



Cassiopea Reports Year End 2020 Results

Lainate, Italy – March 25, 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 financial results for the year ended 31 December 2020.

Key Highlights

- United States Food and Drug Administration (FDA) approval of Winlevi® (clascoterone cream 1%) as a novel drug for the topical treatment of acne in patients 12 years and older.^{1,2} Notwithstanding acne being the most prevalent skin condition in the U.S. affecting up to 50 million Americans annually³, the last FDA approval of an acne drug with a new mechanism of action (MOA) occurred nearly 40 years ago.
- Publication of clascoterone cream 1% Phase III data in the *Journal of the American Medical Association (JAMA) Dermatology*⁴ and the *Journal of the American Academy of Dermatology*⁵, two prestigious peer reviewed medical journals.
- Completion of the enrollment of the Phase II trial that is investigating clascoterone solution for the treatment of androgenetic alopecia (AGA) in females.
- Submission to the US FDA of a special protocol assessment for a Phase III trial of clascoterone solution 7.5% in males with androgenetic alopecia (AGA) and a Type A Meeting held.
- Capital increase reserved for existing shareholders was successfully concluded and 750,000 new registered shares were subscribed at an offer price of EUR 31 with gross proceeds of EUR 23.25 million.

Diana Harbort, CEO of Cassiopea SpA, commented: *“The highlight of the year 2020 was the US FDA approval of Winlevi, our first-in-class topical androgen receptor inhibitor for the treatment of acne in patients twelve years and older. This milestone marks the approval of the first new mechanism of action for the treatment of acne in nearly forty years. During the course of the year, we have made substantial progress in medical affairs, market access, commercial launch planning and product supply. Thousands of dermatologists are now aware of the new mechanism of action in acne and scientific platform of Winlevi. Our priority now is optimizing the US commercial strategy for Winlevi, taking into account the dynamics of COVID-19 affecting the entire pharmaceutical industry.”*

Key financial figures

In EUR thousands (with the exception of the share data in EUR)	2020	2019

Revenue	-	-
Other Income	594	686
Cost of sales	-	-
Research and development expenses	(6,440)	(7,875)
Selling, general and administrative expenses	(5,175)	(3,879)
Net operating expenses	(11,021)	(11,068)
Operating result	(11,021)	(11,068)
Profit (Loss) before taxes	(12,308)	(11,700)
Profit (Loss) after taxes for the period	(12,308)	(11,700)
Profit (Loss) per share	(1.183)	(1.170)
In EUR thousands	31.12.2020	31.12.2019
Non-current assets	12,797	12,536
Inventories	761	-
Other current assets	2,423	2,829
Cash and cash equivalents	2,646	696
Total assets	18,627	16,061
Non-current liabilities	66	10,660
Current Liabilities	2,946	1,674
Total Equity	15,615	3,727
Total Equity & Liabilities	18,627	16,061

Financial Results for the Year Ended December 31, 2020

- No revenues were generated in 2020 since no products were on the market.
- 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 7,875 thousand by EUR 1,435 thousand because the Phase III study 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 costs increase of EUR 1,296 thousand to EUR 5,175 thousand due to the increase of the US pre-commercial operations.
- Cash and cash equivalents increased from EUR 696 thousand to EUR 2,646 thousand following the June 2020 capital increase.
- Non-current liabilities declined to EUR 66 thousand because the loans outstanding under the credit facility from Cosmo Pharmaceuticals NV were set off with the proceeds from the capital increase.
- Total equity increased from EUR 3,727 thousand to EUR 15,615 thousand because of the June issuance of 750,000 new shares for a capital contribution of EUR 23,250 thousand partly offset by the 2020 loss of EUR 12,308 thousand.

2020 results conference call at 16:00 CEST on 25 March 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 2020 financial results 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 Annual Report 2020 and the presentation with further information were published today, 25 March 2021 at 07:00 CEST, and are available for download at the Company's website:

https://www.cassiopea.com/wp-content/uploads/2021/03/Cassiopea_Annual_Report_2020.pdf

and

https://www.cassiopea.com/wp-content/uploads/2021/03/Cassiopea_2020-Financial-Results_Presentation_Final.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

Annual General Shareholders Meeting	April 29, 2021, Lainate
Jefferies Virtual Global Health Care Conference	June 1-3, 2021
Half-Year Report 2021	July 2021
Investora	September 15-16, 2021, Zurich
Credit Suisse Equity Conference	Mid-November 2020, Zurich
Jefferies Global Health Care Conference	November 16-18, 2021, London

Cassiopea SpA

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About Winlevi

Winlevi® (clascoterone cream 1%) is approved for the topical treatment of acne vulgaris in people aged 12 and older. Although WINLEVI's exact mechanism of action is unknown, laboratory studies suggest the active ingredient, clascoterone, competes with androgens, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.⁶ Complete prescribing information is available at www.WINLEVI.com.

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.

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.

1. WINLEVI. Package Insert. Cassiopea. 2020. www.winlevi.com
2. US FDA. Novel Drug Approvals for 2020. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>. Accessed March 15, 2021.
3. The American Academy of Dermatology. Skin conditions by the numbers. American Academy of Dermatology. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed March 15, 2021.
4. Hebert A, et al *JAMA Dermatol.* 2020;156(6):621-630
5. Eichenfield, L., et al. *J Am Acad Dermatol.* 2020 Aug;83(2):477-485. doi: 10.1016/j.jaad.2020.04.087. Epub 2020 Apr 26.
6. Rosette C, et al. *J Drugs Dermatol.* 2019; 18(5):412-418. <https://www.ncbi.nlm.nih.gov/pubmed/31141847>

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.