# **Dermata** Therapeutics

Transforming topical treatment of the skin

Corporate Presentation July 2021



### CAUTIONARY NOTE ON FORWARD LOOKING STATEMENTS AND DISCLAIMERS

This presentation and the accompanying oral presentation contain "forward-looking" statements that are based on our management's beliefs and assumptions and on information currently available to management. Forward-looking statements include all statements other than statements of historical fact contained in this presentation, including information concerning our current and future financial performance, business plans and objectives, current and future clinical and preclinical development activities, timing of announcements, updates and results of our clinical trials and related data, our ability to obtain and maintain regulatory approval, the potential therapendic commic value of our product candidates, competitive position, industry environment and potential market opportunities. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar explaces ons are intended to identify forward looking statements.

Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors including, but not limited to, those related to the success, cost and timing of our product candidate development activities and ongoing and planned clinical trials; our plans to develop and commercialize targeted therapeutics, including our lead product candidates DMT410; the progress of patient enrollment and dosing in our clinical trials; the ability of our product candidates to achieve applicable endpoints in the clinical trials; the safety profile of our product candidates or achieve applicable endpoints in the product candidates. The trials of support a marketing application, as well as the timing of these events; our ability to obtain funding for our operations, development and commercialization of our product candidates; the trials of support a marketing application, as well as the timing of these events; our ability to obtain and maintain regulatory approvals; the rate and degree of market acceptance and clinical utility of our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential or amarkets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and growth potential of the markets for our product candidates; the size and grow

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. Moreover, we operate in a very competitive and rapidly changing environment, and new risks may emerge from time to time. It is not possible for our management to predict all risks, nor can we asses the impact of all factors on our business or the extent to which may factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking vents and circumstances discussed herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Although our management believes that the expectations reflected in our forward-looking statements are easonable, we cannot guarantee results, levels of activity, performance or events and circumstances descurd-looking statements will be achieved or occur. We undertake no obligation to publicly update any forward-looking statements, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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#### FREE WRITING PROSPECTUS

We have filed a registration statement on Form S-1 (including a preliminary prospectus) with the SEC for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the preliminary prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about our company and the offering. You may get these documents for free by visiting EDGAR on the SEC web site at http://www.sec.gov/. The preliminary prospectus supplement and the accompanying prospectus may also be obtained from the offices of Maxim Group LLC, Prospectus DepartMent, SOU Park Avenue, New York, NY, 10022; Telephone; (800) 724-7051; tenes: (800) 724-7051; ten

# **Corporate Highlights**



- Psoriasis: Phase 1b PoC Initiated Q1'21
- Potentially inhibits inflammatory cytokines IL-17A and IL-17F
   Anticipated once-weekly topical application
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- Rosacea: Phase 2 Planned H2'21
- Similar inflammatory lesions to acne
- Reduces IL-17, which facilitates neutrophil recruitment Acne: Phase 3 Planned – H2'22
- Potential anti-inflammatory effects
  - Reduced lipogenesis of sebocytes in-vitro

Hyperhidrosis: Phase 1b PoC Completed

- Topical delivery of botulinum toxin
- Reduction in sweat production
- Aesthetics: Phase 1b PoC Ongoing Results Q3'21
- Potentially broadens uses for botulinum toxin with topical applications
  - Potentially decreases need for injections

\*PoC: Proof of Concept

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DMT31

**DMT410** 

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## **Experienced Management Team**

- Gerry Proehl Founder, Chairman and President & CEO
   Former Founder, President & CEO, Santarus prior to sale to Salix Pharmaceuticals for \$2.6 billion, VP, Global
   Marketing, Hoechst Marion Roussel (now part of Sanofi)
- Tom Insley Chief Financial Officer
   Former CFO, SkinMedica; Former Managing Partner, PwC
- Chris Nardo, M.P.H., Ph.D. SVP, Development
   Former Senior Director, Clinical Development, Allergan; Former VP, Clinical Operations, Spectrum
   Pharmaceuticals
- Maria Bedoya Toro Munera, Ph.D. SVP, Regulatory Affairs & Quality Assurance Former SVP, Regulatory Affairs & Quality Assurance, Receptos and Santarus



### **Experienced Board**

Gerry Proehl – Founder, Chairman and President & CEO
 Former Founder, President & CEO, Santarus prior to sale to Salix Pharmaceuticals for \$2.6 billion; Former VP, Global Marketing, Hoechst
 Marion Roussel (now part of Sanofi)

