

# OUR SKIN TELLS A STORY



1H 2021 Results Presentation  
July 29, 2021

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Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

# Agenda

- 1H 2021 Key Events
- 1H 2021 Financial Results
- Winlevi Commercialization Update
- Clascoterone Solution Update
- 2021 Outlook and Key Milestones

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## 1H 2021 Key Events

# Key Events 1H 2021

- Preparations for the commercial launch of Winlevi<sup>®</sup> (clascoterone cream 1%)
- Advancement of the development of clascoterone solution for androgenetic alopecia
- Multiple transaction structures and opportunities were evaluated over the last twelve months in order to optimize the US commercial launch of Winlevi<sup>®</sup>
- Post period, on 26 July, Cassiopea and Sun Pharma announced the signing of License and Supply Agreements for Winlevi<sup>®</sup> in the United States and Canada

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# H1 2021 Subsequent events – Sun Pharma Transaction

- On 26 July 2021 the Company announced, the signing of License and Supply Agreements for Winlevi® in the US and Canada with Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries is the world's fourth largest specialty generic pharmaceutical company. Sun has a strong established US dermatology presence and Winlevi complements its oral acne portfolio
- Under the terms of the agreements, Sun Pharma will have the exclusive right to commercialize Winlevi® in the United States and Canada, and Cassiopea will be the exclusive supplier of the product.
- Cassiopea will receive an upfront payment of US \$45 million, potential commercial milestones totaling up to US \$190 million and customary double digit royalties. The agreements will close upon the expiration of the HSR waiting period.
- Winlevi® is expected to be available in the US in Q4 2021.
- With the proceeds Cassiopea will be funded to continue the development of its innovative dermatology pipeline and is expecting substantial revenue streams for the foreseeable future.

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# Sun Pharma Transaction Rationale

- **Establishes Commercial Access for Winlevi with an Established Player Medical Dermatology** – Provides Winlevi with immediate access to acne prescriber universe with the support of an established organization in medical dermatology who will prioritize Winlevi
- **Reduces Commercialization Risk** - Given the recent dermatology environment, the risk and cost associated with building an organization from the ground up is mitigated
- **Well Funded for the Foreseeable Future** – Revenue from Sun transaction funds the activities of the company for the years ahead
- **Enables Internal Focus on R&D** – Cassiopea can focus its resources on developing its existing pipeline including Clascoterone solution for androgenetic alopecia, an area that has not seen innovation in 20-30 years

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# 1H 2021 Cassiopea Financial Results



# Consolidated Income Statement and Statement of Comprehensive Income

EUR/1,000	30.06.21	30.06.20
<b>Revenue</b>	-	-
Cost of sales	(-)	(-)
Research and development costs	(3,753)	(2,510)
Selling, general and administrative costs	(2,535)	(2,180)
<b>Net Operating expenses</b>	<b>(6,288)</b>	<b>(4,690)</b>
<b>Operating Result</b>	<b>(6,288)</b>	<b>(4,690)</b>
Financial income	300	18
Financial expenses	(177)	(650)
<b>Profit (loss) Before Taxes</b>	<b>(6,165)</b>	<b>(5,322)</b>
Income tax expenses	-	-
<b>Profit (loss) For The Period</b>	<b>(6,165)</b>	<b>(5,322)</b>
EUR/1,000	30.06.21	30.06.20
<b>Profit (loss) for the period (A)</b>	<b>(6,165)</b>	<b>(5,322)</b>
Other comprehensive income that will be not reclass. to P/L	-	-
Other comprehensive income that will be reclassified to P/L	(278)	22
<b>Total other comprehensive income, net of tax (B)</b>	<b>(278)</b>	<b>22</b>
<b>Total comprehensive income (A)+(B)</b>	<b>(6,443)</b>	<b>(5,300)</b>

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# Discussion of Consolidated Income Statement

- No revenues were generated in H1 2021 and H1 2020
- Net operating expenses are detailed by nature below

