Cassiopea Announces Results for First Half of 2019

Lainate, Italy – 18 July 2019 - Cassiopea SpA (SIX: SKIN), a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products, announced today its half-year results for the period ended 30 June 2019.

Highlights

- Very positive results from the Phase III open label safety study evaluating Winlevi®/Clascoterone 1 % cream for acne for treatment up to one year
- Very positive Phase II twelve months dose ranging study results for Breezula®/Clascoterone solution in treating androgenetic alopecia
- NDA for Winlevi®/Clascoterone to be filed shortly
- US subsidiary Cassiopea, Inc., has been established and small team of dermatology experts hired
- All costs within the approved/foreseen budget.

Diana Harbort, CEO of Cassiopea SpA, commented: “The first half of 2019 has been a very productive time for Cassiopea. We have made major development progress with our late stage pipeline and have begun to lay the foundation for our commercial infrastructure in the US. 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 EUR)	**H1 2019**	**H1 2018**
Revenue	-	-
Cost of sales	-	-
Research and development expenses	(4689)	(6.423)
Selling, general and administrative expenses	(1596)	(663)
Net operating expenses	(6285	(7.086)

Operating result	(6285)	(7.086)
Profit (Loss) before taxes	(6458)	(6.729)
Profit (Loss) after taxes for the period	(6458)	(6.729)
Profit (Loss) per share	(0.646)	(0,673)
In EUR thousands	**30.06.2019**	**31.12.2018**
Non-current assets	9612	9760
Other current assets	2091	2171
Cash and cash equivalents	834	4609
Total assets	**12537**	**16540**
Non-current liabilities	2207	0
Current Liabilities	1854	2028
Total Equity	8476	14512
Total Equity & Liabilities	**12537**	**16540**

- No revenues were generated in H1 2019 since all products are still under development
- No goods were manufactured for sale so there were no Cost of Goods Sold (COGS)
- R&D costs consisted primarily of outsourced preclinical and clinical expenses of EUR 2.502 thousand of which EUR 1.762 thousand were for Winlevi® and EUR 732 thousand were for Breezula®
- Personnel expenses were increased 60.3% to EUR 1.149 thousand. There were 12 directly employed persons, an increase of one third from H1 2018
- Cash and cash equivalents declined to EUR 834 thousand. These funds are held primarily in US$
- Non-current liabilities stood at EUR 2.207 thousand as loan drawn under the credit facility that is being made available by Cosmo Pharmaceuticals
- Total equity declined to EUR 8.476 thousand; 67.6% of assets were financed by equity
- Given the shareholders' approval on 18 March 2019 of a capital increase of up to 3 million shares and given the largely unused credit line from Cosmo Pharmaceuticals, Cassiopea's largest shareholder, there is substantial flexibility in determining how the financing will be raised to fund the Company's approval to the projected approval of Winlevi®.

Half-year 2019 results conference call at 15:00 CEST on 18 July 2019

Diana Harbort, CEO; Luigi Moro, CSO; Alessandro Mazzetti, CMO; Chris Tanner, CFO and Head IR; and Marco Lecchi, Finance Director, will present the half-year results and discuss the outlook for 2019 at a conference call to be held today at 15:00 CEST.

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The Half-Year Report 2019 and the presentation with further information were published today, 18 July 2019, at 07:00 CEST, and are available for download at:
http://www.cassiopea.com/investor-relations/financial-reports/yr-2019.aspx and
http://www.cassiopea.com/investor-relations/presentations/yr-2019.aspx

About Cassiopea

Cassiopea 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, androgenetic 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.

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 and hair follicles. Clascoterone is on track to becoming 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 acnegenic 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 worrying systemic side effects.

In androgenetic alopecia (AGA), high local concentrations of dihydrotestosterone (DHT) bind to androgen receptors within the scalp hair follicles, resulting in shortening of the hair cycle and gradual miniaturization scalp follicles. Over time, these progressively smaller, thinner hair follicles are unable to produce new hair, thus resulting in AGA's characteristic patterned baldness. DHT dependent effects are considered, in most cases, reversible, such that AGA could be responsive to medical treatment with drugs such as Clascoterone. By blocking DHT interaction with the specific hair follicle androgen receptors, Clascoterone, if successful, would be the only topical antiandrogen approved for use in AGA that could potentially be used in both men and women.

Next events

CS Small & Mid Cap Conference, Zurich	13-15 November 2019
Jefferies Health Care Conference, London	20-21 November 2019
Full-year results 2019	February 2020

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