

# Half-Year Report 2021

# Cassiopea at a Glance

Cassiopea is 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, 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 Company's portfolio comprises four unencumbered clinical candidates, for which the Company owns the worldwide rights. These product candidates are based on three new chemical entities ("NCEs") that target unmet medical needs and address significant market opportunities in the medical dermatology market.

Cassiopea's management team has (directly and indirectly through the service agreement with Cosmo) extensive experience in product development and commercialization, having served in prominent roles at several leading pharmaceutical and medical dermatology companies.

The Company's strategy is to leverage this expertise to optimize the commercial potential for its products directly or with a partner in the US and partner the products in countries outside of the US.

## Key events in H1 2021

During the first half of 2021, activities were focused on the preparations for the 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 26 July, Cassiopea and Sun Pharma announced the signing of License and Supply Agreements for Winlevi® (clascoterone cream 1%) in the United States and Canada. Sun Pharma will have the exclusive right to commercialize Winlevi® in the United States 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 the HSR waiting period. Winlevi® is expected to be available in the US in Q4 2021. Complete prescribing information is available on [www.WINLEVI.com](http://www.WINLEVI.com).<sup>1</sup>

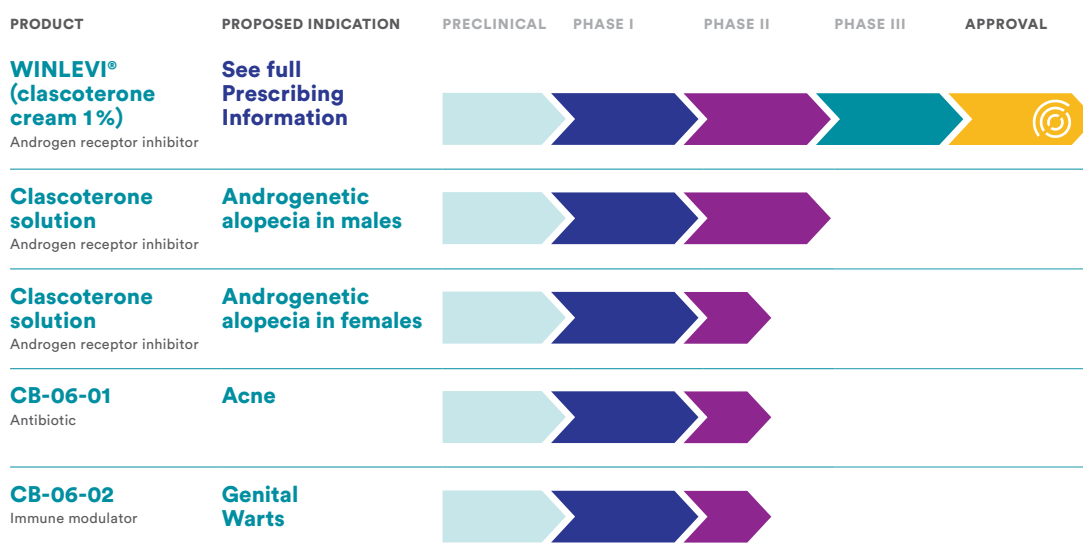
Our development activity was primarily directed to advance the development of clascoterone solution for AGA. In Q2, we completed the Phase II trial of Clascoterone solution for androgenetic alopecia in females. The Phase II multicenter, prospective, randomized, double-blind, vehicle controlled, dose ranging study evaluated the efficacy and safety of clascoterone solution for the treatment of AGA in females. The six-month study enrolled 293 female subjects between 18–55 years of age with mild to moderate AGA in Germany. The four-arm study enrolled approximately 70 subjects per arm in each of four treatment groups: clascoterone solution 5 % BID (twice daily), clascoterone solution 7.5 % BID (twice daily), minoxidil solution 2 % BID (twice daily) and vehicle BID (twice daily). The co-primary endpoints are: (1) change from baseline in non-vellus Target Area Hair Count (TAHC) at month 6 in comparison to vehicle and (2) Hair Growth Assessment (HGA) score at month 6 in comparison to vehicle. Top line results will be available in 3Q 2021.

Additionally, progress was made in the development of a new Patient Reported Outcome (PRO) Questionnaire for AGA which has been requested by the US FDA to be used in the future Phase III trials of Clascoterone solution for AGA in males.

#### Concerning forward-looking statements

This report contains certain “forward-looking statements,” which can be identified by the use of terminology such as “could,” “might,” “propose,” “addressable,” “outlook,” “attractive” or similar wording. Such forward-looking statements reflect the current views of the Management and are not guarantees of future performance and involve risks and uncertainties. Readers are cautioned that actual results may differ materially from those in the forward-looking statements as a result of various factors. Cassiopea is providing the information in this report as of this date and does not undertake any obligation to update any forward-looking statements contained in it as a result of new information, future events or otherwise.

## Cassiopea Pipeline



## Key figures

EUR 1,000	30.06.2021	30.06.2020
<b>Income statement</b>		
Revenue	–	–
Other income	–	–
Cost of sales	–	–
R&D costs	(3,753)	(2,510)
SG&A costs	(2,535)	(2,180)
Operating result	(6,288)	(4,690)
Profit (loss) before taxes	(6,165)	(5,322)
Profit (loss) for the period	(6,165)	(5,322)
<b>Shares</b>		
Weighted average number shares	10,750,000	10,045,330
Basic earnings (loss) per share (in EUR)	(0.573)	(0.530)
<b>Statement of financial position</b>		
EUR 1,000	30.06.2021	31.12.2020
Non-current assets	12,498	12,797
Inventories	1,817	761
Cash and cash equivalents	1,796	2,646
Other current assets	2,291	2,423
Non-current liabilities	–	66
Current liabilities	8,557	2,946
Equity	9,845	15,615
Equity ratio	53.5%	83.8%

# Table of Contents

Cassiopea at a Glance .....	2
Key events in H1 2021 .....	2
Cassiopea's Pipeline .....	4
Letter to Shareholders .....	7
Business Strategy and Markets .....	8
Research and Development .....	10
Patents and Trademarks .....	16
COVID-19 impact .....	19
ESG policy .....	20
Financial review .....	22
Condensed Consolidated Financial Statement (unaudited).....	26
Notes to the Condensed Consolidated Financial Statements (unaudited)....	30
Information for Investors .....	50
Contacts and Addresses .....	52



# Dear Shareholder

The first half of 2021 has been a very productive and exciting time for Cassiopea. Most importantly, our efforts were focused on the commercial launch preparation of Winlevi® (clascoterone cream 1%), advancing multiple opportunities related to optimizing the commercialization of Winlevi® in the US, and the development program for Clascoterone solution.

The highlight of the year to date was the announcement on 26 July by Cassiopea and Sun Pharma of the signing of License and Supply Agreements for Winlevi® (clascoterone cream 1%) in the United States and Canada. 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.

We thank all our shareholders and our employees, including the Cosmo team, for their commitment to our Company. We look forward to an exciting second half of 2021, and to the upcoming launch of Winlevi® by our new partner, Sun.

Lainate, 28 July 2021



Pierpaolo Guzzo  
Chairman  
Cassiopea S.p.A.



Diana Harbort  
CEO  
Cassiopea S.p.A.

# Business Strategy and Markets

It is our intention to focus on therapies for the treatment of skin diseases and to focus solely on innovative new treatments, containing new chemical entities.

Currently, we have a lean organization that is managing the ongoing clinical trials and development programs for our pipeline (located in Italy) as efficiently as possible and managing the pre-launch activities in the USA. Under our Service Agreement with Cosmo, we have ready access to a team, which is very knowledgeable in the history of our programs, and is very experienced in product development and manufacturing, thereby mitigating our need to build a large, expensive organization of our own in the short term.

The Company's strategy is to optimize the commercial potential for its products in the US and partner the products in countries outside of the US.

Acne vulgaris is one of the most common skin conditions, affecting up to 50 million people in the USA, of whom approximately 10 million suffer from moderate to severe acne.<sup>2</sup> It is estimated that approximately 85% of people in the US between the ages of 12 and 24 experience at least mild acne, and acne is the reason most cited for visits to dermatologists by patients 14 to 45 years old.<sup>2,3</sup> For most people, acne diminishes over time and tends to disappear or decrease, by age 25. However, some individuals continue to suffer from acne well into their 30s, 40s and later.<sup>2</sup> Based on US IQVIA data, there were 24.3 million acne product prescriptions in 2018, 62% of which were for topical products. The major product classes predominantly used to treat acne have been available for over 40 years, and we believe that growth in this market recently has been significantly limited by a lack of innovation in new product development.

Based on research by VisionGain, the global dermatological drugs market generated revenues of US\$ 26.23 billion in 2018, and is expected to grow by more than 10% to nearly US\$ 54 billion in 2024 according to Zion Market Research (January 2019). Management's analysis of IQVIA data indicates that the US acne market generated retail sales of US\$ 5.0 billion in 2018. Of these, US\$ 3.6 billion were topical products.

Androgen induced alopecia, also known as Androgenetic Alopecia (AGA) or patterned hair loss, is the most common type of hair loss affecting 50–60 million men and 30–35 million women in the US.<sup>4–6</sup> Of these, only 25–30 million men and 15–20 million women have been diagnosed, and only 2.7 million men and 2 million women or 5–10% of the total are actually being treated.<sup>6</sup> A vast majority of patients have not sought treatment for their condition, likely due to the limitations of current treatments and the lack of available options.<sup>6</sup> With few drug options available, the global hair restoration surgery market has grown very quickly, amounting to US\$ 4.6 billion in 2019, an increase of 16% since 2016 according to a 2020 survey by the International Society of Hair Restoration Surgery.<sup>13</sup> Over three quarters (77.6%) of the estimated 2 million patients undergoing hair restoration procedures in 2019 did so for genetic (AGA) hair loss.<sup>7</sup>



Research & Markets estimates that the global alopecia market reached US\$ 8.5 billion in 2018 and is targeted to grow by 5.5 % p.a. to US\$ 12.4 billion in 2025. In 2018, the global androgenetic alopecia market was estimated at US\$ 7.25 billion, i.e. approximately 85 % of the market. This market is split between the drug market, the hair transplant market and the laser market.