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EUR 1,000

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	<b>30.06.21</b>	<b>30.06.20</b>
Raw materials and consumables used	(153)	(317)
Personnel expenses	(1,742)	(1,785)
Outsourced preclinical and clinical trial costs	(1,733)	(640)
Other operating expenses	(2,511)	(1,918)
Depreciation and amortization	(149)	(30)
<b>Total net operating expenses</b>	<b>(6,288)</b>	<b>(4,690)</b>

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

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# Discussion of Consolidated Income Statement

- In H1 2021, Personnel expenses (EUR 1,742 thousand) are in line with H1 2020 (EUR 1,785 thousand)
  - The average number of employees is 11,0 in H1 2021 and 12,0 in H1 2020
  - In H1 2021, the expense for the value of employees' and executives Directors' services, exchanged for stock options, amounted to EUR 653 thousand (EUR 533 thousand in H1 2020) and it refers to the cost accounted in relation to the options granted by the Board of Directors in the period 2015–2021 and to the options granted by Cosmo Pharmaceuticals N.V.

- The entire staff develop as follows:

No. of people	<b>30.06.21</b>	<b>30.06.20</b>
Managers *	9	9
Junior managers	2	3
<b>Total n. of people</b>	<b>11</b>	<b>12</b>

\* 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

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# Discussion of Consolidated Income Statement

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

	<u>30.06.21</u>	<u>30.06.20</u>
Winlevi®	77	140
Clascoterone solution	1,654	498
CB-06-01	2	2
<b><u>Outsourced preclinical and clinical trials costs</u></b>	<b><u>1,733</u></b>	<b><u>640</u></b>

- Other operating expenses are detailed here below:

	<u>30.06.21</u>	<u>30.06.20</u>
Service costs	2,230	1,914
Other operating costs	281	4
<b><u>Total other operating expenses</u></b>	<b><u>2,511</u></b>	<b><u>1,918</u></b>

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# Discussion of Consolidated Income Statement

- External consultancy services increased in H1 2021 by EUR 126 thousand mainly due to activities for Winlevi®
  - Advertising and marketing costs in H1 2021 increased by EUR 277 thousand in relation to Winlevi® pre-commercial activities
  - In H1 2021 service costs include an amount of EUR 280 thousand (EUR 297 thousand in H1 2020) for Research, Development, and Regulatory services charged by Cosmo S.p.A. (subsidiary of Cosmo Pharmaceuticals N.V.)
  - In H1 2021 the company has been charged by Cosmo S.p.A. for secretarial and accounting services for an amount of EUR 70 thousand, included in External consultancy services (EUR 74 thousand in H1 2020)
- 
- Other operating costs increase because the FDA program fee
  - Depreciation and amortization increase because the amortization of Winlevi ® registration fee for the US

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# Discussion of Consolidated Income Statement

- Financial income in both H1 2021 and H1 2020 is totally composed of foreign exchange differences
- Financial expenses in H1 2021 include EUR 162 thousand (EUR 608 thousand in H1 2020) due to Interests on Cosmo Pharmaceuticals N.V.'s unsecured loan
- Income Tax expenses: on the tax losses for H1 2021 and H1 2020 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

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# Consolidated Statement of Financial Position

<b>EUR/1,000</b>	<b>30.06.21</b>	<b>31.12.20</b>
Tangible and intangible assets	2,889	2,998
Tax receivables	9,609	9,799
<b>Total non-current assets</b>	<b>12,498</b>	<b>12,797</b>
Inventories	1,817	761
Other receivables and other current assets	2,291	2,423
Cash and cash equivalents	1,796	2,646
<b>Total current assets</b>	<b>5,904</b>	<b>5,830</b>
<b>Total assets</b>	<b>18,402</b>	<b>18,627</b>
Total Non-current liabilities	-	66
Total Current liabilities	8,557	2,946
<b>Total liabilities</b>	<b>8,557</b>	<b>3,012</b>
<b>Total equity</b>	<b>9,845</b>	<b>15,615</b>
<b>Total equity and liabilities</b>	<b>18,402</b>	<b>18,627</b>

