# **OUR SKIN TELLS A STORY**





Public Presentation 1H 2020 Results July 29, 2020

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- Review 1H 2020 Financial Results
- Product Development Update
- Commercial Update
- Financing Update





### 1H 2020 Cassiopea Financial Results



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### Consolidated Income Statement and Statement of Comprehensive Income

EUR/1,000	30.06.20	30.06.19
Revenues	-	-
Other income	-	-
Cost of sales	(-)	(-)
Research and development costs	(2,510)	(4,689)
Selling, general and administrative costs	(2,180)	(1,596)
Net Operating expenses	(4,690)	(6,285)
Operating Result	(4,690)	(6,285)
Financial income	18	60
Financial expenses	(650)	(233)
Profit (loss) Before Taxes	(5,322)	(6,458)
Income tax expenses	-	-
Profit (loss) For The Period	(5,322)	(6,458)
EUR/1,000	30.06.20	30.06.19
Profit (loss) for the period (A)	(5,322)	(6,458)
Other comprehensive income that will be not reclass. to P/L	-	-
Other comprehensive income that will be reclassified to P/L	22	7
Total other comprehensive income, net of tax (B)	22	7
Total comprehensive income (A)+(B)	(5,300)	(6,451)



- No revenues were generated in H1 2020 and H1 2019
- Net operating expenses are detailed by nature below

EUR 1,000		
	30.06.20	30.06.19
Raw materials and consumables used	(317)	(186)
Personnel expenses	(1,785)	(1,149)
Outsourced preclinical and clinical trial costs	(640)	(2,502)
Other operating expenses	(1,918)	(2,424)
Depreciation and amortization	(30)	(24)
Total net operating expenses	(4,690)	(6,285)

 Raw materials and consumables mainly include purchase of laboratory supplies and materials for clinical trials



- Personnel expenses increase from EUR 1,149 in H1 2019 to EUR 1,785 in H1 2020 in relation to the setup of the US subsidiary
- The average number of employees is 12 in H1 2020 vs 11,0 in H1 2019
- In H1 2020, the expense for the value of employees' and executives Directors' services, exchanged for stock options, amounted to EUR 533 thousand (EUR 409 thousand in H1 2019) and it refers to the cost accounted in relation to the options granted by the Board of Directors in the period 2015–2020 and to the options granted by Cosmo Pharmaceuticals N.V.
- The entire staff develop as follows:

No. of people		
	30.06.20	30.06.19
Managers*	9	9
Junior managers	3	3
Total No. of people	12	12

\* 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:

EUR 1,000		
	30.06.20	30.06.19
Clascoterone cream 1%	140	1,762
Clascoterone solution	498	732
CB-06-01	2	-
CB-06-02	-	8
Outsourced preclinical and clinical trials costs	640	2,502

#### • Other operating expenses are detailed here below:

EUR 1,000		
	30.06.20	30.06.19
Service costs	1,914	2,420
Other operating costs	4	4
Total other operating expenses	1,918	2,424



#### • Service costs:

EUR 1,000	30.06.20	30.06.19
		••••••
External consultancy services	750	1,020
Patent costs	176	85
Investor relations and web site maintenance	100	101
Technical assistance	5	2
Utilities, telephone, internet	6	3
Insurance	50	40
Non-executive directors	70	70
Stock options non-executive directors	13	6
Management control committee	5	5
Auditing	16	16
Advertising and marketing costs	362	469
Freight and customs	2	3
Travel expenses	42	83
External laboratory services	15	60
R&D and Regulatory services	297	443
Other costs	5	14
Total service costs	1,914	2,420

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- Service costs decrease mainly for the reduction in External consultancy services and in advertising and marketing costs
- In H1 2020, the Company has been charged by Cosmo S.p.A. (subsidiary of Cosmo Pharmaceuticals N.V.) for an amount of EUR 297 thousand (in H1 2019 EUR 443 thousand from Cosmo S.p.A.) for Research/Development/Regulatory services
- In H1 2020, the Company has been charged by Cosmo S.p.A. (subsidiary of Cosmo Pharmaceuticals N.V.) for secretarial and accounting services for an amount of EUR 74 thousand, included in External consultancy services (EUR 76 thousand in H1 2019)



