# INVESTOR PRESENTATION

July 18, 2019



# **Agenda**

- H1 2019 Financial Result
- Development Update
- Cassiopea Inc Update
- Financing Considerations



# H1 2019 FINANCIAL RESULTS





## **Income Statement and Statement of Comprehensive income**

EUR/1,000	30.06.19	30.06.18
Revenues	0	0
Other income	0	0
Cost of sales	(0)	(0)
Research and development costs	(4,689)	(6,423)
Selling, general and administrative costs	(1,596)	(663)
Net Operating expenses	(6,285)	(7,086)
Operating Result	(6,285)	(7,086)
Financial income	60	418
Financial expenses	(233)	(61)
Profit (loss) Before Taxes	(6,458)	(6,729)
Income tax expenses	-	-
Profit (loss) For The Period	(6,458)	(6,729)
EUR/1,000	30.06.19	30.06.18
Profit (loss) for the period (A)	(6,458)	(6,729)
Other comprehensive income that will be not reclass. to P/L	0	0
Other comprehensive income that will be reclassified to P/L	0	0
Total other comprehensive income, net of tax (B)	0	0
Total comprehensive income (A)+(B)	(6,458)	(6,729)



- No revenues were generated in H1 2019 and H1 2018
- Net operating expenses are detailed by nature below

EUR 1,000		
	30.06.19	30.06.18
Raw materials and consumables used	(186)	(140)
Personnel expenses	(1,149)	(717)
Outsourced preclinical and clinical trial costs	(2,502)	(5,169)
Other operating expenses	(2,424)	(1,043)
Depreciation and amortization	(24)	(17)
Total net operating expenses	(6,285)	(7,086)

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



- Personnel expenses increased from EUR 717 thousand to EUR 1,149 in relation to the set-up of the US subsidiary
- The average number of employees is 11 in H1 2019 (9 in H1 2018)
- In H1 2019, the expense for the value of employees' and executives Directors' services, exchanged for stock options, amounted to EUR 409 thousand (EUR 380 thousand in H1 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		
		30.06.18
Managers*	9	6
Junior managers	3	3
Total No. of people	12	9

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

 In addition, the companies of the Cosmo Pharmaceuticals N.V. group provide the services for research and 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		
	30.06.19	30.06.18
Winlevi®	1,762	3,675
Breezula®	732	1,460
CB-06-02	8	34
Outsourced preclinical and clinical trials costs	2,502	5,169

Other operating expenses are detailed here below:

EUR 1,000	_		
	30.06.19	30.06.18	
Service costs	2,420	1,035	
Operating lease expenses	-	5	
Other operating costs	4	3	
Total other operating expenses	2,424	1,043	



#### Service costs:

EUR 1,000	30.06.19	30.06.18
External consultancy services	1,020	196
Patent costs	85	116
Investor relations and web site maintenance	101	97
Technical assistance	2	2
Utilities, telephone, internet	3	3
Insurance	40	59
Non-executive directors	70	58
Stock options non-executive directors	6	41
Management control committee	5	4
Auditing	16	13
Advertising and marketing costs	469	8
Freight and customs	3	5
Travel expenses	83	92
External laboratory services	60	94
R&D and Regulatory services	443	239
Other costs	14	8
Total service costs	2,420	1,035



- External consultancy services increased by EUR 824 thousand mainly due to the preparatory activities for Winlevi's New Drug Application submission
- Advertising and marketing costs increase by EUR 461 thousand in relation to Winlevi's pre-commercial activities
- Service costs in H1 2019 also include EUR 6 thousand (EUR 41 thousand in H1 2018) for the Stock Option Plan to the non-executive directors
- In H1 2019, the Company has been charged by Cosmo S.p.A. (subsidiary of Cosmo Pharmaceuticals N.V.) for an amount of EUR 443 thousand (in H1 2018 EUR 215 thousand from Cosmo S.p.A. and EUR 24 thousand from Bellatrix Inc.) for Research/Development/Regulatory services
- In H1 2019, 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 76 thousand, included in External consultancy services (EUR 76 thousand in H1 2018)
- Operating lease expenses are nil in H1 2019, as the group has recognised depreciation and interest costs as a result of initially application of IFRS 16



- Financial income in H1 2019 includes EUR 50 thousand for foreign exchange differences (EUR 308 thousand in H1 2018) and EUR 10 thousand for interest received on cash and cash equivalents (EUR 109 thousand in H1 2018)
- Financial expenses include EUR 199 thousand due to Interests on Cosmo Pharmaceuticals N.V. unsecured loan
- Income Tax expenses: on the tax losses and on the Italian fiscal relief "ACE" (Aiuto alla crescita economica) for H1 2019 and H1 2018 no deferred tax assets have been recognized in the Company's financial statements due to uncertainties concerning the availability of future taxable profits against which such an asset may be offset