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# Discussion of Consolidated Statement of Financial Position

- Tangible and intangible assets include EUR 2,222 thousand related to the payment of Winlevi ® registration fee to the U.S. Food and Drug Administration (FDA), net of the amortization
- Tax receivables refer to Tax Credit R&D costs
- Inventories refer to the API required for the production for the commercial launch of Winlevi®
- 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 to EUR 1,796 thousand
- Current liabilities mainly include trade payables for EUR 2,246 and EUR 6,226 thousand due to Cosmo Pharmaceuticals N.V. for the draw down from the unsecured credit facility (EUR 6,000 thousand) and interest

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# Discussion of Consolidated Statement of Financial Position

	<i>Number of Shares</i>	<i>Share Capital</i>	<i>Share premium</i>	<i>Capital contribution</i>	<i>Stock option plan reserve</i>	<i>Currency translation reserve</i>	<i>Retained earnings</i>	<i>Losses carried forward</i>	<i>TOTAL</i>
EUR1,000									
	<i>(n)</i>								
<b>Net equity as at 1 January 2020</b>	<b>10,000,000</b>	<b>10,000</b>	<b>1,868</b>	<b>437</b>	<b>3,111</b>	<b>11</b>	<b>(11,700)</b>	<b>-</b>	<b>3,727</b>
Allocation of prior year result			(1,868)	(437)			11,700	(9,395)	-
Capital increase	750,000	750	21,640						22,390
Cost for stock options				77	469				546
Total comprehensive income for the period						22	(5,322)		(5,300)
<b>Net equity as at 30 June 2020</b>	<b>10,000,000</b>	<b>10,750</b>	<b>21,640</b>	<b>77</b>	<b>3,580</b>	<b>33</b>	<b>(5,322)</b>	<b>(9,395)</b>	<b>21,363</b>
EUR1,000									
	<i>(n)</i>								
<b>Net equity as at 1 January 2021</b>	<b>10,750,000</b>	<b>10,750</b>	<b>21,638</b>	<b>123</b>	<b>4,184</b>	<b>623</b>	<b>(12,308)</b>	<b>(9,395)</b>	<b>25,010</b>
Allocation of prior year result							12,308	(12,308)	-
Cost for stock options				72	601				673
Total comprehensive income for the period						(278)	(6,165)		(6,443)
<b>Net equity as at 30 June 2021</b>	<b>10,750,000</b>	<b>10,750</b>	<b>21,638</b>	<b>195</b>	<b>4,785</b>	<b>345</b>	<b>(6,165)</b>	<b>(21,703)</b>	<b>9,845</b>

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# Discussion of Consolidated Statement of Financial Position

- Equity as at 30.06.2021 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 21,638 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 862 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
  - “Stock option plan reserve”: In H1 2021, the expense for the stock options amounted to EUR 601 thousand of which EUR 581 thousand for management and personnel and EUR 20 thousand for non-executive Directors (In H1 2020 EUR 456 thousand and EUR 13 thousand respectively).
  - “Currency translation reserve” arises from the consolidation of foreign entity with functional currency other than the Euro
  - “Losses carried forward” arise from the previous year’s result not allocated

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# Consolidated Cash Flow Statement

EUR/1,000	30.06.21	30.06.20
<b>Profit (loss) before taxes</b>	<b>(6,165)</b>	<b>(5,322)</b>
Interest on loan not paid	162	608
Depreciation and amortization	149	30
Share based payment expenses	673	546
R&D credit offset	190	195
Net unrealised foreign exchange differences on intercompany loan	(276)	(26)
Net unrealized foreign exchange differences on cash and cash equivalents	(10)	4
Change in net working capital	(1,541)	(223)
<b>Cash flows from operating activities</b>	<b>(6,818)</b>	<b>(4,188)</b>
<b>Cash flows from investing activities</b>	<b>(40)</b>	<b>(43)</b>
<b>Cash flows from financing activities</b>	<b>5,998</b>	<b>11,990</b>
<b><i>Net increase/(decrease) in cash and cash equivalents</i></b>	<b><i>(860)</i></b>	<b><i>7,759</i></b>
<b><i>Cash and cash equivalents at the beginning of the period</i></b>	<b><i>2,646</i></b>	<b><i>696</i></b>
Net unrealized foreign exchange differences on cash and cash equivalents	10	(4)
<b><i>Cash and cash equivalents at the end of the period</i></b>	<b><i>1,796</i></b>	<b><i>8,451</i></b>

