hole.” Under prior law, manufacturers were required to provide a 50% discount on prescription drugs purchased in the donut hole. Manufacturers of branded drugs will face much higher liabilities from donut hole payments beginning in 2019, estimated at multiple billions of dollars for some of the largest companies.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

### **Corporate and Other Information**

We were formed in December 2014 as a Delaware limited liability company (“LLC”) under the name Dermata Therapeutics, LLC. On March 24, 2021, we converted from an LLC to a Delaware C-corporation and changed our name to Dermata Therapeutics, Inc.

### **Human Capital Resources**

As of the date of this report, we have eight full time employees, with three employees working in the general and administrative department, two engaged in non-clinical and clinical development, two working in the chemistry, manufacturing, and controls department, and one employee working in the regulatory affairs and quality control department.

We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel. In particular, we depend on the skills, experience and performance of our senior management and research personnel. We compete for qualified personnel with other medical pharmaceutical, and healthcare companies, as well as universities and non-profit research institutions.

We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs (which vary by country/region and employment classification) include incentive compensation plans, healthcare and insurance benefits, retirement investments, paid time off, and family leave, among others. We also use targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly for our key employees.

The success of our business is fundamentally connected to the well-being of our people. Accordingly, we are committed to the health and safety of our employees.

### **ITEM 1A. RISK FACTORS**

*Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this report, including the consolidated financial statements, the notes thereto and the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this report before deciding whether to invest in our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. If any of the following risks actually occur, our business, financial condition, results of operations and future prospects could be materially and adversely affected. In that event, the market price of our common stock and/or Warrants could decline, and you could lose part or all of your investment.*

## Summary of Risks Associated with Our Business

Our business and an investment in our company is subject to numerous risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this summary. Some of these risks include:

- We are a pre-revenue company with a limited operating history;
- We may not be able to successfully develop or commercialize our product candidates or do so on a timely or cost-effective basis;
- Our business may be negatively affected by the impacts of public health emergencies, epidemics and pandemics, such as COVID-19;
- We depend on a limited number of product candidates and our business could be materially adversely affected if one or more of our key product candidates do not perform as well as expected and do not receive regulatory approval;
- The market for our product candidates, including DMT 310 and DMT 410, may not be as large as we expect;
- Our competitors and other third parties may allege that we are infringing their intellectual property, forcing us to expend substantial resources in resulting litigation, and any unfavorable outcome of such litigation could have a material adverse effect on our business;
- We may experience failures of or delays in clinical trials which could jeopardize or delay our ability to obtain regulatory approval and commence product sales;
- We face intense competition from both brand and generic companies which could limit our growth and adversely affect our financial results;
- We are subject to extensive governmental regulation and we face significant uncertainties and potentially significant costs associated with our efforts to comply with applicable regulations;
- We may not be able to develop or maintain sales capabilities or effectively market or sell any products that we may successfully commercialize;
- Manufacturing or quality control problems may damage our reputation, require costly remedial activities, or otherwise negatively impact our business;
- Our profitability will depend on coverage and reimbursement by third-party payors, and healthcare reform and other future legislation may lead to reductions in coverage or reimbursement levels;
- We currently, and may in the future need to, license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms;
- We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop, manufacture and market our products and product candidates;
- The raw material for our product candidates, DMT310 and DMT410, is derived from naturally occurring ingredients that grow only in limited areas that need to be harvested annually. Due to unforeseen environmental conditions or circumstances, our supplier may not be able to harvest as much raw material as we require, or any at all, which may negatively impact our ability to conduct preclinical studies, clinical trials, and ultimately commercialize our product candidates;
- We currently rely on a third party for the raw materials needed for DMT310 and DMT410, and if we encounter any difficulties in accessing or procuring alternative sources on acceptable terms, or at all, our business may suffer;
- Our current licensed patents covering DMT310 expired between 2022 and 2023, which was prior to our anticipated date for any market launch. While we have been issued patents covering DMT410 in certain jurisdictions, other of our current pending patents covering DMT310 and DMT410 have not been issued yet and there is no guarantee they will get issued. We may not be able to obtain additional patent coverage, which could limit our market opportunity due to competition from other products;
- If we fail to comply with our obligations under any of our third-party agreements, we could lose license rights that are necessary to develop our product candidates;
- Our directors, executive officers and certain stockholders (one of which is an affiliate of our Chief Executive Officer) own a significant percentage of our common stock and, if they choose to act together, will be able to exert significant control over matters subject to stockholder approval; and
- We will need to add personnel, which will increase the size and complexity of our organization and we may experience difficulties executing growth and corporate strategies.

## Risks Related to Our Financial Position and Need for Capital

### *We are a clinical stage pharmaceutical company with a limited operating history.*

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We must complete clinical studies and receive regulatory approval before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially early stage clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to, among other things:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully complete the clinical trials, non-clinical testing and other requirements necessary to obtain regulatory approval for the marketing of our drug candidates, including DMT310 and DMT410;
- successfully manufacture our clinical products and establish commercial drug supply;
- secure, maintain and, as necessary, defend our intellectual property rights;
- secure market exclusivity and/or adequate intellectual property protection for our drug candidates;
- attract and retain an experienced management and advisory team;
- secure acceptance of our drug candidates in the medical community and with third-party payors and consumers;
- launch commercial sales of our drug candidates, whether alone or in collaboration with others;
- comply with post-marketing regulatory requirements;
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan; and
- utilize the funds that we have and may raise in the future to efficiently execute our business strategy.

If we cannot successfully execute any one of the foregoing, our business may fail and your investment will be adversely affected.

### *We have incurred losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We are not currently profitable, and we may never achieve or sustain profitability.*

We have never generated revenue from operations, are unlikely to generate revenues for several years, and are currently operating at a loss and expect our operating costs will increase significantly as we incur costs related to preclinical development, the clinical trials for our drug candidates and to operating as a public company. We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. We have incurred losses in each year since we commenced operations in December 2014. We incurred net losses of approximately \$7.8 million and approximately \$9.6 million for the years ended December 31, 2023, and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of approximately \$53.4 million. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any. Revenue from our current and potential future collaborations is uncertain because milestones or other contingent payments under our agreements may not be achieved or received.



As of December 31, 2023, we had capital resources consisting of cash and cash equivalents of \$7.4 million. We will continue to expend substantial cash resources for the foreseeable future for the clinical development of our product candidates and development of any other indications and product candidates we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, manufacturing and supply, as well as marketing and selling any products approved for sale. In particular, our Phase 3 clinical studies for our product candidates will require substantial funds to complete. Because the conduct and results of any clinical trial are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current and any future product candidates.

We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our securities and our ability to raise capital.

***We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we may not be able to complete the development and commercialization of our product candidates.***

We believe that our existing cash, together with interest thereon, will be sufficient to fund our operations into the third quarter of 2024. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available capital resources much faster than we currently expect or require more capital to fund our operations than we currently expect. Our currently anticipated expenditures for the development of our product candidates, DMT310 and DMT410, exceed our existing cash. We will need to raise additional capital to fund our operations and continue to support our planned development and commercialization activities.

The amount and timing of our future funding requirements will depend on many factors, including:

- the timing, rate of progress and cost of any preclinical and clinical trials and other product development activities for our current and any future product candidates that we develop, in-license or acquire;
- the results of the clinical trials for our product candidates in the United States and any foreign countries;
- the timing of, and the costs involved in, FDA approval and any foreign regulatory approval of our product candidates, if at all;
- the number and characteristics of any additional future product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing, co-promotion or other arrangements and the terms and timing of such arrangements;
- the cost of commercialization activities if our current or any future product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- the degree and rate of market acceptance of any approved products;
- costs under our third-party manufacturing and supply arrangements for our current and any future product candidates and any products we commercialize;
- costs and timing of completion of any additional outsourced commercial manufacturing or supply arrangements that we may establish;
- costs of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;
- costs associated with any product recall that could occur;
- costs of operating as a public company;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing products or treatments;
- costs associated with any acquisition or in-license of products and product candidates, technologies or businesses; and
- personnel, facilities and equipment requirements.

We cannot be certain that additional funding will be available on acceptable terms, or at all. In addition, future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us. In addition, our ability to achieve profitability or to respond to competitive pressures would be significantly limited.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or other sources. We do not currently have any committed external source of funds. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate product candidate development or future commercialization efforts.

***The reports of our independent registered public accounting firms for the fiscal years ended December 31, 2023 and 2022 each contain an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern.***

Due to the uncertainty of our ability to meet our current operating and capital expenses, in their reports on our audited annual financial statements as of and for the years ended December 31, 2023, and December 31, 2022, our independent audit firms included explanatory paragraphs regarding concerns about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and Warrants and we may have a more difficult time obtaining financing. Further, the perception that we may be unable to continue as a going concern may impede our ability to raise additional funds or operate our business due to concerns regarding our ability to discharge our contractual obligations.

***Changes in tax laws may materially adversely affect our business financial condition, results of operations and cash flows.***

We are subject to tax laws, regulations and policies of the jurisdictions in which we do business, which may include U.S. federal, state, and local governments and taxing authorities in foreign jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and otherwise adversely affect our tax positions and/or our tax liabilities. The income tax rules in the jurisdictions in which we operate are constantly under review by taxing authorities and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or our stockholders. We are unable to predict what tax proposals may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall effective tax rates in the future in jurisdictions where we have operations, and increase the complexity, burden and cost of tax compliance.

*We are exposed to risks related to foreign currency exchange rates.*

Some of our costs and expenses are denominated in foreign currencies. Most of our foreign expenses are associated with our supply of our raw material for our DMT310 and DMT410 product candidates. When the United States dollar weakens against the Euro, the United States dollar value of the foreign currency denominated expense increases, and when the United States dollar strengthens against the Euro, the United States dollar value of the foreign currency denominated expense decreases. Consequently, changes in exchange rates, and in particular a weakening of the United States dollar, may adversely affect our results of operations.

### **Risks Related to Development, Regulatory Approval and Commercialization**

*We face risks related to public health emergencies, epidemics and other outbreaks of communicable diseases, such as the coronavirus (COVID-19) pandemic, which could significantly disrupt our operations, including our clinical trials and preclinical studies, and adversely affect our business and results of operations.*

Public health crises, such as the COVID-19 pandemic or similar outbreaks, could have an adverse effect our business. Quarantines, travel restrictions and other public health and safety measures implemented in response to a pandemic, including a resurgence of COVID-19, could adversely impact our operations, and the ultimate impact is highly uncertain and cannot be predicted with confidence. Effects of a pandemic, including a resurgence of COVID-19, that may delay or otherwise adversely affect our ongoing and planned preclinical activities, our planned clinical trials as well as our business generally, include:

- delays related to disruptions at CROs and contract manufacturers, or in the supply chain;
- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff who, as healthcare providers, may have heightened exposure;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our planned clinical trials;
- difficulties interpreting data from clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and interruptions, difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely, including those hired during the COVID-19 pandemic.

Any of these effects, and other effects of a pandemic, including a resurgence of COVID-19, could have a material adverse effect on our business, financial condition, results of operations and prospects. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States, Canada, and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

*Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.*

Disruptions to the global economy may impede global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions in lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations.

Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected.

***Adverse global conditions, including economic uncertainty, may negatively impact our financial results.***

Global conditions, dislocations in the financial markets, any negative financial impacts affecting United States as a result of tax reform or changes to existing trade agreements or tax conventions, may adversely impact our business.

In addition, the global macroeconomic environment could be negatively affected by, among other things, public health emergencies, pandemics or epidemics, instability in global economic markets, increased U.S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine, Hamas' attack on Israel and the resulting conflict, and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets.

***Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, in particular DMT310 and DMT410.***

Our portfolio of product candidates includes one late-stage product candidate, DMT310, a once weekly topical, naturally derived product candidate for the treatment of acne and psoriasis, and an early-stage candidate, DMT410, a combination treatment regimen to aid in the topical delivery of botulinum toxin for the treatment of hyperhidrosis and aesthetic skin conditions. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization or partnering of our product candidates. In the future, we may also become dependent on just one of our product candidates or any future product candidates that we may in-license, acquire or develop. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the U.S. Food and Drug Administration, or the FDA, or similar foreign regulatory agencies to conduct additional clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates;
- our ability to develop a suitable drug product release assay;
- our ability to identify an active compound within the drug product that can be detected in a pharmacokinetics study;
- the prevalence, duration and severity of potential side effects experienced in connection with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP, or good agricultural and collection practices, or GACP;

- a continued acceptable safety profile during clinical development and following approval of our product candidates or any future product candidates;
- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, patients and payors of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- our ability to comply with numerous post-approval regulatory requirements;
- our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and
- our ability to in-license or acquire additional product candidates or commercial-stage products that we believe we can successfully develop and commercialize.

If we are unable to achieve one or more of the above factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays and increased costs or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue operations.

***Clinical drug development for our product candidates is very expensive, time-consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.***

Clinical drug development for our product candidates is very expensive, time-consuming, difficult to design and implement and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication, which is impossible to predict. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. Our product candidates are in various stages of development and a failure of one more clinical trials can occur at any stage of testing or at any time during the trial process. We expect that clinical trials for these product candidates will continue for several years, but may take significantly longer than expected to complete.

We have not completed all clinical trials for the approval of any of our product candidates. In previous communications with the FDA they had asked us to show that hydrogen peroxide was not an active ingredient in our DMT310 product. While FDA did not require us to test hydrogen peroxide as a third arm in our current DMT310 Phase 3 clinical program, they may ask for additional evidence to support our belief that hydrogen peroxide is not an active ingredient in our DMT310 product. If we fail to convince the FDA that hydrogen peroxide is not an active ingredient and merely a fluidizing agent, then we may have to alter our clinical plans or reformulate our product based on FDA feedback. If we chose to reformulate our lead product candidate, DMT310, then we may decide to redo our Phase 2 and Phase 3 studies, which would be time consuming and expensive and there is no certainty of success.

We may experience delays in ongoing and future clinical trials for our product candidates and do not know if future clinical trials, if any, will begin on time, need to be redesigned, enroll adequate number of patients on time or be completed on schedule, if at all. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an IRB or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of safety or tolerability concerns, such as serious or unexpected toxicities or side effects or exposure to otherwise unacceptable health risks, experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;

- slower than expected rates of subject recruitment and enrollment rates or inability to enroll a sufficient number of patients in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, or clinical trials for indications for which patients do not as commonly seek treatment;
- delays or difficulties in our clinical trials due to quarantines or other restrictions resulting from public health emergencies, epidemics, and/or pandemics, such as the COVID-19 pandemic;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- difficulty in obtaining IRB approval for studies to be conducted at each clinical trial site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- difficulty or inability to find a partner that will allow us to test their product for our DMT410 program;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective CROs, clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper formulation and dosing;
- failure by us, our employees, our CROs or their employees or other third-party contractors to comply with contractual and applicable regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.