David Hale – Founder and Lead Director
 Chairman & CEO, Hale Bioventures; Former Chairman, Santarus; Former Chairman, SkinMedica prior to sale to Allergan; Former Chairman, Former Chairman of Micromet prior to sale to Amgen

- Wendell Wierenga, Ph.D. Director
   Former EVP, R&D, Santarus; Former EVP, R&D, Ambit Biosciences and Neurocrine Biosciences; Former CEO, Syrrx (acquired by Takeda in 2005); Board of Directors, Cytokinetics and SRI International
- Kathleen Scott Director\*
   Current CFO of Neurana Pharmaceuticals; Former CFO of Recros Medica; Former partner at RA Capital Advisors
- Steven Mento, Ph.D. Director\*
   Current director of Histogen; Former CEO of Conatus Pharmaceuticals; Former CEO of Idun Pharmaceuticals
- Mary Fisher Director\*
   Current CEO and Chair at Colorscience; Former COO of Acorda Therapeutics; Current director of Sientra; Former director of ZELTIQ Aesthetics
- Andrew Sandler, M.D. Director\*
   Current CMO at Kiadis Pharma; Former SVP, Medical Affairs of Medivation

\*Will be elected to the board of directors effective immediately upon the effectiveness of IPO



# **Unique Pipeline Addressing Medical Dermatology & Aesthetics**



• The FDA allowed Dermata to proceed directly to a Phase 2 trial in acne due in part to historical human exposure

\*PoC: Proof of Concept



# **Addressable Markets**

### Acne

- o 50 million US patients have acne, with about 85% of teenagers experiencing some form of acne 1
- The prescription acne market saw about \$2.3 billion in sales in 2019<sup>2</sup>
- o There have been few novel topical treatments approved in recent years, with most new products being reformulations of old compounds

### Psoriasis

- Psoriasis affects about 2% of the world's population with about 80% being affected by plaque-type psoriasis <sup>3</sup>
- o Over 75% of patients with plaque-type psoriasis have mild disease, but they have few treatment options as most effective products are limited to moderate-to-severe disease<sup>3</sup>

### Rosacea

- There are about 16 million patients with rosacea in the US and topical prescription products did about \$374 million in sales in 2019<sup>2</sup>
- Like acne, there have been few novel topical treatment options approved in recent years and most have unwanted side effects

#### Aesthetics

- The American Society of Plastic Surgeons estimates that over 15.4 million cosmetic procedures were performed in 2016 of which 0 about 7 million used botulinum toxin<sup>5</sup>
- There has been a growing demand for aesthetic treatments, including from male patients 0

1 - Guideline for Care and Management of Acne

2 – IQVIA, Inc. Top Line Market and Sales Analysis from years 2015-2020

3 - Guideline for Care and Management of Psoriasis



4 - Markets and Markets Medical Aesthetics Market Report - Medical Aesthetic Market Product, dermata 4 - Markets and Markets integrated to 2025; 2020 End User, Global Forecast to 2025; 2020 5 - Global trends of Botulinum Toxin

# **Unique Natural Platform Technology**

- Complex freshwater sponge, *Spongilla lacustris* or *Spongilla*, harvested based on proprietary environmental conditions resulting in unique characteristics that are optimized for clinical applications
- Possesses multiple complementary chemical and mechanical properties to potentially enhance pharmaceutical treatment effect
- If approved, could be used as a standalone topical product or in a combination with macro molecules to enable intradermal delivery of drugs that typically must be injected





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# **Dual Mechanisms of Action**

### **Mechanical Component:**

Processed sponge contains a large number of uniquely sized siliceous spicules that exfoliate the dermal epithelium, thereby:

- o Creating microchannels into the dermis for delivery of chemical compounds
- o Opening closed comedones (blackheads) to increase oxygen
- o Promoting collagen production (which accelerates the skin's rejuvenation period)

### **Chemical Components:**

Contains multiple chemical compounds that have demonstrated in-vitro:

- Anti-inflammatory activity:
  - Reduction of C. acnes stimulated IL-8 production in NHEK
  - o inhibits IL-17A and IL-17F expression in human cell lines
- Anti-microbial activity against C. acnes
- o Effects on sebum production (inhibits lipogenesis in sebocytes)