- Financial income in H1 2020 includes EUR 17 thousand for foreign exchange differences (EUR 50 thousand in H1 2019) and EUR 1 thousand for interest received on cash and cash equivalents (EUR 10 thousand in H1 2019)
- Financial expenses include EUR 608 thousand (EUR 199 thousand in H1 2019) due to Interests on Cosmo Pharmaceuticals N.V.'s unsecured loan
- Income Tax expenses: on the tax losses for both H1 2020 and 2019 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	30.06.20	31.12.19
Tangible and intangible assets	2,986	2,973
Tax receivables	9,368	9,563
Total non-current assets	12,354	12,536
Other receivables and other current assets	2,954	2,829
Cash and cash equivalents	8,451	696
Total current assets	11,405	3,525
Total assets	23,759	16,061
Total Non-current liabilities	8	10,660
Total Current liabilities	2,388	1,674
Total liabilities	2,396	12,334
Total equity	21,363	3,727
Total equity and liabilities	23,759	16,061



# **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 636 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 increased to EUR 8,451 thousand due to the net inflow from June capital increase
- Non-current liabilities decreased by EUR 10,652 thousand, from EUR 10,660 thousand to EUR 8 thousand mainly in relation to the setting-off of the amount due to Cosmo Pharmaceuticals N.V.(Installment drawn EUR 14,000 thousand of which EUR 4,000 thousand drawn in H1 2020, and EUR 1,258 thousand for interests and signing fee at the date of capital increase) for the credit facility, with the subscription price of the shares in Cassiopea capital increase.
- Current liabilities mainly refer to trade payables



# Discussion of Consolidated Statement of Financial Position

EUR1.000	Number of Shares	Share Capital	Share premium	Capital contribution	Stock option plan reserve	Currency translation reserve	Retained earnings	Losses carried forward	TOTAL
	(n)								
Net equity as at 1 January 2019	10,000,000	10,000	14,524	236	2,408	-	(12,656)	-	14,512
Allocation of prior year result			(12,656)				12,656		-
Cost for stock options				97	318				415
Total comprehensive income for the period						7	(6,458)		(6,451)
Net equity as at 30 June 2019	10,000,000	10,000	1,868	333	2,726	7	(6,458)	-	8,476
EUR1.000	Number of Shares	Share Capital	Share premium	Capital contribution	Stock option plan reserve	Currency translation reserve	Retained earnings	Losses carried forward	TOTAL
LOKI,000	(n)								
Net equity as at 1 January 2020	10,000,000	10,000	1,868	437	3,111	11	(11,700)	-	3,727
Allocation of prior year result			(1,868)	(437)			11,700	(9,395)	-
Capital increase		750	21,640						22,390
Cost for stock options Total comprehensive income for the period				77	469	22	(5,322)		546 (5,300)
Net equity as at 30 June 2020	10,000,000	10,750	21,640	77	3,580	33	(5,322)	(9,395)	21,363



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

- Equity as at 30.06.2020 is composed by:
  - "Share capital": 10,750,000 shares issued, fully subscribed and paid up, each share with a nominal value of EUR 1.00, for a total share capital of EUR 10,750 thousand
  - "Share premium" of EUR 21,640 refers to the proceeds from June 2020 capital increase, equal to a share premium of EUR 30 for share for a total of EUR 22,500 thousand, net of EUR 860 thousand as expenses related to the capital increase
  - "Capital contribution" relates to the stock option of Cosmo Pharmaceuticals N.V. granted to the employees of the Company
  - In H1 2020 the expense for SOP amounts to EUR 469 thousand of which EUR 456 thousand for management and personnel and EUR 13 thousand for non-executive Directors (In H1 2019 EUR 312 thousand and EUR 6 thousand respectively)
  - Currency translation reserve arises from the consolidation of a foreign entity with a functional currency other than the Euro
  - Losses carried forward arise from the previous year's result not allocated.