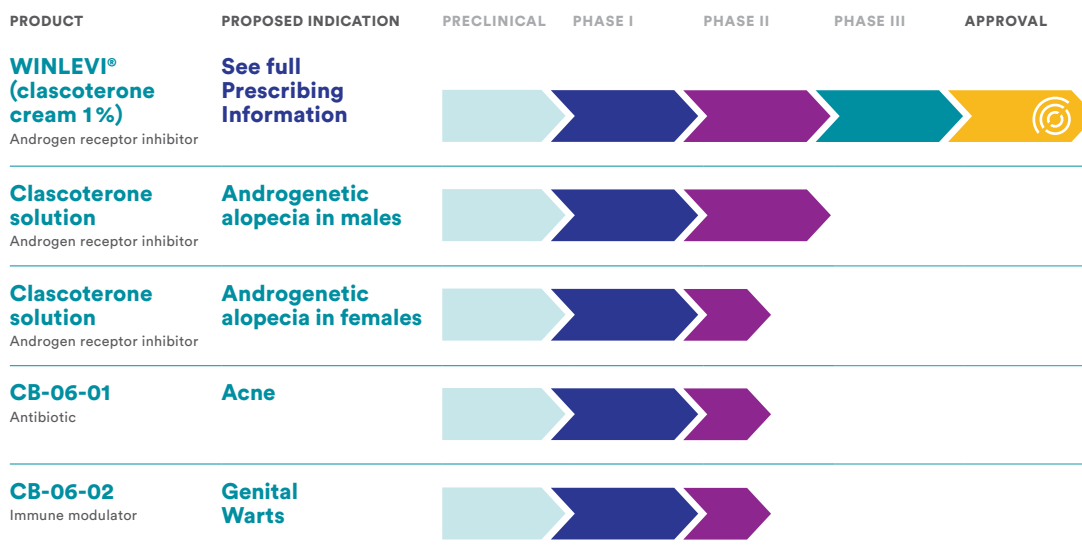
According to the American Sexual Health Organization, in the US approximately 14 million people are newly infected with Human Papillomavirus (“HPV”) every year, and 79 million persons are estimated to be currently infected. HPV is the causative pathogen of anogenital warts.<sup>14</sup>

We believe that an overall lack of innovation in the research and development of new dermatology products has resulted in a limited number of effective treatment options. For example, the three mechanisms of action most commonly used to treat acne have been available for over 40 years. In fact, there has not been a new mechanism of action for the treatment of acne since 1982, when Accutane was launched.<sup>9</sup> Consequently, the few truly innovative therapies launched over the past few decades have resulted in significant sales. Furthermore, as dermatology medications have relatively short clinical trials compared to other pharmaceuticals, development costs are relatively contained.

We believe that the field of dermatology offers an exceptional opportunity to build relationships with opinion leaders, advocacy groups and medical practitioners. We believe that consolidation in the dermatology industry has resulted in an enhanced opportunity for a medical dermatology-focused company to build relationships with these stakeholders and has made available a large and growing talent pool of experienced employees who can make significant contributions to our company.

# Research and Development

## Cassiopea Pipeline



## Winlevi® (clascoterone cream 1%)

On 27 August, 2020, Cassiopea announced the US FDA approval for Winlevi® (clascoterone cream 1%), a first-in-class<sup>10</sup> topical androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.<sup>1</sup> Notwithstanding acne being the most prevalent skin condition in the US affecting up to 50 million Americans annually,<sup>2</sup> the last FDA approval of an acne drug with a new mechanism of action (MOA) occurred nearly 40 years ago.<sup>9</sup>

Cassiopea's first-in-class topical androgen receptor inhibitor, Winlevi®, tackles the androgen hormone component of acne in both males and females.<sup>11</sup> Androgen receptor inhibitors act by limiting the effects of these hormones on increasing sebum production and inflammation.<sup>12</sup>

In pivotal clinical trials, Winlevi® demonstrated treatment success and reductions in acne lesions and was well tolerated when used twice a day. The most frequently observed local skin reaction was mild erythema.<sup>13, 14</sup>

Winlevi® (clascoterone cream 1%) is approved for the treatment of acne vulgaris in people aged 12 and older.<sup>1</sup> Although Winlevi®'s exact mechanism of action in acne is unknown,<sup>1</sup> 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 follicle.<sup>15</sup>

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. Winlevi® has been approved by the United States Food & Drug Administration (FDA) as a novel drug with a unique mechanism of action for the topical treatment of acne in patients 12 years and older.<sup>1,2</sup> 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 calendar 2021. Complete prescribing information is available on [www.WINLEVI.com](http://www.WINLEVI.com).<sup>1</sup>

## Acne

Acne is the eighth most prevalent disease in the world,<sup>16</sup> affecting more than 640 million people.<sup>17</sup> Although acne often coincides with puberty affecting approx. 85% of adolescents, it also impacts young adults (aged 12–25 years) and may persist into,<sup>18</sup> or develop during, adulthood.<sup>19</sup>

Acne is a multifactorial inflammatory condition characterized by excess skin oil (sebum) production, a build-up of dead skin cells that clog the pores and growth of bacteria that further enhance inflammation, redness and pore blockage.<sup>20</sup> These events lead to acne's characteristic lesions including blackheads, whiteheads, and pus-filled inflamed lesions often present on the face, neck, back and shoulders of sufferers.

Treatment of acne usually involves combinations of oral and/or topical treatments. Current first-line therapies target one or two aspects of acne and may include benzoyl peroxide, topical retinoids, and topical or oral antibiotics.<sup>21–23</sup> Antibiotic resistance in acne is a concern.<sup>24</sup> Oral isotretinoin, a potent retinoid, may be considered for more severe acne, but is associated with side effects and must be used with caution in females of childbearing age due to known harm to the fetus.<sup>21–23, 25</sup> Female acne patients can be treated with a combined oral contraceptive (COC) or spironolactone,<sup>26, 27</sup> both of which affect androgens.<sup>23, 28</sup>

Androgen hormones are a key driver of acne in both males and females with acne. Androgen receptors (ARs) are expressed throughout the skin and found in the sebum producing glands.<sup>29</sup> Circulating and locally (skin) synthesized androgens such as testosterone and dihydrotestosterone (DHT) bind to the AR and stimulate sebum production in both males and females.<sup>12, 28, 29</sup>

Androgen inhibition is an effective strategy for the treatment of female acne. Certain COCs (norgestimate, norethindrone) are FDA approved to treat acne in females;<sup>23, 28</sup> these drugs suppress androgen production, thereby reducing circulating androgens.<sup>12, 26</sup> Spironolactone is an aldosterone inhibitor and AR blocker,<sup>12, 28</sup> used off-label to treat female acne.<sup>27, 28</sup>

Both COCs and spironolactone are associated with systemic side effects, are contraindicated in pregnancy, and are unsuitable for male acne patients.<sup>12, 26, 27</sup> AR inhibitors and/or anti-androgens have not been approved for the treatment of acne in males.

Novel therapeutic innovations for the treatment of acne have been sparse in recent years, with no new mechanism of action approved by FDA since isotretinoin in 1982.<sup>9</sup> In 2020, Cassiopea received US FDA approval for a new therapeutic topical drug class to treat acne.<sup>1, 10</sup> In what has been hailed by US dermatologists as an exciting “game changer” in the acne armamentarium, Winlevi® (clascoterone) cream 1% is poised in 2021 to be a ground-breaking treatment for acne in the US dermatology market, one of the largest in the world.

## Clascoterone solution

Whereas Winlevi® (clascoterone cream 1%), is an androgen receptor inhibitor product indicated for the topical treatment of acne vulgaris in patients 12 years of age and older<sup>1</sup>, Clascoterone solution is a liquid formulation with a different strength of same active ingredient.<sup>30</sup>

Clascoterone solution is in late stage development for the treatment of androgenetic alopecia (AGA). Although clascoterone’s exact mechanism of action is unknown, laboratory studies suggest Clascoterone competes with androgen hormones, specifically dihydrotestosterone (DHT), for binding to the androgen receptors within the sebaceous gland and hair follicles.<sup>15, 30</sup>

Based on early clinical review, Cassiopea believes that topical application of Clascoterone will not have the contraindications and safety warnings of an orally administered androgen modulator used for the treatment of AGA in men. It appears Clascoterone does not interfere with the hormonal and, in particular, testosterone profiles of male subjects; libido and sexual behavior changes, the typical side effects of the systemic antiandrogens, have not been observed in clinical trials to date.<sup>31, 32</sup>

Clascoterone is quickly metabolized to cortexolone, a metabolite with a known safety profile.<sup>33, 34</sup> Due to its rapid metabolism and local activity, there appears to be limited systemic exposure to Clascoterone and thus potential systemic side effects are likely minimized.

After a successful Phase IIa trial, a Phase II Dose Ranging Study was conducted in males and results were announced in 2019. In the dose ranging trial, a total of 404 subjects were enrolled in six sites in Germany. This double-blind trial evaluated the efficacy and safety of four different doses of Clascoterone compared to vehicle (placebo) in male subjects 18–55 years of age with mild to moderate androgenetic alopecia in temple and vertex region (rating III vertex to V on the Modified

Norwood- Hamilton Scale, i.e. IIIv, IV, or V), with a history of ongoing hair loss. All subjects applied Clascoterone or vehicle to the balding areas of the scalp twice daily for a total of twelve months. The eligible subjects were randomly assigned to one of the following five treatment groups: 2.5% Clascoterone solution BID; 5.0% Clascoterone solution BID; 7.5% Clascoterone solution BID; 7.5% Clascoterone solution QD (once a day) and vehicle solution in the evening; vehicle solution BID.<sup>35</sup>

The co-primary efficacy endpoints evaluated at month 12 in the trials were: 1) change from baseline in non-vellus TAHC (target area hair count) and 2) HGA (hair growth assessment) score. The target area is defined as an area of one square centimeter.<sup>35</sup>

For the TAHC, statistically highly significant changes were observed in all active treatment groups with the highest change observed in the 7.5% BID group, which reached statistical significance at all timepoints, beginning with the third month (first follow-up visit), while the placebo group had a decrease in TAHC, representing the progression of AGA over time if left untreated. These results indicate that Clascoterone stops the loss of hair and promote the growth of new hair. For the HGA assessment, the subjects used the baseline standardized global photograph of their scalp and compared it, side by side, with a “real time” standardized global photo to assess their hair growth using a seven-point scale from -3 to +3. More subjects in all active groups saw an increase in their hair growth compared to the vehicle group.<sup>35</sup>

The results indicate a safety profile similar to vehicle for both adverse events and local skin reactions, even after 12 months treatment. There were no treatment-related serious adverse events among patients treated with Clascoterone.

Since the chemical structure of Clascoterone is similar to that of a steroid, while its function is not, cortisol levels were tested in a sub-group of patients to verify that Clascoterone is free from systemic steroid activity. The mean absolute changes of cortisol values throughout the study were similar among groups, suggesting that Clascoterone has no systemic effect on cortisol.

In Q2, we completed the Phase II trial investigating clascoterone solution for the treatment of androgenetic alopecia (AGA) in females. Top line results will be available in 3Q 2021.