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# Commercial Update

Acne is the most prevalent skin condition in the U.S...yet the last new mechanism of action approved by the FDA was almost **40** years ago<sup>1,2</sup>

50

Million sufferers in US<sup>3</sup>

\$5

Billion US market<sup>4</sup>

24

Million prescriptions<sup>4</sup>

70%

Total Prescriptions written in the Dermatology Office<sup>4</sup>



Source: 1. Thielitz A, Gollnick H. *Am J Clin Dermatol*. 2008;9(6):369-81; 2. Costa CS et al. *Cochrane Database Syst Rev* 2018;11:CD009435. 3. Skin Conditions by the numbers. American Academy of Dermatology. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. 4. IQVIA National Prescription Audit Sept. 2019.

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# Winlevi (clascoterone) cream 1% Approval Marks the Introduction of a **New Class of Topical Therapy to Dermatology**<sup>1,2</sup>

First in Class Topical Androgen Receptor Inhibitor<sup>1</sup>

Approved for the topical treatment of acne in patients 12 years of age and older<sup>2</sup>

Tackles the androgen hormone component of acne in both males & females<sup>2,3</sup>

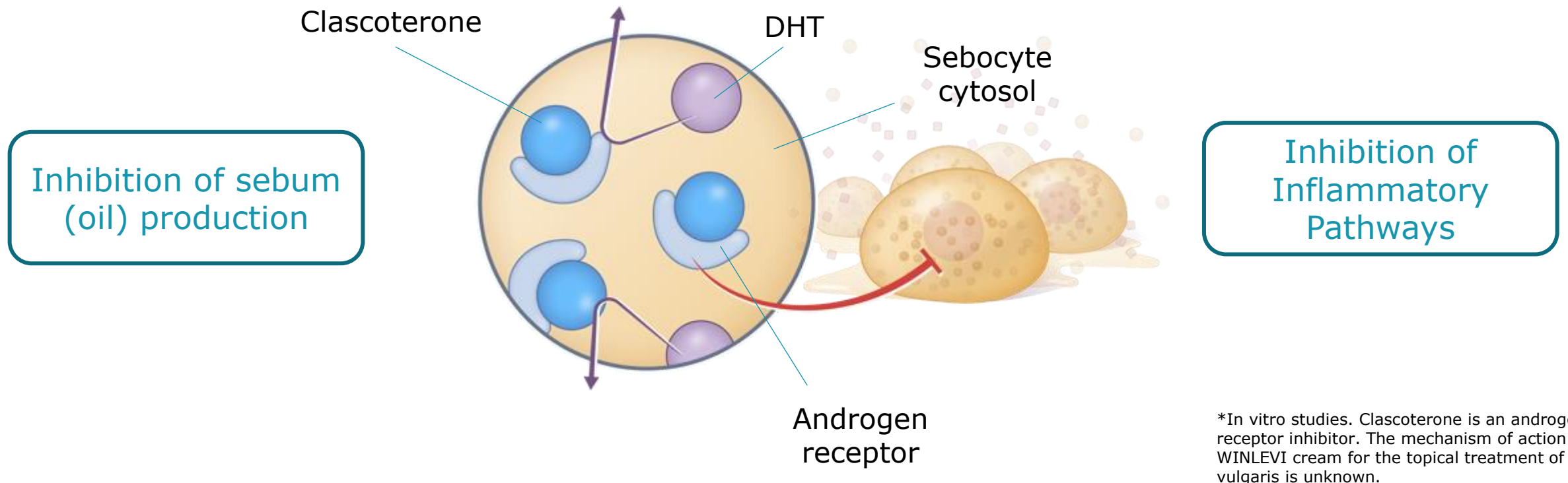
The most frequent observed local skin reaction was mild erythema<sup>1,3</sup>