# **Consolidated Cash Flow Statement**

EUR/1,000	30.06.20	30.06.19
Profit (loss) before taxes	(5,322)	(6,458)
Interest not paid	608	199
Depreciation and amortization	30	24
Share payment-based expenses	546	415
R&D credit offset	195	173
Net Unrealised foreign exchange differences on cash and cash equivalents	4	(2)
Change in net working capital	(249)	(41)
Cash flows from operating activities	(4,188)	(5,690)
Cash flows from investing activities	(43)	(85)
Cash flows from financing activities	11,990	1,998
Net increase/(decrease) in cash and cash equivalents	7,759	(3,777)
Cash and cash equivalents at the beginning of the period	696	4,609
Net Unrealised foreign exchange differences on cash and cash equivalents	(4)	2
Cash and cash equivalents at the end of the period	8,451	834

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# Product Development Update

# Cassiopea Pipeline

PRODUCT	PROPOSED INDICATION	PRE-CLINICAL	PHASE I	PHASE II	I PHASE III	ANTICIPATED 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% Status and Next Steps

#### Status:

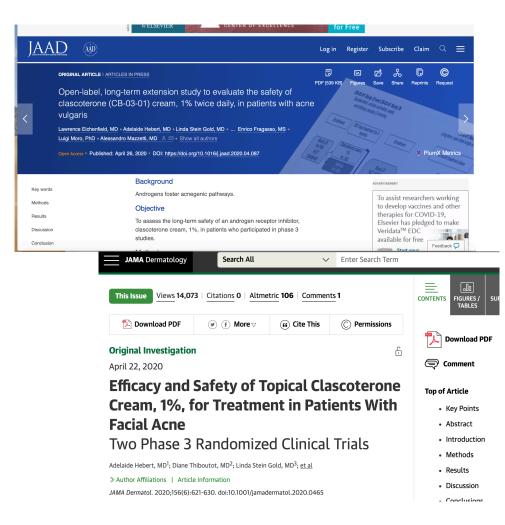
- Received conditional approval from FDA on Winlevi<sup>™</sup> proprietary name
- NDA Filed August 2019
- NDA accepted by FDA and PDUFA date Aug 27, 2020 established
- Extensive Medical Affairs program has increased the visibility of Cassiopea and Clascoterone in the Dermatology community - 5 Published Papers, 23 Posters and Abstracts, 24 (7 this year) Meeting Sponsorships, 100+ Podium Mentions by KOLS
- Completed extensive market research with payers and segmentation research with HCPs

#### **Next Steps:**

• Aug 27, 2020 PDUFA Date



# **Clascoterone Publications**



June 2019	570	VOLUME 18 • ISSUE 6
Copyright © 2019	ORIGINAL ARTICLE	Journal of Drugs in Dermatology

#### A Phase 2b, Randomized, Double-Blind Vehicle Controlled, Dose Escalation Study Evaluating Clascoterone 0.1%, 0.5%, and 1% Topical Cream in Subjects With Facial Acne

Alessandro Mazzetti MD,<sup>a</sup> Luigi Moro PhD,<sup>a</sup> Mara Gerloni PhD,<sup>a</sup> Martina Cartwright PhD<sup>b</sup> <sup>a</sup>Cassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy <sup>b</sup>Cassiopea Inc., San Diego, CA

JUNE 2019	217	Volume 18 • Issue 6
Copyright © 2019	ORIGINAL ARTICLE	Journal of Drugs in Dermatology

Pharmacokinetic Profile, Safety, and Tolerability of Clascoterone (Cortexolone 17-alpha propionate, CB-03-01) Topical Cream, 1% in Subjects With Acne Vulgaris: An Open-Label Phase 2a Study

Alessandro Mazzetti MD,<sup>a</sup> Luigi Moro PhD,<sup>a</sup> Mara Gerloni PhD,<sup>a</sup> Martina Cartwright PhD<sup>b</sup> <sup>a</sup>Cassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy <sup>b</sup>Cassiopea Inc., San Diego, CA

