# **OUR SKIN TELLS A STORY**





2019 Annual Results Public Presentation March 19, 2020

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- Review 2019 Financial Results
- Product Development Update
- Commercial Update
- Financing Update





### 2019 Cassiopea Consolidated Financial Results

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### Consolidated Income Statement and Statement of Comprehensive Income

EUR/1,000	2019	2018*
Revenues	-	-
Other income	686	916
Cost of sales	(-)	(-)
Research and development costs	(7,875)	(12,240)
Selling, general and administrative costs	(3,879)	(1,890)
Net Operating expenses	(11,068)	(13,214)
Operating Result	(11,068)	(13,214)
Financial income	90	878
Financial expenses	(722)	(320)
Profit (loss) Before Taxes	(11,700)	(12,656)
Income tax expenses	-	-
Profit (loss) For The Period	(11,700)	(12,656)
EUR/1,000	2019	2018
Profit (loss) for the period (A)	(11,700)	(12,656)
Other comprehensive income that will be not recla	ass. to P/L -	-
Other comprehensive income that will be reclassif	fied to P/L 11	-
Total other comprehensive income, net of ta	x (B) 11	-
Total comprehensive income (A)+(B)	(11,689)	(12,656)
* The comparative for 2018, refers to the separate FS of Cassiopea S.p.a.		

- No revenues were generated in 2019 and 2018
- Net operating expenses are detailed by nature below

	2019	2018
Other income	686	916
Raw materials and consumables used	(242)	(311)
Personnel expenses	(2,480)	(1,411)
Outsourced preclinical and clinical trial costs	(4,062)	(8,906)
Other operating expenses	(4,915)	(3,463)
Depreciation and amortization	(55)	(39)
Total net operating expenses	(11,068)	(13,214)

- Other income refers to the tax credit for research and development pursuant to Ministerial Decree of May 27, 2015, implementing Law No. 190 of December 23, 2014 (2015 Stability Law)
- Raw materials and consumables mainly include purchase of laboratory supplies and materials for clinical trials

- Personnel expenses increase from EUR 1,411 in 2018 to EUR 2,480 in relation to the setup of the US organization
- The average number of employees is 11,5 in 2019 vs 9,0 in 2018
- In 2019, the expense for the value of employees' and executives Directors' services, exchanged for stock options, amounted to EUR 889 thousand (EUR 737 thousand in 2018) and it refers to the cost accounted in relation to the options granted by the Board of Directors in the period 2015–2019 and to the options granted by Cosmo Pharmaceuticals N.V.

• The entire staff develop as follows:

No. of people	2019	2018
Managers *	9	6
Junior managers	3	2
Total n. of people	12	8

\* Includes the managers provided by Cosmo Pharmaceuticals N.V. as for service agreement

 In addition, Cosmo Pharmaceuticals N.V. group provides research & development, regulatory, secretarial, and accounting services at a cost determined in the Services Agreement

• Outsourced preclinical and clinical trial costs are detailed here below:

Outsourced preclinical and clinical trials costs	4,062	8,906
	11	09
CB-06-02	11	89
CB-03-11 Clascoterone solution	1,921	2,666
CB-03-01 Clascoterone cream	2,130	6,151
	2019	2018

• Other operating expenses are detailed here below:

	2019	2018
Service costs	4,903	3,448
Operating lease expenses	4	9
Other operating costs	8	6
Total other operating expenses	4,915	3,463

#### • Service costs:

	2019	2018
External consultancy services	1,642	1,284
Patent costs	258	170
Investor relations and web site maintenance	169	169
Technical assistance	3	5
Utilities, telephone, internet	4	7
Insurance	90	99
Non executive directors	140	127
Stock options non executive directors	15	77
Management control committee	11	10
Auditing	35	26
Advertising and marketing costs	1,459	540
Freight, customs, warehousing	19	8
Travel expenses	241	170
External laboratory services	70	214
R&D and Regulatory services	732	532
Other costs	15	10
Total service costs	4,903	3,448

