

# Cassiopea reports on financial year 2016 and the development of its clinical programs

**Lainate – 24 February 2017** - Cassiopea SpA (SIX: SKIN), a clinical stage specialty pharmaceutical company focused on developing innovative and differentiated medical dermatology products, today announced the results for the year ended 31 December 2016.

# Financial highlights

- There were no operating revenues because all products are still in development and none were licensed out
- R&D expenses increased by 88.4% to EUR 14,310 thousand. The main costs were the costs of the two phase III pivotal clinical trials of Winlevi® for acne
- General administrative expenses increased from 760 thousand to EUR 2,026 thousand. The Company now has 9 team members
- A tax credit of EUR 5,883 thousand on the R&D costs has been recognized according to the Italian tax law
- Operating losses increased by 25.1% to EUR 10,453 thousand
- A net financial income of EUR 957 thousand resulted from foreign exchange gains
- At year-end 80.3% of the Company's assets were held as cash and cash equivalents which amounted to EUR 33,656 thousand

Diana Harbort, CEO, said: "2016 developed as expected with the continued advancement of our product pipeline. Financially we are on track spending EUR 16,336 thousand in 2016 and we have EUR 33,656 thousand in cash which should suffice until we have data from the phase III clinical trials for Winlevi® in acne. We progressed on our important phase III Winlevi® program for acne, completed the phase II proof of concept (POC) clinical trials for both Breezula (our topical antiandrogen for androgenic alopecia) and our novel antibiotic for acne, and moved our phase II dose ranging trial of Breezula® for alopecia to the point where the first patient will be recruited as soon as we receive the German Federal Institute for Drugs and Medical Devices approval. We are now looking forward to completing the phase III clinical trials of Winlevi® in acne and to the data of the phase II POC clinical trial for our genital warts program this year."

## Key strategic events

 Winlevi<sup>®</sup> (topical antiandrogen for the treatment of acne) phase III clinical trials for treatment of moderate to severe acne continued; at year end 70 sites were active. The program consists of two pivotal trials in both the US and various countries in Europe. Approximately 1,400 male and female subjects ages 9 years or older with moderate to severe acne (grades 3-4 on Investigators Global Assessment (IGA) are targeted for enrolment. At year-end 2016, 762 subjects had been randomized, 519 had completed treatment, and 339 subjects had rolled over to the long-term safety study.

- Breezula® (topical antiandrogen for the treatment of androgenic alopecia) phase II dose ranging study was designed and proposed for approval to the ethical committees. It is a single, 12 months' study, in 400 males aged 18-55, with mild to moderate alopecia in Germany. Five arms, each with 80 subjects, each with different dosages will be tested.
- CB-06-01 (new topical antibiotic for treatment of mild to moderate acne) proof of concept trial in 85 subjects with acne was completed. After evaluating the results, the Company decided to progress to a phase II dose ranging trial with an improved formulation.
- CB-06-02 (topical immunomodulator) phase II POC for treatment of genital warts continued, albeit slower than planned, because the licensor ceased activity and site management in Israel had to be assumed by the Company.
- At year end 9 persons worked for the Company and Cosmo Pharmaceuticals provided services through the service agreement. Louise Dube, Global Director of R&D retired at year end 2016 and was replaced by Alessandro Mazzetti M.D.

# **Key financial figures**

In EUR thousands	2016	2015
(with the exception of the share data in €)		
Revenues	-	-
Other income	5.883	
Cost of sales	-	-
Research and development costs	(14.310)	(7.597)
Selling, general and administrative costs	(2.026)	(760)
Operating Result	(10.453)	(8.357)
Net financial income	957	1.906
Profit/Loss before taxes	(9.496)	(6.451)
Net profit/loss	(9.496)	(6.451)
Profit per share	(0,950)	(1,113)
	31.12.2016	31.12.2015
Cash and cash equivalents	33.656	48.113
Other assets	8.269	1.723
Equity	39.149	47.181
Total assets	41.925	49.836

The Annual Report 2016 is available on the Company's web site at: http://www.cassiopea.com/investor-relations/financial-reports/yr-2017.aspx

# FY16 results presentation and conference call at 4.00 pm CET on 24 February 2017

Diana Harbort, CEO, Luigi Moro, CSO, Alessandro Mazzetti, CMO and Chris Tanner, CFO and Head of Investor Relations, will present the full year results and discuss the outlook for 2017 at a media and analyst telephone conference on 24 February at 4.00 pm CET.

### The dial-in numbers:

+41 (0) 58 310 50 00 Continental Europe

+44 (0) 203 0595 862 UK +1 (1) 613 570 56 13 USA

The presentation will then be available for download at:

http://www.cassiopea.com/investor-relations/presentations/yr-2017.aspx

## **About Cassiopea**

Cassiopea SpA is a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products. Our initial focus is on the topical treatment of acne, androgenic alopecia (or AGA) and genital warts. The portfolio comprises four unencumbered clinical candidates, for which Cassiopea owns the worldwide rights. The company plans to commercialize the products directly in the US and partner the products outside of the US. For further information on Cassiopea, please visit <a href="https://www.cassiopea.com">www.cassiopea.com</a>.

#### **Next events**

Annual General Shareholders Meeting in Lainate 5 April 2017, 3.00 pm CET

## Contact:

Dr. Chris Tanner, CFO and Head of Investor Relations

Tel: +39 02 868 91 124

Some of the information contained in this press release may contain forward-looking statements. Readers are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors. Cassiopea has no obligation to publicly update or revise any forward-looking statements.