### Cassiopea

## Clascoterone Solution Status and Next Steps Status:

- Phase 2 dose ranging study in males successful and most effective dose identified
- End of Phase 2 Meeting with FDA held
- Special Protocol Assessment for Phase 3 Program submitted to FDA
- Extensive Medical Affairs program has increased visibility in the Dermatology community
   9 Published Papers, Abstracts and Posters, 17 KOL podium presentations
- Phase 2 study in females initiated, enrollment ongoing

#### **Next Steps:**

- Finalize Special Protocol Assessment for Phase 3 Program in males with FDA
- Initiate Activities for Phase 3 trials in males after agreement with FDA on SPA
- Complete enrollment of Phase 2 study in females



# Clascoterone Solution for AGA in Females

#### Phase 2 Study Ongoing:

- 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/Next Steps:**

- Enrollment temporarily stopped for 3 months due to COVID19 and re-started in June
- 165 subjects recruited, plus 32 in screening
- Complete enrollment September 30
- Topline Results anticipated 2Q21





# Clascoterone Cream 1%

# Commercial

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# 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



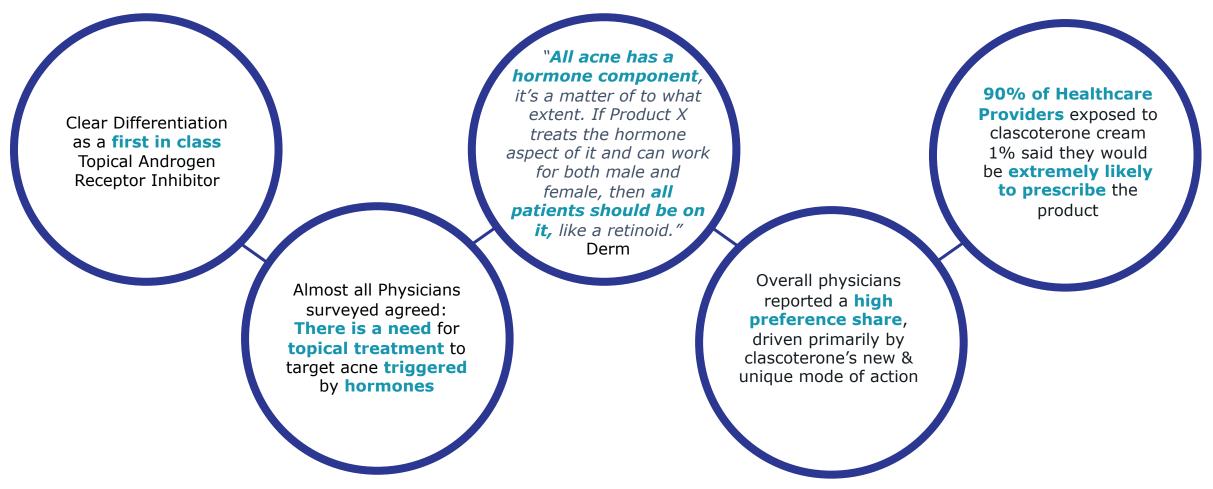
# Acne Market: With 50 Million acne sufferers, Acne continues to be a relevant disease



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



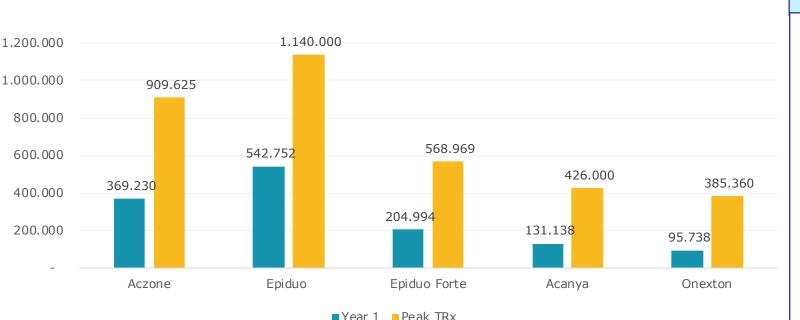
# Market Research confirms clascoterone can be positioned as a foundation for acne treatment



