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## **Commercial Dermatology Company with De-Risked, Blockbuster Phase 3 Asset MM36 (difamilast): Potential \$1 Billion Product for Atopic Dermatitis in U.S.**

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- **Robust commercial business focused in medical dermatology**
- **MM36 is a highly selective topical PDE4 for atopic dermatitis (AD)**
  - Medimetriks owns U.S. rights for all topical indications; MM36 was developed by Otsuka Pharmaceutical Co. Ltd.
  - Annual U.S. gross sales projected to exceed \$1 billion based on potential best-in-class product profile
    - Targeting >90% of the AD market represented by children and adults with mild to moderate disease
  - Successful Japanese Phase 3 trials announced March 2020 demonstrate class-leading efficacy, safety, tolerability and itch relief
  - Positive FDA Type C Meeting September 2020; Japanese Phase 3 data will support U.S. NDA
    - Preparing for one U.S. Pivotal Trial with 336 patients
  - U.S. launch anticipated in 2023; Patent protection through 2033

# Foundation for Growth

## 1 Robust Commercial Business

### Foundation for Expansion and Growth

- Portfolio of medical Dermatology brands sold through national sales force
- Commercial expertise in maximizing brand value in key medical dermatology markets
- Company infrastructure and commercial platform can be leveraged through acquisition of commercialized assets

## 2 Development Expertise & Lifecycle Management

### Development Capabilities Support Lifecycle Management Strategy

- Line extension development provides growth potential prior to MM36 launch
  - Example: Unique brand that will compete in high potency steroid market
- Achieved FDA approval of Xepi® (ozenoxacin) cream, a topical antibiotic for impetigo December 2017
  - Divested license rights for \$36 million to Cutanea Life Sciences
- Additional Authorized Generic opportunity for existing brands

## 3 MM36: Blockbuster Brand

### Potential Peak Gross Revenues >\$1 billion

- De-risked, Phase 3 topical, non-steroidal PDE4 inhibitor for mild-to-moderate AD
- Japanese Phase 3 trials in children and adults completed January 2020 demonstrate class-leading safety, efficacy, tolerability and rapid, sustained itch relief
  - Findings consistent with Phase 2 results across multiple demographics
- Over 19MM U.S. patients affected with AD; >90% of market experience mild-to-moderate symptoms

# Commercial Overview

- **Growing national field force**
  - Dedicated sales force in the highest potential medical dermatology markets
  - Wide breadth and depth across Dermatology and Podiatry
- **Commercial experts in creating, launching and maximizing brands**
  - Senior Management has long-standing relationships with Key Opinion Leaders & High Volume Prescribers
- **Core brand growth drivers**

Skin & Scalp Dermatoses		Acne & Rosacea		Onychodystrophy	
<b>Clodan</b>	(clobetasol propionate)	<b>Clindacin</b> <sup>®</sup>	(clindamycin phosphate)	<b>Genadur</b>	(hydrosoluble nail lacquer)
<b>Ketodan</b> <sup>®</sup>	(ketoconazole foam)	<b>Neuac</b> <sup>®</sup>	(clindamycin/benzoyl peroxide)	<b>Inflammatory Skin Conditions</b>	
NEO-SYNALAR <sup>®</sup>	(fluocinolone acetonide/neomycin)	<b>Sumadan</b> <sup>®</sup>	(sodium sulfacetamide/sulfur)	<b>NICADAN</b> <sup>®</sup>	(niacinamide)
SYNALAR <sup>®</sup>	(fluocinolone acetonide)				
<b>Tovet</b>	(clobetasol foam)				

# MM36: Novel Topical AD Treatment

- **Phase 3 topical, non-steroidal for atopic dermatitis (AD)**
  - Unique, potent PDE4 inhibitor highly selective for PDE4 subtype B, identified as an important therapeutic target to reduce inflammation
- **MM36 has potential to be a disruptive treatment in the large, underserved AD market**
  - Successful Japanese Phase 3 trials in children and adults announced March 2020 consistent with Phase 2 findings, demonstrating potential class-leading efficacy, safety, tolerability and itch relief
    - Superior to vehicle in improving signs of AD at 4 weeks as measured by IGA (primary endpoint) and EASI
    - Safe and well-tolerated, with no reported application site stinging or burning
    - Achieved significance in rapid itch reduction at 24 hours that was sustained through 4 weeks
      - In Phase 2 trials, achieved median time to itch relief in 5.76 hours
- **Summary and key next steps**
  - Composition of Matter patent through 2033
  - Successful EoP2 FDA Meeting October 2018 & FDA Type C Meeting September 2020
  - Pivotal US Phase 3 trial planned for 2021 & commercial launch projected 2023

