



Cassiopea Announces Results for First Half of 2020

Lainate, Italy – 29 July 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, today announced its half-year 2020 results for the period ended 30 June 2020.

Key Events

- Fluid interaction with U.S. FDA in conjunction with filed NDA for Clascoterone Cream 1%, where the PDUFA date is 27 August 2020.
- Submission of special protocol assessment to U.S. FDA for Phase III trial of Clascoterone Solution 7.5% in males with androgenetic alopecia (AGA).
- COVID-19 caused a brief interruption of recruitment in the Phase II trial of Clascoterone Solution in females with AGA. The trial is targeting 280 subjects in four study arms; it restarted in June and currently has recruited 165 subjects.
- Publication of Clascoterone Cream 1% Phase III data in the Journal of the American Medical Association Dermatology and the Journal of the American Academy of Dermatology, two prestigious peer reviewed medical journals in the USA.
- Successful capital increase reserved to existing shareholders issuing 750'000 new shares at a price of EUR 31 each.
- All costs within the approved/foreseen budget.

Diana Harbort, CEO of Cassiopea S.p.A., commented: "The first half of 2020 was marked by constructive interaction with the FDA for the NDA of Clascoterone Cream 1%. We also have made substantial progress in medical affairs, market access, commercial launch planning and product supply in anticipation of the 27 August 2020 PDUFA date for our first product. If approved, Clascoterone Cream 1% would be the first new mechanism of action for acne in nearly 40 years".

Key financial figures

In EUR thousands (with the exception of the share data in EUR)	H1 2020	H1 2019
Revenue	-	-
Cost of sales	-	-
Research and development expenses	(2,510)	(4,689)

Selling, general and administrative expenses	(2,180)	(1,596)
Net operating expenses	(4,690)	(6,285)
Operating result	(4,690)	(6,285)
Profit (Loss) before taxes	(5,322)	(6,458)
Profit (Loss) after taxes for the period	(5,322)	(6,458)
<i>Profit (Loss) per share</i>	<i>(0.530)</i>	<i>(0.646)</i>
In EUR thousands	30.06.2020	31.12.2019
Non-current assets	12,354	12,536
Other current assets	2,954	2,829
Cash and cash equivalents	8,451	696
Total assets	23,759	16,061
Non-current liabilities	8	10,660
Current Liabilities	2,388	1,674
Total Equity	21,363	3,727
Total Equity & Liabilities	23,759	16,061

- No revenues were generated in H1 2020 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 declined primarily because the outsourced pre-clinical and clinical trial costs declined from EUR 2,502 thousand of EUR 640 thousand – because the Phase III for Clascoterone Solution 7.5% in males had not yet started and because of a COVID-19 induced interruption in recruitment for the Phase II proof of concept dose ranging trial of Clascoterone Solution in females.
- SG&A increase of EUR 584 thousand to EUR 2,180 thousand due to the increase of the U.S. operations.
- Cash and cash equivalents increased from EUR 696 thousand to EUR 8.451 thousand due to a cash net inflow from the capital increase.
- Non-current liabilities declined to EUR 8 thousand because the loans outstanding under the credit facility from Cosmo Pharmaceuticals N.V. were set off with the proceeds from the capital increase.
- Total equity increased from EUR 3,727 thousand to EUR 21,363 thousand because of the issuance of 750,000 new shares at a price of EUR 31 per share, for a capital contribution of EUR 23,250 thousand.

Half-year 2020 results conference call at 16:00 CEST on 29 July 2020

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 2020 at a conference call to be held today at 16:00 CEST.

Dial-in numbers:

Switzerland / Europe: +41 (0) 58 310 50 00

From UK: +44 (0) 207 107 06 13

From USA: +1 (1) 631 570 56 13

The Half-Year Report 2020 and the presentation with further information were published today, 29 July 2020, at 7:00 am CEST, and are available for download at:

https://www.cassiopea.com/wp-content/uploads/2020/07/Cassiopea_Half_Year_Report_2020.pdf

and <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. Cassiopea plans to determine the most efficient way to effectively commercialize the products in the U.S. after the planned approval of Clascoterone Cream 1% and to partner the products for countries outside of the US. For further information on Cassiopea, please visit www.cassiopea.com.

About Clascoterone

Clascoterone, a new chemical entity, is a proposed first-in-class topical androgen receptor inhibitor under U.S. Food and Drug Administration (FDA) review for the treatment of acne (in a 1% cream) and in late stage development for the treatment of androgenetic alopecia (in a higher strength solution) in males. Although Clascoterone's exact mechanism of action is unknown, laboratory studies suggest Clascoterone competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles. 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:

HC Wainwright Annual Global Investors Conference	14-15 September, virtual
Investora	23 September 2020, Zurich
Jefferies Global Health Care Conference	17-19 November 2020, London
Credit Suisse Small & Mid Cap Conference	18-20 November 2020, Zurich

Contact:

Dr. Chris Tanner, CFO & 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.