- External consultancy services increased in 2019 by EUR 358 thousand mainly due to the activities for Clascoterone cream New Drug Application submission
- Advertising and marketing costs in 2019 increased by EUR 919 thousand in relation to Clascoterone cream pre-commercial activities
- In 2019 service costs include an amount of EUR 732 thousand (EUR 508 thousand from Cosmo S.p.A. and EUR 24 thousand from Bellatrix Inc. in 2018) for Research, Development, and Regulatory services charged by Cosmo S.p.A. (subsidiary of Cosmo Pharmaceuticals N.V.)
- In 2019 the company has been charged by Cosmo S.p.A. for secretarial and accounting services for an amount of EUR 141 thousand, included in External consultancy services (EUR 144 thousand in 2018)

- Financial income in 2019 includes EUR 78 thousand for foreign exchange differences (EUR 693 thousand in 2018) and EUR 12 thousand for interest received on cash and cash equivalents (EUR 185 thousand in 2018)
- Financial expenses include EUR 654 thousand (nil in 2018) due to Interests on Cosmo Pharmaceuticals N.V.'s unsecured loan
- Other financial expenses mainly include foreign exchange losses and, in 2019, as result of initial application of IFRS 16, EUR 0.6 thousand of interest costs on lease of a company car
- Income Tax expenses: on the tax losses for 2019 and 2018 no deferred tax assets have been recognized due to uncertainties concerning the availability of future taxable profits against which such an asset may be offset

### **Consolidated Statement of Financial Position**

EUR/1,000	31.12.19	31.12.18*
Tangible and intangible assets	2,973	500
Tax receivables	9,563	9,260
Total non-current assets	12,536	9,760
Other receivables and other current assets	2,829	2,171
Cash and cash equivalents	696	4,609
Total current assets	3,525	6,780
Total assets	16,061	16,540
Total Non-current liabilities	10,660	-
Total Current liabilities	1,674	2,028
Total liabilities	12,334	2,028
Total equity	3,727	14,512
Total equity and liabilities	16,061	16,540

\* The comparative for 2018, refers to the separate FS of Cassiopea S.p.a.

### Discussion of Consolidated Statement of Financial Position

- Tangible and intangible assets include EUR 2,339 thousand for the payment of the fee at the submission of Clascoterone Cream New Drug Application (NDA) and EUR 620 thousand as costs for filing and extension of patents owned by the company
- Tax receivables refer to Tax Credit R&D costs
- Other receivables and other assets consist of VAT receivables, current amount of Tax Credit R&D costs and prepaid expenses to the CRO in relation to the clinical trials
- Cash and cash equivalents decreased by EUR 3,913 thousand due to the use of cash for the operations
- Non-current liabilities mainly refer to the draw down (EUR 10,000 thousand) and interest (EUR 654 thousand) on Cosmo Pharmaceuticals N.V. unsecured credit facility
- Current liabilities mainly refer to trade payables

### Discussion of Consolidated Statement of Financial Position

#### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

EUR1,000	Number of Shares	Share Capital	Share premium	Capital contribution	Stock option plan reserve Currency translation reserve	Retained earnings	TOTAL
Net equity as at 1 January 2018	(n) 10,000,000	10,000	28,172	122	1,716 -	(13,656)	26,354
Allocation of prior year result Cost for stock options Forfeited stock options Total comprehensive income for the period			(13,656) 8	114	700 (8)	13,656 (12,656)	- 814 - (12,656)
Net equity as at 31 December 2018	10,000,000	10,000	14,524	236	2,408 -	(12,656)	14,512
- EUR1,000	Number of Shares	Share Capital	Share premium	Capital contribution	Stock option plan reserve Currency translation reserve	<b>Retained</b> carnings	TOTAL
Net equity as at 1 January 2019	(n) 10,000,000	10,000	14,524	236	2,408 -	(12,656)	14,512
Allocation of prior year result Cost for stock options	10,000,000	10,000	(12,656)	201	703	12,656	- 904
Forfeited stock options Total comprehensive income for the period					11	(11,700)	(11,689)
Net equity as at 31 December 2019	10,000,000	10,000	1,868	437	3,111 11	(11,700)	3,727