1. US FDA. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020> 2. Winlevi Prescribing Information - <https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf> 3. US FDA Drug Trial Snapshot: WINLEVI. September 3, 2020. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-winlevi>

# Clascoterone is an androgen receptor inhibitor: *In Vitro* Activity

**Clascoterone competes with DHT for binding to the androgen receptor<sup>1,2\*</sup>**



\*In vitro studies. Clascoterone is an androgen receptor inhibitor. The mechanism of action of WINLEVI cream for the topical treatment of acne vulgaris is unknown.

Source: 1. Ferraboschi P et al. Med Chem Commun 2014;5:904-14; 2. Rosette C, et al. J Drugs Dermatol. 2019; 18(5):412-418. <https://www.ncbi.nlm.nih.gov/pubmed/31141847>

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# Key US Acne Market Insights and Positioning

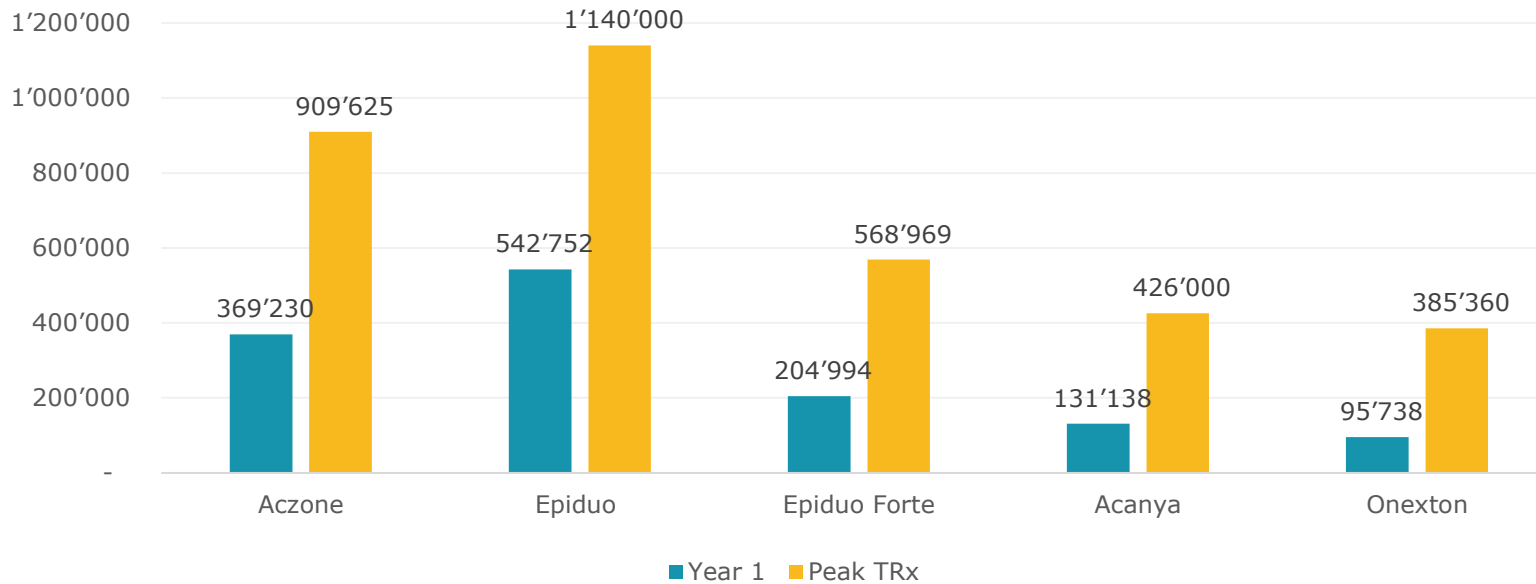
- Acne market continues to be an important market in Dermatology
  - High volume, concentrated target market with 8,200 providers accounting for almost 60% of prescriptions
- Unmet need among providers for a novel approach, especially targeting the hormonal aspect for all acne patients
  - Over the counter retinoids and BPOs are paving the way for innovative prescriptions
  - Antibiotic stewardship in acne has increased the need for alternatives
  - 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 WINEVI around the unique mechanism of action and significant market share uptake predicted among segmented high value providers

