

Creating Innovation in Dermatology

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Cassiopea Overview

- IPO 7/2015 was largest healthcare IPO on Swiss Stock Exchange SIX since 2000
 - Total shares issued 10 million, secondary placement of 5.18 million Cosmo's shares; Cosmo Pharmaceuticals NV continues holding 45.1%
- Exclusive focus on dermatology
- Innovative late stage pipeline of 4 products each containing NCE
- Experienced management team and low overhead through development phases
- Infrastructure and services provided by Cosmo Pharmaceuticals at arms' length
- Strategy:
 - Establish full scale organization in US after Winlevi® approval; Partner in Rest of World after Winlevi Phase 3 results
 - Financing targeted to last through publication of Winlevi Phase 3 results

Key Investment Highlights

Cassiopea is a clinical-stage specialty pharmaceutical company focusing on developing and commercializing innovative and differentiated medical dermatology products

1

Exclusive focus on dermatology: a large specialty-driven market with little innovation and with unmet medical needs in Acne and Alopecia

2

Four unencumbered products with novel mechanisms of action

- Winlevi™ – Lead NCE for Acne⁽¹⁾
- Breezula™ – NCE for Alopecia⁽¹⁾
- CB-06-01 – NCE Antibiotic for Acne
- CB-06-02 – NCE for HPV

3

Winlevi™ in Phase III⁽²⁾ with statistical significance shown in Phase II
Breezula™ successfully completed PoC phase II for Alopecia

4

Strong barriers to entry

5

Multiple catalysts and anticipated value inflection milestones on the horizon

- (1) Winlevi™ and Breezula™ are different formulations of the same NCE, for different indications.
(2) Special Protocol Assessment submitted to the FDA in April 2015.

A Balanced Pipeline

Product	Pre-Clinical	Phase I	Phase II	Phase III	MA / Expected Launch	Next Catalyst	Market Opportunity
Winlevi® ACNE Anti-androgen NCE ⁽¹⁾				H2 2017	2018/19	H2 2017 (Ph 3 data)	US only: \$5bn ⁽²⁾
Breezula® ALOPECIA Anti-androgen NCE ⁽¹⁾			POC completed H1 2016 DR H1 2018	2019-20	2021	H1 2018 (Ph II DR data)	\$1.9bn ⁽³⁾ (surgical) \$600m ⁽⁴⁾ (drugs)
CB-06-01 ACNE Antibiotic NCE			POC H1 2016 DR 2018	2019-20	2021	H1 2016 (POC)	US only: US\$5bn ⁽²⁾
CB-06-02 HPV Integrin activator NCE			POC H2 2016 DR 2018	2019-20	2021	H2 2016 (POC)	US only: c.14m new infections each year ⁽⁵⁾

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.

Income Statement and Statement of Comprehensive Income

EUR/1,000	2015	2014
Revenues	0	0
Cost of sales	(0)	(0)
Research and development costs	(7,597)	(3,858)
Selling, general and administrative costs	(760)	(61)
Net Operating expenses	(8,357)	(3,919)
<i>Operating Result</i>	<i>(8,357)</i>	<i>(3,919)</i>
Financial income	1,980	48
Financial expenses	(74)	(12)
<i>Profit Before Taxes</i>	<i>(6,451)</i>	<i>(3,883)</i>
Income tax expenses	(0)	1,107
<i>Profit For The Period</i>	<i>(6,451)</i>	<i>(2,776)</i>

Statement of Financial Position

EUR/1,000	31.12.15	31.12.14
Non current financial assets	0	1,444
Tangible and intangible assets	232	19
Other receivables and other current assets	1,491	1,520
Cash and cash equivalents	48,113	840
Total assets	49,836	3,823
Employee benefits	0	0
Other non-current liabilities	0	0
Other current liabilities	2,655	197
Total liabilities	2,655	197
Total equity	47,181	3,626
Total equity and liabilities	49,836	3,823

Cassiopea's Pipeline

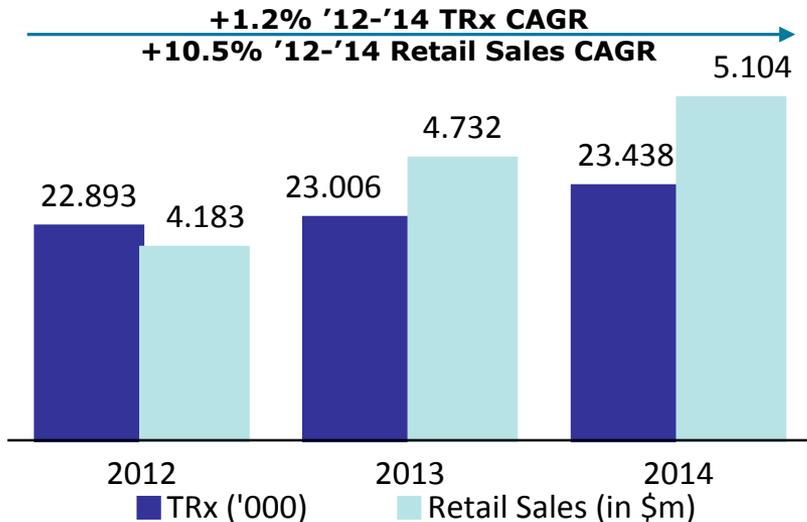


**Creating a New Class of Drugs for Acne:
The First Topical Anti-Androgen**

Acne market dynamics & opportunity

- Acne in the US affects 40m-50m people annually⁽¹⁾ – c.15% of the population⁽²⁾
 - 85% of all people aged 12-24 get acne⁽¹⁾
- In the US, ~24m prescriptions⁽³⁾ are written annually, mostly of older molecules as there are no new drugs