### **Discussion of Consolidated Statement of Financial Position**

- Equity 2019 is composed by:
  - "Share capital": 10,000,000 shares issued, fully subscribed and paid up, each share with a nominal value of EUR 1.00, for a total share capital of EUR 10,000 thousand
  - "Share premium" of EUR 1,868 thousand refers to the proceeds from April 2015 capital increase, reduced in relation to the allocation of the previous losses
  - "Capital contribution" relates to the stock option of Cosmo Pharmaceuticals N.V. granted to the employees of the Company
  - The expense for SOP amounts to EUR 703 thousand of which EUR 688 thousand for management and personnel and EUR 15 thousand for nonexecutive Directors (in 2018 EUR 623 thousand and EUR 77 thousand respectively)
  - Currency translation reserve arises from the consolidation of a foreign entity with a functional currency other than the Euro

### **Consolidated Cash Flow Statement**

EUR/1,000	31.12.19	31.12.18*
Profit (loss) before taxes	(11,700)	(12,656)
Interest on loan not paid	654	-
Depreciation and amortization	55	39
Share payment based expenses	904	814
Tax credit R&D costs	(686)	(916)
R&D credit offset	333	349
Net unrealized foreign exchange differences on cash and cash equivalents	10	(186)
Change in net working capital	(955)	(491)
Cash flows from operating activities	(11,385)	(13,047)
Cash flows from investing activities	(2,514)	(128)
Cash flows from financing activities	9,996	-
Net increase/(decrease) in cash and cash equivalents	(3,903)	(13,175)
Cash and cash equivalents at the beginning of the period	4,609	17,598
Net unrealized foreign exchange differences on cash and cash equivalents	(10)	186
Cash and cash equivalents at the end of the period	696	4,609

\* The comparative for 2018, refers to the separate FS of Cassiopea S.p.a.



# Product Development Update

# Cassiopea Pipeline

PRODUCT	INDICATION	PRE-CLINICAL	PHASE I	PHASE II	PHASE III	APPROVAL
Clascoterone Cream 1% Androgen Receptor Inhibitor	Acne					
Clascoterone Solution	Androgenetic alopecia in Males					
Androgen Receptor Inhibitor	Androgenetic alopecia in Females					
<b>CB-06-01</b> Antibiotic	Acne					
<b>CB-06-02</b> Immune Modulator	Genital Warts					



### Clascoterone Cream 1% 2019 Achievements and Next Steps

#### 2019 Achievements:

- Received conditional approval from FDA on Winlevi proprietary name
- NDA Filed August 2019
- NDA accepted by FDA and PDUFA date Aug 27, 2020 established
- Extensive Medical Affairs program has increased the visibility of Cassiopea and Clascoterone in the Dermatology community - 20+ Published Papers, Posters and Abstracts, 24 Meeting Sponsorships, 55+ Podium Mentions by KOLS
- 2 acne advisory boards
- Completed extensive market research with payers and segmentation research with HCPs

#### **Next Steps:**

• Aug 27, 2020 PDUFA Date



### **Clascoterone Solution 2019 Achievements and Next Steps**

#### **2019 Achievements:**

- Phase 2 dose ranging study in males successful and most effective dose identified
- Extensive Medical Affairs program has increased visibility of clascoterone solution in the Dermatology community - 9 Published Papers, Abstracts and Posters, 17 KOL podium presentations
- 3 advisory boards held
- Phase 2 study in females initiated, enrollment ongoing
- End of Phase 2 Meeting w FDA held November

#### **Next Steps:**

- Finalize Special Protocol Assessment for Phase 3 Program with FDA
- Initiate Activities for Breezula Phase 3 trials in males 4Q 2020/1Q 2021

Clascoterone is under investigation and is not FDA approved.