# **Exclusivities and Intellectual Property Strategies**

### Raw Material Supply

- Signed an Exclusive Supply Agreement in February 2020 with one of the larger harvesters and suppliers of *Spongilla* raw material from a location with known commercial quantities available
- Supplier is a well-established company with over 18 years experience collecting and processing large quantities of raw material per year
- Supplier uses propriety harvesting information and licensed harvesters with boats and harvesting equipment

### • Chemistry, Manufacturing, Controls

Proprietary potency release assay

### Regulatory

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- Planning to seek new drug exclusivity 5 years
- No clear regulatory pathway for abbreviated NDAs (New Drug Applications) for approved botanical NDAs

### Commercialization of DMT310

 Option to seek Rx-to-OTC switch after 5 years, due to safety and market for DMT310 resulting in substantially larger potential sales opportunity

### Patent Protection

- DMT310 patent application pending:
   1 application pending
- DMT400 patent applications pending:
  - DMT410 + botulinum toxin (8 applications pending)
  - DMT420 + select biologics (1 application pending)
  - DMT430 + dermal fillers (1 application pending)



# **Development Timeline & Milestones**



\*PoC: Proof of Concept





**DMT310:** Once-weekly topical treatment



# **DMT310 Addresses Unmet Needs in Acne, Psoriasis and Rosacea**

### • Frequency of treatments

- Current topical treatments are onerous and require 1-2 applications per day, resulting in poor compliance and early discontinuation by patients
- We believe DMT310 (once-weekly application) could optimize compliance

### Time to treatment effect

- o Current topical treatments may take 6-8 weeks before a patient perceives a treatment effect
- DMT310 demonstrated statistically significant reductions in inflammatory and non-inflammatory lesions after one month with only 4 treatments, and continued reduction through week 12 versus placebo

### • Side effects/Tolerability

- For many patients using available products, side effects and tolerability issues, such as burning, stinging, and peeling, occur well before a treatment effect, resulting in poor overall compliance
- We believe DMT310's side effect/tolerability profile coupled with its comparatively fast onset of action could result in better compliance, leading to better outcomes and greater patient satisfaction



# **Application of DMT310**



Sponge 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>

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



# DMT310 Phase 2b Trial: Moderate-to-Severe Acne

### Study Design:

- o Double-Blind, Randomized, Placebo Controlled
- $\circ$  2 Groups DMT310 + H<sub>2</sub>O<sub>2</sub> and Placebo + H<sub>2</sub>O<sub>2</sub>
- o 181 patients enrolled at 14 sites in US with IGA baseline score of 3 or 4
- o 12 years and older
- o 12-week duration
- o Once-weekly application

### **Endpoints:**

- o Absolute Reduction in Inflammatory Lesion Counts
- o Absolute Reduction in Non-inflammatory Lesion Counts
- Investigator Global Assessment (IGA Scale = 0 to 4)
- Responder = 2-Grade Reduction AND 0 or 1

\*Same three primary endpoints required by FDA for Phase 3 studies

### Timing:

o Study complete



# Phase 2b Results: Reduction in Inflammatory Acne Lesions



# Phase 2b Results: Non-Inflammatory Acne Lesions



# Phase 2b Results: Investigator Global Assessment



# Phase 2b Results: Treatment Emergent Adverse Events

	DMT310 (N=91) N (%)	Placebo (N=90) N (%)
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)





# Phase 2b Results: Local Tolerability

# DMT310 Phase 1b Trial: Mild-to-Moderate Psoriasis (Ongoing)

### Study Design:

- Phase 1b Proof-of-Concept, open label study
- $\circ$  DMT310 + H<sub>2</sub>O<sub>2</sub>
- o 30 patients enrolled at 3 sites in US with psoriatic plaque covering 2% to 30% of BSA
- 18 years and older
- o 12-week duration
- o Once-weekly application

### **Endpoints:**

- o 6-point Investigator's Physician's Global Assessment (PGA) at the target lesion site at Week 12
- o 6-point Investigator's Psoriasis Area Severity Index (PASI) scale at the target lesion site at the Week 12
- o Pruritus Visual Analog Scale (VAS) assessment of the target lesion

### **Timing:**

- First patient, first visit March 2021
- Last patient, last visit H2 2021
- Top-line results H2 2021