US Acne Market 2012-2014⁽³⁾



Dermatology market has had little innovation

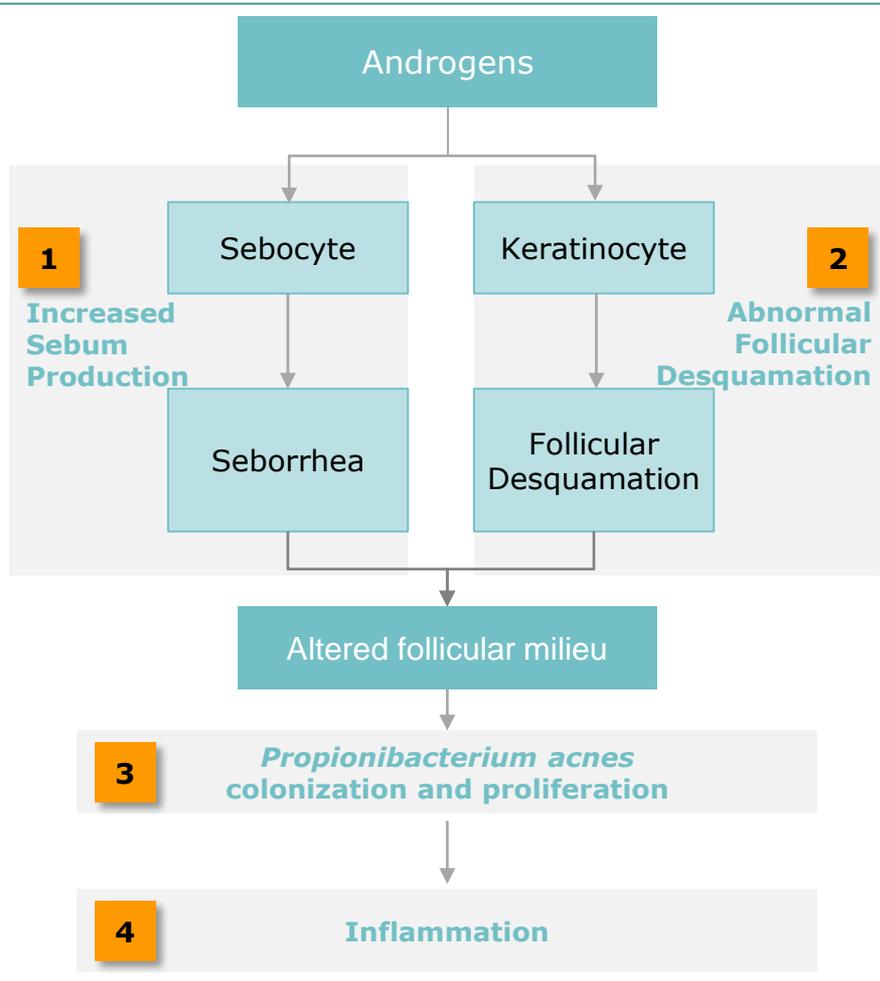
- No NCE in acne in the US market since the mid 1990s (Differin and Tazorac launched in '95 and '97)
- AAD guidelines recommend acne treatment should target as many pathogenic factors as possible
- Derms generally prescribe 2-3 products with complementary MoAs at the same time as the cause of acne is multifactorial
- Historically dermatology has had among the lowest product failure rate in clinical trials
- Acne medications in the US are subject to reimbursement
- Avg branded products have annual revenues of \$250-400MM
- Major topical prescription sellers are the anti-infectives EPIDUO and Aczone

(1) American Academy of Dermatology.

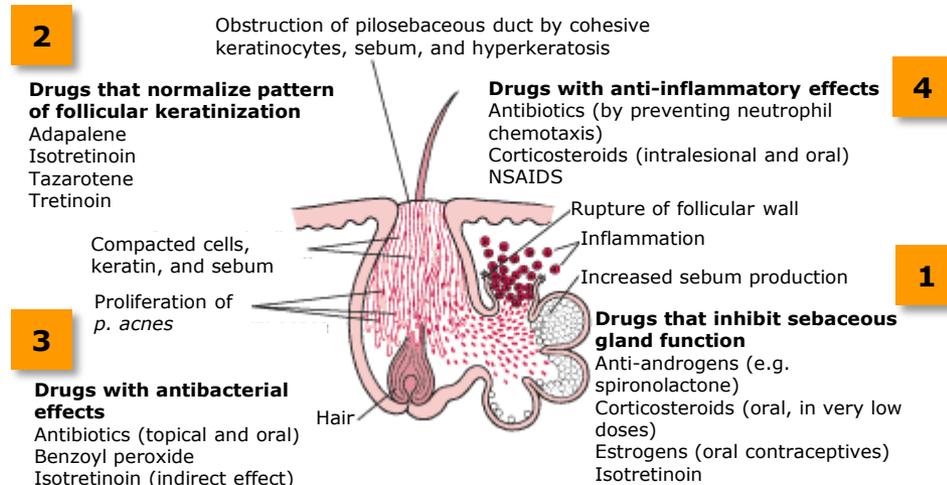
(2) United States Census Bureau, US 2013 population of 317m.

(3) Management analysis of data from IMS Health, IMS SMART MVP Solutions. TRx and Retail sales comprised of USC3 classification 37100 Acne Therapy, Prescription Only, in all specialties; selected anti-acne products Doryx, Monodox, Solodyn and Tazorac, in all specialties; TRx and Retail sales within the Dermatology specialty only for Doxycycline HYC DR, Doxycycline Hyclat, Doxycycline Monohyd, Minocycline HCl, Minocycline HCl ER, and Spironolactone.