# Clascoterone Solution Phase 2 Clinical Study for AGA in Females

### Study design:

- Multicenter, prospective, randomized, double blind
- Minoxidil solution 2% BID, vehicle BID, Clascoterone solution 5% BID and Clascoterone solution 7.5% BID
- Females 18-55
- 6 months treatment
- 280 subjects split in 4 groups of 70 subjects

#### Status:

- 109 subjects recruited
- Complete enrollment 2Q 2020, last patient out 4Q 2020 depending on Covid 19 impact

 $\label{eq:clascoterone} Clascoterone \ \mbox{is under investigation and is not FDA approved}.$ 





# Clascoterone Cream 1%

# **Commercial Update**

## Key US Acne Market Insights and Positioning

 Acne market continues to be an important market in Dermatology
High volume, concentrated target market with 8,200 providers accounting for almost 60% of prescriptions

•Unmet need among providers for a novel approach, especially targeting the hormonal aspect for all acne patients

•Spironolactone (oral anti-androgen) used off label for acne is the third highest prescribed drug in Dermatology for any indication, limited use to females only

•Acne is treated with polypharmacy, using multiple, complementary drugs to address varying parts of the disease

•Market research demonstrates clear positioning for clascoterone cream 1% around the unique mechanism of action and significant market share uptake predicted among segmented high value providers



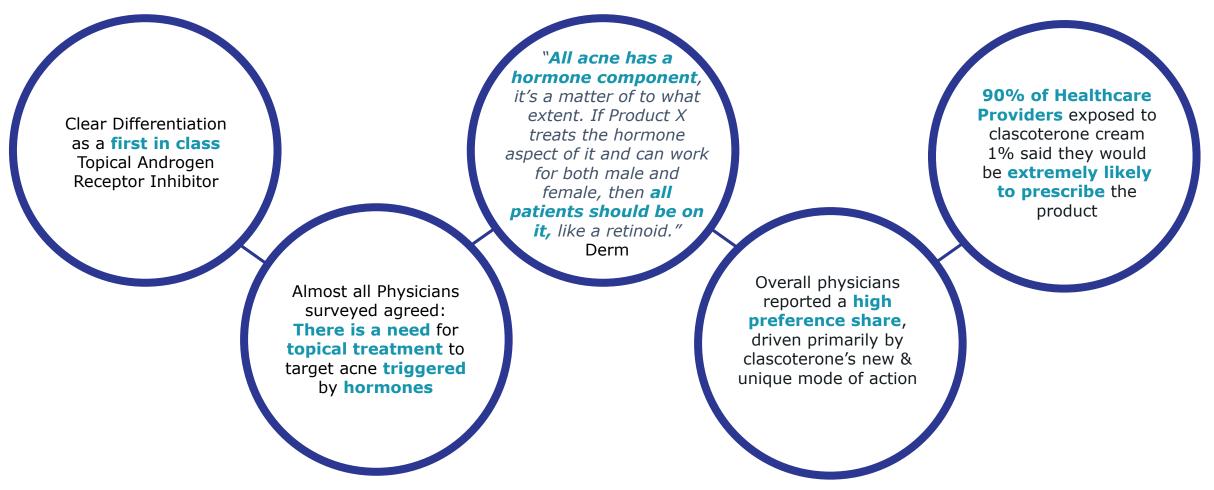
# Acne Market: With 50 Million acne sufferers, Acne continues to be a relevant disease



Dermatology PA/NPs account for almost \$1 Billion of acne business



# Market Research confirms clascoterone can be positioned as a foundation for acne treatment

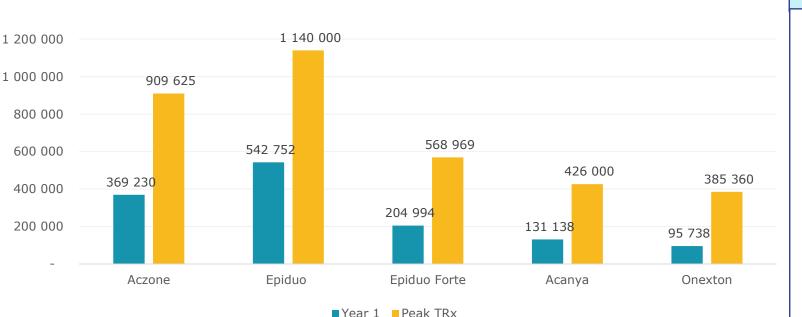


Source: IQVIA Primary Market Segmentation Research July- Sept 2019. Qualitative research n=50. Q. How likely are you to prescribe Product X for your acne patients? *Number of HCPs; Rating 1-7:* 1 = Not Likely; 4 = Somewhat Likely 7 = Extremely Likely



An NDA for clascoterone cream 1% for the treatment of acne is undergoing review by the US FDA

# Market research confirms interest in clascoterone cream 1% is similar to Epiduo and Aczone.



Acne Launch Surrogates: Year 1 & Peak TRx Volume

"This is not only a new product, but also novel product. It's a good option for both men and women struggling with hormonal acne. I would definitely use it!"