In the case of our topical product candidates, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient, or API, through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect. As a result, safety and efficacy can be difficult to establish. The topical route of administration may involve new formulations and dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays. For example, the API for DMT310 is a milled sponge powder, and we are not aware of previous FDA approvals of sponges as a prescription drug.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed.

***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials.

***Approval may be delayed or denied because we cannot satisfy FDA's Chemistry, Manufacturing and Control Requirements.***

Formulation and manufacturing of drugs is another important step in development. Our applications must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP") requirements. The manufacturing process must consistently produce quality batches of the product, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our product candidates may be delayed or denied.

***We may be unable to obtain regulatory approval for DMT310, or our other early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.***

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export, and reporting of safety and other post-market information related to our drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current product candidates in the United States until we receive approval of a new drug application, or NDA, or other applicable regulatory filing from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we or our partners receive the requisite approval from the applicable regulatory authorities of such countries.

To gain approval to market a new drug such as DMT310 or DMT410, the FDA and/or foreign regulatory authorities must receive, among other things, preclinical and clinical data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the drug product for the intended indication applied for in an NDA, or other applicable regulatory filing. The development and approval of a product derived from a natural source and new drug products involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in nonclinical development, clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in clinical trials does not ensure that later clinical trials will be successful, or that nonclinical studies will be successful. The results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct. For example, for DMT310, the results of our Phase 2a and Phase 2b clinical trials may not accurately predict results of the ongoing Phase 3 clinical trials that have a larger number of patients. Nor will the human safety data collected from our Phase 2a and Phase 2b clinical trial predict the outcome of our pharmacokinetic plan.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons. The FDA or the applicable foreign regulatory body may:

- disagree with the design or implementation of one or more clinical trials;
- not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- not find the data from preclinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;
- determine the data collected from clinical trials may not be sufficient to support the submission of an NDA, or other applicable regulatory filing;
- require additional preclinical studies or clinical trials;
- identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;
- grant approval contingent on the performance of costly additional post-approval clinical trials;
- approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested or with strong warnings that may affect marketability;
- not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract;
- consider our products a device instead of a drug requiring a different approval process and manufacturing needs;
- consider one of our products a combination product instead of a singular drug requiring additional clinical trials or increased number of patients per study, or
- change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

There have been only three products approved by the FDA under the botanical guidance. Each of these products' active ingredient was derived from the extract of a plant(s). Further, neither of the products were approved for the indication of acne vulgaris. While freshwater sponges, such as *Spongilla*, are technically animals, FDA has allowed us to reference the botanical guidance for raw material quality control relating to the manufacturing of the drug product. We do not know how any other regulatory authority will treat DMT310 for their approval process. In addition, the FDA or other regulatory authorities may change their policies, issue additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Any delay, limitation or denial in any applicable regulatory approval for any of our product candidates would delay or adversely impact commercialization of our product candidates and would harm our business, financial condition, operating results and prospects.



***We have initiated our first Phase 3 clinical trials for DMT310 and may be unable to successfully complete it or any future clinical trials.***

The conduct of a Phase 3 clinical program is a complicated process. Although members of our management team have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company have not conducted a Phase 3 clinical trial before, and as a result may require more time and incur greater costs than we anticipate. Failure to include the correct treatment regimen, complete, or delays in, our Phase 3 clinical trials, could prevent us from or delay us in commencing future clinical trials for DMT310, obtaining regulatory approval of and commercializing our product candidates, which would adversely impact our financial performance. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as DMT310, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- factors we may not be able to control, such as potential pandemics that may limit subjects, principal investigators or staff or clinical site availability (e.g., the outbreak of COVID-19).

***We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed.***

We expect to enter into agreements with third-party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for our drug candidates and we will control only certain aspects of conducting the clinical studies. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage and assist us with the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

***Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.***

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians, patients and payors for approved indications, and may not be commercially successful. The degree and rate of adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy, including for DMT310, a sponge product, over other available therapies to treat approved indications;
- patients' perception of a product derived from a freshwater sponge as one for which will provide medical treatment;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of any side effects of our product candidates;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- our ability to maintain sufficient quantities of supply to meet demand;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

***We intend to seek NCE exclusivity for DMT310 and future product candidates, and we may be unsuccessful in obtaining such exclusivity.***

As part of our business strategy, we intend to seek new chemical entity, or NCE, exclusivity for DMT310 or future product candidates. In the United States, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of an NCE which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA. An “active moiety” is defined as the molecule or ion responsible for the drug substance’s physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA’s findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification. This exclusivity period may be extended by an additional six months if certain requirements are met to qualify the product for pediatric exclusivity, including the receipt of a written request from the FDA that we conduct certain pediatric studies, the submission of study reports from such studies to the FDA after receipt of the written request and satisfaction of the conditions specified in the written request. We believe that DMT310 constitutes an NCE and should be eligible for NCE exclusivity. However, we may be unable to successfully obtain such exclusivity, and if any of our competitors obtains FDA approval of an NDA for a similar drug product before we do, they, and not us, may be eligible for NCE exclusivity. If we do not obtain NCE exclusivity for DMT310, or if a competitor obtains NCE exclusivity for a similar product before we submit and receive approval of an NDA for DMT310, our ability to commence sales and generate revenue would be adversely affected.

***Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.***

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous pharmaceutical companies, generic drug companies, biotechnology companies, cosmetic companies and academic and research institutions are engaged in the development, patenting, manufacturing and marketing of health care products competitive with those that we are developing, including but not limited to VYNE Therapeutics, Cassiopea, Galderma, Sun Pharmaceuticals Ltd., Sol-Gel, Arcutis Biotherapeutics, Arena Pharmaceuticals, Amgen, AbbVie, Bristol Meyers Squib, Lilly, Nestle, Pfizer, and others. Many of our competitors have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including over-the-counter treatments, for a share of some patients’ discretionary budgets and for physicians’ attention within their clinical practices.

We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved, off-label, and over the counter treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects. For more information about the competition we face, see “Business—Competition.”

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States.

***We expect to face generic or similar type of product competition for our product candidates, which could adversely affect our business, financial condition, operating results and prospects.***

Upon the expiration or loss of any patent protection for any of our product candidates that are approved, or upon the “at-risk” launch, despite pending patent infringement litigation against the generic product or its equivalent, by a generic competitor of a generic version of any of our product candidates that are approved, which may be sold at significantly lower prices than our approved product candidates, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects.

It is unknown how the FDA or any regulatory authority will view an attempted generic version of DMT310 because it is derived from a natural material that refers to principles of the botanical guidance. There are no currently approved generic versions of a natural product on the market and no FDA guidelines on the approval process for a generic version of a natural product. Therefore, it is unknown how difficult it will be for a generic version of a natural product to be approved for commercial sale in the United States. It is unclear whether the FDA will view *Spongilla lacustris* or a similar sponge species that is harvested from a different location than DMT310 raw material is harvested as identical to DMT310 raw material and therefore could follow the generic pathway to approval.

***Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review.***

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate’s approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements, with the FDA’s good clinical practice, or GCP, or good agricultural and collections practices, or GACP, requirements and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

If we, our partners, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

***We may in the future conduct clinical trials for our product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials.***

We may in the future choose to conduct one or more of our clinical trials outside the United States, including in Canada, Europe and South America. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

***Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action.***

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way; the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

***We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- inability to gain regulatory approval of our product candidates;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

We currently maintain product liability insurance coverage, which may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

***If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.***

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

***We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.***

At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

For example, on December 5, 2022, we announced topline results from our Phase 2 trial of once-weekly topical application of DMT310 for the treatment of moderate-to-severe rosacea. While the data was supportive of DMT310 as a treatment for inflammatory skin diseases, the rosacea study did not meet its primary endpoints. Based on the foregoing, we decided not to devote any further financial resources to development of this indication for DMT310, and we determined not to pursue further development efforts regarding this indication for DMT310.

***We or our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.***

We or our current and prospective partners may be subject to product recalls, withdrawals or seizures if any of our product candidates, if approved for marketing, fail to meet specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to the manufacture, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

***If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.***

For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Further, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

***Healthcare legislative or regulatory reform measures, including government restrictions on pricing and reimbursement, may have a negative impact on our business and results of operations.***

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in the United States, the Patient Protection and Affordable Care Act of 2010, or the ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of the ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of the ACA. There is continued uncertainty about the implementation of the ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.



Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The United States Department of Health and Human Services (“HHS”) plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act (the “IRA”) in August 2022, which will, among other things, allow the HHS to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services (“CMS”) reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

Other examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for DMT310 or any future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of DMT310 or other product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

***We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.***

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients’ rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

***Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

The manufacturing activities of our third-party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party suppliers and manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

***Our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

***Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize DMT310 or our other product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain market access and appropriate reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace
- import or export licensing requirements;
- longer accounts receivable collection times;

- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

***Development of test methodology for DMT310 presents unique challenges due to the complex mixture of constituents in the product. Determination of appropriate assay(s) for release and quality control evaluations could require significant development time and cost to successfully complete and uncertain.***

DMT310 is comprised of both inorganic and organic constituents, and unlike most pharmaceutical products, there is no single active component to characterize for purposes of assay development. In order to release the drug product and test for stability we plan to develop a cell-based bioassay to assess inhibitory effects of DMT310 on pro-inflammatory cytokines known to play a role in the pathogenesis of various skin diseases. While this approach may show activity, it may not be suitable as a quality control release potency assay for DMT310. Furthermore, this technique may not have sufficient sensitivity to be considered stability-indicating and detect small changes or degradation to the product. If we are not able to develop a suitable potency assay utilizing this approach, we may have to identify and develop an alternative bioassay platform or secondary approaches that may require additional orthogonal methodologies to meet our testing requirements. This could be expensive, time consuming and its success uncertain, leading to delays in filing of the NDA.

#### **Risks Related to Our Dependence on Third Parties**

***We are dependent on one supplier for the raw material used to produce DMT310 and DMT410. The termination of this contract would result in a disruption to product development and our business will be harmed.***

We currently only have one qualified source of supply for the raw material used in DMT310 and DMT410. While we have an exclusive supply agreement with our supplier, our supplier may not comply with the terms of our agreement and may supply to third parties. DMT310 and DMT410 contain a wild growing freshwater sponge that grows in an area of the Volga River delta in Russia that is partially protected by a Russian government entity. The Russian government entity allocates a quantity of freshwater sponge that may be harvested each harvest season and may determine in any year that no sponge or a smaller quantity of sponge than harvested in previous years may be harvested in a particular year, which could impact our ability to obtain raw material to manufacture and supply DMT310 and DMT410. If we have not adequately stockpiled raw materials, or even if we do stockpile raw material, we could not have enough raw material to meet the quantity demands to conduct our non-clinical and clinical studies or to supply product for the market if approved.

The freshwater sponge contained in DMT310 and DMT410 can only be harvested once per year based on the presence of certain environmental conditions. If these environmental conditions are not present during the harvest season, then our supplier may not be able to harvest the raw material required, which could impact our ability to manufacture and supply DMT310 and DMT410. The ability of our supplier to harvest the sponge may also be impacted by severe weather and limit the length of time they can harvest, which could limit the amount of raw material that can be harvested, which may impact our ability to manufacture and supply DMT310 and DMT410. The portion of the Volga River delta where the sponge grows could also become contaminated from pollutants, which could contaminate the sponge to be harvested by our supplier, making it unusable in humans, impacting our ability to manufacture and supply DMT310 and DMT410.

Even if we are able to obtain supply, we and our supplier are exposed to a number of environmental and geopolitical risks, including:

- risk of contamination being introduced in the Volga River, thereby polluting the *spongilla lacustris* population through environmental factors that we cannot control, which could result in new impurities or reduced supply of raw materials;
- loss of *Spongilla lacustris* habitat and other similar environmental risks to the sponge population whether due to climate change, over-development, or otherwise;
- risk of disease in the *Spongilla lacustris* geographic area where harvested;

- risk of trade issues between the U.S. and Russia;
- restrictions on trade of certain items between the U.S. and Russia;
- restriction on means of payment with Russian entities; and
- other unforeseen geopolitical factors that limit our ability access our supply of raw material.

Restrictions could be imposed on the harvesting of the raw material. Such events could have a significant impact on our cost and ability to produce DMT310 and DMT410 and anticipated line extensions. The country from which we obtain the raw material could change its laws and regulations regarding the export of the natural products or impose or increase taxes or duties payable by exporters of such products. In addition, any business, global or economic challenges our existing supplier faces, whether in the ordinary course of business or not, could impair its ability to supply our needs for raw materials. Accordingly, there is a risk that supplies of our raw materials may be significantly delayed by or may become unavailable as a result of any issues affecting our supply and production of naturally sourced products. In addition, if we need a new or additional suppliers, it may take a substantial amount of time and financial resources to identify any additional supplier(s) who can supply our required raw materials in the quality and quantity required for our pre-clinical and we may not be able to negotiate new agreements with an alternate or new supplier on terms that we deem commercially reasonable or at all, and the failure by us to enter into such agreements could harm our financial condition, business, clinical trials and prospects.

***Our business may be affected by new sanctions and export controls targeting Russia and other responses to Russia's invasion of Ukraine.***

As a result of Russia's invasion of Ukraine, the United States, the United Kingdom and the European Union governments, among others, have developed coordinated sanctions and export-control measure packages against Russian individuals and entities. We are currently a party to an exclusive supply agreement for the supply of the *Spongilla* raw material used in DMT310 and DMT410. The counterparty to this supply agreement is a Russian entity. To date, none of these sanctions or export-controls have impacted our ability to perform under our supply agreement. However, the imposition of enhanced export controls and economic sanctions on transactions with Russia and Russian entities by the United States, the United Kingdom, and/or the European Union could prevent us from performing under this existing contract or any future contract we may enter or remitting payment for raw material purchased from our supplier. We've received multiple shipments of *Spongilla* raw material from our supplier during fiscal years 2022 and 2023 containing additional quantities of *Spongilla* raw material which we believe will provide us with sufficient quantities of *Spongilla* to initiate and complete the DMT310 Phase 3 clinical program in moderate-to-severe acne and support filing an NDA for DMT310 in acne in the event of the successful completion of the DMT310 Phase 3 clinical program. Depending on the extent and breadth of new sanctions or export controls that may be imposed against Russia, otherwise or as a result of the impact of the war in the Ukraine, it is possible that our business, results of operations, and financial condition could be materially and adversely affected.