The 4 pathways of Acne pathogenesis



Acne formation⁽¹⁾



- 1** Seborrhea
- 2** Obstruction
- 3** *P. acnes*
- 4** Inflammation



	Mild		Moderate		Severe
	Non-inflammatory	Inflammatory	Inflammatory	Inflammatory	Inflammatory
	Comedonal	Papular/pustular	Papular/pustular	Nodular	Nodular/conglobate
First choice	Topical retinoid	Topical retinoid + topical antimicrobial	Oral antibiotic + topical retinoid +/- BPO	Oral antibiotic + topical retinoid +/- BPO	Oral isotretinoin
Alternatives (males and females)	Azelaic acid or salicylic acid	Alt. topical antimicrobial agent + all. topical retinoid or azelaic acid	Alt. oral antibiotic + alt. topical retinoid +/- BPO	Oral isotretinoin or alt. oral antibiotic alt. topical retinoid +/- BPO/azelaic acid	High-dose oral antibiotic + topical retinoid + BPO
Alternatives (females only)	See first choice	See first choice	Oral anti-androgen ⁽¹⁾ + topical retinoid/azelaic acid +/- BPO	Oral anti-androgen ⁽²⁾ + topical retinoid +/- oral antibiotic +/- alt. antimicrobial	High-dose oral anti-androgen ⁽²⁾ + topical retinoid +/- alt. topical Antimicrobial
Maintenance therapy	Topical retinoid		Topical retinoid +/- BPO		

Notes: BPO = Benzoyl peroxide.

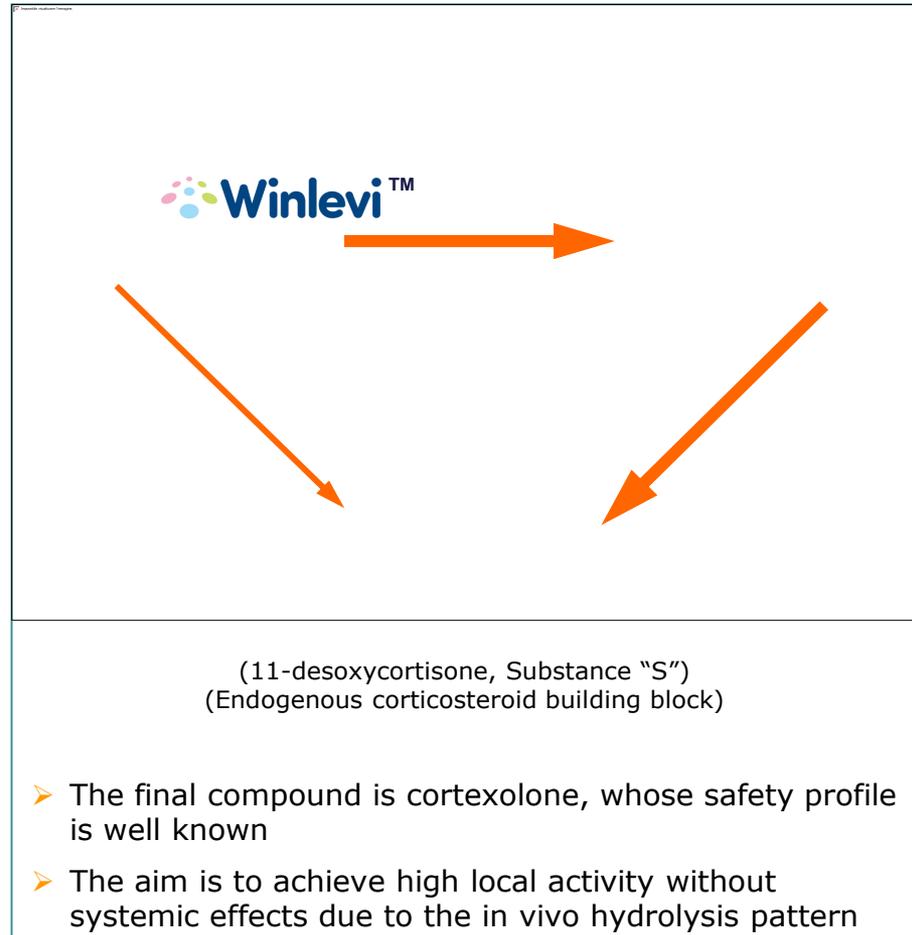
(1) Expert Rev Clin Pharmacol 2010 Expert Reviews Ltd.

(2) Off-label spironolactone.

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 follicle cell keratinization
- As a result, the follicle is not obstructed, preventing colonization by *p. acnes* and subsequent inflammation
- Winlevi™ is metabolized to cortexolone, a physiological component of the body's endogenous pool of corticosteroids

Metabolic Pathway



Key Takeaways

- If approved, will be the first ever topical anti-androgen, fully developed in-house
- A new chemical entity (NCE) with a new mechanism of action
- Expansive to the existing acne market
- Clean safety profile
- An active anti-inflammatory agent
- Clinically superior and better tolerated than topical tretinoin (based on our trial results)
- Has the potential to be used in combination with other drugs such as anti-infectives or retinoids

Note: These properties are all as seen in trials thus far but testing / development are not complete and final clinical results may vary.

