



## **Cassiopea announces 2019 Results in line with expectations**

**Lainate, Italy – 19 March 2020** – Cassiopea S.p.A. (SIX: SKIN), a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, announced today results for the year ended 31 December 2019.

### **Key Highlights**

- Positive safety and efficacy data for Phase III open label safety study evaluating Clascoterone cream 1% in acne for a treatment period of up to one year
- A New Drug Application (NDA) was submitted to the FDA for Clascoterone cream 1%, a proposed first-in-class topical androgen receptor inhibitor for the treatment of acne on 20 August 2019 and FDA set the PDUFA date for 27 August 2020
- Conditional approval from FDA received for Winlevi™ proprietary name
- Completed extensive acne market evaluation and segmentation work with health care providers, along with positioning and messaging research for Clascoterone cream 1% to estimate market share uptake
- Conducted thorough US payer acne landscape research with specific analysis to identify the payer value proposition and the pricing-access model for Clascoterone cream 1%
- Positive results of the 12 months Phase II dose ranging study for Clascoterone solution in androgenetic alopecia (AGA) in males and identified best dose as 7.5%
- End of Phase II meeting held with FDA for Clascoterone Solution in males
- Phase II trial for Clascoterone solution in AGA in females initiated and enrolment ongoing
- All operations were carried out within the budgeted framework

### **Financial Highlights**

- There were no operating revenues because all products are still in development and there was no out-licensing activity
- R&D expenses decreased by 35.7% to EUR 7,875 thousand. The main costs were the costs of the Phase II dose ranging trial for Clascoterone solution in AGA in males and the Phase II for Clascoterone Solution in females
- SG&A expenses increased by 105.2% to EUR 3,879 thousand primarily because of Clascoterone cream 1% pre-commercial activities
- A net tax credit of EUR 686 thousand on the R&D costs has been recognized according to the Italian tax law
- Operating losses decreased by 16.2% to EUR 11,068 thousand
- Financial expenses increased by 125.6% to EUR 772 thousand mainly because of the interest expenses associated with the loan agreement from Cosmo
- At year-end, cash and cash equivalents amounted to EUR 696 thousand. Total equity declined by 74.3% to EUR 3,727 thousand and interest bearing loans increased to EUR 10,660 thousand as part of a EUR 20,000 thousand credit facility made available by the largest shareholder Cosmo Pharmaceuticals N.V.

Diana Harbort, CEO of Cassiopea S.p.A., commented: “2019 has been a very productive year for Cassiopea. We made major development progress with our late-stage pipeline and have begun preparing for the commercialization of our first product in the USA. Most importantly, in August we submitted our New Drug Application (NDA) for Clascoterone cream 1%, the first new mechanism of action for acne in nearly 40 years. 2020 will be the pivotal year for Cassiopea as we look forward to the 27 August 2020 PDUFA date for Clascoterone cream 1% in acne and then to commercialization, once approved”.

Diana Harbort continued “As to financing, Cassiopea is an Italian company and the Italian company law does not allow a company to operate with a negative equity. Thus, we need to do a small capital increase in the range of EUR 15-20 million at the latest by end of May, unfortunately – for technical reasons – before the PDUFA date. This is not a liquidity issue as cash is already provided by Cosmo through loans. We are pursuing two options simultaneously: either a small capital increase with external investors to increase the free float or a rights offering to all existing shareholders. We will decide which way to go depending on the opportunity and on market conditions. In the event of a rights offering to all existing shareholders, Cosmo has already stated that it will subscribe its portion and also all eventually un-opted shares. We are therefore in a very comfortable position and I thank Cosmo for its continuous support and commitment for the benefit of all shareholders”.

### Key Financial Figures

In EUR thousands (with the exception of the share data in €)	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)
<b>Operating Result</b>	<b>(11,068)</b>	<b>(13,214)</b>
Net financial income	(632)	558
<b>Loss before taxes</b>	<b>(11,700)</b>	<b>(12,656)</b>
<b>Net loss</b>	<b>(11,700)</b>	<b>(12,656)</b>
<i>Loss per share</i>	<i>(1.170)</i>	<i>(1.266)</i>
	<b>31.12.2019</b>	<b>31.12.2018</b>
Non-current assets	12,536	9,760
Cash and cash equivalents	696	4,609
Other current assets	2,829	2,171
<b>Total assets</b>	<b>16,061</b>	<b>16,540</b>
Total equity	3,727	14,512
Interest bearing loans	10,664	-
Other liabilities	1,670	2,028
<b>Total equity and liabilities</b>	<b>16,061</b>	<b>16,540</b>

The Annual Report 2019 is available on the Company's web site at:

[https://www.cassiopea.com/wp-content/uploads/2020/03/Cassiopea\\_Annual\\_Report\\_2019.pdf](https://www.cassiopea.com/wp-content/uploads/2020/03/Cassiopea_Annual_Report_2019.pdf)

**2019 results presentation and conference call at 16:00 CET on 19 March 2020:**

Diana Harbort, CEO; Luigi Moro, CSO; Alessandro Mazzetti, CMO; Chris Tanner, CFO; and Marco Lecchi, Deputy CFO will present the 2019 results at a conference call to be held today at 16:00 CET.

The dial-in numbers:

Switzerland / Europe: +41 (0) 58 310 50 00  
United Kingdom: +44 (0) 207 107 0613  
United States: +1 (1) 631 570 56 13

The presentation for this call can be found on the Company's website:

<https://www.cassiopea.com/investor-relations/#publicationsAndCalendar>

**About Cassiopea**

Cassiopea is a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia and genital warts. Cassiopea is investing in innovation that is driving scientific advancement in areas that have been largely ignored for decades. The portfolio comprises four unencumbered clinical candidates, for which Cassiopea owns the worldwide rights. If approved, Cassiopea plans to commercialize the products directly in the USA and partner the products for countries outside of the USA. For further information on Cassiopea, please visit [www.cassiopea.com](http://www.cassiopea.com).

**About Clascoterone**

Clascoterone, a new chemical entity, is a proposed first in class topical androgen receptor inhibitor under FDA review for the treatment of acne (in a 1% cream) and in late stage development for androgenetic alopecia (in a higher strength solution). Laboratory studies suggest Clascoterone competes with androgens, specifically DHT, for binding to the androgen receptors within the sebaceous gland and hair follicles. When applied directly to the skin surface, Clascoterone appears to target only local androgen receptors within the skin. Because of Clascoterone's likely local effect at the site of application, the risk of off-target, or systemic side effects, is minimized.

**Next events**

H.C. Wainwright Annual Global Life Sciences Conference – 19-21 April 2020, London  
Annual General Shareholders Meeting – 29 April 2020, Lainate  
Extraordinary Shareholders Meeting – 28 May 2020, Lainate  
Jefferies Global Health Care Conference – 2-4 June 2020, New York  
Half Year Report 2020 – July 2020  
Investora – 23-24 September 2020, Zürich  
Credit Suisse Small & Mid Cap Conference – 18-20 November 2020, Zurich

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