

# Innovation in Dermatology

**Dermatology Summit**

January 2018



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# Cassiopea Overview

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- Publicly traded on SIX - Cosmo Pharma holds 45.1%
- Innovative late stage pipeline of 4 dermatology NCE products
- Plan to establish full US organization after Winlevi® approval & partner in ROW after Phase 3 results
- Follow-on raise planned 2H 2018

# Innovative Late Stage Pipeline

| Product   | Pre-Clinical | Phase I | Phase II                    | Phase III | MA / Expected Launch | Next Catalyst   | Market Opportunity   |
|---|--------------|---------|-----------------------------|-----------|----------------------|---|--|
| <b>Winlevi®</b><br>ACNE<br>Anti-androgen<br>NCE <sup>(1)</sup>      |              |         |                             | H2 2017   | 4Q2019/<br>1Q2020    | H1 2018<br>(Ph 3 data)                                | <b>US only:</b><br>\$5bn <sup>(2)</sup>                                |
| <b>Breezula®</b><br>ALOPECIA<br>Anti-androgen<br>NCE <sup>(1)</sup> |              |         | POC completed<br>DR H2 2018 | 2019-2020 | 2021                 | H1 & 2 2018<br>(Ph II interim<br>and full DR<br>data) | \$1.9bn <sup>(3)</sup> (surgical)<br>\$600m <sup>(4)</sup><br>(drugs)  |
| <b>CB-06-01</b><br>ACNE<br>Antibiotic<br>NCE                        |              |         | POC completed<br>DR 2019    | 2020-2021 | 2022                 | H2 2019<br>(Ph II DR<br>data)                         | <b>US only:</b><br>US\$5bn <sup>(2)</sup>                              |
| <b>CB-06-02</b><br>HPV<br>Integrin activator<br>NCE                 |              |         | POC 2017<br>DR 2019         | 2020-2021 | 2022                 | H1 2018<br>(POC)                                      | <b>US only:</b><br>c.14m new<br>infections each<br>year <sup>(5)</sup> |

POC = Proof of Concept  
DR = Dose Ranging

- (1) Winlevi® and Breezula® are different formulations of the same NCE, for different indications.
- (2) Management estimates based on IMS Health, IMS SMART MVP Solutions. Comprised of USC3 Classification 37100 Acne Therapy, Prescription Only, plus antibiotics Doryx, Monodox, Solodyn and Tazorac – Manufacturing prices increased by 20%.
- (3) International Society of Hair Restoration Surgery. Note: 2012 survey figure.
- (4) EvaluatePharma.
- (5) Centers for Disease Control and Prevention.

# Cassiopea's Pipeline

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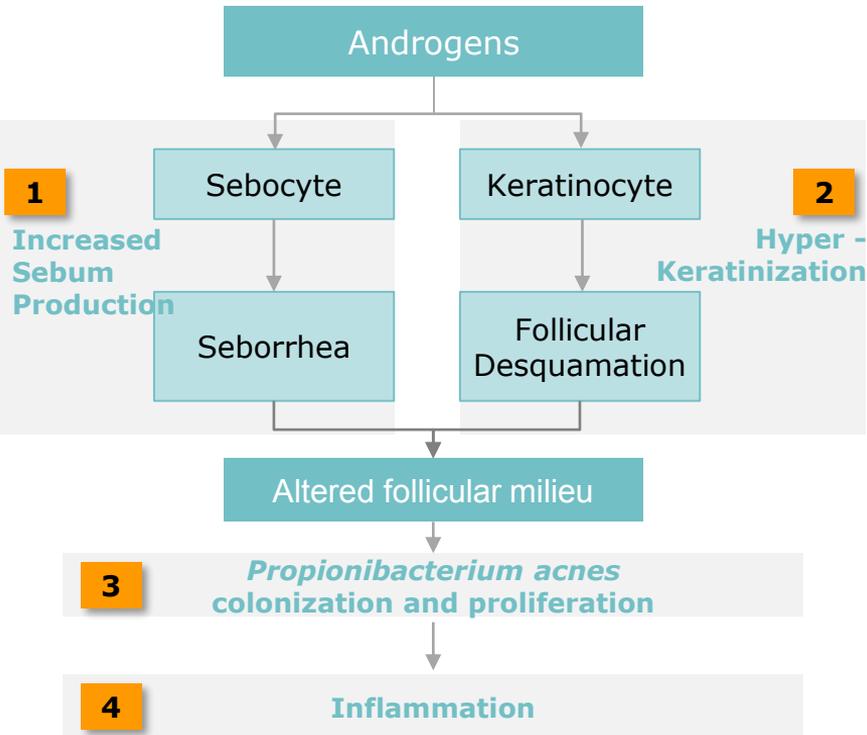
**Creating a New Class of Drugs for Acne:  
The First Topical Anti-Androgen**