Trial Highlights

- Successful FDA End Of Phase II attained January 28, 2015
- 360 patients – 4 doses + vehicle (12 weeks treatment)
- Dose escalating trial – 4:1 randomization ratio
- Best dose identified (1% BID)
- No adverse events
- 110 patients treated in Phase I/IIa
- 290 patients treated in Phase IIb
- Winlevi™ has shown statistical significance in Phase II primary end-points with only 72 patients per cohort
- Winlevi™ therefore has high potential for showing statistical superiority vs. vehicle

Results of best identified dose vs. vehicle

Statistical significance in IGA improvement (co-primary endpoint)

ITT	BID 1.0%	VEHICLE	P value
2-Point Improvement	17.1%	6.7%	0.0321

Statistical significance in total lesion count reduction (co-primary endpoint)

ITT	BID 1.0%	VEHICLE	P value
Mean	(35.7%)	(13.1%)	0.0173

IGA = Investigator Global Assessment.

Successful also in secondary endpoint showing reduction in Inflammatory Lesion Counts

ITT	BID 1.0%	VEHICLE	P value
Mean	(37.2%)	(27.0%)	0.0384

Successful also in secondary endpoint showing reduction in Non-Inflammatory Lesion Counts

ITT	BID 1.0%	VEHICLE	P value
Mean	(32.9%)	(16.1%)	0.0178

Phase III Program and Trial Design

- Special Protocol Assessment (SPA) approved by FDA in July 2015
- Winlevi® 1% cream applied twice-daily for 12 weeks in subjects with facial acne
- FDA requires at least 1,000 patients treated for safety evaluation
- 2 pivotal trials (sites in both US + EU) with 700 patients/each
 - FPI November 2015 / LPO in H1 2017
 - Enroll subjects from 9 years of age and older with moderate to severe acne (Grades 3 and 4 on IGA)
 - **Data expected to be available H2 2017**
- 1 longterm open label safety trial: 300+ subjects 6 months, 100 subjects 12 months exposure
- NDA filing targeted for Q1 2018

Study Endpoints

Primary

- Proportion of subjects with IGA score 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
- %age change from baseline in non-inflammatory lesion count at week 12
- %age change from baseline in inflammatory lesion count at week 12

IGA = Investigator Global Assessment.

Phase 3 Study 25 US (as of 06Jun16)

- All 36 sites activated
- 165 screened subjects; 126 randomized subjects
- 32 completed

Phase 3 Study 26 EU and US (as of 06Jun16)

- All 26 EU sites are activated plus twelve US sites = Total 48 sites
- 216 screened subjects; 202 randomized subjects
- 24 completed

Phase 3 Study 27 EU/US Open Label Long Term Safety study

- 23/56 rolled over from Studies 25 and 26

Pediatric PK and HPA study: 20 subjects aged 9-12

- 6 sites (3US/3 Poland)
- EC and RA approvals
- Initiation June 2016
- Expected completion Q3 2017

Cassiopea's Pipeline


BreezulaTM

A Novel Approach To Alopecia In Phase II

Breezula[®] Alopecia Market Overview

- US population of 317m⁽¹⁾ in 2013, of which 35m men and 21m women experienced hair loss in 2012⁽²⁾
- Worldwide, US\$1.9bn was spent on hair restoration surgery in 2012, an increase of 48% since 2008⁽²⁾
- Globally, US\$600m was spent on drugs in 2013⁽³⁾
 - Propecia and Rogaine are the only approved drugs in the US and EU (generically available), yet both have low levels of efficacy and Propecia is not indicated for women
 - Current drug market size of limited relevance given off-patent status of both Propecia and Rogaine
- Hair loss sufferers are highly motivated to seek treatment
 - 47% say they would spend their life savings to regain a full head of hair⁽²⁾
 - 60% say they would rather have more hair than more money and friends⁽²⁾
 - 30% say they would give up sex if it meant they could get their hair back⁽²⁾

- **Very large market where current treatments do not meet all patient needs**
- **Excellent opportunity for new topical drugs with novel treatment forms and potentially low side effects**

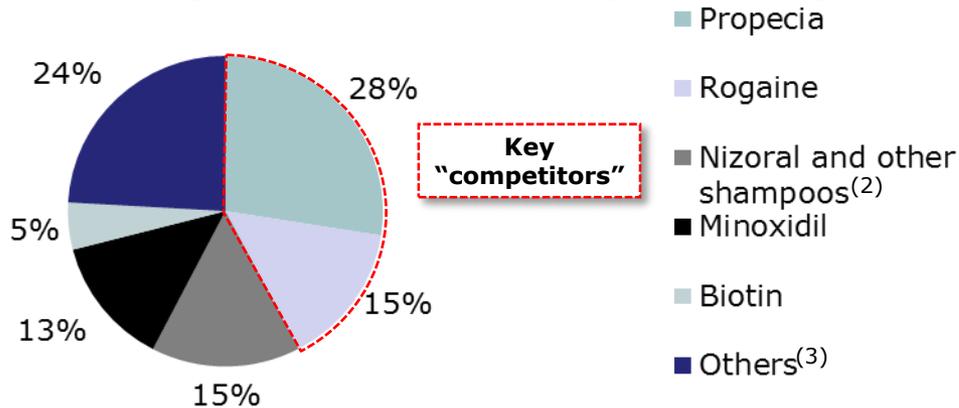
(1) United States census bureau.

(2) International Society of Hair Restoration Surgery, survey from 2014.

(3) EvaluatePharma.