-High Priority Segment Derm

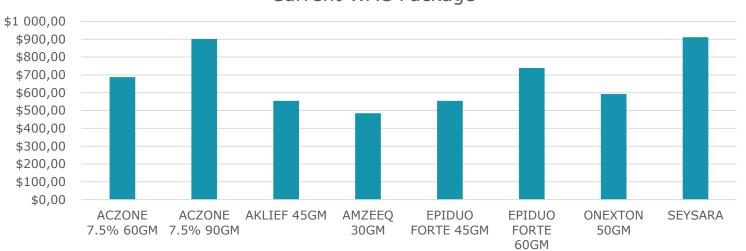
Provider Response to clascoterone cream 1%

- Average clascoterone efficacy ratings were similar to products like Adapalene, and Aczone Gel 7.5%, given that it provided decent reduction in inflammatory lesions and sufficient long term efficacy (especially in truncal acne)
- clascoterone had the highest tolerability rating of all the products that were rated, given its very positive tolerability profile and its small rate of discontinuation
- HCPs saw most value of Winlevi in moderate patients so they can target both the inflammation and the hormonal component of acne in these patients

Source: IQVIA NPA Sept. 2019 Data, Aczone & Epiduo Peak Volume in 2015, Acanya 2013, Onexton 2016



# Acne Brand Prices range from \$500-\$900 and vary in pack sizes from 30gm -90gm



Current WAC Package

- The average wholesale acquisition cost (WAC) of approximately 1 month's supply for a topical acne product is \$613
- New topical brands launched are Aklief (45gm-\$554.25) and Amzeeq (30gm-\$485.00)
- New systemic brand is Seysara (\$911.60)

Source: Analysource, First DataBank Pricing March 2020



### Market Access Insights and Expected Coverage

- Acne is a fairly stable and predictable payer market
  - They manage the products consistently, without major category evaluations
- Our market research confirms that payers will continue to treat acne as a medical disease and will provide coverage for patient acne visits and products
- Although price in acne is a key driver of the decision for the level of coverage, innovation and new mechanism of action does matter
  - Drugs over \$600 monthly cost may have higher restrictions
  - Clascoterone targeting to be in a unique category as a first in class androgen receptor inhibitor
- Coverage expected in at least 70% of commercial lives without highly restrictive PAs or multiple step edits at the <\$400 Net price per month</li>

Source: In depth interviews conducted June and August 2019 by Precisions Xtract Inc. Perception and coverage expectation data based on primary research conducted June 2019; N=12 Payers (~92M Commercial Lives). Price-Access projections are based on primary research conducted August 2019; N=10 Payers (~79M Commercial Lives)



### Clascoterone launch approach

- Adopted a step wise approach to investment and launch preparation
- Built a US management team with extensive dermatology experience in over 20 derm launches
- Built a solid foundation for launch
  - Extensive Medical Affairs program has rapidly increased awareness of clascoterone new MOA and clinical data in the dermatology community
  - Marketing research conducted on positioning, messaging and market segmentation
  - Market access research conducted on value proposition, downstream payer analysis and pricing
  - Professional relations to build Cassiopea awareness among key provider stakeholders
- Identified areas of external or contract support, rather than build internally
  - Intend to launch with a contract sales organization (~75 Representatives)
- 2 step launch approach: Market Access Launch at PDUFA (Sept. 2020), Commercial Sales Launch March 2021