The Phase II multicenter, prospective, randomized, double-blind, vehicle controlled, dose ranging study evaluated the efficacy and safety of clascoterone solution for the treatment of AGA in females. The six-month study enrolled 293 female subjects between 18–55 years of age with mild to moderate AGA in Germany. The four-arm study enrolled approximately 70 subjects per arm in each of four treatment groups: clascoterone solution 5% BID (twice daily), clascoterone solution 7.5% BID (twice daily), minoxidil solution 2% BID (twice daily) and vehicle BID (twice daily). The co-primary endpoints were: (1) change from baseline in non-vellus Target Area Hair

Count (TAHC) at month 6 in comparison to vehicle and (2) Hair Growth Assessment (HGA) score at month 6 in comparison to vehicle.

There has been little clinical development for AGA in over the last 20 years. In teen dermatological conditions, especially those with a profound effect on self-esteem and well-being, the US FDA has focused on the importance of including disease-specific, validated patient reported outcome (PRO) questionnaires within clinical trials.

The FDA has requested inclusion of an AGA-specific patient reported outcome (PRO) questionnaire to be included as part of the endpoints for Phase III clinical AGA studies. As there is no currently validated AGA PRO tool, we are in the process, along with an expert CRO in this area, to develop and validate a proprietary AGA PRO tool. Developing such a tool portends an advantage to Cassiopea, as the company would be retain exclusive ownership of the tool for future AGA studies. We continue to remain in communication with the US FDA before executing enrollment for the Phase III studies.

### Androgenetic alopecia

Androgen induced alopecia, also known as Androgenetic Alopecia (AGA) or patterned hair loss, is the most common type of hair loss affecting 50–60 million men and 30–35 million women in the US.<sup>4–6</sup> Of these, only 25–30 million men and 15–20 million women have been diagnosed, and only 2.7 million men and 2 million women or 5–10 % of the total are actually being treated.<sup>6</sup> A vast majority of patients have not sought treatment for their condition, likely due to the limitations of current treatments and the lack of available options.<sup>6</sup>

In the US, treatment of AGA in men and women is limited to topical minoxidil, laser therapy, platelet rich plasma (PRP), and over the counter nutritional supplements.<sup>36</sup> Balding men may also use oral finasteride,<sup>7</sup> which is associated with a number of systemic side effects such as loss of libido and feminization.<sup>37</sup> In the US, oral finasteride is not FDA approved for females with AGA.

In AGA, high local concentrations of DHT bind to androgen receptors within the scalp hair follicles, resulting in shortening of the hair cycle and gradual miniaturization of scalp follicles in men and women with a genetic predisposition. Over time, these progressively smaller, thinner hair follicles are unable to produce new hair, thus resulting in AGA's characteristic patterned baldness.<sup>12, 38</sup> DHT dependent effects are considered, in most cases, reversible,<sup>12</sup> yet a topical treatment that can be used in both males and females with AGA remains elusive.

AGA could be responsive to medical treatment with topical androgen receptor inhibitors. Indeed, Clascoterone solution through its proposed MOA of direct inhibition of testosterone and DHT binding to local hair follicle androgen receptors,<sup>30</sup> has the potential to be the only topical androgen receptor inhibitor for use in both men and women with AGA if approved by the FDA.

## CB-06-01

CB-06-01, an NCE, is a topical antibiotic (licensed from Naicons, an Italian company) that is highly effective on bacteria implicated in acne, including strains resistant to some other antibiotics. We aim to develop and then market the product to replace the current topical antibiotics used in the treatment of acne.

Based on the results of the phase II proof of concept trial, it was decided to continue the development of this product. During 2018, the synthesis of the new API was completed. We are planning to develop a new absorption-improved formulation, conduct skin penetration tests and to begin the preparation for the Phase II Dose Ranging Trial.

## CB-06-02

CB-06-02, also an NCE (licensed from BioMas, an Israeli company), is being developed for the treatment of genital warts. We believe that it is the first potential treatment for this condition based on tellurium, a rare element. It acts as a low-toxicity immunomodulator in supporting the natural immune response against Human Papilloma Virus, or HPV. Based on the drug profiling we have performed to date, we believe that CB-06-02 has the potential to have a faster onset of action and a lower recurrence rate than currently available topical treatments.

Based on the positive results of the phase II proof of concept trial, it was decided to continue the development of this product. We are planning to produce a new GMP batch, develop a new improved formulation and to begin the preparation for the Phase II Dose Ranging Trial.

### Genital warts

External genital warts are extremely common, currently 79 million Americans are infected with HPV, with about 14 million people becoming newly infected each year and an estimated 80% of sexually active people contracting HPV in their lifetime.<sup>8,39</sup> There are more than 120 distinct subtypes of human papillomavirus identified. Current treatment options are largely centred upon removal of the warts rather than elimination of the underlying viral infection. There are many therapies in use, which differ in cost, dosing schedules, duration of treatment, and overall effectiveness. As of yet, no single therapy has emerged as the gold standard of care in the treatment of genital warts.<sup>40</sup>

# Patents and Trademarks

## Patents granted in 2021

- One patent granted in China (CB-03-11 Clascoterone solution – expiry date 2036);
- One patent granted in South Africa (CB-03-11 Clascoterone solution – expiry date 2036);
- One patent granted in the USA (CB-03-11/CON2 Clascoterone solution – expiry date 2036 – continuation-in-part application);

## Patent New Filings in 2021

- One patent application in Japan (CB-03-11/DIV Clascoterone solution – divisional application);
- One patent application in the USA (CB-03-01/01/DIV1/DIV1/CON1/CON2 crystalline forms/Clascoterone cream 1% – continuation application);

## Trademarks Registered in 2021

- Two trademarks registered in Puerto Rico for company trademark (Cassiopea® device in color/logo – class 5 and class 42);
- One trademark registered in Puerto Rico for Clascoterone cream 1% (Winlevi® device in color/logo)

## Trademarks New Filings in 2021

- No new trademark filings in year 2021.



## References

- 1 Cassiopea S.p.A. WINLEVI Prescribing Information. <https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf>
- 2 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 19 July 2021.
- 3 Stern S: Dermatologists and office-based care of dermatologic disease in the 21st century. *J Invest Dermatol Symp Proc* 2004;9:126–130.
- 4 Ramos PM, Miot HA. Female pattern hair loss: a clinical and pathophysiological review. *An Bras Dermatol*. 2015;90(4):529–543.
- 5 US National Library of Medicine. Androgenetic Alopecia. August 2020. <https://medlineplus.gov/genetics/condition/androgenetic-alopecia/> Accessed 19 July 2021.
- 6 Triangle Insights Report. Commercial assessment of Breezula® (clascoterone solution). November, 2018.
- 7 The International Society of Hair Restoration Surgery (ISHRS). Worldwide demand for effective hair restoration procedures continues to increase. Results from a ISHRS member survey. June 2020. <https://ishrs.org/2020/06/03/worldwide-demand-for-effective-hair-restoration-procedures-continues-to-increase/> Accessed 1 February 2021.
- 8 The American Sexual Health Association. ASHA. Human Papilloma Virus (HPV). [https://www.ashsexualhealth.org/human\\_papilloma\\_virus/](https://www.ashsexualhealth.org/human_papilloma_virus/) Accessed 8 February 2021.
- 9 Leyden JJ, Del Rosso JQ, Baum EW. The use of isotretinoin in the treatment of acne vulgaris: clinical considerations and future directions. *J Clin Aesthet Dermatol*. 2014;7(2 Suppl):S3-S21.
- 10 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>
- 11 US FDA Drug Trial Snapshot: WINLEVI. 3 September 2020. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-winlevi>
- 12 Lai J-J, Chang P, Lai KP, Chen L, Chang C. The role of androgen and androgen receptor in skin-related disorders. *Arch Derm Res*. 2012;304(7):499-510.
- 13 Hebert A, Thiboutot D, Stein Gold L, et al. Efficacy and safety of topical clascoterone cream, 1%, for treatment in patients with facial acne: two phase 3 randomized clinical trials. *JAMA Dermatol*. 2020;156(6):621-630.
- 14 Eichenfield L, Hebert A, Gold LS, Cartwright M, Fraggasso E, Moro L, Mazzetti A. Open-label, long-term extension study to evaluate the safety of clascoterone (CB-03-01) cream, 1% twice daily, in patients with acne vulgaris. *J Am Acad Dermatol*. 2020 Aug;83(2):477-485.
- 15 Rosette C, Agan FJ, Mazzetti A. Cortisolone 17a-propionate (clascoterone) is a novel androgen receptor antagonist that inhibits production of lipids and inflammatory cytokines from sebocytes in vitro. *J Drugs Dermatol*. 2019; 18(5):412-418.
- 16 Tan JK, Bhate K. A global perspective on the epidemiology of acne. *Br J Dermatol*. 2015;172 Suppl 1:3-12.
- 17 Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380(9859):2163-2196.
- 18 Lynn DD, Umari T, Dunnick CA, Dellavalle RP. The epidemiology of acne vulgaris in late adolescence. *Adolesc Health Med Ther*. 2016;7:13-25.
- 19 Rocha MA, Bagatin E. Adult-onset acne: prevalence, impact, and management challenges. *Clin Cosmet Investig Dermatol*. 2018;11:59-69.
- 20 Moradi Tuchayi S, Makrantonaki E, Ganceviciene R, Dessinioti C, Feldman SR, Zouboulis CC. Acne vulgaris. *Nat Rev Dis Primers*. 2015;1:15029.
- 21 Hauk L. Acne vulgaris: treatment guidelines from the AAD. *Am Fam Physician*. 2017;95:740-741.
- 22 Thiboutot DM, Dreno B, Abanmi A, Alexis AF, Aravitskaia E, Barona Cabal MI, et al. Practical management of acne for clinicians: an international consensus from the Global Alliance to Improve Outcomes in Acne. *J Am Acad Dermatol*. 2018;78(2) Suppl 1:S1-S23 e1.