Competitive Landscape

Non-Surgical Patient Prescription Usage⁽¹⁾

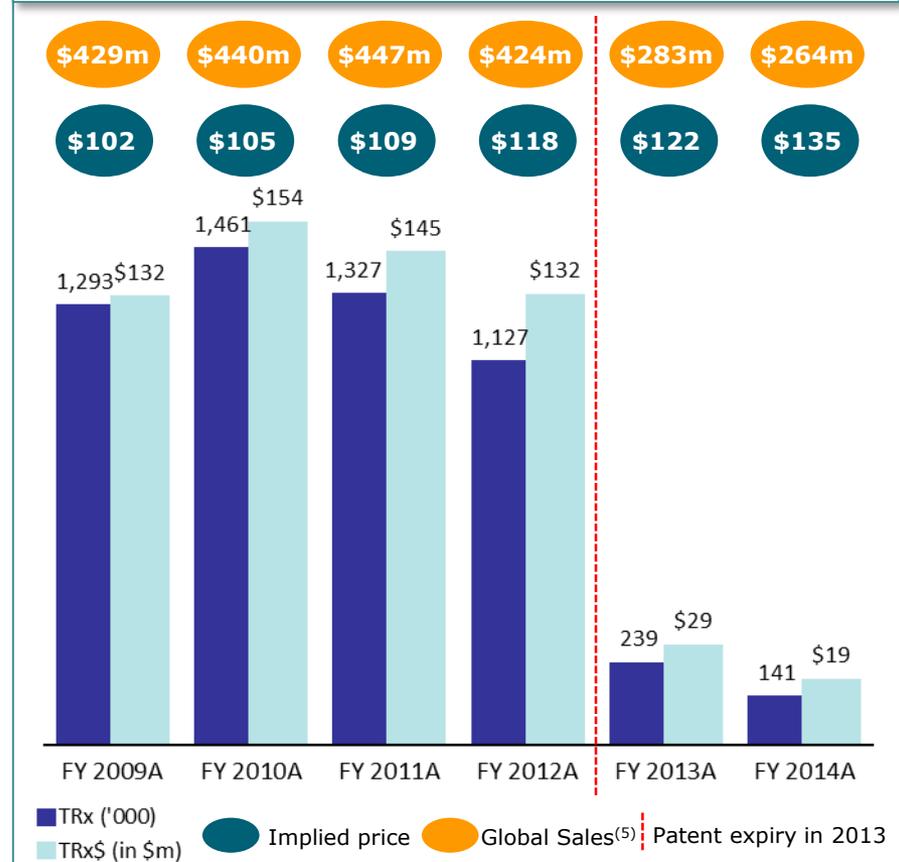


➤ Overview of key competitors:

- 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

US Propecia Case Study⁽⁴⁾

US launch in 1998



(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 with additives, home and clinical low level laser therapy, herbs & vitamins and Avodart.

(4) IMS Health, IMS SMART MVP Solutions.

(5) EvaluatePharma.



Existing Treatments

Propecia™
(finasteride)

- Shows anti-androgenic activity on follicle
- However, 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

Key Takeaways

- Positive POC results in androgenic alopecia
- NCE⁽¹⁾ with topical anti-androgenic properties
- All available alopecia treatments have a very low and transient (treatment-lasting) efficacy
- Large opportunity in a significantly underexploited market
- Can be used by men and women
- Can be used in sunlight exposure
- Chronic treatment
- No systemic side effects in trials thus far

Mechanism of Action

- Breezula[®] is formulated to act at 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 behaviour unaffected) in trials to date

Note: These properties are all as seen in trials thus far but testing / development are not complete and final clinical results may vary.

(1) Winlevi[®] and Breezula[®] are different formulations of the same NCE, for different indications.

Breezula™ Positive PoC Results

70 AGA patients (M & F) subdivided into 4 groups

Breezula™ 5%

Cyproterone Acetate

Breezula™ 1%

17 α -Estradiol

Gel applied weekly to scalp in 5 sessions of hydroelectrophoresis, each of 20 minutes duration

Clinical Evaluation

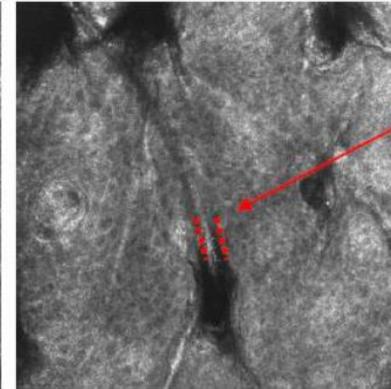
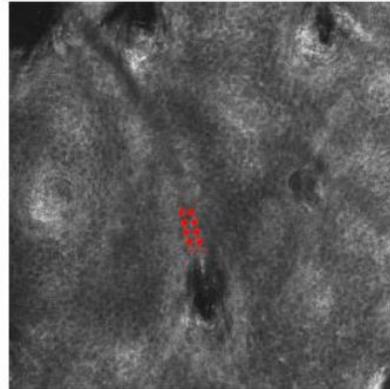
Impact on scalp hair follicle density

Pull test

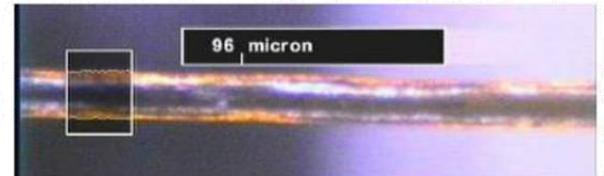
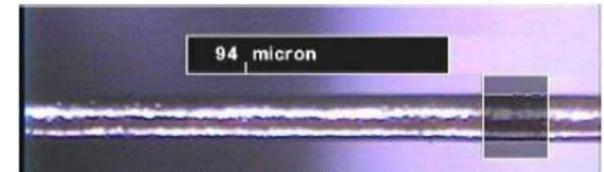
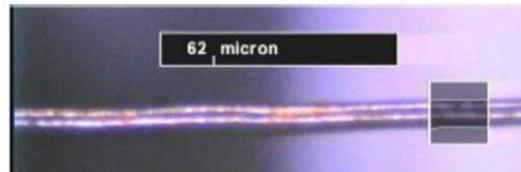
Hair shaft diameter