# US \$5B Acne Market with Little Innovation

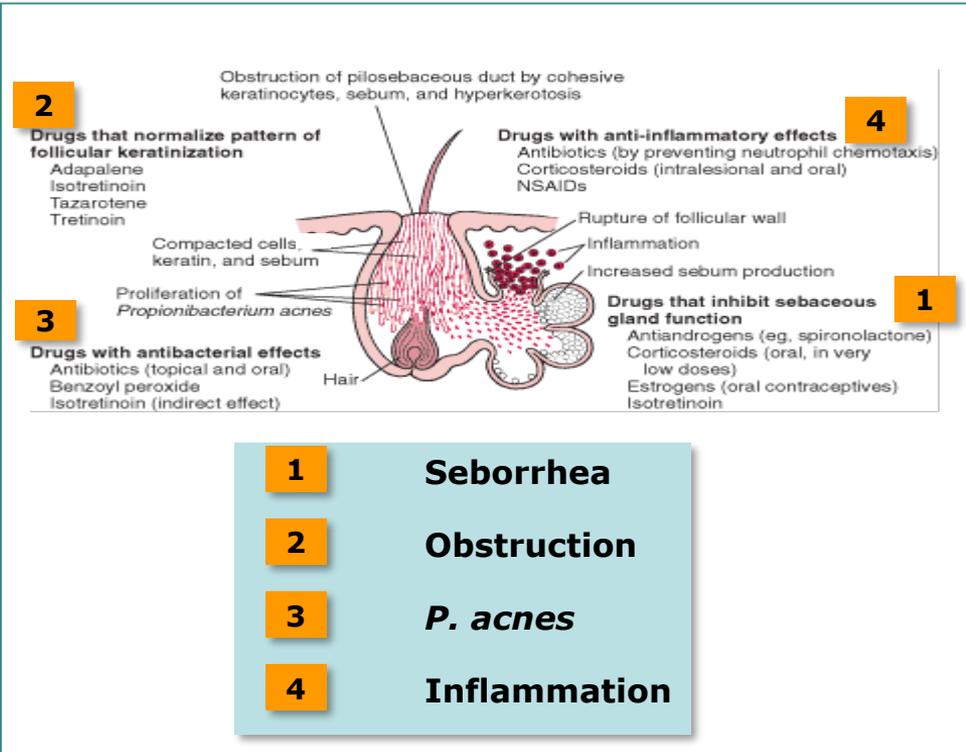
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- No NCE in the US market since mid 1990s (Differin and Tazorac launched '95 & '97)
- AAD acne treatment guidelines recommend targeting multiple pathogenic factors
- Derms generally co-prescribe 2-3 products with complementary MoAs
- Average branded topical products have annual revenues of \$200-400MM

## Acne Pathogenesis



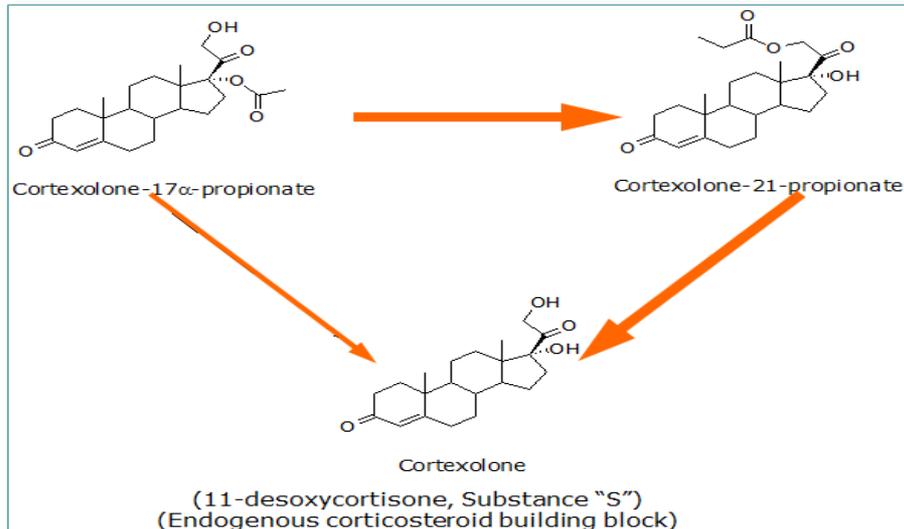
## Acne Therapy by Function<sup>(1)</sup>