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



# 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

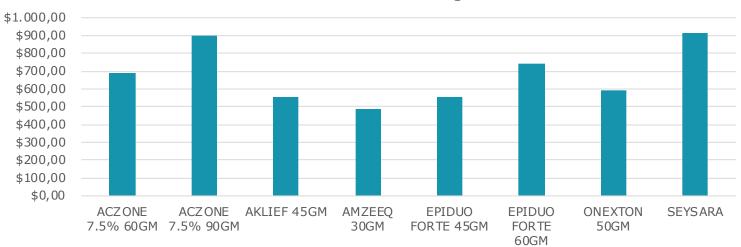
Provider Response to clascoterone cream 1%

- 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 WAC 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<sup>®</sup> (45gm-\$554.25) and Amzeeq<sup>™</sup> (30gm-\$485.00)
- New systemic brand is Seysara® (\$911.60)

\*There is a significant deduction from WAC to net price based on the percent discounted to wholesaler for distribution and to payers and patients for market access. This will vary over the life of the product.

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 an acceptable Net Price per month
- Early Payer reception/willingness to meet with Cassiopea for introductory calls is strong
  - Payers representing >75mm lives scheduled meetings within the first week of contact

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
- Exploring M&A options to optimize commercialization and profitability before building own organization
- 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, and introductory meetings with payers scheduled over next 8 weeks
- Identified areas of external or contract support, rather than build internally
  - Intend to launch with a contract sales organization (~75 Representatives) Size TBD post COVID
- 2 step launch approach: Market Access Launch at PDUFA (Sept. 2020), Commercial Sales Launch March 2021



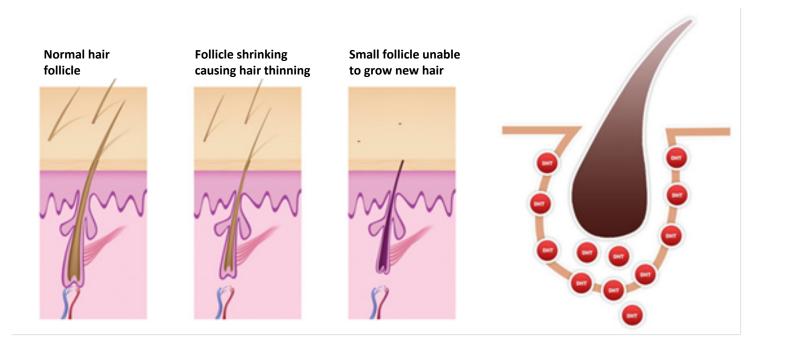
# OUR SCIENCE TELLS A STORY

Clascoterone Solution 7.5% First in Class Androgen Receptor Inhibitor Targeting Androgenetic Alopecia

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Clascoterone solution is not FDA approved. It is poised as a first in class therapy for androgenetic alopecia