Sebaceous gland dimensions

Breezula™ at either dose was more effective than Cyproterone Acetate or 17 α -Estradiol in all four efficacy measures⁽¹⁾



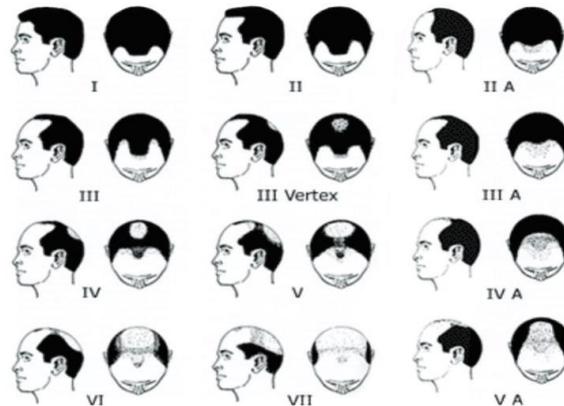
From left to right:
Improvement of hair shaft diameter (64 μ \rightarrow 97 μ)
Reduction of sebaceous gland dimension inside all the ostium follicularis in the picture



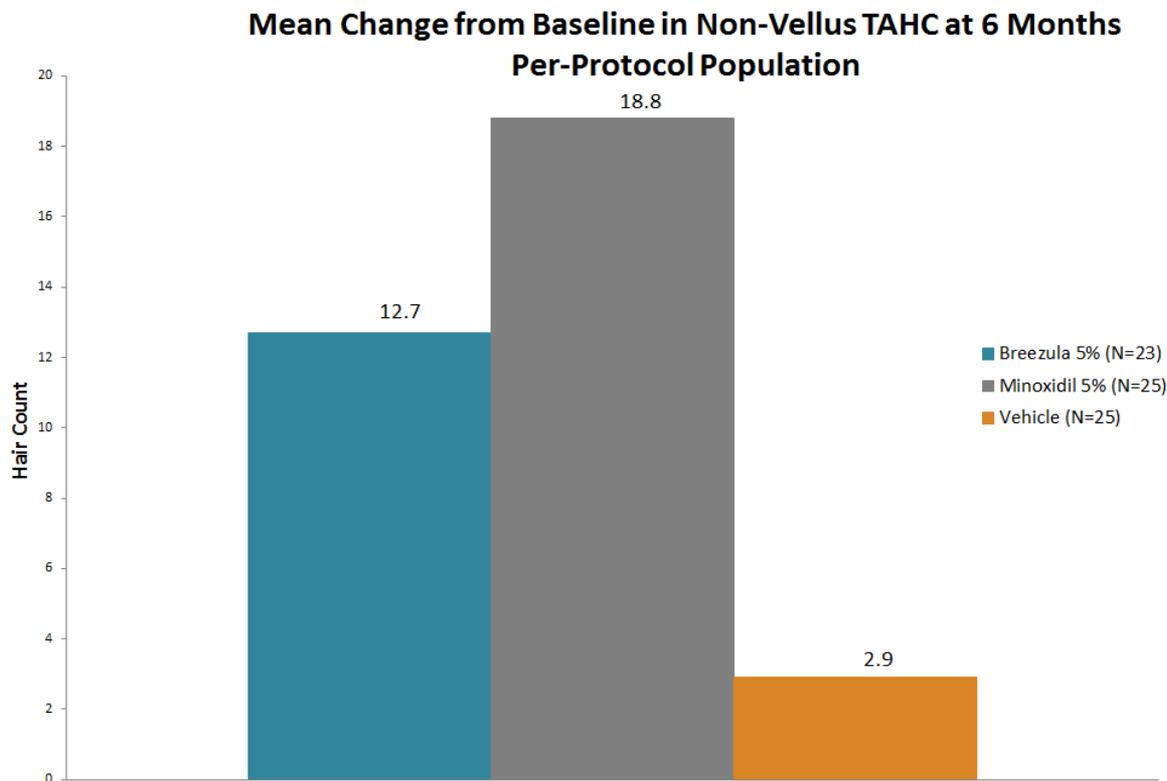
Measurements of the shaft diameter, before and after the treatment

- ❖ 95 enrolled, 78 completed treatment period, 73 per protocol efficacy analysis
- ❖ Double blind, 3 parallel arms, Breezula 5% (N=31), placebo (N=33) and Minoxidil 5% control (n=31), 6-months of treatment, BID, study conducted 10/2014 to 12/2015
- ❖ Co-primary endpoints on total hair count (TAHC within 1 cm²) increase from baseline and subject hair growth assessment (HGA) using 7-point scale at Month 6
- ❖ Other secondary endpoints: Change from baseline in hair width (TAHW) and density (TAHD), subject satisfaction and changes at Months 2 and 4. Local tolerability, local and systemic AEs, ECGs, physical, clinical labs
- ❖ Subjects (18-50 years old) had mild to moderate androgenic alopecia in temple and vertex region rating Modified Norwood-Hamilton Scale III vertex to V (IIIv, IV, V) with ongoing hair loss to be eligible for this study. Mean age 40