## Mechanism of Action

- A topical anti-androgen would prevent the cascade of physiological events that leads to acne formation
- Winlevi™ displaces the androgen hormones from the androgen receptors located at the sebaceous gland and hair follicle
- This reduces sebum secretion and cell keratinization
- The follicle is not obstructed, preventing *p. acnes* colonization and subsequent inflammation
- Winlevi™ is metabolized to cortexolone, a physiological component of the body's endogenous pool of corticosteroids which exhibits anti-inflammatory effects

## Metabolic Pathway



- The final compound is cortexolone, whose safety profile is well known
- The aim is to achieve high local activity without systemic effects due to the *in vivo* hydrolysis pattern

## Phase III Program and Trial Design

- Special Protocol Assessment (SPA) approved by FDA in July 2015
- 1% cream vs placebo twice-daily for 12 weeks in subjects 9+ years with facial acne (IGA grades 3 & 4)
- FDA requires at least 1,000 patients treated for safety evaluation
- 2 pivotal trials (sites in both US + EU) with 700 patients/each
- 1 longterm open label safety trial: 300+ subjects 6 months, 100 subjects 12 months exposure
- NDA filing targeted for 4Q 2018/1Q 2019

## Study Endpoints

### Primary

- Proportion of subjects with IGA of 0 (clear) or 1 (almost clear) and at least a two-point reduction in IGA compared to baseline
- Absolute change from baseline in non-inflammatory lesion count at week 12
- Absolute change from baseline in inflammatory lesion count at week 12

### Secondary

- Absolute and % change from baseline in total lesion count at week 12
- Percentage change from baseline in non-inflammatory lesion count at week 12
- Percentage change from baseline in inflammatory lesion count at week 12

## Key Takeaways

- First topical anti-androgen, new chemical entity (NCE) with a new mechanism of action
- Clean safety profile in >1300 patients exposed to drug
- An active anti-inflammatory agent
- Has shown statistical significance in Phase II primary end-points (17% IGA improvement vs 6.7% and 35.7% TLC reduction vs 13%)
- Clinically superior & better tolerated than topical tretinoin based on Phase 2a trial results (22% IGA improvement vs 11.5%, 66% TLC reduction vs 52%)
- Has the potential to be used in combination with other drugs such as anti-infectives or retinoids either as complementary therapy or in a dual active product

# Cassiopea's Pipeline

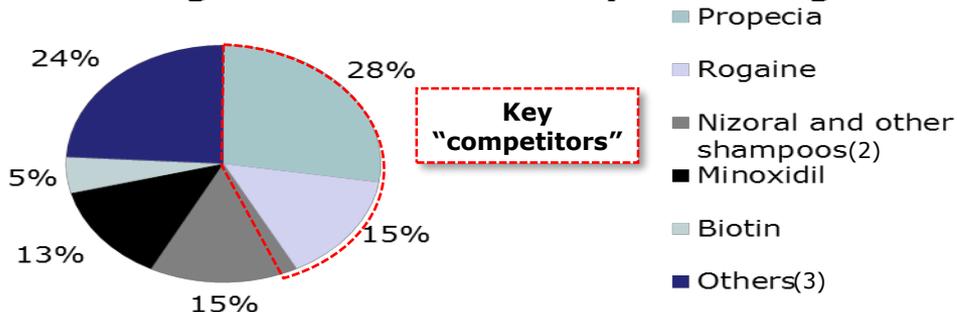
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**Breezula**

**A Novel Approach To Alopecia In Phase II**

## Competitive Landscape

### Non-Surgical Patient Prescription Usage<sup>(1)</sup>



#### Overview of key competitors:

- Rogaine (topical): shows a vasodilator effect, ensuring a better flow of nutrients to the papilla
- Propecia (oral): Shows anti-androgenic activity on follicle, however, serious side effects due to systemic hormonal imbalance. Not indicated for women

(1) International Society of Hair Restoration Surgery, 2014.

