Cassiopea Announces Results for First Half of 2021

Ad hoc announcement pursuant to Art. 53 LR

Lainate, Italy – July 29, 2021 – Cassiopea SpA (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, today announced half-year results for the period ended 30 June 2021.

Key Highlights

- During the first half of 2021, activities were focused on the preparations for the US commercial launch of Winlevi® (clascoterone cream 1 %) and advancing the development of clascoterone solution for androgenetic alopecia (AGA).
- Multiple transaction structures and opportunities were evaluated over the last twelve months in order to optimize the US commercial launch of Winlevi®.
- Post period, on July 26, Cassiopea and Sun Pharmaceuticals Industries Ltd. announced the signing of License and Supply Agreements for Winlevi® (clascoterone cream 1%) in the US and Canada. Under terms of the agreements, Sun Pharma will commercialize Winlevi® in the US and Canada and Cassiopea will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of US $45 million, potential commercial milestones totalling up to US $190 million and customary double digit royalties. The agreements will close upon the expiration of HSR waiting period. Winlevi® is expected to be available in the US in Q4 2021.
- The Phase II trial investigating clascoterone solution for the treatment of androgenetic alopecia (AGA) in females was completed in the reporting period. Top line results will be available in 3Q 2021.
- Progress was made in the development of a new Patient Reported Outcome (PRO) Questionnaire for AGA which has been requested by the FDA to be used in the future Phase III trials of clascoterone solution for AGA in males.

Diana Harbort, CEO of Cassiopea SpA, commented: “The highlight of the year to date was the announcement on July 26 of the signing of License and Supply Agreements for Winlevi® in the US and Canada with Sun Pharmaceutical Industries Ltd. We are very pleased to partner with Sun Pharma. Sun Pharma has a strong established US dermatology presence and will make Winlevi® widely available to dermatology health care providers and their patients. Following this transaction, Cassiopea will be expecting substantial revenue streams for the foreseeable future and will be well funded to continue the development of its innovative dermatology pipeline. Until the end of 2021, our priorities are supporting Sun Pharma in the successful launch of Winlevi® and the continuing the development of clascoterone solution for AGA, an area that has not seen innovation in 20-30 years. We estimate that Cassiopea will become profitable in 2021 with revenues in the range of EUR 37-39 million and operating profit in the range of EUR 24-28 million”.

Key financial figures

In EUR thousands (with the exception of the share data in EUR)	**H1 2021**	**H1 2020**
Revenue	-	-
Cost of sales	-	-
Research and development expenses	(3,753)	(2,510)
Selling, general and administrative expenses	(2,535)	(2,180)
Net operating expenses	(6,288)	(4,690)
Operating result	(6,288)	(4,690)
Profit (Loss) before taxes	(6,165)	(5,322)
Profit (Loss) after taxes for the period	(6,165)	(5,322)
Profit (Loss) per share	(0.573)	(0.530)
In EUR thousands	**30.06.2021**	**31.12.2020**
Non-current assets	12,498	12,797
Inventories	1,817	761
Other current assets	2,291	2,423
Cash and cash equivalents	1,796	2,646
Total assets	**18,402**	**18,627**
Non-current liabilities	-	66
Current Liabilities	8,557	2,946
Total Equity	9,845	15,615
Total Equity & Liabilities	**18,402**	**18,627**

Financial Results for the Half Year Ended June 30, 2021

- No revenues and consequently no cost of sales were generated in H1 2021 since no products were on the market.
- R&D costs increased mainly due to Phase II trials of Clascoterone solution for androgenetic alopecia in females.

- SG&A in line with the same period of the previous year.
- Loss for the period increase from EUR 5,322 thousand to EUR 6,165 thousand.
- Non-current assets, which include intangible and the R&D credit, stable at EUR 12,498 thousand.
- Inventories, EUR 1,817 thousand, refer to the API (Active Principle Ingredient) stock required for the production for the commercial launch of Winlevi®.
- Current liabilities include EUR 6,226 thousand related to the draw down from the Cosmo Pharmaceuticals N.V. unsecured credit facility (EUR 6,000 thousand) and interest, that will be reimbursed in the course of the following months.
- Total equity decreased from EUR 15,615 thousand to EUR 9,845 thousand mainly because of the loss for the period.

Half Year 2021 results conference call at 16:00 CEST on July 29, 2021
Diana Harbort, CEO; Luigi Moro, CSO; Alessandro Mazzetti, CMO; Pierpaolo Guzzo, CFO; and Marco Lecchi, Finance Director, will host a conference call to discuss the half year 2021 financial results to be held today at 16:00 CEST.

Dial-in numbers:
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The Half-Year Report 2021 and the presentation with further information were published today, July 29, 2021, at 7:00 am CEST, and are available for download at:
https://www.cassiopea.com/wp-content/uploads/2021/07/Cassiopea_Half_Year_Report_2021.pdf
and
https://www.cassiopea.com/wp-content/uploads/2021/07/Cassiopea_Half_Year_2021-Financial-Results_Presentation.pdf

About Cassiopea
Cassiopea is a specialty pharmaceutical company developing and commercializing prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia (or AGA) 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. The Company's strategy is to leverage this expertise to optimize the commercial potential for its products directly or with a partner. For further information on Cassiopea, please visit www.cassiopea.com.

Next events

Credit Suisse Equity Conference	November 16-19, 2021, Zurich
Jefferies Global Health Care Conference	November 16-18, 2021, London

Contact

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About Winlevi

Indication

Winlevi® (clascoterone cream 1%), is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older. See www.WINLEVI.com for complete prescribing information and important safety information.

Important Safety Information

CONTRAINDICATIONS:
None.

WARNINGS
Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with WINLEVI. In the PK trial, HPA axis suppression was observed in 1/20 (5%) of adult subjects and 2/22 (9%) of adolescent subjects at Day 14. All subjects returned to normal HPA axis function at follow-up 4 weeks after stopping treatment. Conditions which augment systemic absorption include use over large surface areas, prolonged use, and the use of occlusive dressings. Attempt to withdraw use if HPA axis suppression develops.

Pediatric patients may be more susceptible to systemic toxicity.

Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials. Shifts from normal to elevated potassium levels were observed in 5% of WINLEVI-treated subjects and 4% of vehicle-treated subjects.

ADVERSE REACTIONS
Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.