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# Market research confirms interest in WINLEVI 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*

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

## 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
- Reported market share of 18-24%

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# Market Access

## Summary Insights and Coverage Progress

- Payers continue to provide coverage for acne patient visits and products
- While price is a key driver for coverage decisions, innovation and new MOA does matter
  - Drugs over \$600 WAC monthly cost may have higher restrictions - \$550 WAC set
  - Clascoterone is in a unique category as a first-in-class androgen receptor inhibitor, increasing Payer interest and contracting engagement
- Contracting Negotiations have been initiated with Payers representing 98% of all Commercial/DoD lives (175MM) - 4 contracts signed, 3 additional contracts in process with rebate terms accepted
- Coverage expected in at least 80% of commercial lives at launch, without highly restrictive PAs or multiple step edits

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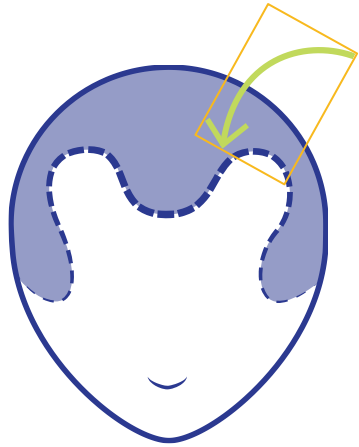
**OUR SCIENCE TELLS A STORY**

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

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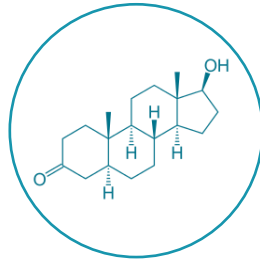
Clascoterone solution is under investigation and is not FDA approved.

# US Androgenetic Alopecia Market



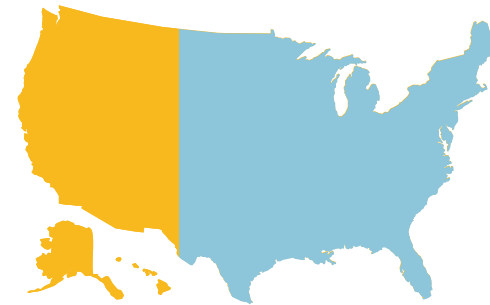
**Androgenetic alopecia**, also known as **pattern baldness**, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern<sup>1</sup>

It is caused by high concentrations of **dihydrotestosterone (DHT)** at the hair-follicle, which shortens the hair growth cycle in those with a genetic predisposition<sup>1</sup>



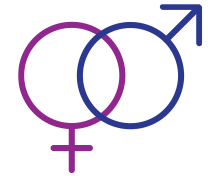
Known psychosocial complications of androgenetic alopecia include **depression, low self-esteem, and less frequent and enjoyable social engagement**<sup>2</sup>

Studies have indicated that **women are more likely to suffer from psychological complications than men**<sup>2</sup>