Modified Norwood-Hamilton Scale



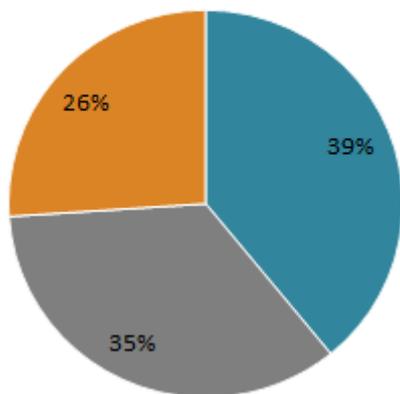
- ❖ Both active treatment groups had directionally larger changes from Baseline compared to Vehicle; although results among the three treatment groups were not statistically significant ($p=0.0971$)



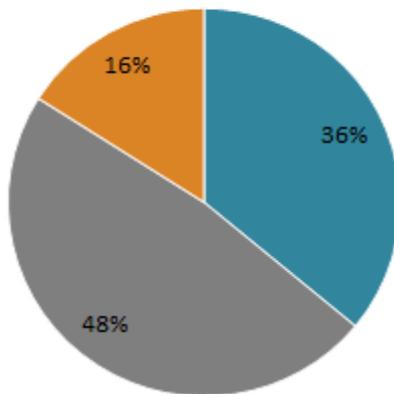
- ❖ Proportion of subjects who rated scalp hair growth as favorable was directionally larger in Breezula/CB0301 (39%) and Minoxidil (36%) compared to Vehicle (16.0%); however, no statistical difference among the three treatment groups ($p=0.2213$)

Hair Growth Assessment (HGA) at Month 6 Per Protocol Population

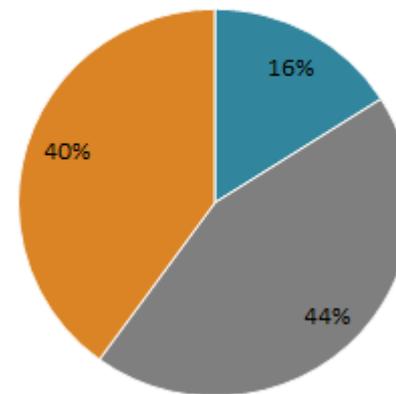
CB-03-01



Minoxidil



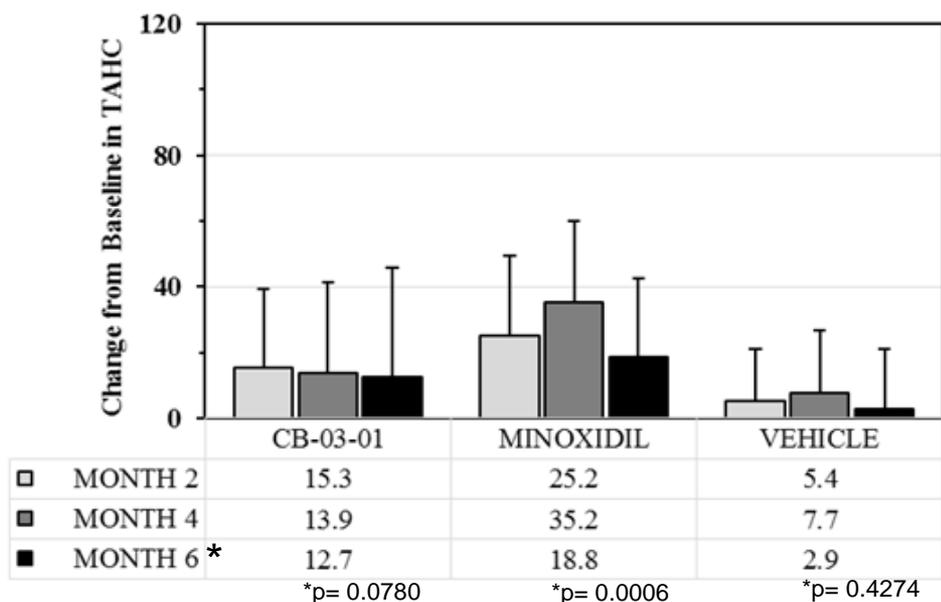
Vehicle



- Favorable = Slightly Increased (+1), Moderately Increased (+2), Greatly Increased (+3)
- No Change
- Unfavorable = Slightly Decreased (-1), Moderately Decreased (-2), Greatly Decreased (-3)

- ❖ Change from Baseline in TAHC was directionally larger in the active treatment groups (Breezula/CB0301 and Minoxidil) compared to Vehicle at Months 2, 4, and 6
- ❖ Minoxidil peaked at Month 4 and decreased at Month 6

**Change from Baseline in TAHC Over Time
Per Protocol Population**



Hair Count Data

- ❖ Both actives (Minoxidil and Breezula/CB-03-01) showed directional superiority over Vehicle at Month 6
- ❖ Study was not sized for statistical significance given the small n
- ❖ Minoxidil showed significance over the 6 month period compared to baseline ($p=0.0006$) and CB-03-01 approaches significance ($p=0.0780$), Vehicle was not effective ($p=0.4274$)
- ❖ Magnitude of efficacy at Month 6 was slightly higher for Minoxidil (difference from vehicle ~ 16 TAHC) vs. CB-03-01 (difference of ~ 10 TAHC). But not likely significant considering variability of response

Hair Count Data Commercial PH 3 Data Comparisons – preliminary Breezula results favorable

- ❖ Minoxidil in terms of TAHC in this study was very similar to what has been reported in prior studies with peak effect at $\sim 16-24$ weeks and tends to decrease over time
- ❖ Oral Finasteride (antiandrogen), significant increase is observed at Month 6 with peak effect seen at 12 months (75% of peak effect at month 6)
- ❖ Maximal effect with CB-03-01 TBD; may not have been reached at Month 6. Finasteride Mean change of 62 TAHC within 5 cm^2 at Month 6 vs. 13 within 1 cm^2 with CB-03-01 ($\times 5 \sim 65$)