(2) Other shampoos include Nioxin, other special shampoos and Head & Shoulders.

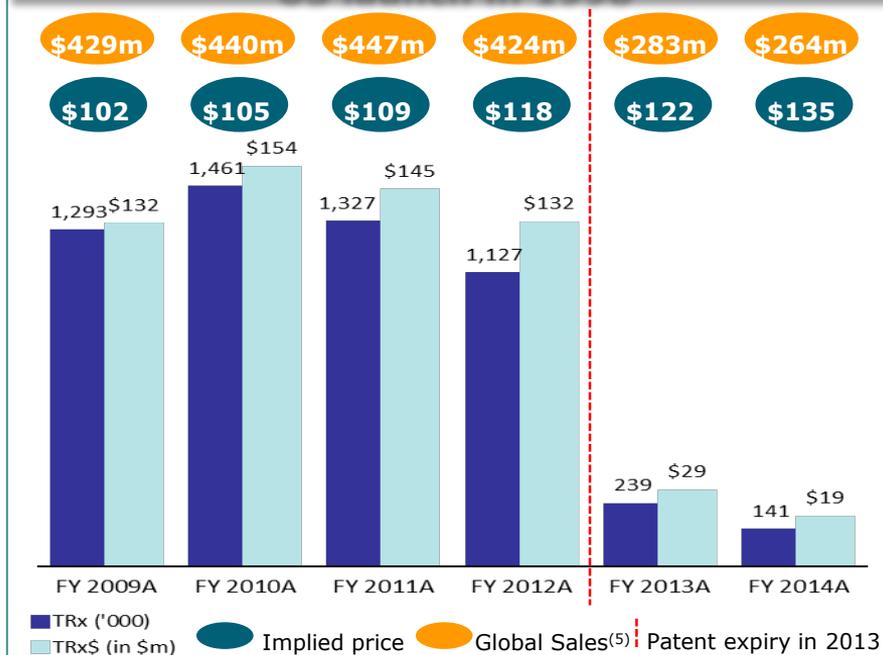
(3) Other treatments include Proscar, Compounded minoxidil, home and clinical low level laser therapy, herbs & vitamins and Avodart.

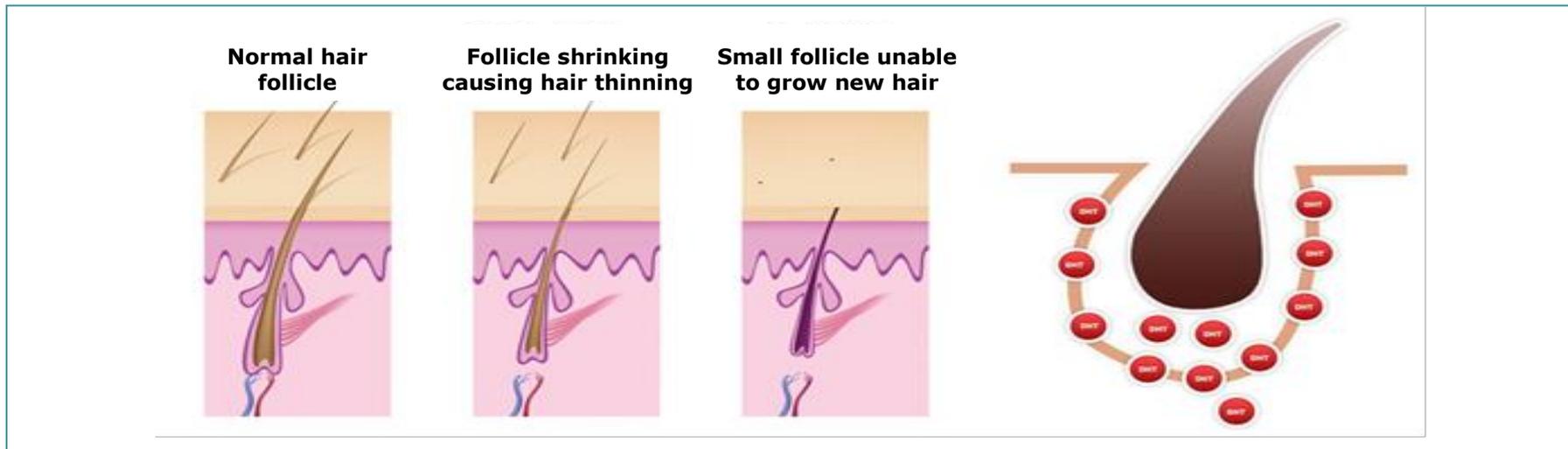
(4) IMS Health, IMS SMART MVP Solutions.