# OUR SCIENCE TELLS A STORY

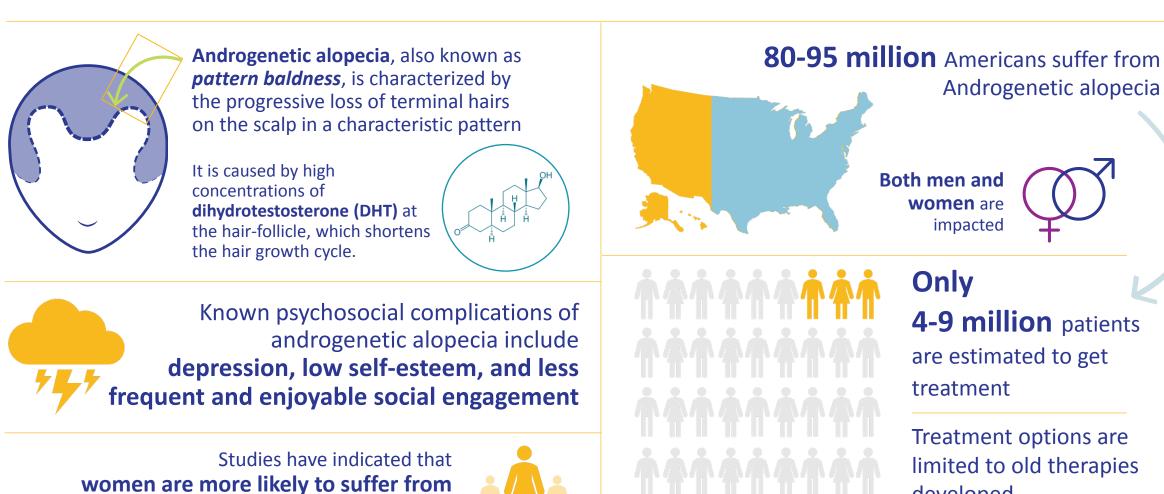
### Clascoterone Solution First in Class Androgen Receptor Inhibitor Targeting Androgenetic Alopecia



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### US Androgenetic Alopecia Market

psychological complications than men



Both men and women are impacted Only 4-9 million patients are estimated to get treatment

Androgenetic alopecia

Treatment options are limited to old therapies developed **20 - 30 years ago** 

Cassiopea

# Doctors and Patients are excited about Clascoterone Solution for AGA

- Doctors were highly receptive to the product profile, emphasizing the novel mechanism and impressive clinical photographs
  - All physician specialties suggest high utilization with a reported adoption of over 60% of male patients and 50% of female patients
  - Physicians reported high adoption rates and would take replace finasteride and minoxidil equally
- Nearly half of Rogaine patients indicated that they would be at least highly likely to request Clascoterone Solution from their physician
- Clascoterone Solution could be priced like other cash pay lifestyle drugs ie \$100-200 per month





"I have never been able to give my female patients something that could really fix their issue. This product could give a bit of hope to female alopecia patients."

- Primary Care Physician

Clascoterone is under investigation and is not FDA approved.





# **Financing Update**



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## **Financing Update**

- Italian company law does not allow companies to operate with negative equity
- Cassiopea thus need to do an equity bridge prior to the Winlevi PDUFA, estimated around € 20m
- Cassiopea is preparing the prospectus for a rights offering to all shareholders, to be executed in May, but it is also in discussions with potential investors, who may step in with the exclusion of the preemption right of other shareholders
- Choice between the two alternatives will depend on market conditions
- Cosmo has stated it will fully underwrite any rights issue up to € 20m and provide additional financing if needed
- Cassiopea is also exploring non-dilutive financing (though this does not solve the equity issue)
- Upon approval of Clascoterone Cream 1%, if Cassiopea will decide to commercialize the asset by itself in absence of a strategic transaction, a more significant equity raise will be needed to advance the pipeline and establish the commercial organization in the US



### **Upcoming Company Milestones**

- Capital increase/financing in next 60 days
- Finalize SPA with FDA on Phase 3 program and initiate activities for Clascoterone Solution Phase 3 Studies in Men 2H 2020/1Q2021
- Clascoterone Cream 1% PDUFA Date Aug 27, 2020





### Information

**Number of shares:** 10,000,000

Listing: SIX Swiss exchange, Main board

**ISIN:** IT0005108359

Ticker: SKIN

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