***We have in the past relied and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials and other aspects of product development. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates when expected or at all.***

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our clinical trials and other aspects of product development. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP, GLP, and GACP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP, GLP and GACP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP, GLP and GACP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

***We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.***

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the raw materials and APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

We rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. Any of our existing suppliers or manufacturers may:

- fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise;
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our commercial needs;
- be unable to meet our production demands due to issues related to their reliance on sole-source suppliers and manufacturers;
- supply us with product that fails to meet regulatory requirements;
- become unavailable through business interruption or financial insolvency;
- lose regulatory status as an approved source;
- be unable or unwilling to renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or
- discontinue production or manufacturing of necessary drug substances or products.

In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and, in most cases, require review and approval by the FDA. Any need to find and qualify new suppliers or manufacturers could significantly delay production of our product candidates, adversely impact our ability to market our product candidates and adversely affect our business. Replacements may not be available to us on a timely basis, on acceptable terms or at all. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials. Any interruption in the supply of a drug substance or other material or in the manufacture of our product candidates could have a material adverse effect on our business, financial condition, operating results and prospects.

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs and GACP, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs or GACP for production of raw materials, APIs, and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP and GACP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all.

In addition, these contract manufacturers are engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

In addition, the manufacturing facilities of certain of our suppliers, including our supplier of *Spongilla lacustris*, are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

***If we are not able to establish and maintain collaborations, we may have to alter our development and commercialization plans.***

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. In order to fund further development of our product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and experience, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

Future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaborations typically impose detailed obligations on each party. If we were to breach our obligations, we may face substantial consequences, including potential termination of the collaboration, and our rights to our partners' product candidates, in which we have invested substantial time and money, would be lost.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

### **Risks Related to Managing Our Growth, Our Employees and Our Operations**

*We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.*

Our management, personnel, systems and facilities currently in place are not adequate to support our business plan and near-term future growth. We will need to further expand our chemistry and manufacturing team, clinical team, managerial, operational, financial, and other resources to support our planned research, development and commercialization activities.



To manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales and distribution capability;
- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;
- establish and maintain relationships with development and commercialization partners;
- manage our preclinical and clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

***If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.***

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel, including: our Chief Executive Officer, President and Chairman of our board of directors (the “Board”), Gerald T. Proehl; our Senior Vice President, Chief Financial Officer, Kyri K. Van Hoose, C.P.A., M.B.A.; our Senior Vice President, Development, Christopher J. Nardo, M.P.H., Ph.D.; and our Senior Vice President, Regulatory Affairs and Quality Assurance, Maria Bedoya Toro Munera, Ph.D., M.B.A.. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

***Our ability to attract and retain qualified members of our Board may be impacted due to new state laws, including recently enacted gender and diversity quotas.***

In September 2018, the state of California enacted SB 826 requiring public companies headquartered in California to maintain minimum female representation on their boards of directors as follows: by the end of 2019, at least one woman on its board, by the end of 2020, public company boards with five members will be required to have at least two female directors, and public company boards with six or more members will be required to have at least three female directors. In September 2020, the state of California enacted AB 979 requiring public companies headquartered in California to maintain minimum representation on their boards of directors from members of underrepresented communities as follow: by the end of 2021, at least one director from an underrepresented community, by end of 2022, public company boards with more than four but fewer than nine members will be required to have at least two directors from underrepresented communities, and public company board with nine or more members will be required to have at least three directors from underrepresented communities. Failure to achieve designated minimum levels in a timely manner exposes such companies to financial penalties and reputational harm. We cannot assure that we can recruit, attract and/or retain qualified members of the board and meet the above quotas as a result of the California laws, which may expose us to penalties and/or reputational harm.

***We currently have limited marketing capabilities and no outside sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.***

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the United States, Canada, the European Union and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our management team has experience in the marketing, sale and distribution of pharmaceutical products from prior employment at other companies, we as a company have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with additional third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are unable to successfully commercialize our product candidates, either on our own or through collaborations with one or more third parties, our business, financial condition, operating results and prospects would suffer.

***Our failure to successfully in-license, acquire, develop, and market additional product candidates or approved products would impair our ability to grow our business.***

We intend to in-license, acquire, develop, and market additional products and product candidates and we may in-license or acquire commercial-stage products or engage in other strategic transactions. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists, and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating, and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales, and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain our key employees or those of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results, and prospects.

***Manufacturing and supply of the APIs and other substances and materials used in our product candidates is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.***

Manufacturing and supply of APIs, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price, and successful delivery of our product candidates and can impede, delay, limit or prevent the successful development and commercialization of our product candidates. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include:

- failure of our manufacturers to follow cGMP or GACP requirements or mishandling of product while in production or in preparation for transit;
- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency and stability;
- our inability to develop an FDA approved bioassay for release of any future product;
- difficulty in establishing optimal drug delivery substances and techniques, production and storage methods and packaging and shipment processes;
- transportation and import/export risk, particularly given the global nature of our supply chain;

- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of any future product;
- natural disasters, pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and
- latent defects that may become apparent after the product has been released and which may result in recall and destruction of product.

Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, which could harm our business, financial condition, operating results and prospects.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.***

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;

- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

***Our operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn.***

Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary medical products and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider certain of our product candidates to be discretionary, and if full reimbursement for such products is not available, demand for these products may be tied to the discretionary spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for certain of our products and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, our partners have extensive global operations, indirectly exposing us to risk.

***Our business and operations would suffer in the event of failures in our internal computer systems.***

Despite the implementation of security measures, our internal computer systems, and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

***We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.***

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store, and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners, or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

## Risks Related to Our Intellectual Property

*We may not be able to obtain or enforce patent rights or other intellectual property rights that cover our product candidates and technologies that are of sufficient breadth to prevent third parties from competing against us.*

Our success with respect to our product candidates and technologies will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights. Our ability to protect any of our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents or enforce confidentiality contracts.

Our patents include licensed patents and patent applications in the United States and foreign jurisdictions where we believe there is a market opportunity for our products. The covered technology and the scope of coverage vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our technologies. Any patents that we may obtain may be narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents, third parties may be able to make, use, or sell products identical to, or substantially similar to, our product candidates.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any existing patents or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, patents, and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Although we believe that our technology includes certain inventions that are unique and not duplicative of any prior art, we do not have outstanding issued patents covering all of the recent developments in our technology and we are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do successfully issue, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated, or held unenforceable. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain on our in-licensed issued patents may not be valid or enforceable; and
- we may not develop additional proprietary technologies that are patentable.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years from its earliest non-provisional priority application filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates. The licensed U.S. patents relating to DMT310 expired in 2022 and 2023 or we have abandoned and will not be eligible for patent term extension if approval occurs after patent expiration.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality agreements with third parties, and intellectual property protection agreements with certain employees, consultants and advisors, third parties may still obtain this information, or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our suppliers, manufacturers and other third parties. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.***

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.



***If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.***

We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects. For more information about these license arrangements, see “Business—Collaborations and License Agreements.”

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.***

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot guarantee that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties’ intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party’s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party’s patents.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on commercially acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, re-examination or other post-grant proceedings declared or granted by the USPTO, and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or of our other products.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results, and prospects.

Because we rely on certain third-party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results, and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some of our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition, or operating results.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.***

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive and time-consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation, or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic, or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock or Warrants could be significantly harmed.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.***

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, collaborators, contractors, and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, collaborators, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our employees, consultants, collaborators, contractors and advisors to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.***

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome.

***If our patent term expires before or soon after our products are approved, or if manufacturers of generic or biosimilar drugs successfully challenge our patents, our business may be materially harmed.***

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including generic or biosimilar medications.

Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use. As a result, our revenue from applicable products could be reduced, possibly materially.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our unregistered trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

***Our proprietary information may be lost, or we may suffer security breaches.***

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

## Risks Related to the Securities Markets and Ownership of Our Common Stock and Warrants

*The market price of our common stock and Warrants have been volatile and can fluctuate substantially, which could result in substantial losses for holders of our securities.*

The market price of our common stock is highly volatile. The market price for our common stock and Warrants may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- actual or anticipated changes in the pace of our corporate achievements or our growth rate relative to our competitors;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our common stock or Warrants;
- additions or departures of key management or other personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock or Warrants by us, our insiders or our other stockholders; and
- general economic, market or political conditions in the United States or elsewhere.

In particular, the market prices of clinical-stage companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure in a clinical trial for our product candidates or receive approval from the FDA and other regulatory agents;
- developments or disputes concerning our product candidate's intellectual property rights;
- our or our competitors' technological innovations;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies or patents;
- failure to complete significant transactions or collaborate with vendors in manufacturing our product; and
- proposals for legislation that would place restrictions on the price of medical therapies.

These and other market and industry factors may cause the market price and demand for our common stock and Warrants to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock or Warrants and may otherwise negatively affect the liquidity of our common stock and Warrants. In addition, the stock market in general, and Nasdaq Capital Markets and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a security has been volatile, holders of that security have instituted securities class action litigation against the company that issued the security. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

***Our Warrants may not have any value.***

There can be no assurance that the market price of our common stock will ever equal or exceed the exercise price of our outstanding Warrants. In the event that our common stock price does not exceed the exercise price of the Warrants during the period when the Warrants are exercisable, the Warrants may not have any value.

***A Warrant does not entitle the holder to any rights as common stockholders until the holder exercises the Warrant for a share of our common stock.***

Until you acquire shares of our common stock upon exercise of your Warrants, your Warrants will not provide you any rights as a common stockholder. Upon exercise of your Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

***We are an “emerging growth company,” and will be able take advantage of reduced disclosure requirements applicable to “emerging growth companies,” which could make our common stock and Warrants less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act and, for as long as we continue to be an “emerging growth company,” we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an “emerging growth company” for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1.235 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three year period.

We intend to take advantage of these reporting exemptions described above until we are no longer an “emerging growth company.” Under the JOBS Act, “emerging growth companies” can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

We cannot predict if investors will find our common stock or Warrants less attractive if we choose to rely on these exemptions. If some investors find our common stock or Warrants less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and Warrants and the price of our common stock and Warrants may be more volatile.

***There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company. If we fail to remediate a material weakness, or if we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock and Warrants.***

Prior to the completion of our initial public offering in August 2021, we had been a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. As a public company, we have designed a control environment as required of public companies under the rules and regulations of the SEC.

Proper systems of internal controls over financial accounting and disclosure controls and procedures are critical to the operation of a public company. We may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

Moreover, we do not expect that disclosure controls or internal control over financial reporting, even if established, will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock and Warrants depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our securities would be negatively impacted. If we obtain securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our securities or publishes inaccurate or unfavorable research about our business, our stock price and Warrant price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our securities could decrease, which could cause the price of our securities and trading volume to decline.

***Future sales of our common stock, Warrants or securities convertible into our common stock may depress our stock price.***

Sales of a substantial number of shares of our common stock, Warrants or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock and Warrants. If a large number of shares of our common stock, Warrants or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and Warrants and impede our ability to raise future capital.

***Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock and/or our Warrants***

On November 15, 2023, we received a letter from the Listing Qualifications Staff of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we are not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Notice"). We were provided a compliance period of 180 calendar days from the date of the Notice, or until May 13, 2024, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

We will continue to monitor the closing bid price of our common stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock and/or Warrants. If we do not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock and Warrants will be subject to delisting. We would then be entitled to appeal that determination to a Nasdaq hearings panel. There can be no assurance that we will regain compliance with the minimum bid price requirement during the 180-day compliance period or maintain compliance with the other Nasdaq listing requirements. A delisting could substantially decrease trading in our common stock and Warrants, adversely affect the market liquidity of our common stock and Warrants as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of our common stock and/or our Warrants may decline further and stockholders may lose some or all of their investment.

***Anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.***

Our amended and restated certificate of incorporation, bylaws and Delaware corporate law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board. Our corporate governance documents include provisions:

- classifying our Board into three classes;
- authorizing “blank check” preferred stock, which could be issued by our Board without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- limiting the liability of, and providing indemnification to, our directors and officers;
- limiting the ability of our stockholders to call and bring business before special meetings;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board;
- controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and
- providing our Board with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our amended and restated certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock or Warrants, and could also affect the price that some investors are willing to pay for our common stock and Warrants.

***Our ability to use our net operating loss carryforwards may be limited.***

As of December 31, 2023, we had net operating loss carryforwards, or NOLs, of approximately \$14.2 million for federal income tax purposes and approximately \$5.0 million for state income tax purposes. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. Ownership changes that materially limit our use of our historical NOLs could harm our future operating results by effectively increasing our future U.S. federal income tax and U.S. state income tax obligations. In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, however, the deductibility of our federal NOLs generated in such years will be limited to 80% of taxable income if utilized in taxable years beginning after December 31, 2020. Federal net operating losses incurred in years beginning before January 1, 2018, are subject to a twenty-year carryforward but are not limited to 80% of taxable income.

***We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.***

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock and Warrants after price appreciation, which may never occur, as the only way to realize any future gains on their investment.



*Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.*

Our amended and restated certificate of incorporation requires that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for each of the following:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim for breach of any fiduciary duty owed by any director, officer or other employee of ours to the Company or our stockholders;
- any action asserting a claim against us or any director or officer of ours arising pursuant to, or a claim against us or any of our directors or officers, with respect to the interpretation or application of any provision of, the DGCL, our certificate of incorporation or bylaws; or
- any action asserting a claim governed by the internal affairs doctrine;

provided, that, if and only if the Court of Chancery of the State of Delaware dismisses any of the foregoing actions for lack of subject matter jurisdiction, any such action or actions may be brought in another state court sitting in the State of Delaware.

The exclusive forum provision is limited to the extent permitted by law, and it will not apply to claims arising under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or for any other federal securities laws which provide for exclusive federal jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation.

Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, this provision may limit or discourage a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees, and may result in increased costs for investors to bring a claim. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We note that there is uncertainty as to whether a court would enforce the provision and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 1C. CYBERSECURITY**

### *Cybersecurity Risk Management and Strategy*

We have certain processes for assessing, identifying, and managing cybersecurity risks, which are built into our overall information technology function and are designed to help protect our information assets and operations from internal and external cyber threats, and protect employee, collaborator, and patient information from unauthorized access or attack, as well as secure our networks and systems. Such processes include physical, procedural, and technical safeguards, response plans, tests on our systems, review of our policies and procedures to identify risks and refine our practices. We engage certain external parties, including consultants and computer security firms, to enhance our cybersecurity oversight including by gaining valuable insights into the ever-evolving cybersecurity landscape. We consider the internal risk oversight programs of third-party service providers before engaging them in order to help protect us from any related vulnerabilities.