**80-95 million** Americans suffer from Androgenetic alopecia<sup>3</sup>

**Both men and women** are impacted<sup>2</sup>

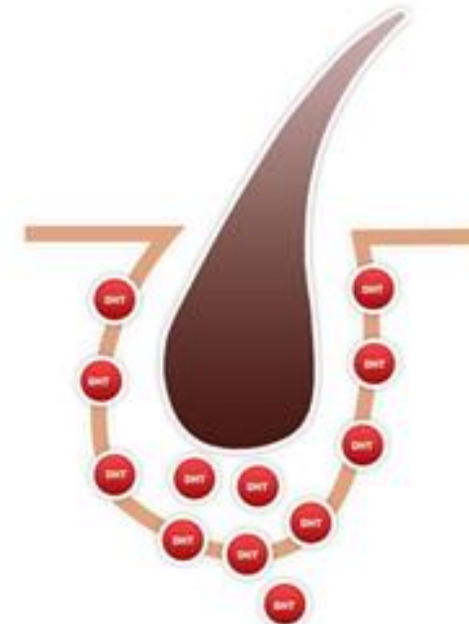
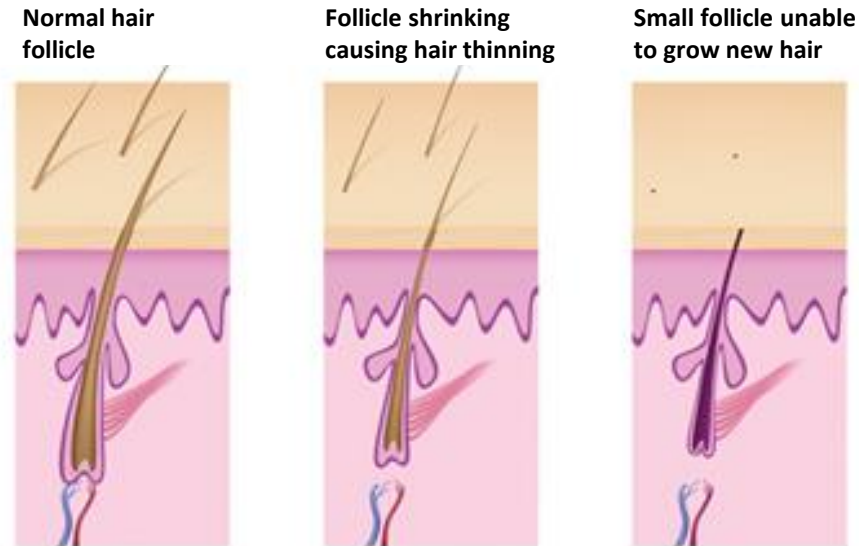


**Only 4-9 million** patients are estimated to get treatment

Treatment options are limited to old therapies developed

**20 -30 years ago**<sup>4</sup>

# Clascoterone Solution: A Potential New Topical Treatment for Androgenetic Alopecia in Males and Females<sup>1,2</sup>



DHT = Dihydrotestosterone

## Existing Treatments

### Propecia™ (finasteride)

- Has anti-androgenic activity on follicle by inhibiting 5 alpha reductase, an enzyme required for synthesis of DHT<sup>3</sup>
- However, serious side effects due to hormonal imbalance<sup>3</sup>
- Not indicated for women<sup>3</sup>

### Minoxidil®

- ◆ Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla<sup>3</sup>

## Clascoterone Solution A Novel Topical Androgen Receptor Inhibitor

- Antagonizes DHT's negative effects on dermal papilla by competing with DHT at the androgen receptor<sup>1</sup>
- Reduces hair miniaturization<sup>1</sup>
- Reduces dermal inflammation<sup>1</sup>

1. Rosette C, Rosette N, Mazzetti A et al.. *J Drugs Dermatol.* 2019; 18(2)197-201. 2. Cassiopea S.p.A.: Elevating the science of dermatology with new therapeutics. Nature Dealmakers. 2020; Nov 30, 2020. 3. Ashique S, et al. . *Nat Prod Bioprospect.* 2020;10(6):345-365. doi:10.1007/s13659-020-00267-9

# Clascoterone Solution Clinical Program Status

## Status:

- Phase 2 dose ranging study in males successful and most effective dose identified at 7.5% BID
- End of Phase 2 Meeting with FDA held
- Special Protocol Assessment for Phase 3 Program submitted to FDA and Type A meeting held
- Development of Patient Reported Outcome questionnaire underway
- Phase 2 study in females recently completed

## Next Steps:

- Phase 2 data in females top line results 3Q21
- Finalize Phase 3 Program in males upon FDA feedback on PRO

7.5% Solution BID Baseline



Month 6



Representative photos.