- 23 Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74(5):945-973.e33.
- 24 Adler BL, Kornmehl H, Armstrong AW. Antibiotic Resistance in Acne Treatment. *JAMA Dermatol*. 2017;153(8):810–811.
- 25 Layton A. The use of isotretinoin in acne. *Dermatoendocrinol*. 2009;1:162-169.
- 26 Huber J, Walch K. Treating acne with oral contraceptives: use of lower doses. *Contraception*. 2006;73:23-29.
- 27 Layton AM, Eady EA, Whitehouse H, Del Rosso JQ, Fedorowicz Z, van Zuuren EJ. Oral spironolactone for acne vulgaris in adult females: a hybrid systematic review. *Am J Clin Dermatol*. 2017;18:169-191.
- 28 Elsaie ML. Hormonal treatment of acne vulgaris: an update. *Clin Cosmet Investig Dermatol* 2016;9:241–8.
- 29 Dart DA. Androgens have forgotten and emerging roles outside of their reproductive functions, with implications for diseases and disorders. *J Endocr Disord*. 2014;1:1005.
- 30 Rosette C, Rosette N, Mazzetti A, Moro L, Gerloni M. Cortexolone 17alpha-propionate (clascoterone) is an androgen receptor antagonist in dermal papilla cells in vitro. *J Drugs Dermatol*. 2019;18:197-201.
- 31 Celasco G, Moro L, Bozzella R, Ferraboschi P, Bartorelli L, Quattrocchi C, et al. Biological profile of cortexolone 17alpha-propionate (CB-03-01), a new topical and peripherally selective androgen antagonist. *Arzneimittelforschung*. 2004;54:881-886.
- 32 Data on File. Cassiopea. 2020.
- 33 Ferraboschi P, Legnani L, Celasco G, Moro L, Ragonesi L, Colombo D. A full conformational characterization of antiandrogen cortexolone-17a-propionate and related compounds through theoretical calculations and nuclear magnetic resonance spectroscopy. *Med Chem Commun*. 2014;5:904-914.
- 34 Dehertogh R, Hoet JJ, Materazzi F, Ekka E. *Acta Endocrinol (Copenh)*. 1964;47:165-76.
- 35 Blume-Peytavi U, Hordinsky M, Moro L, Fragasso E, Cartwright, M, Mazzetti, A. S11223 – Clascoterone Topical Solution, An Investigational, Selective Androgen Receptor Antagonist: Results from a Pivotal Phase II Dose Ranging Study in Men with Androgenetic Alopecia (AGA). Presented at the 2019 AAD Annual Conference. S034 Late-breaking Research: Clinical Trials. S11223. Saturday 2 March 2019. Washington DC. <https://bit.ly/330h2nt>
- 36 Ashique S, Sandhu NK, Haque SN, Koley K. A systematic review on topical marketed formulations, natural products, and oral supplements to prevent androgenic alopecia: a review. *Nat Prod Bioprospect*. 2020;10(6):345-365.
- 37 Hirshburg JM, Kelsey PA, Therrien CA, Gavino AC, Reichenberg JS. Adverse effects and safety of 5-alpha reductase inhibitors (finasteride, dutasteride): a systematic review. *J Clin Aesthet Dermatol*. 2016;9(7):56-62.
- 38 Ustuner ET. Cause of androgenic alopecia: crux of the matter. *Plast Reconstr Surg Glob Open*. 2013;1(7):e64.
- 39 The Cleveland Clinic. Human Papilloma Virus (HPV). Available at : <https://my.clevelandclinic.org/health/diseases/11901-hpv-human-papilloma-virus> Accessed 2 February 2021.
- 40 Chesson HW, Dunne EF, Hariri S, Markowitz LE. The estimated lifetime probability of acquiring human papillomavirus in the United States. *Sex Transm Dis*. 2014;41(11):660-664.

# COVID-19 impact

In light of the ongoing COVID-19 pandemic, we are committed to keeping our stakeholders informed as the situation evolves. In the face of this highly unpredictable and complex scenario, the Board of Directors promptly took action to:

- understand the immediate consequences for the Company;
- adopt all safeguard measures for employee health;
- understand, as far as possible, the evolution of the emergency;
- adopt all the solutions to be put in place to protect the company's assets.

In addition, the Company promptly implemented all the requested measures based on the legislation currently in force for the protection of the health of workers and places. The Company decided to prudently suspend, where possible, any work activity at the Company's offices, organizing work in "smart working" mode, with the necessary electronic equipment. For people for whom smart working is not possible, we have stringent cleaning and sanitation protocols in place, and we strictly respect social distancing policies at all times, in order to minimize risk of exposure. These actions have allowed the continuation of the main operating activities, among which the preparation of the Financial Statements, the convocations and teleconference meetings of the Board of Directors and of the Shareholders Meeting.

The ongoing Phase II trial of Clascoterone solution in females with androgenetic alopecia, which started in Q4 2019, was affected by the COVID-19 pandemic as enrollment was suspended for about three months. Recruitment restarted in June 2020 and we announced the completion of enrolment on 8 October 2020. Top line results will be available in 3Q 2021.

# ESG policy

In order to fully spread and implement the sustainability principles within its business culture, In 2020 the Board of Directors has appointed a Committee, made of two board members, as responsible for the implementation and supervision of Cassiopea's ESG approved policy. Cassiopea's ultimate objective on this matter, is to integrate the "ESG framework" into the corporate strategy, with the aim to get a complete alignment of internal and external stakeholders' interests.

The tasks for 2021 of the ESG Committee are:

- \_\_ ESG STRATEGY: a list of KPIs and intermediate goals, set on the basis of the approved criteria and, where applicable, linked to incentive plans;
- \_\_ ESG CONSULTANTS: hiring external experts providing for advice on ESG topics;
- \_\_ ESG POLICIES: to be integrated in all the operative procedures of the Company;
- \_\_ ESG'S CRITERIA: set within a specific roadmap policy and checked annually (the criteria approved by the Board of Directors are shown in the table below).

---

## **a. Environmental policy**

- i. Hazardous waste disposal
  - ii. Disposal of expired products
  - iii. Electricity usage
  - iv. Water usage
- 

## **b. Freedom of association policy**

- i. Trade unions
- 

## **c. Employee relations & Diversity programs**

- i. Male female composition by levels
  - ii. Turn over
  - iii. Accidents at work place
  - iv. Work days lost
  - v. Minorities
  - vi. Handicapped persons
- 

## **d. Human capital development programs**

- i. Determination of training needs on a yearly basis
  - ii. % of employees in external career development programs
    - 1. How much is spent on this
  - iii. inhouse training programs
- 

## **e. Scope of Supplier Standards**

- i. Standards required
  - ii. Reports on maintenance of standards
  - iii. Inspections of standard maintenance
- 

## **f. Product and Service Safety Programs**

- i. Reported adverse events
  - ii. Returned products
-

---

**g. Drug Promotion Standards**

---

- i. Scientific Advisory Boards
  - ii. KOL policy
  - iii. Trade fairs & congresses
- 

**h. Access to Medicine Program**

---

**i. Lobbying policy**

---

**j. Bribery & Corruption Policy**

---

**k. Whistleblower Programs**

---

**l. Clinical Trial Standards**

---

- i. Quality of CRO
  - ii. Minimal country criteria
  - iii. GCP criteria and Supervision standards
    - 1. Adverse events reporting
    - 2. Extraordinary event reporting
  - iv. Animal Welfare Policy
- 

**m. Accounting & Taxation policy**

---

**n. Intellectual property policy**

---

**o. Financial flexibility policy**

---

**p. Governance policy**

---

- i. Board composition
    - 1. Independence
    - 2. Gender
    - 3. Age
    - 4. Duration
    - 5. Board meeting attendance
  - ii. Management composition
    - 1. Gender
    - 2. Age
    - 3. Duration
-

# Financial review

## Income statement

EUR 1,000	30.06.2021	30.06.2020	Change	% change
<b>Revenue</b>	–	–	–	0.0%
Other income	–	–	–	0.0%
Cost of sales	–	–	–	0.0%
Research and development costs	(3,753)	(2,510)	(1,243)	49.5%
Selling, general and administrative costs	(2,535)	(2,180)	(355)	16.3%
<b>Net operating expenses</b>	<b>(6,288)</b>	<b>(4,690)</b>	<b>(1,598)</b>	<b>34.1%</b>
<b>Operating result</b>	<b>(6,288)</b>	<b>(4,690)</b>	<b>(1,598)</b>	<b>34.1%</b>
Financial income	300	18	282	1566.7%
Financial expenses	(177)	(650)	473	–72.8%
<b>Profit (loss) before taxes</b>	<b>(6,165)</b>	<b>(5,322)</b>	<b>(843)</b>	<b>15.8%</b>
Income tax expenses	–	–	–	–
<b>Profit (loss) for the period</b>	<b>(6,165)</b>	<b>(5,322)</b>	<b>(843)</b>	<b>15.8%</b>

### Revenue

The Company has no products on the market, so it had no operating revenues in H1 2021 and H1 2020.

### Net Operating expenses

Net operating expenses increased by EUR 1,598 thousand from EUR 4,690 thousand to EUR 6,288 thousand, mainly due to the increase in research and development costs (EUR 1,243 thousand) related to Phase II trials of Clascoterone solution for androgenetic alopecia in females and to the increase of the selling, general and administrative costs (EUR 355 thousand).

## Net operating expenses as per nature

EUR 1,000	30.06.2021	30.06.2020	Change	% change
Other income	–	–	–	0.0%
Raw materials and consumables used	(153)	(317)	164	–51.7%
Personnel expenses	(1,742)	(1,785)	43	–2.4%
Outsourced preclinical and clinical trial costs	(1,733)	(640)	(1,093)	170.8%
Other operating expenses	(2,511)	(1,918)	(593)	30.9%
Depreciation and amortization	(149)	(30)	(119)	396.7%
<b>Total net operating expenses</b>	<b>(6,288)</b>	<b>(4,690)</b>	<b>(1,598)</b>	<b>34.1%</b>

Broken down by nature, the bulk of the operating expenses is composed of i) other operating expenses which increased by 30.9% from EUR 1,918 thousand to EUR 2,511 thousand and mainly related to pre-commercial activities; and ii) personnel expenses, which is in line (EUR 1,742 thousand) to H1 2020 (EUR 1,785 thousand).

Outsourced preclinical and clinical trial costs increased from EUR 640 thousand to EUR 1,733 thousand mainly as a consequence of the development activities of Clascoterone solution which became the most important cost factor increasing from EUR 498 thousand to EUR 1,654 thousand and representing 95.4% of the total Outsourced preclinical and clinical trial costs.

Raw materials and consumables necessary for the development of these projects decreased from EUR 317 thousand to EUR 153 thousand.

Depreciation and amortization increased from EUR 30 thousand to EUR 149 thousand, mainly in relation to the amortization of the Winlevi® registration fee in the US, that started in the period.

### Financial income and Expenses

In H1 2021, financial income consists of foreign exchange gains on cash and cash equivalents and financial expenses include EUR 162 thousand related to interests on Cosmo Pharmaceuticals N.V. unsecured loan.

### Income tax expenses

In both H1 2021 and H1 2020, the Company did not recognize deferred tax assets relating to the loss before tax, due to the uncertainty of the availability of future tax profits against which such an asset may be offset.

### Profit (loss) for the period

The loss for H1 2021 increased by EUR 843 thousand to EUR 6,165 thousand.