In an effort to deter and detect cyber threats, we annually provide all employees with a data protection, cybersecurity, incident response, and prevention, training and compliance program, which covers timely and relevant topics, including social engineering, phishing, password protection, confidential data protection, asset use and mobile security, and educates employees on the importance of reporting all incidents immediately. We also use technology-based tools that are designed to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

### *Governance; Board Oversight*

The Audit Committee of our Board provides direct oversight over cybersecurity risk and provides updates to the Board regarding such oversight on a periodic basis. The Audit Committee receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding significant new cybersecurity threats or incidents.

## **ITEM 2. PROPERTIES**

Our mailing address is 3525 Del Mar Heights Rd., #322, San Diego, California 92130. All of our employees work remotely. We believe our virtual work offices are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space would be readily available on commercially reasonable terms.

## **ITEM 3. LEGAL PROCEEDINGS**

From time to time, we may be involved in claims that arise during the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

## **ITEM 4. MINE SAFETY DISCLOSURES**

This item is not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market Information

Our common stock and Warrants trade on The Nasdaq Capital Market under the symbols "DRMA" and "DRMAW" respectively since August 12, 2021.

#### Holdings

As of March 18, 2024, there were approximately 65 stockholders of record of our Common Stock. This number does not include beneficial owners whose shares were held in street name. The actual number of holders of our Common Stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

#### Dividends

We have never declared or paid cash dividends on our Common Stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the common stock will rest solely within the discretion of our Board and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

### ITEM 6. [RESERVED]

### ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. References in the following discussion to "we", "our", "us", "Dermata", or "the Company", refer to Dermata Therapeutics, Inc.*

#### Overview

We are a late-stage medical dermatology company focused on identifying, developing, and commercializing innovative pharmaceutical product candidates for the treatment of medical and aesthetic skin conditions and diseases we believe represent significant market opportunities.

Dermatological diseases such as acne vulgaris (or acne), psoriasis vulgaris (or psoriasis), hyperhidrosis, and various aesthetic indications, affect millions of people worldwide each year which may negatively impact their quality of life and emotional well-being. While there are multiple current treatment options for these indications on the market, we believe that most have significant drawbacks, including underwhelming efficacy, cumbersome application regimens and varying negative side effects, all of which we believe lead to decreased patient compliance. A majority of these indications are first treated with topical therapy; however, many patients frequently switch treatments or discontinue treatment altogether due to patient dissatisfaction. This is primarily due to slow and modest response rates, early onset of negative side effects, daily application schedules and long duration of therapy. Given the limitations with current topical therapies, we believe there is a significant opportunity to address the needs of frustrated patients searching for topical products that satisfy their dermatological and lifestyle needs.

Our two product candidates, DMT310 and DMT410, both incorporate our proprietary, multifaceted, *Spongilla* technology to topically treat a variety of dermatological conditions. Our *Spongilla* technology is derived from a naturally grown freshwater sponge, *Spongilla lacustris* or *Spongilla*, which is processed into a powder that is mixed with a fluidizing agent immediately prior to application to form an easily applicable paste. *Spongilla* is a unique freshwater sponge that only grows in commercial quantities in select regions of the world and under specific environmental conditions, all of which give it its distinctive anti-microbial, anti-inflammatory, and mechanical properties. The combination of these environmental conditions, the proprietary harvesting protocols developed with our exclusive supplier, and our post-harvest processing procedures produce a pharmaceutical product candidate that optimizes the mechanical components as well as the chemical components of the sponge to create a product candidate with multiple mechanisms of action for the treatment of inflammatory skin conditions and aesthetic applications.

We believe our *Spongilla* technology platform will enable us to develop and formulate singular and combination products that are able to target the topical delivery of chemical compounds into the dermis for a variety of dermatology indications. We believe the combination of *Spongilla*'s mechanical and chemical components (which we believe have demonstrated, *in-vitro*, anti-microbial and anti-inflammatory properties), add to the versatility of our *Spongilla* technology platform's effectiveness as a singular product, in the treatment of a wide variety of medical skin diseases like acne and psoriasis. We also believe the mechanical properties of our *Spongilla* technology allows for the intradermal delivery of a variety of large molecules, like botulinum toxins, monoclonal antibodies, or dermal fillers, to target treatment sites, through topical application without the need for needles.

Our lead product candidate, DMT310, is intended to utilize our *Spongilla* technology for once weekly treatment of a variety of skin diseases, with our initial focus being the treatment of acne vulgaris, which has a U.S. market size of approximately 50 million patients. We have recently initiated a Phase 3 program of DMT310 in moderate-to-severe acne and began enrolling patients in the first of two identical studies in December of 2023. Both studies will be double blind, randomized, placebo controlled, and enroll about 550 patients, age 9 years in older across sites in the United States and Latin America. The primary endpoints include absolute reduction in inflammatory and noninflammatory lesions and the improvement in investigators global assessment (IGA) of acne, which are the same endpoints used in our Phase 2b study of DMT310 for moderate-to-severe acne. Patients will be treated once a week for 12 weeks with either DMT310 or placebo and will be evaluated monthly. We expect to have top-line results from the first Phase 3 study in the first quarter of 2025. Previously DMT310 has shown its ability to treat the multiple causes of acne in a Phase 2b study where we initially saw a 45% reduction in inflammatory lesions after four treatments, with DMT310 achieving statistically significant improvements at all time points for all three primary endpoints throughout the study (reduction in inflammatory lesions, reduction in non-inflammatory lesions, and improvement in IGA). In addition, based on the multiple mechanisms of action and anti-inflammatory effect seen with DMT310 acne trial, we completed a Phase 1b proof of concept, or POC, trial in psoriasis where we saw encouraging results warranting further investigation.

DMT310 consists of two grams of powder processed from the naturally grown freshwater sponge, *Spongilla lacustris*. The patient mixes the powder with a fluidizing agent (hydrogen peroxide) immediately prior to application by the patient to form an easy-to-apply paste. The paste is applied similar to a mud mask and is left on the skin for approximately ten to fifteen minutes, after which time it is washed off with water. Due to the unique combination of DMT310's mechanical components and chemical components, and based on our Phase 2 acne data, we believe patients will only need to apply DMT310 once weekly to produce a desired treatment effect. The mechanical components of the *Spongilla* powder consist of many microscopic siliceous, needle-like spicules that, when massaged into the skin, penetrate the stratum corneum (the skin's outermost protective layer) and create microchannels into the dermis where pro-inflammatory cytokines and bacteria reside. We believe that the penetration of the spicules also leads to the opening of microchannels, which allow oxygen to enter pilosebaceous glands, helping to kill *C. acnes*, which grow in an anaerobic (without oxygen) environment (*C. acnes* is the bacteria that cause inflammatory lesions in acne patients). The spicules also cause rejuvenation of the top layer of dead skin, thereby increasing collagen production. Additionally, we believe the newly created microchannels provide a conduit for DMT310's naturally occurring chemical compounds to be delivered to the dermis and pilosebaceous glands, helping to kill the *C. acnes* and fight inflammation. In addition to these anti-microbial compounds, DMT310 also appears to have anti-inflammatory chemical compounds, as demonstrated in *in vitro* experiments, that inhibit inflammation through the reduction of *C. acnes* stimulated IL-8 production and by inhibiting IL-17A and IL-17F expression in human cell lines. Also, during *in vitro* studies of DMT310's organic compounds, we observed the inhibition of the lipogenesis of sebocytes, which may translate to a reduction in sebum (an oily and waxy substance produced by the human body's sebaceous glands) production and the oiliness of the skin in patients, which was observed by a number of clinical investigators in our Phase 2 acne studies. We believe the combination of these biological and mechanical effects could be important factors in treating multiple inflammatory skin diseases, as seen in our clinical trials.

Our second product candidate utilizing our *Spongilla* technology is DMT410, our combination treatment. DMT410 is intended to consist of one treatment of our proprietary sponge powder followed by one topical application of botulinum toxin for delivery into the dermis. Currently, botulinum toxin is only approved to be delivered to the dermis by intradermal injections, which can be painful for the patient and time-consuming for the physician. However, we believe DMT410's ability to topically deliver botulinum toxin into the dermis could have similar levels of efficacy to existing delivery techniques, with fewer tolerability issues, and a quicker application time, possibly replacing the need for intradermal injections. We first tested DMT410 in a Phase 1 POC trial of axillary hyperhidrosis patients, which saw 80% of patients achieve a reduction in gravimetric sweat production greater than 50% four weeks after a single treatment. With almost 40% of the hyperhidrosis market currently being treated with intradermal injections of botulinum toxin, we believe there could be significant opportunity for DMT410 to break into this market and replace intradermal injections of botulinum toxin. Based on DMT410's ability to effectively deliver botulinum toxin to the dermis as observed in the Phase 1 axillary hyperhidrosis trial, we also conducted a Phase 1 POC trial of DMT410 for the treatment of multiple aesthetic skin conditions, including reduction of pore size, sebum production, and fine lines, among others. In November 2021, we announced top-line results from this trial, where we saw promising data that we believe warrants further investigation of DMT410. We are currently in the process of discussing partnering opportunities with botulinum toxin companies to move the DMT410 program into Phase 2 studies.

We have a limited operating history. Since our inception, our operations have focused on developing DMT310 and DMT410, organizing and staffing our company, raising capital, establishing our supply chain and manufacturing processes, further characterizing the multiple mechanisms of action of our *Spongilla* technology, building an intellectual property portfolio, and conducting non-clinical and clinical trials. We do not have any product candidates approved for marketing and have not generated any revenue from product sales. We have funded our operations primarily through the sale of our equity securities and debt securities. Since inception, we have raised an aggregate of approximately \$61.0 million of gross proceeds from the sale of our debt and equity securities, including the securities sold in our initial public offering.

We have not generated any revenue to date and have incurred significant operating losses. Our net losses were \$7.8 million and \$9.6 million for years ended December 31, 2023, and 2022, respectively, and as of December 31, 2023, we had an accumulated deficit of \$53.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- complete development of DMT310 for the treatment of acne, including non-clinical studies and Phase 3 clinical trials;
- prepare and file for regulatory approval of DMT310 for the treatment of moderate-to-severe acne upon positive results from the Phase 3 clinical program;
- continue development of DMT310 for the treatment of psoriasis, including a Phase 2 clinical trial and Phase 3 clinical trials, pending additional finances or strategic partner;
- sign a partnership agreement with a botulinum toxin partner for DMT410 for the treatment of aesthetic and medical skin conditions;
- prepare for commercialization of DMT310, if approved, including the hiring of sales and marketing personnel;
- manufacture our product candidates for Phase 2 and Phase 3 trials and commercial sale;
- hire additional research and development and selling, general and administrative personnel;
- maintain, expand, and protect our intellectual property portfolio; and
- incur additional costs associated with operating as a public company.

We will need additional financing to support our operations. We may seek to fund our operations through public or private equity or debt financings or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital when needed or on favorable terms would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

## Components of Results of Operations

### Revenue

We have not generated any revenue since inception and do not expect to generate any revenue from the sale of products in the near future until we obtain regulatory approval of, and commercialize, our product candidates.

### Operating Expenses

#### *Research and Development Expenses*

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of late-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as our pipeline of product candidates progress further into clinical trials. However, we do not believe it is possible at this time to accurately project total program-related expenses to reach commercialization based on numerous factors. In addition, there are numerous unknown expenses related to the commercialization of our product candidates including continued regulatory requirements, many of which cannot be determined with accuracy at this time.

Research and development expenses consist of expenses incurred in connection with the development of our product candidates. We expense development costs as incurred. These expenses include:

- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply and commercial supply, including manufacturing validation batches; and
- outsourced laboratory services, including materials and supplies used to support our research and development activities, including payments made for license fees and milestone payments.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the size of patient populations participating in the clinical trials;
- the number of doses a patient receives;
- the duration of patient follow-ups;
- the development state of the product candidates; and
- the efficacy and safety profile of the product candidates.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending, and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay, or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take several years and millions of dollars in development costs.

### *General and Administrative Expenses*

General and administrative expenses consist principally of salaries and related costs for personnel in executive and administrative functions, travel expenses and recruiting expenses. Other general and administrative expenses include stock-based compensation expenses, professional fees for legal, accounting and tax related services, insurance costs, as well as payments made to consultants. We expense all general and administrative expenses as incurred.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and higher consulting, legal and tax related services associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company.

### **Interest Income**

Interest income consists of interest income earned on cash equivalents from interest bearing demand accounts.

### **Critical Accounting Policies and Significant Judgments and Estimates**

We have based our management's discussion and analysis of financial condition and results of operations on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued research and development expenses, stock-based compensation, and warrants. We base our estimates on historical experience and on various other factors that we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our audited financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

### **Accrued Research and Development Expenses**

As part of the process of preparing our financial statements, we are required to record actual research and development expenses and to estimate accrued research and development expenses, current assets, and other current liabilities. This process involves reviewing open contracts and commitments, communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued research and development expenses, current assets, and other current liabilities as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses, prepaid assets, and other current liabilities include fees paid to contract manufacturers made in connection with the manufacturing of clinical trials materials and contract research organizations made in connection the performance of clinical trials on our behalf.

We base our expenses related to clinical manufacturing and clinical trials on our estimates of the services performed pursuant to contracts with the entities performing those services on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. Payments under these types of contracts depend heavily upon the successful completion of many separate tasks involved in the manufacturing of drug product and the performance of clinical trials. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. Other indirect costs are generally recognized on a straight-line basis over the estimated period of the study. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed materially from the actual costs incurred. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

We accrue and expense clinical trial activities performed by third parties based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with agreements established with clinical research organizations (“CROs”) and clinical trial sites. We determine the estimates by reviewing contracts, vendor agreements and purchase orders, and through discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and the agreed-upon fee to be paid for such services. However, actual costs and timing of clinical trials are highly uncertain, subject to risks and may change depending upon a number of factors, including our clinical development plan.

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed, or services are performed.

### Income Taxes

Dermata operates as a C-Corporation and account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize net deferred tax assets to the extent that we believe these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that we would be able to realize our deferred tax assets in the future in excess of our recorded net amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

We record uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. We recognize interest and penalties related to unrecognized tax benefits, if any, within income tax expense. Any accrued interest and penalties are included within the related tax liability.