(5) EvaluatePharma.

## US Propecia Case Study<sup>(4)</sup>

### US launch in 1998





## Existing Treatments

**Propecia™**  
(finasteride)

- Shows anti-androgenic activity on follicle
- Serious side effects due to hormonal imbalance
- Not indicated for women

**Minoxidil®**

- Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla

## Breezula® A Novel Anti-androgen

**Breezula**

- Antagonizes DHT's negative effects on dermal papilla
- Reduces hair miniaturization
- Reduces dermal inflammation

DHT = Dihydrotestosterone

- Single 12-month study with interim analysis at 6 months
- Male subjects 18-55 years of age with mild to moderate AGA
- Co-Primary Endpoints:
  - Changes from Baseline in TAHC [in number of non-vellus hairs] at Month 12
  - The subject's evaluation of treatment benefit via the HGA question at Month 12
- 400 subjects, 80 per treatment arm
- 5 arms: 2.5%, 5.0%, 7.5%, vehicle BID and 7.5% QD
- CRO: Bioskin; 6 German sites and 1 Back up site
- First Patient In June 2017; Enrollment completed December 2017
- **Interim results due 2Q 2018 and Topline 12 month results due 4Q 2018**

## Key Takeaways

- Positive POC results in androgenic alopecia
- NCE<sup>(1)</sup> with topical anti-androgenic properties
- Very large opportunity in a significantly underexploited market with high unmet needs
- Chronic cash pay treatment
- All available alopecia treatments have a very low and transient (treatment-lasting) efficacy
- Can be used by men and women
- No significant systemic side effects like Propecia

## Mechanism of Action

- Breezula<sup>®</sup> acts at the cutaneous (scalp) level:
  - Antagonizes DHT's negative effects on dermal papilla
  - Reduces prostaglandin D2 production by human skin fibroblasts
  - Controls sebum secretion, reduces hair miniaturization, reduces dermal inflammation
- No exhibited interference with the hormonal (testosterone) profile of patients (libido and sexual behavior unaffected) in trials to date

(1) Winlevi<sup>®</sup> and Breezula<sup>®</sup> are different formulations of the same NCE, for different indications.

# Key Milestones

2017

- Q4 Complete enrollment in Winlevi Phase 3 Trials
- Q4 Complete enrollment in Breezula Dose Ranging Study
- Complete enrollment in CB06-02 Genital Warts POC Study

2018

- H1 Winlevi® Phase 3 Results
- H1 PoC data CB-06-02 HPV
- H1 Breezula Phase 2 Six Month Interim Results
- H2 Pre NDA Meeting Winlevi
- H2 Breezula Phase 2 DR 12 Month Results
- Q4 2018/Q1 2019 NDA filing Winlevi®

Note: Current timing is based on certain assumptions with regards to progression through clinical trials and may be subject to delays.

# Cassiopea SpA

| Information  | Contacts  |
|--|---|
| <ul style="list-style-type: none"><li>• Number of shares: 10,000,000</li><li>• Listing: SIX Swiss exchange, Main board</li><li>• ISIN: IT0005108359</li><li>• Ticker: SKIN</li></ul> | <ul style="list-style-type: none"><li>• Diana Harbort, CEO<br/><a href="mailto:dkharbort@cassiopea.com">dkharbort@cassiopea.com</a></li><li>• Luigi Moro, CSO<br/><a href="mailto:lmoro@cassiopea.com">lmoro@cassiopea.com</a></li><li>• Alessandro Mazzetti, CMO<br/><a href="mailto:amazetti@cassiopea.com">amazetti@cassiopea.com</a></li><li>• Chris Tanner, CFO<br/><a href="mailto:ctanner@cassiopea.com">ctanner@cassiopea.com</a></li></ul> |