# DMT310 Phase 2 Trial: Moderate-to-Severe Rosacea (Planned)

### Study Design:

- o Double-Blind, Randomized, Placebo Controlled
- $\circ$  2 Groups DMT310 + H<sub>2</sub>O<sub>2</sub> and Placebo + H<sub>2</sub>O<sub>2</sub>
- $\circ$  180 patients enrolled at 24 sites in US with IGA baseline score of 3 or 4
- 18 years and older
- 12-week duration
- o Once-weekly application

### **Endpoints:**

- Absolute Reduction in Inflammatory Lesion Counts
- Investigator Global Assessment (IGA Scale = 0 to 4)
  - Responder = 2-Grade Reduction AND 0 or 1

### Timing:

- First patient, first visit H2 2021
- Last patient, last visit H2 2022
- Top-line results H2 2022





# **DMT410:** enabling topical application of botulinum toxin



# **DMT410's Combination Regimen for Botulinum Toxin**

DMT410 is a combination treatment regimen that uses sponge technology to allow for needle-free topical application of botulinum toxin, which customarily must be injected



# **Application of DMT410**

- 1. Sponge mixture is massaged into the treatment area to enhance spicule penetration and create microchannels
- 2. After 10-15 minutes the sponge mixture is removed
- Then botulinum toxin is expressed from a syringe in precise amounts onto the skin and massaged into the treatment area to take advantage of the newly created microchannels





# DMT410 Increases Potential Benefits of Botulinum Toxin vs Injections

### **Molecule Size**

- o Botulinum toxin molecules are between 400-900 kDa and are currently injected for clinical efficacy
- We believe DMT410 creates microchannels in the skin that are large enough to allow topical penetration of botulinum toxin into the dermis for targeted treatment

### **Increased Coverage**

- Currently botulinum toxin is injected into the muscle or intradermally, limiting the spread of the toxin to the area around the injection
- We believe that with the creation of a significant number of microchannels, the topical application of toxin can more easily deliver toxin to a larger surface area

### **Additional Uses**

- Certain aesthetic conditions, fine lines, pore size, luminosity, brightness, etc., that botulinum toxin has shown improvement, but difficulty targeting treatment with injections limits its commercial opportunity
- We believe DMT410's topical delivery allows the toxin to reach the layer of skin necessary for treatment of these aesthetic conditions

### **No Injections Necessary**

- o Current treatments with botulinum toxin, like hyperhidrosis, require 10-20 injections in each axilla that can be painful for patients
- o DMT410's topical application had acceptable tolerability in our recent hyperhidrosis clinical trial



# DMT410 Phase 1b Trial: Moderate-to-Severe Axillary Hyperhidrosis

### Study Design:

- o Open-label, 2-arm study
- $\circ$  2 Groups DMT410 + H<sub>2</sub>O<sub>2</sub> and DMT410 + H<sub>2</sub>O
- $\circ \qquad \text{10 patients enrolled at 1 site in US}$
- At least 18 years of age
- o DMT410: One application of sponge powder, followed by one topical application of BOTOX®
- o 4-week duration

### **Endpoints:**

- Percent of patients with ≥50% reduction in gravimetrically measured sweat production from baseline
- Percent of patients with gravimetric sweat production ≤ 50mg
- o Percent change in gravimetric sweat production

### Timing:

o Study complete



# **Phase 1b Results: Reduction in Sweat Production**

Endpoints at 4 weeks	DMT410 n=20*	
	Response Rate	
Decrease in gravimetric sweat production $\geq$ 50%	80%	
Gravimetric sweat production <50mg	85%	
Change in gravimetric sweat production	-75%	

\*Each patient contributed 2 axillae to the analysis; 1 axilla received DMT410+  $H_2O_2$  & 1 axilla received DMT410+  $H_2O_2$  on difference was observed between the two treatment arms



# DMT410 Phase 1b Trial: Facial Aesthetics (Ongoing)

### **Study Design:**

- Open-label, 1-arm study
- o 10 patients enrolled at 1 site in US
- One application of sponge mixture, followed by 1 topical application of BOTOX\*
- At least 18 years of age
- o Patients will be assessed at 4 weeks, 8 week, 12 weeks and 16 weeks post application

### **Endpoints:**

• Moderate to severe glabellar, lateral canthal, forehead lines, luminosity, brightness, pore size, sebum production, Global Aesthetic Improvement, laxity under the eye and fine lines under the eye

### Timing:

- First patient, first visit November 2020
- Last patient, last visit H1 2021
- Top-line results Q3 2021



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