### Comparison of the Years Ended December 31, 2023, and 2022

The following table summarizes our results of operations for the years ended December 31, 2023, and 2022, respectively:

	<b>Year Ended December 31,</b>		
	<b>2023</b>	<b>2022</b>	<b>Difference</b>
Operating expenses:			
Research and development .....	\$ 4,069,766	\$ 5,651,041	\$ (1,581,275)
General and administrative .....	3,972,140	4,023,445	(51,305)
Total operating expenses .....	8,041,906	9,674,486	(1,632,580)
Losses from operations .....	(8,041,906)	(9,674,486)	1,632,580
Other income and expenses:			
Interest income, net.....	(247,216)	(63,573)	(183,643)
Net loss .....	\$ (7,794,690)	\$ (9,610,913)	\$ 1,816,223

### Research and Development Expenses

Research and development expenses decreased by approximately \$1.6 million from \$5.7 million for the year ended December 31, 2022, to \$4.1 million for the year ended December 31, 2023. The decrease in research and development expense was the result of \$1.8 million of decreased clinical trial expenses and \$0.4 million of decreased non-clinical expenses, offset by \$0.2 million in increased chemistry, manufacturing, and controls, or CMC, expenses in preparation for the DMT310 Phase 3 program, as well as increased employee and personnel expenses of \$0.4 million.



### *General and Administrative Expenses*

General and administrative expenses were approximately \$4.0 million for the years ended December 31, 2022, and 2023. Insurance costs decreased by \$0.3 million from the year ended December 31, 2022, to December 31, 2023, which were offset by \$0.3 million of increased public company costs, including the expenses related to audit fees and shareholder meetings.

### *Interest income*

The Company earns interest income via overnight deposits on the Company's cash and cash equivalents. Interest income increased by approximately \$0.2 million from \$63,573 for the year ended December 31, 2022, to \$247,216 for the year ended December 31, 2023, as result of the timing of when the sweep accounts were opened, which were opened during the third quarter of 2022.

### *Cash Flows*

The following table summarizes our cash flows from operating and financing activities:

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
Statements of cash flows data:		
Total cash used in operating activities .....	\$ (6,408,931)	\$ (8,834,164)
Total cash provided by financing activities .....	\$ 7,605,772	\$ 4,276,652
Increase (decrease) in cash and cash equivalents.....	\$ 1,196,841	\$ (4,557,512)

### *Operating activities*

Cash used in operations of \$6.4 million for the year ended December 31, 2023, was the result of the net loss of \$7.8 million, offset by non-cash stock-based compensation of \$0.5 million, an increase in accounts payable of \$0.4 million and an increase in accrued and other current liabilities of \$0.3 million, as well as a decrease in prepaid expenses and other current assets of \$0.2 million.

Cash used in operations of \$8.8 million for the year ended December 31, 2022, was the result of the net loss of \$9.6 million and a decrease in accounts payable and accrued and other current liabilities of \$0.3 million, offset by non-cash stock-based compensation of \$0.9 million and a decrease in prepaid expenses and other current assets of \$0.2 million.

### *Financing activities*

Cash provided by financing activities of \$7.6 million for the year ended December 31, 2023, was the result of \$4.2 million of net proceeds received from the issuance of common stock and warrants issued in the March 2023 Offering, \$1.5 million of net proceeds received from the issuance of common stock and warrants in the May 2023 Offering, as well as \$2.0 million of net proceeds from the November 2023 Warrant Inducement.

Cash provided by financing activities of \$4.3 million for the year ended December 31, 2022, was the result of the net proceeds received from the issuance of common stock and warrants issued in April 2022 from a private placement of the Company's securities.

### **Liquidity and Capital Resources**

Since our inception, we have not generated any revenue or commercialized any products. As of December 31, 2023, our cash and cash equivalents totaled \$7.4 million, and we had an accumulated deficit of \$53.4 million. For the year ended December 31, 2023, and 2022, we used cash of \$6.4 million and \$8.8 million, respectively, in operations.

Historically, our principal sources of cash have included proceeds from the issuance of equity and debt. Our principal uses of cash have included cash used in operations (including clinical development of our product candidates and general and administrative expenses) and payments for license rights. We expect that the principal uses of cash in the future will be for continuing operations, funding of research and development, and general working capital requirements. We expect that as research and development expenses continue to grow for our Phase 3 development program, we will need to raise additional capital to sustain operations and fund research and development activities, including our ongoing Phase 3 STAR-1 clinical study.

## Future Capital Requirements

We plan to focus in the near term on the development, regulatory approval, and potential commercialization of DMT310 for the treatment of acne and psoriasis. We anticipate we will continue to incur net losses for the next several years as we complete clinical development of DMT310 for the treatment of acne and psoriasis and continue research and development of DMT410 for the treatment of aesthetic and medical skin conditions. In addition, we plan to seek opportunities to identify, acquire or in license and develop additional drug candidates, potentially build commercial capabilities, and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our drug candidate arising out of our current clinical trials when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support development of our drug candidates.

As a publicly traded company, we will incur significant legal, accounting, and other expenses that we were not required to incur as a private company. In addition, the Sarbanes- Oxley Act of 2002, as well as rules adopted by the SEC and Nasdaq, requires public companies to implement specified corporate governance practices that were not applicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the third quarter of 2024. We have based this estimate of cash runway on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We will require additional capital to conduct Phase 3 studies for DMT310 for the treatment of acne, and to pursue in licenses or acquisitions of other drug candidates.

Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations and the pursuit of our growth strategy.

We may raise additional capital through the sale of equity or convertible debt securities. In such an event, the terms of these securities may include liquidation or other preferences that adversely affect the rights of a holder of our common stock.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the number and characteristics of the drug candidates we pursue;
- the scope, progress, results, and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our drug candidates;
- the cost of manufacturing our drug candidates and any drugs we successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future drug candidates, if any.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in license and develop additional products and product candidates to augment our internal development pipeline. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue development, acquisition or in licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in licensing or similar strategic business transaction.

If we raise additional funds by issuing equity securities, our stockholder will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our stockholder. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

### **Going Concern**

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change and is largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of the Company's efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for 12 months after the issuance date of our financial statements. The accompanying financial statements have been prepared on a going concern basis. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We incurred a net loss of \$7.8 million for the year ended December 31, 2023, and had an accumulated deficit of \$53.4 million as of December 31, 2023. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our primary source of capital has been the issuance of debt and equity securities.

### **Recently Issued Accounting Standards**

For a discussion of recent accounting pronouncements, please see the Summary of Significant Accounting Policies in the Notes to our financial statements included elsewhere in this Annual Report.

### **JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company". As an "emerging growth company," we are electing to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation. These exemptions will apply until the fifth anniversary of the completion of our initial public offering or until we no longer meet the requirements for being an "emerging growth company," whichever occurs first.

### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not Applicable.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this item appears in a separate section of this Annual Report on Form 10-K beginning on page F-1 and is incorporated herein by reference.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

### Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorizations of management and our Board; and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting were effective as of December 31, 2023.

### Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2023, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Inherent Limitations on Effectiveness of Controls**

Our management, including our chief executive officer and chief financial officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## **ITEM 9B. OTHER INFORMATION**

- (a) None
- (b) During the fiscal quarter ended December 31, 2023, no director or “officer” (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(c) of Regulation S-K.

## **ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

None.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE**

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

### **ITEM 11. EXECUTIVE COMPENSATION**

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (a)(1) Financial Statements

The financial statements and related notes, together with the report of Moss Adams LLP and Mayer Hoffman McCann P.C. appear at pages F-1 through F-22 following the Exhibit List as required by “Part II—Item 8—Financial Statements and Supplementary Data” of the Form 10-K.

#### (a)(2) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

#### (a)(3) Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Amendment.

<b>Exhibit No.</b>	<b>Description of Document</b>
3.1	Amended and Restated Certificate of Incorporation of Dermata Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
3.2	Amendment No. 1 of the Amended and Restated Certificate of Incorporation of Dermata Therapeutics, Inc., filed with the Secretary of State of the State of Delaware on July 11, 2022 (incorporated by reference to Exhibit 3.1 of the Company’s Current Report on Form 8-K filed with the SEC on July 11, 2022).
3.3	Amendment No. 2 to the Amended and Restated Certificate of Incorporation of Dermata Therapeutics, Inc., dated March 13, 2023. (incorporated by reference to Exhibit 3.1 to the Company’s Current Report file on Form 8-K filed on March 13, 2023).
3.4	Amended and Restated Bylaws of Dermata Therapeutics, Inc. (incorporated by reference to Exhibit 3.4 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
3.5	Amendment No. 1 to the Amended and Restated Bylaws of Dermata Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 of the Company’s Current Report on Form 8-K filed with the SEC on September 23, 2022).
4.1	Specimen Certificate representing shares of common stock of Dermata Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
4.2	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.3 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
4.3	Form of Common Stock Purchase Warrant issued in the Company’s Initial Public Offering (incorporated by reference to Exhibit 4.4 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
4.4	Form of Underwriter Warrant issued in the Company’s Initial Public Offering (incorporated by reference to Exhibit 4.2 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
4.5	Form of Warrant Agency Agreement between Dermata Therapeutics, Inc. and Direct Transfer, LLC entered into in connection with the Company’s Initial Public Offering (incorporated by reference to Exhibit 4.5 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
4.6	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.10 to the Company’s Registration Statement on Form S-1/A (File No. 333-270195) filed on March 13, 2023).
4.7	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on May 24, 2023).

- 4.8 Form of Warrant (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed on May 24, 2023).
- 4.9 Form of Placement Agent Warrant (incorporated by reference to Exhibit 4. to the Company’s Current Report on Form 8-K filed on May 24, 2023).
- 4.10 Form of New Warrant (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on November 17, 2023).
- 4.11 Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed on November 17, 2023).
- 4.12 Description of Securities.\*
- 10.1 Form of Indemnification Agreement entered into by Dermata Therapeutics, Inc. and its Officers and Directors (incorporated by reference to Exhibit 10.1 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
- 10.2 Dermata Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).†
- 10.3 Amendment No. 1 to the Dermata Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.15 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).†
- 10.4 Amendment No. 2 to the Dermata Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on August 3, 2023).†
- 10.5 Form of Nonqualified Stock Option Award under 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).†
- 10.6 Form of Incentive Stock Option Award under 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).†
- 10.7 Employment Agreement dated December 6, 2021 by and between Dermata Therapeutics, Inc. and Gerald T. Proehl (incorporated by reference to Exhibit 10.1 of the Company’s Current Report on Form 8-K filed with the SEC on December 10, 2021).†
- 10.8 Form of Employment Agreement dated August 17, 2021 by and between Dermata Therapeutics, Inc. and Christopher J. Nardo, M.P.H., Ph.D. (incorporated by reference to Exhibit 10.6 of the Company’s Registration Statement on Form S-1 filed with the SEC on August 6, 2021).†
- 10.9 Amendment No. 1 dated December 6, 2021 to the Employment Agreement by and between Dermata Therapeutics, Inc. and Christopher J. Nardo (incorporated by reference to Exhibit 10.4 of the Company’s Current Report on Form 8-K filed with the SEC on December 10, 2021). †
- 10.10 Amendment No. 2 dated January 1, 2022 to the Employment Agreement by and between Dermata Therapeutics, Inc. and Christopher J. Nardo (incorporated by reference to Exhibit 10.9 of the Company’s Annual Report on Form 10-K filed with the SEC on March 8, 2022).†
- 10.11 Amendment No. 3 dated July 1, 2022 to the Employment Agreement by and between Dermata Therapeutics, Inc. and Christopher Nardo (incorporated by reference to Exhibit 10.4 of the Company’s Quarterly Report on Form 10-Q filed with the SEC on August 15, 2022).†
- 10.12 Employment Agreement dated December 6, 2021 by and between Dermata Therapeutics, Inc. and Maria Bedoya Toro Munera, Ph.D., M.B.A. (incorporated by reference to Exhibit 10.3 of the Company’s Current Report on Form 8-K filed with the SEC on December 10, 2021).†
- 10.13 Amendment No. 1 dated January 1, 2022 to the Employment Agreement by and between Dermata Therapeutics, Inc. and Maria Bedoya Toro Munera, Ph.D. (incorporated by reference to Exhibit 10.11 of the Company’s Annual Report on Form 10-K filed with the SEC on March 8, 2022).†

- 10.14 Employment Agreement dated December 6, 2021 by and between Dermata Therapeutics, Inc. and Kyri K. Van Hoose (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on December 10, 2021).†
- 10.15 Amendment No. 1 dated January 1, 2022 to the Employment Agreement by and between Dermata Therapeutics, Inc. and Kyri K. Van Hoose. (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A (File No. 333-270195) filed March 16, 2023).†
- 10.16 Supply Agreement between Dermata Therapeutics LLC and Reka-Farm LLC, dated as of February 27, 2020 (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed with the SEC on August 6, 2021).#
- 10.17 License Agreement between Dermata Therapeutics LLC and Villani, Inc. dated as of March 31, 2017 (incorporated by reference to Exhibit 10.9 of the Company's Registration Statement on Form S-1 filed with the SEC on August 6, 2021).#
- 10.18 Amended and Restated Annex A to the License Agreement between Dermata Therapeutics LLC and Villani, Inc. dated as of March 31, 2017 (incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 filed with the SEC on August 6, 2021).
- 10.19 License Amendment and Settlement Agreement between Dermata Therapeutics LLC and Villani, Inc. dated as of June 4, 2019 (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 filed with the SEC on August 6, 2021).#
- 10.20 Amendment to the License Amendment and Settlement Agreement between Dermata Therapeutics, Inc. and Villani, Inc., dated July 30, 2021 (incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 filed with the SEC on August 6, 2021).#
- 10.21 Form of Securities Purchase Agreement Dated April 20, 2022 between Dermata Therapeutics, Inc. and the Purchaser (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 25, 2022).
- 10.22 Form of Registration Rights Agreement dated April 20, 2022 between Dermata Therapeutics, Inc. and the Purchaser (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on April 25, 2022).
- 10.23 Form of Placement Agent Agreement dated April 20, 2022 between the Registrant and Maxim Group LLC (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on April 25, 2022).
- 10.24 Form of Purchase Agreement (incorporated by reference to Exhibit 10.23 to the Company's Registration Statement on Form S-1/A (File No. 333-270195) filed on March 16, 2023).
- 10.25 Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 24, 2023).
- 10.26 Form of Inducement Letter (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 17, 2023).
- 16.1 Letter of Mayer Hoffman McCann P.C. to the Securities and Exchange Commission, dated August 3, 2023 (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed on August 3, 2023).
- 23.1 Consent of Moss Adams LLP.\*
- 23.2 Consent of Mayer Hoffman McCann P.C.\*
- 31.1 Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).\*



- 31.2 Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).\*
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).\*\*
- 97.1 Clawback Policy of Dermata Therapeutics, Inc.\*
- 101.INS\* XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
- 101.SCH\* Inline XBRL Taxonomy Extension Schema Document
- 101.CAL\* Inline XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF\* Inline XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB\* Inline XBRL Taxonomy Extension Label Linkbase Document
- 104 Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101)

# Portions of this exhibit (indicated by asterisks) are omitted in accordance with the rules of the SEC.

\* Filed herewith.

\*\* Furnished, not filed.