## Assets

EUR 1,000	30.06.2021	31.12.2020	Change	% change
<b>Assets</b>				
<b>Non-current assets</b>				
Property, plant and equipment	6	9	(3)	-33.3%
Other intangible assets	2,883	2,989	(106)	-3.5%
Tax receivables	9,609	9,799	(190)	-1.9%
<b>Total non-current assets</b>	<b>12,498</b>	<b>12,797</b>	<b>(299)</b>	<b>-2.3%</b>
<b>Current assets</b>				
Inventories	1,817	761	1,056	138.8%
Current tax assets	370	370	-	0.0%
Other receivables and other assets	1,921	2,053	(132)	-6.4%
Cash and cash equivalents	1,796	2,646	(850)	-32.1%
<b>Total current assets</b>	<b>5,904</b>	<b>5,830</b>	<b>74</b>	<b>1.3%</b>
<b>Total assets</b>	<b>18,402</b>	<b>18,627</b>	<b>(225)</b>	<b>-1.2%</b>

Non-current assets slightly decreased from EUR 12,797 thousand to EUR 12,498 thousand and mainly consist of the non-current tax receivable (EUR 9,609 thousand at the end of the period) in relation to the tax credit for research and development pursuant to Italian Law No. 190 of 23 December 2014 and subsequent implementation decrees.

Other intangible assets refer to the costs for filing and extension of patents owned by the Company and include also EUR 2,222 for Winlevi® registration fee for the US.

In Current assets, inventories refer to the API (Active Principle Ingredient) stock required for the production for the commercial launch of Winlevi®.

Other receivables and other assets slightly decreased by EUR 132 thousand to EUR 1,921 thousand and mainly include prepaid expenses and VAT receivables.

Cash and cash equivalents decreased by EUR 850 thousand to EUR 1,796 thousand.



## Equity and liabilities

EUR 1,000	30.06.2021	31.12.2020	Change	% change
<b>Equity</b>				
Share capital	10,750	10,750	–	0.0%
Share premium	21,638	21,638	–	0.0%
Capital contribution	195	123	72	58.5%
Stock option plan reserve	4,785	4,184	601	14.4%
Currency translation reserve	345	623	(278)	–44.6%
Losses carried forward	(21,703)	(9,395)	(12,308)	131.0%
Profit/(Loss) for the period	(6,165)	(12,308)	6,143	–49.9%
<b>Total equity</b>	<b>9,845</b>	<b>15,615</b>	<b>(5,770)</b>	<b>–37.0%</b>
<b>Liabilities</b>				
<b>Non-current liabilities</b>				
Interest-bearing loans and borrowings	–	66	(66)	–100.0%
<b>Total non-current liabilities</b>	<b>–</b>	<b>66</b>	<b>(66)</b>	<b>–100.0%</b>
<b>Current liabilities</b>				
Interest-bearing loans and borrowings	6,230	4	6,226	155650.0%
Trade payables	2,246	2,839	(593)	–20.9%
Other current liabilities	81	103	(22)	–21.4%
<b>Total current liabilities</b>	<b>8,557</b>	<b>2,946</b>	<b>5,611</b>	<b>190.5%</b>
<b>Total liabilities</b>	<b>8,557</b>	<b>3,012</b>	<b>5,545</b>	<b>184.1%</b>
<b>Total equity and liabilities</b>	<b>18,402</b>	<b>18,627</b>	<b>(225)</b>	<b>–1.2%</b>

Equity decreased from EUR 15,615 thousand to EUR 9,845 thousand mainly as a consequence of the loss for the period.

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 twelve months.

# Condensed Consolidated Financial Statement (unaudited)

## Condensed Consolidated income statement (unaudited)

For the six months ended 30 June

EUR 1,000	Notes	30.06.2021	30.06.2020
<b>Revenue</b>		–	–
Other income		–	–
Cost of sales		–	–
Research and development costs		(3,753)	(2,510)
Selling, general and administrative costs		(2,535)	(2,180)
<b>Net operating expenses</b>	4	<b>(6,288)</b>	<b>(4,690)</b>
<b>Operating result</b>		<b>(6,288)</b>	<b>(4,690)</b>
Financial income	5	300	18
Financial expenses	5	(177)	(650)
<b>Profit (loss) before taxes</b>		<b>(6,165)</b>	<b>(5,322)</b>
Income tax expenses	6	–	–
<b>Profit (loss) for the period</b>		<b>(6,165)</b>	<b>(5,322)</b>
<b>Earnings (loss) per share</b>			
Basic		<b>(0.573)</b>	(0.530)
Diluted		<b>(0.573)</b>	(0.530)

## Condensed Consolidated statement of comprehensive income (unaudited)

For the six months ended 30 June

EUR 1,000	Notes	30.06.2021	30.06.2020
<b>Profit (loss) for the period (A)</b>		<b>(6,165)</b>	<b>(5,322)</b>
Total other comprehensive income that will not be reclassified subsequently to profit or loss, net of tax (B1)		–	–
Exchange differences on translating foreign operations		(278)	22
Total other comprehensive income that will be reclassified subsequently to profit or loss, net of tax (B2)		(278)	22
<b>Total other comprehensive income, net of tax (B)=(B1+B2)</b>		<b>(278)</b>	<b>22</b>
<b>Total comprehensive income (A)+(B)</b>		<b>(6,443)</b>	<b>(5,300)</b>

The accompanying notes form an integral part of the Half-Year Condensed Consolidated Financial Statements.

## Condensed Consolidated statement of financial position (unaudited)

As at 30 June 2021

EUR 1,000	Notes	30.06.2021	31.12.2020
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	8	6	9
Other intangible assets	9	2,883	2,989
Tax receivables	10	9,609	9,799
<b>Total non-current assets</b>		<b>12,498</b>	<b>12,797</b>
<b>Current assets</b>			
Inventories	11	1,817	761
Current tax assets	12	370	370
Other receivables and other assets	13	1,921	2,053
Cash and cash equivalents	14	1,796	2,646
<b>Total current assets</b>		<b>5,904</b>	<b>5,830</b>
<b>Total assets</b>		<b>18,402</b>	<b>18,627</b>
<b>Equity</b>			
Share capital		10,750	10,750
Share premium		21,638	21,638
Capital contribution		195	123
Stock option plan reserve		4,785	4,184
Currency translation reserve		345	623
Losses carried forward		(21,703)	(9,395)
Profit / (Loss) for the period		(6,165)	(12,308)
<b>Total equity</b>	15	<b>9,845</b>	<b>15,615</b>
<b>Liabilities</b>			
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings		–	66
<b>Total non-current liabilities</b>	16	<b>–</b>	<b>66</b>
<b>Current liabilities</b>			
Interest-bearing loans and borrowings	16	6,230	4
Trade payables	17	2,246	2,839
Other current liabilities	18	81	103
<b>Total current liabilities</b>		<b>8,557</b>	<b>2,946</b>
<b>Total liabilities</b>		<b>8,557</b>	<b>3,012</b>
<b>Total equity and liabilities</b>		<b>18,402</b>	<b>18,627</b>

The accompanying notes form an integral part of the Half-Year Condensed Consolidated Financial Statements.

## Condensed Consolidated cash flow statement (unaudited)

For the six months ended 30 June

EUR 1,000	Notes	30.06.2021	30.06.2020
<b>Loss for the period before tax</b>		<b>(6,165)</b>	<b>(5,322)</b>
<b>Adjustment for:</b>			
Interest on loan not paid		162	608
Depreciation and amortization	4	149	30
Share-based payment expenses	19	673	546
R&D credit offset		190	195
Net unrealised foreign exchange differences on intercompany loan		(276)	(26)
Net unrealised foreign exchange differences on cash and cash equivalents		(10)	4
<b>Operating cash outflow before changes in working capital</b>		<b>(5,277)</b>	<b>(3,965)</b>
Change in inventories		(1,056)	–
Change in trade payables		(595)	(66)
Change in other receivables and other assets		132	(125)
Change in other current liabilities		(22)	(32)
<b>Cash flows from operating activities</b>		<b>(6,818)</b>	<b>(4,188)</b>
Investments in other intangible assets	9	(40)	(43)
<b>Cash flows from investing activities</b>		<b>(40)</b>	<b>(43)</b>
Proceeds from interest-bearing loans and borrowings	16	6,000	4,000
Repayments of interest-bearing loans and borrowings		(2)	(2)
Share capital increase		–	7,992
<b>Cash flows from financing activities</b>		<b>5,998</b>	<b>11,990</b>
<b>Net increase / (decrease) in cash and cash equivalents</b>		<b>(860)</b>	<b>7,759</b>
<b>Cash and cash equivalents at the beginning of the period</b>	14	<b>2,646</b>	<b>696</b>
<b>Net unrealised foreign exchange differences on cash and cash equivalents</b>		<b>10</b>	<b>(4)</b>
<b>Cash and cash equivalents at the end of the period</b>	14	<b>1,796</b>	<b>8,451</b>
Bank accounts	14	1,796	8,451
<b>Total cash and cash equivalents at the end of the period</b>		<b>1,796</b>	<b>8,451</b>

The accompanying notes form an integral part of the Half-Year Condensed Consolidated Financial Statements.

## Condensed Consolidated Statement of Changes in Equity (unaudited)

For the six months ended 30 June

		Number of Shares	Share capital	Share premium	Capital contribution	Stock option plan reserve	Currency translation reserve	Retained earnings	Losses carried forward	Total
EUR 1,000										
<b>Net equity as at 1 January 2020</b>	<b>10,000,000</b>	<b>10,000</b>	<b>1,868</b>	<b>437</b>	<b>3,111</b>	<b>11</b>	<b>(11,700)</b>	<b>-</b>	<b>3,727</b>	
Allocation of prior year result	-	-	(1,868)	(437)	-	-	11,700	(9,395)	-	
Capital increase	750,000	750	21,640	-	-	-	-	-	22,390	
Cost for stock options	-	-	-	77	469	-	-	-	546	
Total comprehensive income for the period	-	-	-	-	-	22	(5,322)	-	(5,300)	
<b>Net equity as at 30 June 2020</b>	<b>10,750,000</b>	<b>10,750</b>	<b>21,640</b>	<b>77</b>	<b>3,580</b>	<b>33</b>	<b>(5,322)</b>	<b>(9,395)</b>	<b>21,363</b>	

		Number of Shares	Share capital	Share premium	Capital contribution	Stock option plan reserve	Currency translation reserve	Retained earnings	Losses carried forward	Total
EUR 1,000										
<b>Net equity as at 1 January 2021</b>	<b>10,750,000</b>	<b>10,750</b>	<b>21,638</b>	<b>123</b>	<b>4,184</b>	<b>623</b>	<b>(12,308)</b>	<b>(9,395)</b>	<b>25,010</b>	
Allocation of prior year result	-	-	-	-	-	-	12,308	(12,308)	-	
Cost for stock options	-	-	-	72	601	-	-	-	673	
Total comprehensive income for the period	-	-	-	-	-	(278)	(6,165)	-	(6,443)	
<b>Net equity as at 30 June 2021</b>	<b>10,750,000</b>	<b>10,750</b>	<b>21,638</b>	<b>195</b>	<b>4,785</b>	<b>345</b>	<b>(6,165)</b>	<b>(21,703)</b>	<b>9,845</b>	

The accompanying notes form an integral part of the Half-Year Condensed Consolidated Financial Statements.