EUR/1,000	30.06.19	31.12.18
Tangible and intangible assets	575	500
Tax receivables	9,037	9,260
Total non-current assets	9,612	9,760
Other receivables and other current assets	2,091	2,171
Cash and cash equivalents	834	4,609
Total current assets	2,925	6,780
Total assets	12,537	16,540
Total Non-current liabilities	2,207	0
Total Current liabilities	1,854	2,028
Total liabilities	4,061	2,028
Total equity	8,476	14,512
Total equity and liabilities	12,537	16,540



- Tangible and intangible assets include EUR 559 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 3,775 thousand due to the use of cash for the operations

- Non-current liabilities mainly refer to the draw down (EUR 2,000 thousand) of Cosmo Pharmaceuticals N.V. unsecured credit facility
- Current liabilities mainly refer to trade payables



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	51	370 (8)		13,656 (6,729)	- 421 - (6,729)
Net equity as at 30 June 2018	10,000,000	10,000	14,524	173	2,078	-	(6,729)	20,046
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 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 Currency translation reserve Total comprehensive income for the period			(12,656)	97	318	7	12,656 (6,458)	- 415 7 (6,458)
Net equity as at 30 June 2019	10,000,000	10,000	1,868	333	2,726	7	(6,458)	8,476



- 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 prior year 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 318 thousand of which EUR 312 thousand for management and personnel and EUR 6 thousand for non-executive Directors (In H1 2018 EUR 329 thousand and EUR 41 thousand respectively)
- Currency translation reserve arise from the consolidation of foreign entity with a functional currency other than the Euro

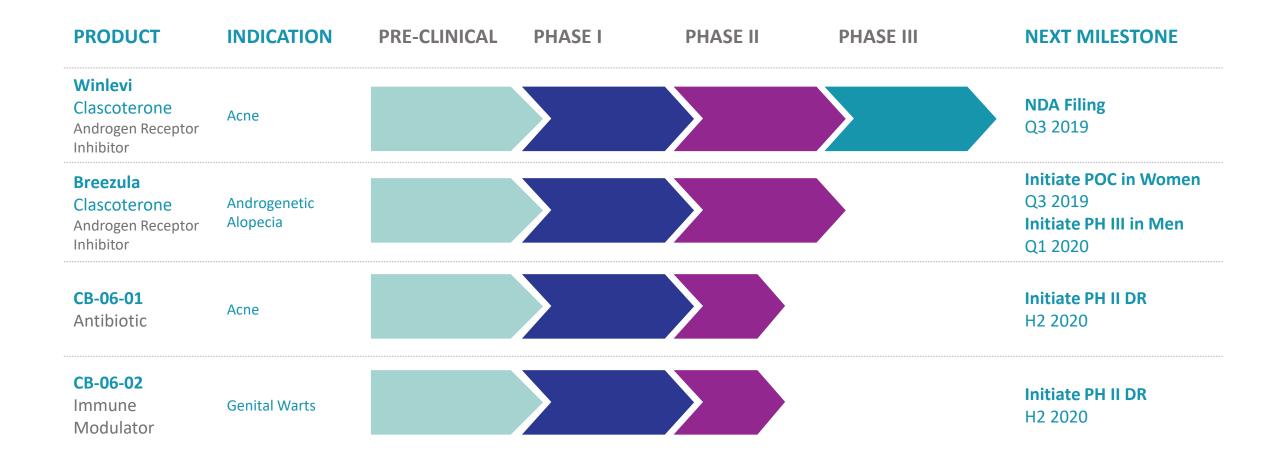


## **Cash Flow Statement**

EUR/1,000	30.06.19	30.06.18
Profit (loss) before taxes	(6,458)	(6,729)
Interest not paid	199	0
Depreciation and amortization	24	17
Share payment-based expenses	415	421
R&D credit offset	173	176
Net Unrealised foreign exchange differences on cash and cash equivalents	(2)	(267)
Change in net working capital	(41)	(69)
Cash flows from operating activities	(5,690)	(6,451)
Cash flows from investing activities	(85)	(53)
Cash flows from financing activities	1,998	0
Net increase/(decrease) in cash and cash equivalents	(3,777)	(6,504)
Cash and cash equivalents at the beginning of the period	4,609	17,598
Net Unrealised foreign exchange differences on cash and cash equivalents	2	267
Cash and cash equivalents at the end of the period	834	11,361



# **Cassiopea Pipeline**





# DEVELOPMENT UPDATE





### Winlevi

### **1H 2019 Achievements:**

- Received conditional approval from FDA on Winlevi proprietary name
- Pre NDA meeting held May 6, 2019
- 20+ Published Papers, Posters and Abstracts
- 22 Meetings Sponsorships
- 40+ Podium Mentions
- Completed second round of market access research

### **Next Step:**

NDA Filing in coming weeks





### Breezula

#### **1H 2019 Achievements:**

- Phase 2 dose ranging study successful and most effective dose identified
- Published Mechanism of Action Manuscript
- 9 Published Papers, Abstracts and Posters
- Late Breaker Poster & Presentation at 2019 AAD
- Study design for POC in women complete