† Indicates a management contract or compensation plan, contract or arrangement.

#### **ITEM 16. FORM 10-K SUMMARY**

None.

**DERMATA THERAPEUTICS, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**As of December 31, 2023, and 2022, and the  
Years Ended December 31, 2023, and 2022**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of  
Dermata Therapeutics, Inc.

### *Opinion on the Financial Statements*

We have audited the accompanying balance sheet of Dermata Therapeutics, Inc. (the “Company”) as of December 31, 2023, the related statement of operations, stockholders’ equity, and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited the adjustments to the 2022 financial statements to retrospectively reflect the impact of the reverse stock split, described in Note 1. In our opinion, such adjustments are appropriate and have been properly applied. We were not engaged to audit, review or apply procedures to the 2022 financial statements of the Company other than with respect to the adjustments and, accordingly, we do not express an opinion or any other form of assurance on the 2022 financial statements taken as a whole.

### *Going Concern Uncertainty*

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### *Basis for Opinion*

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Moss Adams LLP

San Diego, California  
March 21, 2024

We have served as the Company’s auditor since 2023.

## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and  
Stockholders of Dermata Therapeutics, Inc.

### **Opinion on the Financial Statements**

We have audited, before the effects of the adjustments to retrospectively apply the reverse stock split described in Note 1, the accompanying balance sheet of Dermata Therapeutics, Inc. (“Company”) as of December 31, 2022, and the related statements of operations and comprehensive loss, stockholders’ equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). The 2022 financial statements before the effects of the adjustments discussed in Note 1 are not presented herein. In our opinion, the financial statements, before the effects of the adjustments to retrospectively apply the reverse stock split described in Note 1, present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

We were not engaged to audit, review, or apply any procedures to the adjustments to retrospectively apply the reverse stock split described in Note 1 and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by Moss Adams LLP.

### **Going Concern Uncertainty**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management’s plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### **Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

We served as the Company’s auditor from 2016 to 2023.

/s/ Mayer Hoffman McCann P.C.

San Diego, California  
February 21, 2023

**DERMATA THERAPEUTICS, INC.**  
**Balance Sheets**

	<b>December 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Assets:</b>		
Cash and cash equivalents.....	\$ 7,438,135	\$ 6,241,294
Prepaid expenses and other current assets.....	540,499	703,194
<b>Total assets .....</b>	<b>\$ 7,978,634</b>	<b>\$ 6,944,488</b>
<b>Liabilities and Stockholders' Equity:</b>		
<b>Liabilities:</b>		
Accounts payable .....	\$ 866,028	\$ 496,702
Accrued and other current liabilities .....	757,588	425,932
<b>Total liabilities .....</b>	<b>1,623,616</b>	<b>922,634</b>
<b>Commitments and Contingencies (see Note 7)</b>		
<b>Stockholders' Equity:</b>		
Common Stock, par value \$0.0001, 250,000,000 shares authorized as of December 31, 2023, and 2022; 3,930,840 and 770,115 shares issued and outstanding as of December 31, 2023, and 2022, respectively.....	393	77
Additional paid-in capital.....	59,742,503	51,614,965
Accumulated deficit .....	(53,387,878)	(45,593,188)
<b>Total stockholders' equity .....</b>	<b>6,355,018</b>	<b>6,021,854</b>
<b>Total liabilities and stockholders' equity.....</b>	<b>\$ 7,978,634</b>	<b>\$ 6,944,488</b>

The accompanying notes are an integral part of these financial statements.

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

	<b>For the year ended</b>	
	<b>December 31,</b>	
	<u><b>2023</b></u>	<u><b>2022</b></u>
Operating expenses:		
Research and development .....	\$ 4,069,766	\$ 5,651,041
General and administrative .....	3,972,140	4,023,445
Total operating expenses .....	<u>8,041,906</u>	<u>9,674,486</u>
Loss from operations .....	<u>(8,041,906)</u>	<u>(9,674,486)</u>
Other income and expenses:		
Interest income, net.....	<u>(247,216)</u>	<u>(63,573)</u>
Net loss .....	<u><u>\$ (7,794,690)</u></u>	<u><u>\$ (9,610,913)</u></u>
Net loss per share of common stock, basic and diluted .....	<u><u>\$ (2.67)</u></u>	<u><u>\$ (13.92)</u></u>
Weighted-average basic and diluted common shares .....	<u><u>2,924,398</u></u>	<u><u>690,666</u></u>

The accompanying notes are an integral part of these financial statements.

**DERMATA THERAPEUTICS, INC.**  
**Statements of Stockholder's Equity (Deficit)**

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Par Value</u>	<u>Paid-in</u>	<u>Deficit</u>	<u>Stockholders'</u>
			<u>Capital</u>		<u>Equity</u>
Balance at December 31, 2021.....	520,540	\$ 52	\$ 46,089,327	\$ (35,982,275)	\$ 10,107,104
Issuance of Common Stock and warrants, net of issuance costs .....	56,162	6	4,276,359	-	4,276,365
Issuance of Common Stock upon exercise of pre-funded warrants .....	179,688	18	269	-	287
Issuance of restricted stock unit awards.....	-	-	166,875	-	166,875
Issuance of Common Stock upon conversion of restricted stock units.....	13,725	1	(1)	-	-
Stock-based compensation .....	-	-	1,082,136	-	1,082,136
Net loss .....	-	-	-	(9,610,913)	(9,610,913)
Balance at December 31, 2022.....	<u>770,115</u>	<u>\$ 77</u>	<u>\$ 51,614,965</u>	<u>\$ (45,593,188)</u>	<u>\$ 6,021,854</u>
Issuance of Common Stock and warrants, net of issuance costs .....	543,555	55	5,651,613	-	5,651,668
Issuance of Common Stock upon exercise of pre-funded warrants .....	1,875,445	187	-	-	187
Issuance of Common Stock upon exercise of warrants, net of issuance costs .....	742,095	74	1,953,883	-	1,953,957
Settlement of fractional shares paid in cash.....	(370)	-	(40)	-	(40)
Stock-based compensation .....	-	-	522,082	-	522,082
Net loss .....	-	-	-	(7,794,690)	(7,794,690)
Balance at December 31, 2023.....	<u>3,930,840</u>	<u>\$ 393</u>	<u>\$ 59,742,503</u>	<u>\$ (53,387,878)</u>	<u>\$ 6,355,018</u>

The accompanying notes are an integral part of these financial statements.

**DERMATA THERAPEUTICS, INC.**  
**Statements of Cash Flows**

	<b>For the year ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Cash flows from operating activities:		
Net loss.....	\$ (7,794,690)	\$ (9,610,913)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation.....	522,082	930,325
Increase (decrease) in cash resulting from changes in:		
Prepaid expenses and other current assets .....	162,695	121,940
Accounts payable.....	369,326	(18,543)
Accrued and other current liabilities .....	331,656	(256,973)
Total adjustments to reconcile net loss to cash used in operations .....	1,385,759	776,749
Net cash used in operating activities.....	(6,408,931)	(8,834,164)
Cash flows from financing activities:		
Proceeds from issuance of Common Stock and warrants, net of issuance costs .....	7,605,625	4,276,365
Proceeds from exercise of pre-funded warrants .....	187	287
Payment for fractional shares in reverse stock split .....	(40)	-
Net cash provided by financing activities .....	7,605,772	4,276,652
Net increase (decrease) in cash and cash equivalents .....	1,196,841	(4,557,512)
Cash and cash equivalents at beginning of period .....	6,241,294	10,798,806
Cash and cash equivalents at end of period .....	\$ 7,438,135	\$ 6,241,294
Supplemental disclosure:		
Cash paid for taxes .....	\$ 950	\$ 950
Non-cash financing activities:		
Incremental fair value of March 2023 warrant modification.....	\$ 144,765	\$ -
Incremental fair value of November 2023 warrant inducement .....	\$ 2,995,343	\$ -

The accompanying notes are an integral part of these financial statements.



**DERMATA THERAPEUTICS, INC.**  
**Notes to Financial Statements**

**1. Organization and Basis of Presentation**

Dermata Therapeutics, Inc., (the “Company”), was formed in December 2014 as a Delaware limited liability company (“LLC”) under the name Dermata Therapeutics, LLC. On March 24, 2021, the Company converted from an LLC to a Delaware C-corporation and changed its name to Dermata Therapeutics, Inc. The Company is a clinical-stage biotechnology company focused on the treatment of medical and aesthetic skin conditions and diseases.

**Initial Public Offering**

On August 17, 2021, the Company completed its initial public offering (“IPO”), in which it sold 160,714 shares of its common stock, par value \$0.0001 per share (“Common Stock”), together with 160,714 warrants to purchase one share of Common Stock with an exercise price of \$112.00 per share, at a combined offering price of \$112.00. Additionally, the underwriters exercised their option to purchase an additional 24,106 warrants to purchase Common Stock with an exercise price of \$112.00 per share, resulting in total IPO warrants issued of 184,820 at an exercise price of \$112.00. The Company received net cash proceeds of approximately \$15.4 million from the IPO after deducting underwriters’ discounts and offering expenses of approximately \$2.6 million.

The Company’s shares of Common Stock and warrants are listed on the Nasdaq Stock Market LLC (“Nasdaq”) under the symbols “DRMA,” and “DRMAW,” respectively, and both began trading in August 2021.

**Reverse Stock Split**

On March 13, 2023, the Company effected a reverse stock split of shares of the Company’s Common Stock at a ratio of 1-for-16 pursuant to an amendment to the Company’s certificate of incorporation approved by the Company’s board of directors (the “Board”), and stockholders. The par value and authorized shares were not adjusted as a result of the reverse split. All issued and outstanding shares of Common Stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

**Liquidity and Going Concern Uncertainty**

Since its inception, the Company has devoted substantially all of its resources to research and development activities and has not generated any revenue or commercialized any product candidates. As of December 31, 2023, cash and cash equivalents totaled \$7.4 million and the Company had an accumulated deficit of \$53.4 million. For the year ended December 31, 2023, the Company used cash of \$6.4 million in operations. The Company’s cash and cash equivalents are expected to fund operations into the third quarter of 2024. The Company anticipates that it will continue to incur net losses for the foreseeable future. These factors raise substantial doubt about the Company’s ability to continue as a going concern for the one-year period following the date that these financial statements were issued.

Historically, the Company’s principal sources of cash have included proceeds from the issuance of equity securities and debt. The Company’s principal uses of cash have included cash used in operations and payments for license rights. The Company expects that the principal uses of cash in the future will be for continuing operations, funding of research and development, conducting preclinical studies and clinical trials, and general working capital requirements. The Company expects that as research and development expenses continue to grow, it will need to raise additional capital to sustain operations and research and development.

**Management’s Plan to Continue as a Going Concern**

To continue as a going concern, the Company will need, among other things, to raise additional capital resources. Until the Company can generate significant cash from operations, management’s plans to obtain such resources for the Company include proceeds from offerings of the Company’s equity securities or debt, or transactions involving product development, technology licensing or collaboration. Management can provide no assurance that any sources of a sufficient amount of financing or collaboration agreements will be available to the Company on favorable terms, if at all. The Company’s ability to raise additional capital may be adversely impacted by potential worsening of global economic conditions, potential future global pandemics or health crises, and the recent disruptions to, and volatility in, the credit and financial markets in the United States. Because of historical and expected operating losses and net operating cash flow deficits, there is substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the consolidated financial statements, which is not alleviated by management’s plans. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of the Company to continue as a going concern.

## ***Basis of Presentation***

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ materially from those estimates.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The Company’s financial statements are prepared in accordance with GAAP. The preparation of the Company’s financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and disclosure of contingent assets and liabilities in the financial statements and accompanying notes. On an ongoing basis, management evaluates these estimates and judgments, including those related to accrued research and development expenses, stock-based compensation, and the estimated fair values of equity instruments. Management evaluates its estimates on an ongoing basis. The Company bases its estimates on various assumptions that it believes are reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

### **Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company and the Company’s chief operating decision maker view the Company’s operations and manage its business in one operating segment, which is the business of developing and commercializing pharmaceuticals.

### **Cash and Cash Equivalents**

The Company deposits its cash and cash equivalents with accredited financial institutions that are insured by the Federal Deposit Insurance Corporation (“FDIC”), which are held in checking and cash sweep accounts. At times, deposits held may exceed the amount of insurance provided by the FDIC. The Company maintains an insured cash sweep account in which cash from its main operating checking account is invested overnight in highly liquid, short-term investments. The Company considers all highly liquid investments with a maturity date of 90 days or less at the date of purchase to be cash equivalents.

### **Concentrations of Credit Risk**

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. The Company is exposed to credit risk in the event of a default by the financial institutions holding the Company’s cash and cash equivalents to the extent of the amounts held in excess of FDIC limits. The Company limits its credit risk by placing its cash and cash equivalents with financial institutions it believes are of high quality. To date, the Company has not experienced any losses on its deposits of cash and cash equivalents.

### **Fair Value Measurement**

The Company uses a three-tier fair value hierarchy to prioritize the inputs used in the Company’s fair value measurements. These tiers include Level 1, defined as observable inputs such as quoted prices in active markets for identical assets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. The Company believes the carrying amount of cash and cash equivalents, accounts payable and accrued expenses approximate their estimated fair values due to the short-term nature of these assets and liabilities.

### **Interest Income**

Interest income consists of interest income earned on cash and cash equivalents from interest bearing demand accounts.

## **Patent Costs**

Patent costs related to obtaining and maintaining patent protection in both the United States and other countries are expensed as incurred. Patent costs are classified as general and administrative expenses.

## **Research and Development**

Research and development costs consist of expenses incurred in connection with the development of the Company's product candidates. Such expenses include expenses incurred under agreements with contract research organizations, manufacturing and supply scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial supply, outsourced laboratory services, including materials and supplies used to support the Company's research and development activities, and payments made for license fees and milestones that have not been demonstrated to have commercial value. Such costs are expensed in the periods in which they are incurred. Upfront payments and milestone payments for licensed technology are expensed as research and development as incurred or when the milestone is achieved or is determined to be probable of being achieved. Advanced payments for goods or services to be received in the future for research and development activities are recorded as prepaid expenses and expensed as the related goods are received or services are performed.

## **Income Taxes**

The Company has operated as a C-Corporation since March 2021 and accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

## **Stock-Based Compensation**

In March 2021, the Company's board of directors and shareholders approved the Dermata Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). For stock options granted under the 2021 Plan, the Company measures and recognizes compensation expense for all stock-based awards made to employees, directors, and non-employees, based on estimated fair values recognized using the straight-line method over the requisite service period. The fair value of options to purchase Common Stock granted to employees is estimated on the grant date using the Black-Scholes valuation model. The calculation of stock-based compensation expense requires that the Company make certain assumptions and judgments about variables used in the Black-Scholes model, including the expected term of the stock-based award, expected volatility of the underlying Common Stock, dividend yield, and the risk-free interest rate. Forfeitures are accounted for in the period they occur. Restricted stock units ("RSUs") granted under the 2021 Plan are measured at the grant date fair value of the Common Stock, with corresponding compensation expense recognized ratably over the requisite service period.