# Notes to the Condensed Consolidated Financial Statements (unaudited)

## 1 General information

### The company and its core business

Cassiopea S.p.A. with its subsidiaries (“Cassiopea” or the “Company” or “Group”) is a specialty pharmaceutical company established and domiciled in Italy. The address of the registered office is Via Cristoforo Colombo 1, Lainate (MI), Italy.

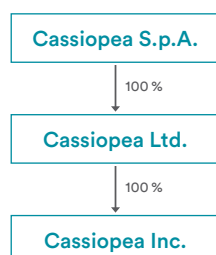
Cassiopea is a specialty pharmaceutical company developing and preparing to commercialize prescription drugs with novel mechanisms of action (MOA) to address long-standing and essential dermatological conditions, particularly acne, androgenetic alopecia (or AGA) and genital warts. Cassiopea is investing in innovation that is driving scientific advancement in areas that have been largely ignored for decades. The Company’s portfolio comprises four unencumbered clinical candidates, for which the Company owns the worldwide rights. These product candidates are based on three new chemical entities (“NCEs”) that target unmet medical needs and address significant market opportunities in the medical dermatology market. Cassiopea’s management team directly and indirectly through the service agreement with Cosmo, has extensive experience in product development and commercialization, having served in prominent roles at several leading pharmaceutical and medical dermatology companies. The Company’s strategy is to leverage this expertise to optimize the commercial potential for its products directly or with a partner in the US and partner the products in countries outside of the US.

The four product candidates represent a diversified portfolio of late and mid stage clinical programs addressing significant market opportunities and unmet needs in the medical dermatology space:

- Clascoterone cream 1% (Winlevi®), first-in-class topical androgen receptor inhibitor, which on 27 August 2020 has been approved by the FDA for the treatment of acne in patients 12 years and older;
- Clascoterone solution, which is being developed as the first androgen receptor inhibitor for the topical treatment of androgenetic alopecia;
- CB-06-01, a first-time application of an antibiotic with a targeted antibacterial spectrum for the treatment of acne; and
- CB-06-02, a novel formulation using the rare element tellurium to treat genital warts.

Since 1 July 2015, Cassiopea’s shares have been publicly listed on the Swiss Stock Exchange (SIX: SKIN). The Company’s stock market capitalization as at 30 June 2021 was equal to CHF 489,125,000.

The structure of the Company as at 30 June 2021 is as follow:



## 2 Basis of preparation

### Authorization of Condensed Consolidated Financial Statements

These Half-year Condensed Consolidated Financial Statements, together with notes thereto of Cassiopea S.p.A. at 30 June 2021 were authorized for issuance by the Board of Directors on 28 July 2021.

### Basis of Preparation

These Half-year Condensed Consolidated Financial Statements as at 30 June 2021, have been prepared in accordance with the International Financial Reporting Standards issued by the International Accounting Standards Board (IASB) and adopted by the European Union (following IFRS) and with the orders issued in implementation of Article 9 of Legislative Decree no 38/2005. The designation IFRS also includes all valid International Accounting Standards (IAS), as well as all interpretations of the International Financial Reporting Interpretations Committee (IFRIC), formerly the Standing Interpretations Committee (SIC).

In particular, these Half-year Condensed Consolidated Financial Statements have been prepared in accordance with IAS 34, “Interim Financial Reporting”, and accordingly do not include all information and disclosures as required by IFRS for complete financial statements.

The accounting principles and policies used in preparation of the interim consolidated financial statements are consistent with those used in the Financial statements for the year ended 31 December 2020, except as otherwise stated under “New accounting standard and IFRIC interpretations” in the following paragraphs.

The preparation of the interim consolidated financial statements requires the Management to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent assets and liabilities at the date of the interim financial statements. If in the future such estimates and assumptions, which are based on the Management’s best judgement at the date of the interim financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the period in which the circumstances change.

These condensed consolidated interim financial statements should be read in conjunction with the financial statements for the year ended 31 December 2020 as they provide an update of previously reported information. Operating results for the six months ended 30 June 2021 are not necessarily indicative of the results that may be expected for the year ending 31 December 2021. The interim consolidated financial statements are expressed in EUR thousand unless stated otherwise, rounding the amounts to the nearest thousand.

## 3 Basis of accounting

### 3.1 Classification criteria

For presentation of these Half-year Condensed Consolidated Financial Statements, the Group uses a classification based on the function of expenses, rather than based on their nature, as it is more representative of the format used for internal reporting and management purposes and is consistent with international practice in the pharmaceuticals

sector. The statement of financial position has been prepared presenting assets and liabilities as current and non-current; the statements of cash flows present cash flows from operating activities using the indirect method and the statement of changes in equity includes all the changes in equity.

### 3.2 Measurement criteria

The Interim Condensed Consolidated Financial Statements have been prepared under the historical cost convention, modified as required for the valuation of certain financial instruments, as well as on the going concern assumption.

#### Going concern

Cassiopea's financials are particular to the business model of pharmaceuticals companies developing new drugs and having no products on the market. At this stage high costs must be sustained, linked to the clinical and pharmaceutical development of new drugs, and a return is expected only in forthcoming years.

In keeping with the accounting arrangements adopted, which envisage the recognition of all research and development costs in the Income Statement in the year they are incurred, from its incorporation the Company has always reported losses.

The Company is subject to the classical uncertainties associated with the sector in which it operates and the ongoing product testing, in terms of results that it may effectively achieve, and the methods and timeframes with which these results could be attained.

Following the License and Supply Agreement for Winlevi® in the US and Canada signed with Sun Pharmaceutical Industries Ltd. (see note 22 "Subsequent events"), Cassiopea will be funded to continue the development of its innovative dermatology pipeline and is expecting substantial revenue streams for the foreseeable future.

### 3.3 Critical accounting estimates and assumptions

The preparation of the Company consolidated financial statements and the related notes requires the use of estimates and assumptions that affect the application of accounting policies and the reported amount of assets, liabilities, income and expenses. However, as they are estimates, actual future results could differ from those included in the financial statements. The management exercises judgment in selecting and applying the accounting principles, particularly in cases where the existing IFRS standards offer alternative recognition, valuation or presentation methods.

### 3.4 Accounting policies

The accounting policies applied in these interim condensed financial statements are the same as those applied in the Group's consolidated financial statements as at and for the year ended 31 December 2020. A number of new standards and interpretations are effective from 1 January 2021, but they do not have a material effect on the Group's financial statements.



## 4 Net operating expenses

Net operating expenses presented in the income statements by function are detailed and commented by nature below:

EUR 1,000	30.06.2021	30.06.2020
Raw materials and consumables used	(153)	(317)
Personnel expenses	(1,742)	(1,785)
Outsourced preclinical and clinical trial costs	(1,733)	(640)
Other operating expenses	(2,511)	(1,918)
Depreciation and amortization	(149)	(30)
<b>Total net operating expenses</b>	<b>(6,288)</b>	<b>(4,690)</b>

### Raw materials and consumables used

The item “Raw materials and consumables used” comprises the following:

EUR 1,000	30.06.2021	30.06.2020
Purchase of raw materials	1,056	–
Purchase of laboratory supplies and materials for clinical trial	153	317
<b>Total purchases</b>	<b>1,209</b>	<b>317</b>
Changes in raw materials inventories	(1,056)	–
<b>Total raw materials and consumables used</b>	<b>153</b>	<b>317</b>

Purchase of Raw materials refer to the API (Active Principle Ingredient) required for the production for the commercial launch of Winlevi®, in stock at the end of the period.

### Personnel expenses

This item, which includes the cost of the entire staff, comprises the following:

EUR 1,000	30.06.2021	30.06.2020
Salaries and wages	998	1,153
Social security contributions	77	82
Employee benefits	8	10
Stock options	653	533
Other costs	6	7
<b>Total personnel expenses</b>	<b>1,742</b>	<b>1,785</b>

Personnel expenses slightly decreased from EUR 1,785 thousand to EUR 1,742 thousand and reflect the evolution of the Company’s staff.

In H1 2021, the expense for the value of employees’ and executives Directors’ services exchanged for stock options amounted to EUR 653 thousand (EUR 533 thousand in H1 2020) and it refers to the cost accounted in relation to the options granted by the Board of Directors in the period 2015–2021 and to the options granted by Cosmo Pharmaceuticals N.V. (see note 19 “Share-based payments” and note 20 “Related-parties transactions”).

The entire staff as at 30 June 2021 and 2020 is shown by category here below:

No. of people	30.06.2021	30.06.2020
Managers*	9	9
Junior managers	2	3
<b>Total average number</b>	<b>11</b>	<b>12</b>

\*Includes the managers provided by Cosmo Pharmaceuticals N.V. as for service agreement (see note 20 "Related parties transactions")

In addition, Cosmo Pharmaceuticals N.V. group provides the services for research and development, regulatory, secretarial, and accounting services at a cost determined in the Services Agreement (see note 20 "Related parties transactions").

#### Outsourced preclinical and clinical trial costs

The item "Outsourced preclinical and clinical trial costs" comprises the following:

EUR 1,000	30.06.2021	30.06.2020
Winlevi®	77	140
Clascoterone solution	1,654	498
CB-06-01	2	2
<b>Outsourced preclinical and clinical trials costs</b>	<b>1,733</b>	<b>640</b>

#### Other operating expenses

Other operating expenses comprises the following:

EUR 1,000	30.06.2021	30.06.2020
Service costs	2,230	1,914
Other operating costs	281	4
<b>Total other operating expenses</b>	<b>2,511</b>	<b>1,918</b>

The item "Service costs", detailed here below, mainly comprises costs for professional and consultancy services (i.e. scientific and administrative services), advertising and marketing costs, cost for the maintenance of the patent, and costs for the investor relations activities.

Service costs in H1 2021 also include EUR 20 thousand (EUR 13 thousand in H1 2020) for the Stock Option Plan to the non-executive directors.

EUR 1,000	30.06.2021	30.06.2020
External consultancy services	876	750
Patent costs	210	176
Investor relations and web site maintenance	77	100
Technical assistance	1	5
Utilities, telephone, internet	6	6
Insurance	25	50
Non-executive directors	52	70
Stock options non-executive directors	20	13
Management control committee	4	5
Auditing	16	16
Advertising and marketing costs	639	362
Freight and customs	2	2
Travel expenses	1	42
External laboratory services	19	15
R&D and Regulatory services	280	297
Other costs	2	5
<b>Total service costs</b>	<b>2,230</b>	<b>1,914</b>

In H1 2021, the Company under a service agreement has been charged by Cosmo Pharmaceuticals Group for an amount of EUR 280 thousand (in H1 2020 EUR 297 thousand) for research / development / regulatory services, and for an amount of EUR 70 thousand (EUR 74 thousand in H1 2020) for secretarial and accounting services.

