



Cassiopea announces 2018 Results in line with expectations

Lainate, Italy – 8 February 2019 – Cassiopea SpA (SIX: SKIN), a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products, today announced its results for the year ended December 31, 2018.

Key Highlights:

- The results of the two pivotal phase III clinical trials for the topical anti-androgen Clascoterone (Winlevi® cream 1%) in acne demonstrated highly statistically significant improvements for all primary and secondary clinical end points and that the drug is generally safe and well tolerated.
- The top line results of the planned six-month interim analysis for the phase II dose ranging study for Clascoterone (Breezula®) solution in androgenic alopecia in men demonstrated statistically significant improvement for Target Area Hair Count (TAHC) and directional improvement for Hair Growth Assessment (HGA).
- Positive top line results of the phase II proof of concept trial for CB-06-02, a novel integrin activator for the treatment of genital warts.
- All operations were carried out within the budgeted framework. In 2018, Cassiopea spent EUR 14,130 thousand, predominantly in the advancement of our clinical programs. At end of 2018, cash amounted to EUR 4,609 thousand, which is in line with what had originally been planned.

Financial Highlights:

- There were no operating revenues because all products are still in development and none were licensed out.
- R&D expenses decreased by 6,3% to EUR 12,240 thousand. The main costs were the costs of the two phase III pivotal clinical trials for Winlevi® in acne and the phase II dose ranging trial for Breezula® in alopecia.
- SG&A expenses increased by 27,4% to EUR 1,890 thousand, primarily because of Winlevi® pre-commercial activities.
- A net tax credit of EUR 916 thousand on the R&D costs has been recognized according to the Italian tax law.
- Operating losses increased by 23,2% to EUR 13,214 thousand.
- A net financial income of EUR 558 thousand resulted from foreign exchange gain given that the majority of financial assets were held in US\$.
- At year-end, cash and cash equivalents amounted to EUR 4,609 thousand. In addition to this, the Company had an undrawn credit facility of EUR 10 million granted by its largest shareholder Cosmo Pharmaceuticals N.V. that has indicated the willingness to increase this to EUR 20 million.

Diana Harbort, CEO of Cassiopea SpA, commented: “2018 was very successful year. We made substantial progress in each of our programs. We met the desired clinical endpoints for all three ongoing trials: The Phase III data for Winlevi®, the interim six-month results for the Breezula® Dose Ranging Trial and the POC results for CB-06-02. 2019 will be a year of growth and change for Cassiopea, as we submit the NDA to the FDA and invest in the pre-commercial activities for Winlevi®, advance Breezula® into Phase III for androgenetic alopecia, and begin to build the infrastructure of the Company. Cosmo has provided a EUR 10 million term loan, but completion of the clinical trials and building the sales and marketing organization in the US will require substantial funds. We thus plan to access capital with the intention to give existing shareholders – as well as new US-based investors – the opportunity to invest in our Company. We are convinced that we have one of the most innovative pipelines in the dermatology industry and view the future with great optimism.”

Key Financial Figures

In EUR thousands (with the exception of the share data in €)	2018	2017
Revenues	-	-
Other income	916	3,820
Cost of sales		
Research and development costs	(12,240)	(13,061)
Selling, general and administrative costs	(1,890)	(1,484)
Operating Result	(13,214)	(10,725)
Net financial income	558	(2,931)
Loss before taxes	(12,656)	(13,656)
Net loss	(12,656)	(13,656)
<i>Loss per share</i>	<i>(1.266)</i>	<i>(1.366)</i>
	31.12.2018	31.12.2017
Cash and cash equivalents	4,609	17,598
Other assets	11,931	10,871
Equity	14,512	26,354
Total assets	16,540	28,469

The Annual Report 2018 is available on the Company's website at:
www.cassiopea.com/investor-relations/financial-reports/yr-2019.aspx

2018 results presentation and conference call at 15:00 CET on 8 February 2019:

Diana Harbort, CEO; Luigi Moro, CSO; Alessandro Mazzetti, CMO; Chris Tanner, CFO; and Marco Lecchi, Deputy CFO, will present the 2018 results and discuss the outlook for 2019 at a conference call to be held today at 15:00 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 is available on the Company's website via:

www.cassiopea.com/investor-relations/presentations/yr-2019.aspx

About Clascoterone:

Clascoterone, a new chemical entity, is a topically applied anti-androgen in late stage development for the treatment of acne (in a 1% cream) and androgenetic alopecia (in a higher strength solution). When applied directly to the skin surface, Clascoterone penetrates the skin to reach the androgen receptors within the sebaceous glands. Clascoterone is on course to become the first effective and safe topical anti-androgen without systemic side effects.

Clascoterone intervenes at several key points in the acne cascade and works by binding to androgen receptors at the site of application. By competing with circulating androgens at the site of androgen receptors in the sebaceous gland and hair follicle, Clascoterone acts as a local, selective androgen inhibitor and limits the acneogenic effects of androgens on sebum production and inflammation. Clascoterone is quickly metabolized to cortexolone, a naturally occurring metabolite found throughout all human tissues, cells, blood and urine; cortexolone's safety and metabolic fate are well characterized. Due to its rapid metabolism and local activity, Clascoterone does not produce systemic side effects.

A different formulation containing a higher strength of Clascoterone is also in Phase II clinical development for the treatment of androgenetic alopecia.

About Cassiopea:

Cassiopea SpA is a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products. Our 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 www.cassiopea.com.

Next events:

Leerink Conference, New York	27 February
American Academy of Dermatology, Washington DC	1-4 March
Credit Suisse one on one Healthcare Conference, London	5-6 March
Annual General Shareholders Meeting, Lainate	18 March
Jefferies Global Health Care Conference, New York	4-6 June
Half Year Report 2019	July 2019
Jefferies Global Health Care Conference, London	13-14 November
Credit Suisse Small & Mid Cap Conference, Zurich	13-15 November

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