## Warrants

The Company performs an assessment of warrants upon issuance to determine their proper classification in the financial statements based upon the warrant's specific terms, in accordance with the authoritative guidance provided in Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 480 *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480 and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed in the Company's own common stock and whether the warrant holders could potentially require cash settlement of the warrants. The Company accounts for modifications and exchanges of warrants in accordance with ASU 2021-04, *Earnings Per Share (Topic 260)*, *Debt — Modifications and Extinguishments (Subtopic 470-50)*, *Compensation — Stock Compensation (Topic 718)*, and *Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the Emerging Issues Task Force)* ("ASU 2021-04").

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be liability-classified and recorded at their initial fair value on the date of issuance and remeasured at fair value at each balance sheet date thereafter. The Company has performed an assessment of all warrants issued and modified and determined that the Company's warrants are equity-classified.

## Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive income (loss) for the periods presented. The Company did not have other comprehensive income (loss) items such as unrealized gains and losses and so for the years ended December 31, 2023, and 2022, comprehensive loss was equal to the net loss.

## Net Loss Per Share of Common Stock

Basic net loss per share is calculated by dividing net loss attributable to common shareholders by the weighted-average number of shares outstanding during the period. The weighted-average number of shares of common stock outstanding includes (i) contingently issuable restricted stock units for which no future service is required as a condition to the delivery of the underlying Common Stock, (ii) pre-funded warrants because their exercise requires only nominal consideration for the delivery of shares, and (iii) shares held in abeyance because there is no consideration required for delivery of the shares, (collectively, "basic shares"), without consideration of common share equivalents. Diluted net loss per share is calculated by adjusting basic shares outstanding for the dilutive effect of common share equivalents outstanding for the period. For purposes of the diluted net loss per share calculation, stock options and warrants are considered to be common share equivalents but are excluded from the calculation of diluted net loss per common share if their effect would be anti-dilutive.

As the Company has reported a net loss for the periods presented, diluted net loss per common share is the same as the basic net loss per common share for the periods presented.

	Year Ended December 31,	
	2023	2022
Net loss .....	<u>\$ (7,794,690)</u>	<u>\$ (9,610,913)</u>
Basic and diluted net loss per common share .....	<u>\$ (2.67)</u>	<u>\$ (13.92)</u>
Weighted-average basic and diluted common shares .....	<u>2,924,398</u>	<u>690,666</u>

The common share equivalents that are not included in the calculation of diluted net loss per common share but could potentially dilute basic earnings per share in the future are as follows:

	As of December 31,	
	2023	2022
Common Stock Options.....	102,074	65,983
Common Stock Warrants.....	8,358,697	437,102
Total potentially dilutive securities.....	<u>8,460,771</u>	<u>503,085</u>

## Recent Accounting Pronouncements

For the year ended December 31, 2023, the Company has reviewed recent accounting standards and identified the following as relevant to the Company.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 requires disaggregated information about a reporting entity’s effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this guidance on its financial statements and income tax footnote.

### 3. Balance Sheet Details

The following provides certain balance sheet details:

	<u>As of December 31,</u>	
	<u>2023</u>	<u>2022</u>
Prepaid expenses and other current assets		
Prepaid insurance.....	\$ 426,413	\$ 586,407
Prepaid research and development costs.....	91,232	92,581
Prepaid other.....	14,498	11,604
Interest receivable.....	8,356	12,602
Total prepaid expenses and other current assets.....	<u>\$ 540,499</u>	<u>\$ 703,194</u>
Accrued and other current liabilities		
Accrued research and development costs.....	\$ 40,596	\$ 254,787
Accrued compensation and benefits.....	716,490	170,389
Accrued other.....	502	756
Total accrued and other current liabilities.....	<u>\$ 757,588</u>	<u>\$ 425,932</u>

### 4. Equity Securities

On July 11, 2022, the Company filed a Certificate of Amendment to the Company’s Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of the Company’s Common Stock from 90,000,000 shares to 250,000,000 shares. The increase in the number of authorized shares was approved by the holders of a majority of the outstanding shares of Common Stock of the Company at its annual meeting on July 11, 2022.

A summary of the Company’s equity securities as of December 31, 2023, is as follows:

<u>Description</u>	<u>Authorized</u>	<u>Issued</u>	<u>Held in Abeyance</u>	<u>Reserved</u>	<u>Outstanding</u>
Common Stock, par value \$0.001.....	250,000,000	3,930,840	2,730,000	-	3,930,840
Preferred Stock.....	10,000,000	-	-	-	-
Warrants.....	-	8,358,697	-	-	8,358,697
2021 Omnibus Equity Incentive Plan.....	629,069	115,792	-	513,277	102,074
Total equity securities.....	<u>260,629,069</u>	<u>12,405,329</u>	<u>2,730,000</u>	<u>513,277</u>	<u>12,391,611</u>

#### Common Stock

On November 20, 2023, the Company closed on an inducement agreement (the “Inducement”) with a holder (the “Holder”) of certain of its existing warrants to purchase up to 3,472,095 shares of the Company’s common stock, issued to the Holder on (i) April 25, 2022 (as amended on March 20, 2023, the “April 2022 Warrants”) and (ii) March 20, 2023 (the “March 2023 Warrants” together with the April 2022 Warrants, the “Existing Warrants”). The Existing Warrants had an exercise price of \$2.82. Pursuant to the Inducement, the Holder agreed to exercise for cash its Existing Warrants at a reduced exercise price of \$0.6511 per share in consideration for the Company’s agreement to issue in a private placement (i) new series A Common Stock purchase warrants (the “November 2023 Series A Common Warrants”) to purchase 3,707,944 shares of Common Stock and (ii) new series B Common Stock purchase warrants (the “November 2023 Series B Common Warrants”) and together with the November 2023 Series A Common Warrants, the “New Warrants”) to purchase 3,236,246 shares of Common Stock. The New Warrants are exercisable subject to stockholder approval, which the Company received at a stockholder meeting on January 12, 2024. The Company received net cash proceeds of approximately \$2.0 million from the Inducement after deducting underwriters’ discounts and offering expenses of approximately \$0.3 million.

On May 26, 2023, the Company closed a private placement (the “2023 PIPE”) priced at the market under Nasdaq rules, in which it sold 458,555 shares of its Common Stock together with 342,322 pre-funded warrants to purchase up to an aggregate of 342,322 shares of Common Stock with an exercise price of \$0.0001 per share (the “May 2023 Pre-Funded Warrants”), and 800,877 warrants to purchase up to an aggregate of 800,877 shares of Common Stock with an exercise price of \$2.16 per share (the “May 2023 PIPE Common Warrants”) at a combined offering price of \$2.285. The Company received net cash proceeds of approximately \$1.5 million from the 2023 PIPE after deducting underwriters’ discounts and offering expenses of approximately \$0.3 million. The May 2023 Pre-Funded Warrants were exercised fully during the second quarter of 2023.

On March 20, 2023, the Company closed a public offering (the “March 2023 Offering”) priced at the market under Nasdaq rules, in which it sold an aggregate of (i) 85,000 shares of Common Stock, (ii) pre-funded warrants (the “March 2023 Pre-Funded Warrants”) to purchase up to an aggregate of 1,533,123 shares of Common Stock with an exercise price of \$0.0001 per share, (iii) Series A warrants (the “March 2023 Series A Common Warrants”) to purchase up to an aggregate of 1,618,123 shares of Common Stock, and (iv) Series B warrants (the “March 2023 Series B Common Warrants” and collectively with the March 2023 Series A Common Warrants, the “March 2023 Offering Warrants”) to purchase up to an aggregate of 1,618,123 shares of Common Stock. The March 2023 Offering Warrants had an exercise price of \$2.82 per share. The Company received net cash proceeds of approximately \$4.2 million after deducting the underwriter’s discounts and offering expenses of approximately \$0.8 million. The March 2023 Pre-Funded Warrants were fully exercised during the first quarter of 2023, and the March 2023 Offering Warrants were exercised as part of the Inducement in November 2023.

On April 25, 2022, the Company closed a private placement (the “April 2022 PIPE”), in which it sold 56,161 shares of its Common Stock together with 179,687 pre-funded warrants to purchase up to an aggregate of 179,687 shares of Common Stock with an exercise price of \$0.0001 per share (the “April 2022 PIPE Pre-Funded Warrants”), and 235,849 warrants to purchase up to an aggregate of 235,849 shares of Common Stock with an exercise price of \$21.20 per share (the “April 2022 PIPE Common Warrants”) at a combined offering price of \$21.20. The Company received net cash proceeds of approximately \$4.3 million from the April 2022 PIPE after deducting underwriters’ discounts and offering expenses of approximately \$0.7 million. The April 2022 PIPE Pre-Funded Warrants were fully exercised during 2022, and the April 2022 PIPE Common Warrants were exercised as part of the Inducement in November 2023.

### Preferred Stock

While the Company has 10,000,000 shares of preferred stock authorized with a par value of \$0.0001, no shares of preferred stock are outstanding as of December 31, 2023, or 2022, respectively.

### Abeyance Shares

Related to the November 2023 Inducement, the Holder left 2,730,000 shares in abeyance at the Company’s transfer agent to be delivered to the Holder at their request. The 2,730,000 shares held in abeyance were delivered to the Holder on January 8, 2024. Accordingly, as of December 31, 2023, 2,730,000 shares were held in abeyance, have not been issued and are not outstanding.

### Warrants

#### Summary of Warrants Outstanding

The table below lists outstanding warrants for the dates presented. The warrants outstanding at December 31, 2023 are exercisable into 8,358,697 shares of common stock which had a fair value of \$0.61 per share, based on the closing trading price on that day. The aggregate intrinsic value of warrants outstanding as of December 31, 2023, is calculated as the difference between the exercise price of the warrants and the closing market price of the Company’s Common Stock on that date. The intrinsic value of warrants outstanding as of December 31, 2023, was zero due to the warrants’ exercise prices above market value.

Description	Quantity of Warrants Outstanding as of December 31,		Exercise Price	Expiration Date
	2023	2022		
Pre-IPO Series 1a Warrants .....	4,321	4,321	\$ 328.00	11/15/2026
Pre-IPO Class B Common Warrants.....	4,077	4,077	91.84	12/31/2024
IPO Warrants .....	184,820	184,820	112.00	8/17/2026
IPO Underwriter Warrants.....	8,035	8,035	128.80	8/17/2026
April 2022 PIPE Common Warrants .....	-	235,849	2.82	3/20/2028
March 2023 Series A Common Warrants .....	-	-	2.82	3/20/2028
March 2023 Series B Common Warrants .....	-	-	2.82	7/20/2025
March 2023 Offering Placement Agent Warrants .....	113,269	-	3.8625	3/16/2028
May 2023 PIPE Common Warrants .....	800,877	-	2.16	11/27/2028
May 2023 PIPE Placement Agent Warrants .....	56,061	-	2.8563	5/23/2028
November 2023 Series A Common Warrants.....	3,707,944	-	0.6511	11/20/2028
November 2023 Series B Common Warrants.....	3,236,246	-	0.6511	3/20/2026
November 2023 Offering Placement Agent Warrants .....	243,047	-	0.8139	11/20/2028
Total warrants outstanding.....	8,358,697	437,102		

### *Warrant Inducement*

In November 2023, the Company completed the Inducement, in which a Holder agreed to exercise 3,472,095 common warrants to purchase Common Stock at a reduced exercise price of \$0.6511 per share in exchange for the 3,707,944 November 2023 Series A Common Warrants and 3,236,246 November 2023 Series B Common Warrants with an exercise price of \$0.6511 per share. The New Warrants are exercisable subject to stockholder approval, which the Company received at a stockholder meeting on January 12, 2024. The Inducement, which resulted in the lowering of the exercise price of the Existing Warrants and the issuance of the New Warrants, is considered a modification of the Existing Warrants under the guidance of ASU 2021-04. The modification is consistent with the equity issuance classification under that guidance as the reason for the modification was to induce the holders of the Existing Warrants to cash exercise their warrants, which raised equity capital and generated net proceeds for the Company of approximately \$2.0 million. As the Existing Warrants and the New Warrants were classified as equity instruments before and after the exchange, and as the exchange is directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$3.0 million as an equity issuance cost.

### *Warrant Modification*

In connection with the March 2023 Offering, the Company agreed to amend the terms of the April 2022 PIPE Common Warrants, which were held by the purchaser in the March 2023 Offering. The exercise price of the April 2022 PIPE Common Warrants was reduced from \$21.20 to \$2.82 per share upon closing of the March 2023 Offering. The original expiration date of the April 2022 PIPE Common Warrants was May 12, 2027, which was extended to five years after the closing of the March 2023 Offering, or March 20, 2028. The modification of the April 2022 PIPE Common Warrants was accounted for as a modification of equity-linked instruments. In accordance with ASU 2021-04, as the warrants were classified as equity instruments before and after the modification, and as the modification was directly attributable to an equity offering, the Company recognized the effect of the modification of approximately \$0.1 million as an equity issuance cost.

## **5. Equity Incentive Plan**

Under the Company's 2021 Omnibus Equity Incentive Plan (the "2021 Plan"), as amended, the Company may grant options to purchase shares of Common Stock, restricted stock awards, performance stock awards, incentive bonus awards, other cash-based awards or directly issue shares of Common Stock to employees, directors, and consultants of the Company. Effective January 1, 2022, an evergreen provision contained in the Company's 2021 Plan increased the total number of shares of common shares issuable under the 2021 Plan in an amount equal to one percent of the Company's common shares outstanding as of December 31, 2021. This evergreen provision resulted in an additional 7,701 and 5,205 shares of Common Stock issuable pursuant to the 2021 Plan as of January 1, 2023, and 2022, respectively. At the Company's 2023 Annual Meeting of Stockholders held on August 3, 2023, the Company's stockholders approved an amendment to the Company's 2021 Plan to increase the number of shares of common stock authorized for issuance thereunder by 513,150 shares to 629,069 shares.

Stock awards may be granted at an exercise price per share of not less than 100% of the fair market value at the date of grant. Stock awards granted are exercisable over a maximum term of 10 years from the date of grant and generally vest over a period of four years for employees and one year for directors of the Company's Board and consultants.

As of December 31, 2023, there remain 513,277 shares reserved for issuance under the 2021 Plan, as amended. See Note 9 for a discussion of cancellation of stock options during the first quarter of 2024.