The item "Other operating costs" in H1 2021 include EUR 278 thousand for the FDA program fee.

### Depreciation and amortization

The item comprises the following:

EUR 1,000	30.06.2021	30.06.2020
Depreciation of property, plant and equipment	3	3
Amortization of other intangible assets	146	27
<b>Total depreciation and amortization</b>	<b>149</b>	<b>30</b>

The increase (EUR 119 thousand) in Amortization of other intangible assets (EUR 146 thousand) is mainly due to the amortization of the Winlevi® registration fee for the US, that started in the period.

## 5 Financial income / expenses

The item comprises the following:

EUR 1,000	30.06.2021	30.06.2020
<b>Financial income</b>		
Foreign exchange gains	300	18
<b>Total financial income</b>	<b>300</b>	<b>18</b>
<b>Financial expenses</b>		
Interests on Cosmo Pharmaceuticals N.V. unsecured loan	162	608
Foreign exchange losses	7	38
Other	8	4
<b>Total financial expenses</b>	<b>177</b>	<b>650</b>
<b>Financial income (expense), net</b>	<b>123</b>	<b>(632)</b>

Financial income, as at 30 June 2021 and 2020, is totally composed of foreign exchange differences (of which EUR 276 thousand and EUR 26 thousand respectively for foreign exchange differences on the intercompany loan).

Financial expenses include EUR 162 thousand (EUR 608 thousand in H1 2020) due to interests on Cosmo Pharmaceuticals N.V. unsecured credit facility.

## 6 Income tax expenses

On the tax losses and on the Italian fiscal relief “ACE” (Aiuto alla crescita economica) for H1 2021 and H1 2020, no deferred tax assets have been recognized in the Company’s financial statements due to uncertainties concerning the availability of future taxable profits against which such an asset may be offset.

## 7 Basic and diluted earnings (loss) per share

Basic earnings (loss) per shares are calculated by dividing the net profit (loss) for the period attributable to ordinary shareholders by the weighted average number of shares outstanding during the period.

Basic earnings (loss) per share are as follows:

	30.06.2021	30.06.2020
Net profit (loss) attributable to Shareholders (in EUR 1,000)	(6,165)	(5,322)
Weighted average number shares	10,750,000	10,045,330
<b>Basic earnings (loss) per share</b> (in EUR)	<b>(0.573)</b>	<b>(0.530)</b>

Diluted earnings (loss) per share are calculated by dividing the net profit for the period attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period, plus the weighted average number of potential ordinary shares.

Potential ordinary shares from the exercise of stock options only have a dilutive effect if the new ordinary shares from the exercise of stock options led to a lower result per share. Under consideration of the current result of Cassiopea, potential new ordinary shares do therefore not induce a dilutive effect.

## 8 Property plan and equipment

The amount refers to the net carrying value of right of use asset in relation to a company car.

## 9 Other intangible assets

The item comprises the following:

EUR 1,000	Patents and rights	Other intangibles	Total
<b>Net book value as at 1 January 2021</b>	<b>650</b>	<b>2,339</b>	<b>2,989</b>
Additions of the period	40	–	40
Amortization charge for the period	(29)	(117)	(146)
<b>Net book value as at 30 June 2021</b>	<b>661</b>	<b>2,222</b>	<b>2,883</b>

The item “Patents and rights” refers to the costs for filing and extension of patents owned by the Company and are amortized considering the patents expiry date as their useful life (patents expiry from 2025 to 2036 and their average useful life is equal to 10,6 years).

The item “Other intangibles” refers to the payment of the Winlevi® registration fee to the US Food and Drug Administration (FDA), net of the amortization calculated on the estimated useful life (10 years).

## 10 Tax receivables (non current)

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Tax credit R&D costs (non current)	9,609	9,799
<b>Total tax receivables</b>	<b>9,609</b>	<b>9,799</b>

The item “Tax receivables” refer to the non-current amount of the tax credit for research and development pursuant to Italian Law No. 190 of 23 December 2014 and subsequent implementation decrees.

## 11 Inventories

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Raw materials, auxiliary materials and consumables	1,817	761
<b>Total inventories</b>	<b>1,817</b>	<b>761</b>

The item “Raw materials, auxiliary materials and consumables” refers to the API required for the production for the commercial launch of Winlevi®.

## 12 Current tax assets

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Advance payments of income taxes	20	20
Tax credit R&D costs (current)	350	350
<b>Total current tax assets</b>	<b>370</b>	<b>370</b>

Tax credit R&D costs refer to the amount of tax credit for research and development pursuant to Italian Law No. 190 of 23 December 2014 and subsequent implementation decrees, that will be offset against social security contributions and withholdings tax in the course of the following twelve months.

## 13 Other receivables and other assets

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
VAT receivables	1,286	1,128
Prepaid expenses	587	871
Other prepaid	48	54
<b>Total other receivables and other assets</b>	<b>1,921</b>	<b>2,053</b>

## 14 Cash and cash equivalents

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Cash at hand	–	–
Bank accounts	1,796	2,646
<b>Total cash and cash equivalents</b>	<b>1,796</b>	<b>2,646</b>

The item “Bank accounts” includes availability on current bank accounts. Part of the availability is held in US\$, and in particular as at 30 June 2021, the amount includes US\$ 596 thousand equals to EUR 502 thousand at 30 June 2021 exchange rate.

## 15 Total shareholders' equity

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Share capital	10,750	10,750
Share premium	21,638	21,638
Capital contribution	195	123
Stock option plan reserve	4,785	4,184
Currency translation reserve	345	623
Losses carried forward	(21,703)	(9,395)
Profit/(Loss) for the period	(6,165)	(12,308)
<b>Total equity</b>	<b>9,845</b>	<b>15,615</b>

### Share capital

As at 30 June 2021 Cassiopea S.p.A. had 10,750,000 shares issued, fully subscribed and paid up, each share with a nominal value of EUR 1.00, for a total share capital of EUR 10,750 thousand.

### Share premium

As at 30 June 2021, "Share premium" refers to the proceeds from June 2020 Capital increase, equal to a share premium of EUR 30 for share for a total of EUR 22,500 thousand, net of EUR 862 thousand as expenses related to the capital increase.

### Capital contribution

"Capital contribution" has accounted in relation to the stock options of Cosmo Pharmaceuticals N.V. granted to the employees of the Company.

### Stock option plan reserve

In H1 2021, the expense for the stock options allocated in the period 2015–2021, amounted to EUR 601 thousand of which EUR 581 thousand for management and personnel and EUR 20 thousand for non-executive Directors (In H1 2020 EUR 456 thousand and EUR 13 thousand respectively).

### Currency translation reserve

Currency translation reserve arises from the consolidation of foreign entity with a functional currency other than the Euro.

### Losses carried forward

Losses carried forward arise from the previous year's result not allocated.

## 16 Interest bearing loans and borrowings (non current and current)

Non current and current interest bearing loans and borrowings are detailed as follows:

### A Non current

EUR 1,000	30.06.2021	31.12.2020
Cosmo Pharmaceuticals N.V. unsecured loan	–	64
Financial lease liabilities	–	2
<b>Total interest-bearing loans and borrowings (non current)</b>	<b>–</b>	<b>66</b>

### B Current

EUR 1,000	30.06.2021	31.12.2020
Cosmo Pharmaceuticals N.V. unsecured loan	6,226	–
Financial lease liabilities	4	4
<b>Total interest-bearing loans and borrowings (current)</b>	<b>6,230</b>	<b>4</b>

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 twelve months.

## 17 Trade payables

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Trade payables	1,896	2,489
Trade payables related company	350	350
<b>Total trade payables</b>	<b>2,246</b>	<b>2,839</b>

Trade payables related company refers to the payables for the services rendered by Cosmo Pharmaceuticals Group.

## 18 Other current liabilities

The item comprises the following:

EUR 1,000	30.06.2021	31.12.2020
Social security payables	18	21
Withholding tax for employees	11	15
Withholding tax for consultants	20	14
Other liabilities	32	53
<b>Total other current liabilities</b>	<b>81</b>	<b>103</b>



## 19 Share-based payment

The extraordinary shareholders' meeting of 28 May 2020, after revocation of the proxy granted on 18 March 2019, authorized the Board of Directors to increase the capital by up to a maximum nominal amount of EUR 900 thousand by issuing up to 900,000 new common shares with a nominal value of EUR 1 each to service an ESOP according to terms to be set by the Board of Directors.

On 24 March 2021, the Board of Directors granted a total of 14,000 options of which

- 4,670 with a vesting period of 1 year, expiring on 23 March 2027 and an exercise price of CHF 47.50 ("Option series 11a")
- 4,666 with a vesting period of 2 years, expiring on 23 March 2027 and an exercise price of CHF 47.50 ("Option series 11b")
- 4,664 with a vesting period of 3 years, expiring on 23 March 2027 and an exercise price of CHF 47.50 ("Option series 11c")

The fair value of options granted, determined on the basis of a binomial tree generated by the Fincad program – technique similar to the Black-Scholes valuation model, resulted in a value of CHF 6.36 per option ("Option series 11a"), of CHF 8.94 per option ("Option series 11b") and of CHF 10.91 per option ("Option series 11c").

All the option series issued since 2015 (as at 30 June 2021 n 720,564 options allocated and outstanding) are "equity-settled share-based payment transactions" in which the Company receive services as consideration for its own equity instruments and foresee as vesting condition in the vesting period, only the "service condition", that requires the counterparty to complete a specified period of service during which services are provided to the Company (no performance target to be met). Except for any exceptions provided by the ESOP regulation, if the counterparty ceases to provide service during the vesting period, it has failed to satisfy the condition.

The options granted are recognized as costs over the vesting period.

In H1 2021, in relation to the Option series outstanding and not yet vested, the expense for the value of employees' and Directors' services exchanged for stock options amounted to EUR 601 thousand of which EUR 581 thousand for management and personnel and EUR 20 thousand for non-executive Directors.

As at 30 June 2021, 720,564 options of the total program of 900,000 options are allocated and outstanding, of which 370,348 exercisable.