Blume-Peytavi U, et al. S11223 - ). Presented at the 2019 AAD Annual Conference. S034 Late-breaking Research Saturday March 2, 2019. Washington DC. <https://bit.ly/330h2nt>

# Key Market Insights & Opportunity for Breezula



## Simple Tx Algorithm, poised for market disruption

- Few therapeutic options for Physicians, limited to finasteride and minoxidil, results in underdeveloped AGA Market
- No promotional competition on the horizon

- ✓ HCPs were highly receptive to the product profile, emphasizing the novel mechanism and impressive clinical photographs – 60% reported adoption



## Highly Engaged & Motivated Patient Base

- Over 70% of patients express a high level of concern and impact on their lives
- Most common treatment is Rogaine, along with vitamins & supplements
- Women have fewer options than men
- Forhims, keeps.com have impacted the distribution model directly to consumers

- ✓ Almost half of the patients surveyed said they would be extremely likely to request a Rx, with another 30% moderately likely.



## Payers call this a “lifestyle” drug category

- Finasteride and minoxidil are not considered covered drugs
- Payers express unlikely to cover future AGA drugs
- Cosmetic disease, rather than medical

- ✓ Breezula could be priced \$100-200 per month like other lifestyle drugs

Source: Triangle Insights Group Primary Market Research Among Patients, Payers and Physicians Q3-4 2018



## 2021 Outlook and Key Milestones



# 2021 Guidance

- Guidance is based on
  - Obtaining HSR clearance for Sun transaction
  - Receiving USD \$45 million upfront payment
  - Launch of Winlevi (clascoterone) cream, 1% by Sun in Q4 2021
- Revenue in the range of 37M-39M Euro
- Operating Expenses in the range of 11M-13M Euro
- Operating Profit in the range of 24M-28M Euro

# Upcoming Company Milestones

- Announce topline results for Phase 2 study for Clascoterone Solution in Females 3Q21
- Winlevi (clascoterone) cream, 1% launch 4Q 2021
- Finalize Phase 3 program for Clascoterone Solution in males upon FDA feedback on PRO

# Cassiopea Pipeline

## PRODUCT

## PROPOSED INDICATION

**WINLEVI®**  
**(clascoterone cream 1%)**  
Androgen receptor inhibitor

**Acne Vulgaris**



**Clascoterone solution**  
Androgen receptor inhibitor

**Androgenetic alopecia in males**



**Clascoterone solution**  
Androgen receptor inhibitor

**Androgenetic alopecia in females**



**CB-06-01**  
Antibiotic

**Acne**



**CB-06-02**  
Immune modulator

**Genital warts**



Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

# Cassiopea SpA

## Information

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

**Listing:** SIX Swiss exchange, Main board

**ISIN:** IT0005108359

**Ticker:** SKIN

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# WINLEVI<sup>®</sup> (clascoterone) cream, 1% Indication & Important Safety Information

## INDICATIONS AND USAGE

WINLEVI<sup>®</sup> (clascoterone) cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

## DOSAGE AND ADMINISTRATION

- Apply a thin layer (approximately 1 gram) to affected area twice daily (morning and evening). Avoid contact with eyes, mouth, and mucous membranes.
- Not for ophthalmic, oral or vaginal use.

## DOSAGE FORM AND STRENGTHS

Cream 1%.

## CONTRAINDICATIONS

None.

## WARNINGS AND PRECAUTIONS

Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

- Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with clascoterone.
- Attempt to withdraw use if HPA axis suppression develops.
- Pediatric patients may be more susceptible to systemic toxicity.
- Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials.

## ADVERSE REACTIONS

Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

See

<https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf> for full prescribing information