### **Fair Value Measurement**

The Company uses the Black-Scholes option valuation model, which requires the use of highly subjective assumptions, to determine the fair value of stock-based awards. The fair value of each employee stock option is estimated on the grant date under the fair value method using the Black-Scholes model. The estimated fair value of each stock option is then expensed over the requisite service period, which is generally the vesting period. The assumptions and estimates that the Company uses in the Black-Scholes model are as follows:

- *Fair Value of Common Stock.* The estimated fair value of the Common Stock underlying the Company's stock option plan was determined by management by considering various factors as discussed below. All options to purchase shares of the Company's Common Stock are intended to be exercisable at a price per share not less than the per-share fair value of the Company's Common Stock underlying those options on the date of grant. The fair value of Common Stock is measured as the Company's closing price of Common Stock on the date of grant.
- *Risk-Free Interest Rate.* The Company bases the risk-free interest rate used in the Black-Scholes valuation model on the implied yield available on U.S. Treasury zero-coupon issues with a term equivalent to that of the expected term of the options.
- *Expected Term.* The expected term represents the period that the Company's stock-based awards are expected to be outstanding, which is calculated using the simplified method, as the Company has insufficient historical information to provide a basis for an estimate. The simplified method calculates the expected term as the average of the vesting term plus the contractual life of the options.

- *Volatility.* The Company determines the price volatility based on the historical volatilities of industry peers as it has limited trading history for its Common Stock price. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics, including clinical trials progress and therapeutic indications.
- *Dividend Yield.* The expected dividend assumption is based on the Company's current expectations about its anticipated dividend policy. To date, the Company has not declared any dividends to common shareholders and, therefore, the Company has used an expected dividend yield of zero.

The following table presents the weighted-average assumptions used for stock options granted during the following periods:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Grant date fair value .....	\$ 4.23	\$ 23.36
Risk-free interest rate.....	3.9%	1.5%
Dividend yield .....	0.00%	0.00%
Expected life in years.....	6.1	5.4
Expected volatility .....	112%	123%

### ***Stock-based Compensation Expense***

In general, stock-based compensation is allocated to research and development expense or general and administrative expense according to the classification of cash compensation paid to the employee, director, or consultant to whom the stock award was granted.

In December 2021, the Board authorized a stock option grant in lieu of a cash bonus for the Company's Chairman and Chief Executive Officer. The stock-based compensation expense of \$0.4 million related to the stock option grant was booked to the fiscal year ended December 31, 2021; however, the impact to additional paid-in capital was not booked until the first quarter of 2022, when the stock option award was granted.

The following table summarizes the total stock-based compensation expense related to stock options and RSUs included in the Company's statements of operations:

	<b>Year Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Research and development .....	\$ 193,700	\$ 218,324
General and administrative .....	328,382	712,001
	<u>\$ 522,082</u>	<u>\$ 930,325</u>

### ***Stock Option Award Activity***

A summary of the Company's 2021 Plan stock option activity is as follows:

	<b>Number of Options Outstanding</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Remaining Contractual Term (in Years)</b>
Balance at December 31, 2022 .....	65,983	\$ 60.32	8.2
Options granted.....	36,091	4.96	9.0
Options exercised.....	-	-	-
Options cancelled.....	-	-	-
Balance at December 31, 2023 .....	<u>102,074</u>	<u>\$ 40.77</u>	<u>7.8</u>
Options exercisable at December 31, 2023.....	53,413	\$ 63.51	7.3

The aggregate intrinsic value of options exercisable as of December 31, 2023, is calculated as the difference between the exercise price of the underlying options and the closing market price of the Company's Common Stock on that date, which was \$0.61 per share. The intrinsic value of options outstanding and exercisable as of December 31, 2023, was zero.

As of December 31, 2023, total unrecognized compensation cost related to stock options was approximately \$0.6 million and the weighted average period over which this cost is expected to be recognized is 1.8 years.



## ***Restricted Stock Units***

During the year ended December 31, 2022, the Company issued 219,634 restricted stock units, or RSUs, as partial compensation to certain members of the Board for their services during 2022. The Company recognized stock-based compensation expense of approximately \$0.2 million for the year ended December 31, 2022, related to the RSU awards. There were no RSUs issued or outstanding for the year ended December 31, 2023, and there is no unrecognized compensation expense related to RSUs as of December 31, 2023.

## **6. 401(k) Employee Benefit Plan**

The Company sponsors a 401(k) savings plan for all eligible employees. The Company may make discretionary matching contributions to the plan to be allocated to employee accounts based upon employee deferrals and compensation. To date, the Company has not made any matching contributions to the savings plan.

## **7. Commitments and Contingencies**

### ***Clinical Trials***

During the fourth quarter of 2023, the Company initiated a Phase 3 clinical trial, STAR-1, which is expected to report data in 2025. The total contract amount with the clinical research organization is approximately \$6.9 million, which will extend from the fourth quarter of 2023 to the first half of 2025, which has a 30-day termination notice period.

### ***Supplier Agreement***

As a result of Russia's invasion of Ukraine, the United States, the United Kingdom, and the European Union governments, among others, have developed coordinated sanctions and export-control measure packages against Russian individuals and entities. The Company is currently a party to an exclusive supply agreement for the supply of the *Spongilla* raw material used in DMT310 and DMT410. The counterparty to this supply agreement is a Russian entity. The imposition of enhanced export controls and economic sanctions on transactions with Russia and Russian entities by the United States, the United Kingdom, and/or the European Union could prevent the Company from performing under this existing contract or any future contract it may enter or may prevent the Company from remitting payment for raw material purchased from the Company's supplier. The Company has received multiple shipments of raw material from its supplier subsequent to the implementation of export controls and sanctions, containing additional quantities of *Spongilla* raw material, which will provide the Company with sufficient quantities of *Spongilla* to initiate and complete two Phase 3 studies in moderate-to-severe acne and support filing a new drug application for DMT310 in acne upon the successful completion of two Phase 3 studies. Depending on the extent and breadth of new sanctions or export controls that may be imposed against Russia, otherwise or as a result of the impact of the war in Ukraine, it is possible that the Company's ability to obtain additional supply of the *Spongilla* raw material used in DMT310 and DMT410 could be negatively impacted, which could adversely affect its business, results of operations, and financial condition.

### ***License Agreements***

On March 31, 2017, the Company entered into a license agreement, as amended (the "License Agreement") with Villani, Inc. whereby Villani has granted the Company an exclusive, sub-licensable, royalty-bearing license (the "License") under the Licensed Patents (as defined in the License Agreement), to formulate, develop, seek regulatory approval for, make or sell products that contain *Spongilla lacustris* (alone or in combination with other active or inactive ingredients) for the treatment of diseases, disorders and conditions of the skin, including but not limited to acne, rosacea, psoriasis, atopic dermatitis, seborrheic dermatitis, actinic keratosis and eczema that were developed using certain licensed know-how ("Licensed Products"). The Company is responsible for the development (including manufacturing, packaging, non-clinical studies, clinical trials and obtaining regulatory approval and commercialization (including marketing, promotion, distribution, etc.)) for all Licensed Products. The original License Agreement was amended in 2019, and pursuant to the amended License Agreement, the Company was required to make future milestone payments to Villani in an aggregate amount of up to \$20.25 million upon the achievement of specified development and sales milestones, payable in cash or in equity, at the option of Villani, as well as single-digit royalty payments on net sales. On July 30, 2021, the Company further amended the License Agreement in the Second Amendment to the License and Settlement Agreement (the "Second Amendment"). Pursuant to the Second Amendment, the Company is required to make future milestone payments to Villani in an aggregate amount of up to \$40.5 million upon the achievement of specified development and sales milestones, payable in cash or in equity, at the option of Villani, as well as single-digit royalty payments on net sales. The Second Amendment includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies, and warranties. As of December 31, 2023, the Company evaluated the likelihood of the Company achieving the specified milestones and determined that the likelihood is not yet probable and as such no accrual of these payments is required as of December 31, 2023.

## Legal Proceedings

In the normal course of business, the Company may be involved in legal proceedings or threatened legal proceedings. The Company is not a party to any legal proceedings or aware of any threatened legal proceedings which are expected to have a material adverse effect on its financial condition, results of operations or liquidity.

## 8. Income Taxes

Dermata operates as a corporation, and accordingly, the Company is taxable at the entity level for U.S. federal and state tax purposes. A reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate is as follows:

<i>(in thousands)</i>	<b>Years Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
U.S. Federal statutory income tax rate.....	\$ (1,637)	\$ (2,018)
Permanent and other differences.....	55	68
Stock-based compensation expense.....	86	89
Research and development credits.....	(259)	(219)
Valuation allowance.....	1,755	2,080
Total tax provision.....	\$ -	\$ -

Significant components of the Company's net deferred tax assets are as follows:

<i>(in thousands)</i>	<b>As of December 31,</b>	
	<b>2023</b>	<b>2022</b>
Net operating loss carryforwards.....	\$ 2,980	\$ 1,927
Research and development carryforwards.....	596	337
Capitalized research and development.....	1,508	1,068
Stock-based compensation expense.....	246	311
Intangible assets.....	5	49
Other, net.....	129	17
Gross deferred tax assets.....	5,464	3,709
Less: valuation allowance.....	(5,464)	(3,709)
Total deferred tax assets.....	\$ -	\$ -

The Company has established a full valuation allowance for its deferred tax assets due to uncertainties that preclude it from determining that it is more likely than not that the Company will be able to generate sufficient taxable income to realize such assets. Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to utilize the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred since inception.

Such objective evidence limits the ability to consider other subjective evidence such as the Company's projections for future growth. Based on this evaluation, as of December 31, 2023, and 2022, a valuation allowance of \$5.5 million and \$3.7 million, respectively, or an increase of \$1.8 million, has been recorded against all of the Company's net deferred tax assets, as the Company has determined that none of the Company's balance of deferred tax assets is more likely than not to be realized. The amount of deferred tax assets considered realizable, however, could be adjusted in the future if objective negative evidence in the form of cumulative losses is no longer present and additional weight may be given to subjective evidence, such as estimates of future taxable income during carryforward periods and the Company's projections for growth.

As of December 31, 2023, the Company had federal net operating loss carryforwards, or NOLs, available of \$14.2 million before consideration limitations under Section 382 of the Internal Revenue Code of 1986, or Section 382 of the Code, as further described below. The NOL will carryforward indefinitely and be available to offset up to 80% of future taxable income each year. The Company had state NOL carryforwards available of \$5.0 million as of December 31, 2023. The state NOL may be used to offset future taxable income and will begin to expire in 2041, unless previously utilized.

As of December 31, 2023, the Company had federal and state research and development tax credit carryforwards available of \$0.7 million and \$0.1 million, respectively. The federal credit carryforwards will begin to expire in 2041, unless previously utilized. The state research and development credits carry forward indefinitely.

Utilization of the Company’s NOL and research and development credit carryforwards may be subject to substantial annual limitations in the event a cumulative ownership change has occurred, or that occur in the future, as required by Section 382 of the Code. In general, an ownership change, as defined by the Code, results from a transaction, or series of transactions over a three-year period, resulting in an ownership change of more than 50% of the outstanding common stock of a company by certain stockholders or public groups. Such an ownership change may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed such an ownership change analysis pursuant to Section 382 of the Code and therefore has established a full valuation allowance as the realization of such deferred tax assets has not met the more likely than not threshold requirement. If ownership changes have occurred or occurs in the future, the amount of remaining tax attribute carryforwards available to offset taxable income and income tax expense in future years may be restricted or eliminated. If eliminated, the related asset would be removed from deferred tax assets with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company’s effective tax rate.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination by the tax authorities. The Company does not expect that there will be a significant change in the unrecognized tax benefits over the next twelve months. Further, due to the existence of the valuation allowance, future changes in the Company’s unrecognized tax benefits will not impact the effective tax rate.

The following table summarizes the activity related to the Company’s gross unrecognized tax benefits at the beginning and end of the periods presented:

<i>(in thousands)</i>	<b>Years Ended December 31,</b>	
	<b>2023</b>	<b>2022</b>
Beginning balance of unrecognized tax benefits .....	\$ 557	\$ 41
Additions based on tax positions related to the current year .....	64	81
Additions for tax positions of prior years .....	24	435
Reductions for tax positions in prior years .....	-	-
Ending balance of unrecognized tax benefits .....	<u>\$ 645</u>	<u>\$ 557</u>

The unrecognized tax benefit amounts are reflected in the determination of the Company’s deferred tax assets. If recognized, none of these amounts would affect the Company’s effective tax rate, since it would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

The Company’s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on the Company’s balance sheets as of December 31, 2023, or 2022 and has not recognized interest and/or penalties in the statements of operations for the years ended December 31, 2023, and 2022.

The Company is subject to taxation in the United States and various states. The Company is subject to examination by tax authorities in those jurisdictions from inception.

## **9. Subsequent Event**

In January 2024, the Company granted 410,000 stock option awards to employees of the Company, subject to four-year vesting, with an exercise price of \$0.6099.

In January 2024, the Board unanimously approved to provide employees and directors of the Company the opportunity to cancel outstanding, out of the money, stock options without consideration, in accordance with an option cancellation agreement. Accordingly, 101,465 of the 102,074 stock options outstanding as of December 31, 2023, were cancelled in February 2024.

## SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**DERMATA THERAPEUTICS, INC.**  
(Registrant)

Date: March 21, 2024

\_\_\_\_\_  
/s/ Gerald T. Proehl  
Gerald T. Proehl  
*Chief Executive Officer*  
(Principal Executive Officer)

Date: March 21, 2024

\_\_\_\_\_  
/s/ Kyri K. Van Hoose  
Kyri K. Van Hoose  
*Chief Financial Officer*  
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
_____ /s/ Gerald T. Proehl Gerald T. Proehl	President, Chief Executive Officer, Chairman (Principal Executive Officer)	March 21, 2024
_____ /s/ Kyri K. Van Hoose Kyri K. Van Hoose	Chief Financial Officer (Principal Financial and Accounting Officer)	March 21, 2024
_____ /s/ David Hale David Hale	Lead Director	March 21, 2024
_____ /s/ Wendell Wierenga, Ph.D. Wendell Wierenga, Ph.D.	Director	March 21, 2024
_____ /s/ Mary Fisher Mary Fisher	Director	March 21, 2024
_____ /s/ Andrew Sandler, M.D. Andrew Sandler, M.D.	Director	March 21, 2024
_____ /s/ Steven J. Mento, Ph.D. Steven J. Mento, Ph.D.	Director	March 21, 2024
_____ /s/ Kathleen Scott Kathleen Scott	Director	March 21, 2024
_____ /s/ Brittany Bradrick Brittany Bradrick	Director	March 21, 2024