# Androgenetic Alopecia and Existing Treatments

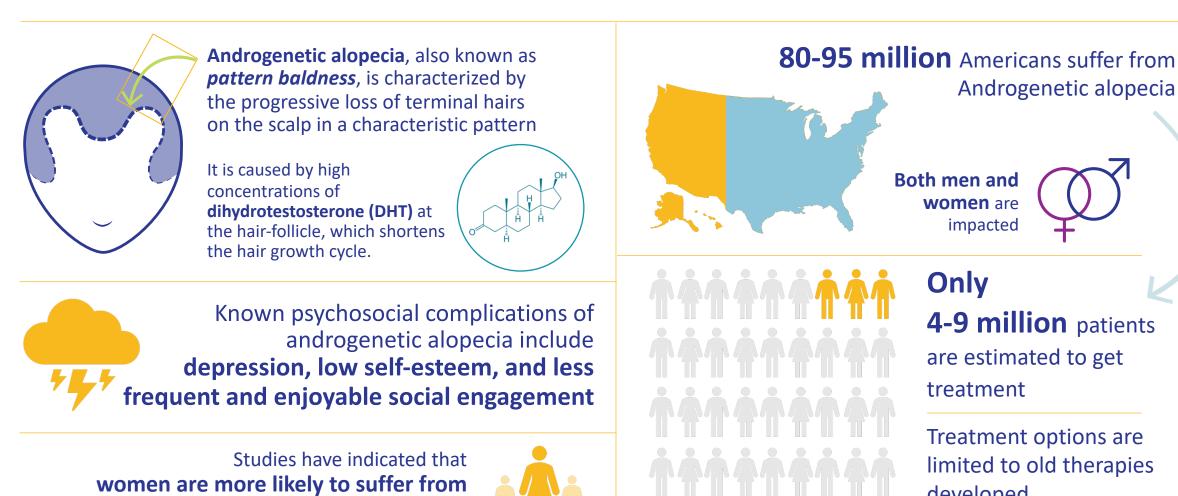


DHT = Dihydrotestosterone

Existing Treatments		Clascoterone Solution A Novel Androgen Receptor Inhibitor
<ul> <li>Propecta (finasteride)</li> <li>Shows anti-androgenic activity on follicle</li> <li>However, serious side effects due to hormonal imbalance</li> <li>Not indicated for women</li> </ul>	<ul> <li>Minoxidil<sup>®</sup></li> <li>Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla</li> </ul>	<ul> <li>Antagonizes DHT's negative effects on dermal papilla</li> <li>Reduces hair miniaturization</li> <li>Reduces dermal inflammation</li> </ul>



# 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



# Providers and Patients are excited about Clascoterone Solution for AGA

- HCPs were highly receptive to the product profile, emphasizing the novel mechanism and impressive clinical photographs
  - All provider 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<sup>®</sup> 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



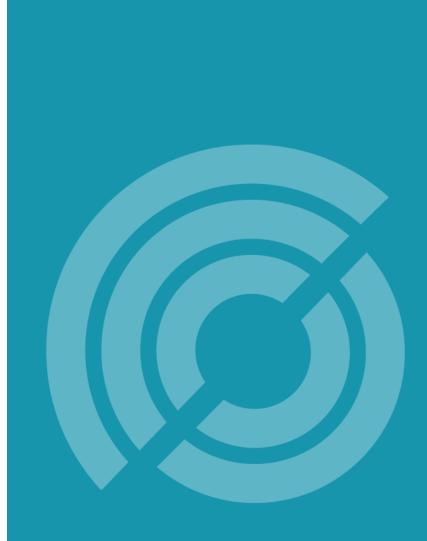


"I have never been able to give my female patients something that could really fix their issue. This product could give a bit of hope to female alopecia patients."

- Primary Care Physician



# FINANCIAL OVERVIEW





### **Financial Overview**

- Capital increase of 750,000 shares reserved to existing shareholders raised €23.3 m in June (because Italian co law does not allow negative equity)
- Cash position of € 8 m; no debt; € 6 m undrawn credit facility
- Non dilutive financing currently being considered
- Strategic options are being considered, including the possible purchase of an existing commercial organisation, a merger or other strategic alternatives



# **Upcoming Company Milestones**

- Clascoterone Cream 1% PDUFA Date Aug 27, 2020
- Clascoterone Cream 1% launch
  - Market Access 4Q2020, Sales launch March 2021
- Finalize SPA with FDA on Phase 3 program for Clascoterone Solution in Men
- Complete enrollment (Sept) and announce topline results for Phase 2 program for Clascoterone Solution in Females 2Q21





#### Information

**Number of shares:** 10,750,000

Listing: SIX Swiss exchange, Main board

**ISIN:** IT0005108359

Ticker: SKIN

#### Contacts

Diana Harbort, CEO <u>dharbort@cassiopea.com</u>

Chris Tanner, CFO <u>ctanner@cassiopea.com</u>