Hair Growth Assessment (HGA)

- ❖ Both Breezula and Minoxidil subjects experienced an increase in HGA score
 - ❖ Breezula 39.1%
 - ❖ Minoxidil 36%
- ❖ Data by subjects correlates with the hair count outcomes for all treatment groups
- ❖ Subjects HGA profile is very similar to what has been observed with other products i.e. Minoxidil, finasteride
- ❖ Overall, results of this POC study indicate a favorable efficacy profile of CB-03-01 5% with potential of showing greater and sustained efficacy long-term, without having the systemic effects of oral finasteride

Local Tolerability and Safety Profile

- ❖ Local skin reactions observed at baseline and during treatment period for all treatment groups were mostly minimal or mild and decreased over time
- ❖ No significant systemic AEs

Cassiopea's Pipeline CB-06-01



A NCE In Phase II POC For Acne

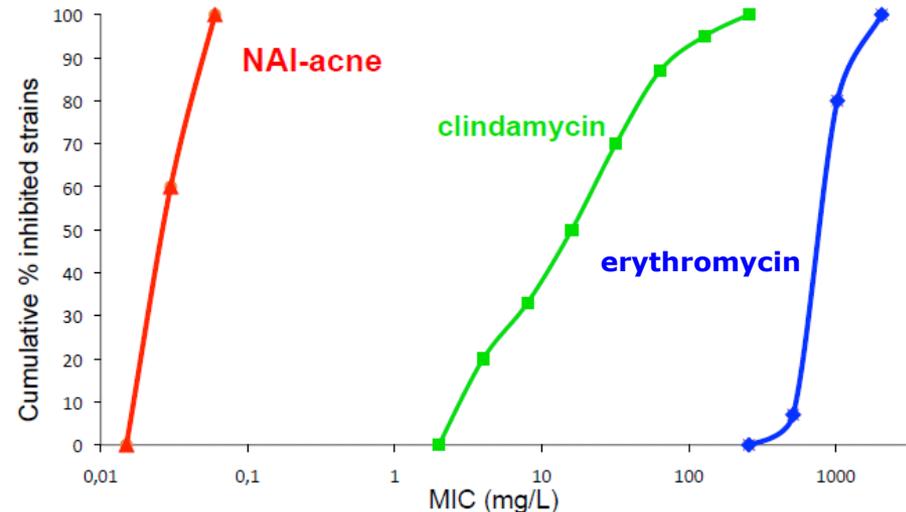
CB-06-01 Highlights

Key Takeaways

- Topical antibiotic for the treatment of Acne; inhibits bacterial protein synthesis
- NCE with very potent and selective properties
- Effective on bacterial strains resistant to certain other antibiotics
- PoC Phase II ongoing with a gel formulation, completion by H1 2016
- Complementary to Winlevi®
- In-licensed worldwide from Italian company Naicons

Specifically more effective on *p. acnes* than currently available alternatives

- Incidence of erythromycin-resistant *p. acnes* can be as high as 70%
- Most erythromycin-resistant strains are cross-resistant to clindamycin



Note: These properties are all as seen in trials thus far but testing / development are not complete and final clinical results may vary.

CB-06-01 Phase II POC Features & Status

Trial Design & Status

- Placebo controlled trial
- 90 patients (Slovakia)
- 12 weeks of treatment
- 3% gel treatment twice per day
- Treatment phase completed
- Results expected H1 2016

Endpoints

Primary

- Absolute and percent change in inflammatory lesion count from baseline to week 12 compared between treatments

Secondary

- Absolute and percent change in inflammatory lesion count from baseline compared between treatments
- Proportion of subjects with IGA score reduction of at least 2 (defined as a success) from baseline to week 12 compared between treatments
- Change in CADI from baseline to week 12 compared between treatments

Safety

- Evaluation of safety, tolerability and local tolerability as compared to the matching placebo

IGA= Investigator Global Assessment.
CADI= Cardiff Acne Disability Index (Quality of life index).

Cassiopea's Pipeline CB-06-02



A NCE In Phase II POC For Genital Warts

CB-06-02 Highlights

Key Takeaways

- Genital warts market consists of products with low efficacy and high recurrence rates
- Tellurium-based topical product for treatment of HPV ano-genital warts
- Proven anti-viral agent on cutaneous viral warts caused by HPV, most commonly located on the skin and genitalia
- Demonstrated safety in hundreds of patients in different topical formulations for dermatological indications (Verruca vulgaris, Condiloma Acuminata)
- 75.7% of all patients treated (n=74) were completely cured⁽¹⁾
- In-licensed worldwide from Israeli company BioMas

Mechanism of Action

- Acts as a low toxicity immunomodulator in supporting the natural immune response against HPV and its warts for quicker clearance and reduced recurrence⁽²⁾

Phase II POC Trial Design

- POC Phase II ongoing in Israel on 30 + 30 patients, double blind, parallel arms, 12 weeks of treatment + 3 months of follow up, endpoints on remission and recurrence rates
- Trial completion anticipated by H2 2016

Note: These properties are all as seen in trials thus far but testing / development are not complete and final clinical results may vary.

(1) Friedmann N., British Journal (2009), 160, 403-8.

(2) BioMas preclinical study.

Key Future Milestones

2016

- H1 PoC data CB-06-01 Acne antibiotic
- H2 PoC data CB-06-02 HPV
- H2 Breezula PH2 DR study begins

2017

- H2 EoPIII Winlevi®
- H2 Winlevi Phase 3 results & Pre - NDA meeting

2018

- H1 NDA filing Winlevi®
- H2 Breezula Phase 2 DR results

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
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