### **Next Steps:**

- Clinical and Regulatory Pathway:
  - Q3 Initiate Breezula POC trial in Women
  - Q4 Breezula End of Phase 2 Meeting w FDA
  - January Initiate Breezula Phase 3 trials





# **Exciting Time at Cassiopea**

- Expanding footprint in Dermatology
  - US subsidiary, Cassiopea Inc, established
  - Small team of executives with decades of derm experience has been hired
  - Extensive Medical Affairs program has rapidly increased awareness of clascoterone new MOA and clinical data in the dermatology community
  - Strategy to balance investment pre and post PDUFA to minimize risk
- Late stage development projects are progressing on schedule
- Continued interest in our early stage development pipeline
- Poised to be the next leader in Dermatology



# Market Access 2019/2020 Plan Overview

- 1. Understand current Acne formulary access decisions & identify and test the Key Access Value Drivers for the Acne treatment market COMPLETE
  - Identify the 'Value Driver' or attributes of Winlevi most important to Payers in their decision-making process
- 2. Understand the evolving PBM downstream alignment and how well they follow National Payer formularies when it comes to Acne medications? Due August
  - What % of lives are covered by each PBM & what is the expected impact of formulary restrictions on Winlevi?
- 3. Winlevi® Payer Value Proposition (PVP) Messaging Development Due September
  - Use the Value Drivers to create, review, and finalize Key Messages to be used with Payers when seeking formulary
    placement and plan coverage for Winlevi
- 4. Develop Price-Access Projections & Market Access Forecast Support Due October
  - Understand U.S. Payer price-access sensitivity and expected coverage decisions across a range of price points
  - Project the price-access decisions (i.e, the expected coverage across a range of price points (by a # of lives)
  - Develop a set of Market Access forecast assumptions based on those projected price-access decisions
- 5. Test the credibility and impact of the draft Winlevi Payer Value Proposition (PVP) Due Q1 2020
  - Test the PVP with a series of key access decision makers at U.S. Payers
  - Find price benchmarks and pricing boundaries, trade-offs and tipping points



# Understand current Acne formulary access decisions & identify and test the Key Access Value Drivers for the Acne treatment market COMPLETE

- Goals
  - Identify how acne treatments are currently managed by Payers and their underlying rationale for formulary decisions
  - Understand preliminary Payer perceptions of Clascoterone
  - Identify and test 'Value Drivers' to direct our Payer Value Proposition (PVP) development
- 21 top Value Drivers for Clascoterone were identified and tested with a panel of 12 Payers, representing 92 million lives
  - All 21 Drivers were ranked in aggregate from most to least important. 9 of top 12 drivers were related to efficacy or economics
- Key Takeaways
  - Overall, acne vulgaris is of *moderate to low management priority*, due to perceived relatively *lower spend* in the category
  - In general, no perceived desire to change acne management approach in the next 12 18 months and/or will continue to treat it is a medical condition
  - NET price is the highest rated value driver for acne vulgaris treatment options because the market is highly genericized with additional OTC treatment options
  - The importance of a new MOA in Acne increases when linked to key drivers like Efficacy & Safety
  - Durability and long-term efficacy demonstrated by 52-week data is important as acne is generally not short-term
  - Absolute reduction and percent reduction in total lesion count are highly and equally important efficacy measures
  - An indication for acne vulgaris is important to determine the appropriate patient population and may inform utilization management criteria language
  - The Payer Value Story (PVP) should establish Clascoterone's efficacy & safety, while showing the benefits of a Novel MOA
- This preliminary research anticipates that many Payers will likely cover Winlevi on a non-preferred tier, but ultimate access is largely dependent on WAC and NET price



# **Key Milestones 2019**

 July- File NDA Winlevi

Initiate Breezula
 POC trial in Women

 Breezula End of Phase II Meeting w/ FDA Initiate Breezula Phase
 III trials in Men

Q3 2019 Q4 2019 Q1 2020











# FINANCING CONSIDERATIONS





# **Financing Considerations**

- The planned operating cash requirements for H2 2019 are EUR 14.8m
- At mid year EUR 2m of the EUR 10m credit line granted by Cosmo Pharma was drawn
- Cosmo has indicated that it would be willing to increase the credit facility to EUR 20m
- On April 5, 2018 and on March 18, 2019 Shareholders approved capital increase by issuance of up to 1m shares and up to 3m shares respectively



# **CASSIOPEA**

Information	Contacts
<ul> <li>Number of shares: 10,000,000</li> </ul>	<ul> <li>Diana Harbort, CEO <u>dharbort@cassiopea.com</u></li> </ul>
<ul> <li>Listing: SIX Swiss exchange, Main board</li> </ul>	• Luigi Moro, CSO
• ISIN: IT0005108359	<u>Imoro@cassiopea.com</u>
Ticker: SKIN	<ul> <li>Alessandro Mazzetti, CMO <u>amazzetti@cassiopea.com</u></li> </ul>
	<ul> <li>Chris Tanner, CFO <u>ctanner@cassiopea.com</u></li> </ul>