Option series	Options granted	Forfeited	Options outstanding	Grant date	Vesting date	Expiry date	Exercise price CHF	Fair value of the option at the grant date CHF
1a) Issued 3 December 2015	49,800	14,000	35,800	03/12/2015	03/12/2016	03/12/2021	34.00	14.45
1b) Issued 3 December 2015	46,600	14,000	32,600	03/12/2015	03/12/2017	03/12/2022	34.00	19.28
1c) Issued 3 December 2015	43,600	12,000	31,600	03/12/2015	03/12/2018	03/12/2023	34.00	22.56
2a) Issued 23 February 2016	6,800	5,100	1,700	23/02/2016	23/02/2017	23/02/2022	34.00	11.28
2b) Issued 23 February 2016	6,700	5,000	1,700	23/02/2016	23/02/2018	23/02/2023	34.00	15.87
2c) Issued 23 February 2016	6,500	4,900	1,600	23/02/2016	23/02/2019	23/02/2024	34.00	18.98
3a) Issued 23 February 2017	4,100	700	3,400	23/02/2017	23/02/2018	23/02/2023	34.00	11.59
3b) Issued 23 February 2017	4,000	700	3,300	23/02/2017	23/02/2019	23/02/2024	34.00	15.84
3c) Issued 23 February 2017	3,900	600	3,300	23/02/2017	23/02/2020	23/02/2025	34.00	18.84
4a) Issued 14 November 2017	24,400	–	24,400	14/11/2017	14/11/2018	14/11/2023	34.00	10.46
4b) Issued 14 November 2017	24,300	–	24,300	14/11/2017	14/11/2019	14/11/2024	34.00	14.32
4c) Issued 14 November 2017	21,300	–	21,300	14/11/2017	14/11/2020	14/11/2025	34.00	17.11
5a) Issued 7 February 2019	49,224	–	49,224	07/02/2019	07/02/2020	06/02/2025	38.60	3.87
5b) Issued 7 February 2019	49,223	–	49,223	07/02/2019	07/02/2021	06/02/2025	38.60	5.51
5c) Issued 7 February 2019	49,219	–	49,219	07/02/2019	07/02/2022	06/02/2025	38.60	6.78
6a) Issued 18 March 2019	10,002	–	10,002	18/03/2019	18/03/2020	17/03/2025	45.10	4.52
6b) Issued 18 March 2019	9,999	–	9,999	18/03/2019	18/03/2021	17/03/2025	45.10	6.40
6c) Issued 18 March 2019	9,999	–	9,999	18/03/2019	18/03/2022	17/03/2025	45.10	7.87
7a) Issued 17 July 2019	1,667	–	1,667	17/07/2019	17/07/2020	16/07/2025	44.00	5.22
7b) Issued 17 July 2019	1,667	–	1,667	17/07/2019	17/07/2021	16/07/2025	44.00	7.35
7c) Issued 17 July 2019	1,666	–	1,666	17/07/2019	17/07/2022	16/07/2025	44.00	8.98
8a) Issued 17 December 2019	44,117	–	44,117	17/12/2019	17/12/2020	16/12/2025	42.00	5.00
8b) Issued 17 December 2019	44,112	–	44,112	17/12/2019	17/12/2021	16/12/2025	42.00	7.04
8c) Issued 17 December 2019	44,105	–	44,105	17/12/2019	17/12/2022	16/12/2025	42.00	8.61
9a) Issued 28 May 2020	21,116	–	21,116	28/05/2020	28/05/2021	27/05/2026	34.80	4.18
9b) Issued 28 May 2020	21,113	–	21,113	28/05/2020	28/05/2022	27/05/2026	34.80	5.91
9c) Issued 28 May 2020	21,103	–	21,103	28/05/2020	28/05/2023	27/05/2026	34.80	7.24
10a) Issued 22 December 2020	47,748	–	47,748	22/12/2020	22/12/2021	21/12/2026	48.50	6.48
10b) Issued 22 December 2020	47,745	–	47,745	22/12/2020	22/12/2022	21/12/2026	48.50	9.10
10c) Issued 22 December 2020	47,739	–	47,739	22/12/2020	22/12/2023	21/12/2026	48.50	11.09
11a) Issued 24 March 2021	4,670	–	4,670	24/03/2021	24/03/2022	23/03/2027	47.50	6.36
11b) Issued 24 March 2021	4,666	–	4,666	24/03/2021	24/03/2023	23/03/2027	47.50	8.94
11c) Issued 24 March 2021	4,664	–	4,664	24/03/2021	24/03/2024	23/03/2027	47.50	10.91
<b>Total</b>	<b>777,564</b>	<b>57,000</b>	<b>720,564</b>					

Share options	Numbers	Weighted average exercise price CHF
<b>Outstanding as at 31 December 2020</b>	<b>706,564</b>	<b>40.01</b>
Exercisable as at 31 December 2020	290,010	36.44
Granted during the period	14,000	–
Forfeited during the period	–	–
Exercised during the period	–	–
Expired during the period	–	–
<b>Outstanding as at 30 June 2021</b>	<b>720,564</b>	<b>40.16</b>
Exercisable as at 30 June 2021	370,348	29.43

The share options outstanding at the end of the financial period had a weighted exercise price of CHF 29.43 and a weighted average remaining contractual life of 3.9 years.

<b>Option series 1</b>	<b>a)</b>	<b>b)</b>	<b>c)</b>
<b>Issued 3 December 2015</b>			
Share price at grant date (in CHF)	35.40	35.40	35.40
Previous monthly average at grant date share price (in CHF)	32.30	32.30	32.30
Exercise price (in CHF)	34.00	34.00	34.00
Expected volatility	30%	30%	30%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,826 days	1,826 days	1,826 days
Risk-free interest rate	0.84%	1.02%	1.18%
<b>Option series 2</b>			
<b>Issued 23 February 2016</b>			
Share price at grant date (in CHF)	30.95	30.95	30.95
Previous monthly average at grant date share price (in CHF)	29.88	29.88	29.88
Exercise price (in CHF)	34.00	34.00	34.00
Expected volatility	30%	30%	30%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,826 days	1,826 days	1,826 days
Risk-free interest rate	0.73%	0.91%	1.07%
<b>Option series 3</b>			
<b>Issued 23 February 2017</b>			
Share price at grant date (in CHF)	34.35	34.35	34.35
Previous monthly average at grant date share price (in CHF)	33.26	33.26	33.26
Exercise price (in CHF)	34.00	34.00	34.00
Expected volatility	30%	30%	30%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,826 days	1,826 days	1,827 days
Risk-free interest rate	0.50%	0.67%	0.86%
<b>Option series 4</b>			
<b>Issued 14 November 2017</b>			
Share price at grant date (in CHF)	34.50	34.50	34.50
Previous monthly average at grant date share price (in CHF)	33.85	33.85	33.85
Exercise price (in CHF)	34.00	34.00	34.00
Expected volatility	25%	25%	25%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,826 days	1,827 days	1,826 days
Risk-free interest rate	0.33%	0.49%	0.65%

<b>Option series 5</b>	<b>a)</b>	<b>b)</b>	<b>c)</b>
<b>Issued 7 February 2019</b>			
Share price at grant date (in CHF)	38.60	38.60	38.60
Previous monthly average at grant date share price (in CHF)	39.80	39.80	39.80
Exercise price (in CHF)	38.60	38.60	38.60
Expected volatility	25%	25%	25%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,826 days	1,460 days	1,095 days
Risk-free interest rate	0.20%	0.27%	0.33%
<b>Option series 6</b>			
<b>Issued 18 March 2019</b>			
Share price at grant date (in CHF)	45.10	45.10	45.10
Previous monthly average at grant date share price (in CHF)	40.84	40.84	40.84
Exercise price (in CHF)	45.10	45.10	45.10
Expected volatility	25%	25%	25%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,825 days	1,460 days	1,095 days
Risk-free interest rate	0.11%	0.17%	0.23%
<b>Option series 7</b>			
<b>Issued 17 July 2019</b>			
Share price at grant date (in CHF)	44.00	44.00	44.00
Previous monthly average at grant date share price (in CHF)	44.47	44.47	44.47
Exercise price (in CHF)	44.00	44.00	44.00
Expected volatility	30%	30%	30%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,825 days	1,460 days	1,095 days
Risk-free interest rate	-0.16%	-0.13%	-0.09%
<b>Option series 8</b>			
<b>Issued 17 December 2019</b>			
Share price at grant date (in CHF)	42.00	42.00	42.00
Previous monthly average at grant date share price (in CHF)	42.02	42.02	42.02
Exercise price (in CHF)	42.00	42.00	42.00
Expected volatility	30%	30%	30%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,825 days	1,460 days	1,095 days
Risk-free interest rate	-0.08%	-0.05%	-0.02%

<b>Option series 9</b>	<b>a)</b>	<b>b)</b>	<b>c)</b>
<b>Issued 28 May 2020</b>			
Share price at grant date (in CHF)	34.80	34.80	34.80
Previous monthly average at grant date share price (in CHF)	35.51	35.51	35.51
Exercise price (in CHF)	34.80	34.80	34.80
Expected volatility	30%	30%	30%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,825 days	1,460 days	1,095 days
Risk-free interest rate	0.20%	0.22%	0.26%
<b>Option series 10</b>			
<b>Issued 22 December 2020</b>			
Share price at grant date (in CHF)	48.50	48.50	48.50
Previous monthly average at grant date share price (in CHF)	45.53	45.53	45.53
Exercise price (in CHF)	48.50	48.50	48.50
Expected volatility	34%	34%	34%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,825 days	1,460 days	1,095 days
Risk-free interest rate	-0.30%	-0.27%	-0.24%
<b>Option series 11</b>			
<b>Issued 24 March 2021</b>			
Share price at grant date (in CHF)	47.50	47.50	47.50
Previous monthly average at grant date share price (in CHF)	46.74	46.74	46.74
Exercise price (in CHF)	47.50	47.50	47.50
Expected volatility	34%	34%	34%
Employee Exit Rate	0%	0%	0%
Dividend Yield	0%	0%	0%
Option life	1,825 days	1,460 days	1,094 days
Risk-free interest rate	-0.26%	-0.22%	-0.18%

## 20 Related-parties transactions

In H1 2021, the Company under a service agreement has been charged by Cosmo Pharmaceuticals Group for an amount of EUR 280 thousand (in H1 2020 EUR 297 thousand) for research/development/regulatory services and for an amount of EUR 70 thousand (EUR 74 thousand in H1 2020) for secretarial and accounting services.

From May 2015 to December 2020, under a service agreement with Cosmo Pharmaceuticals N.V., former Cosmo's managers, Chris Tanner and Luigi Moro, provided Cassiopea with the Chief Financial Officer and Chief Scientific Officer services respectively.

However, Cosmo Pharmaceuticals' manager Marco Lecchi and an administrative employee continue to provide Cassiopea S.p.A with Finance Director and administrative services respectively.

Cosmo provides these services to Cassiopea at no cost. During the period 2017 to June 2021, the Board of Directors of the Company resolved to grant to the individuals listed above 208,832 options in total to subscribe Cassiopea shares. The cost of these options in Cassiopea financial statements for H1 2021, determined on the basis of the fair value of the option, is equal to EUR 142 thousand (EUR 158 thousand in H1 2020).

During the period 2017 to June 2021, Cosmo Pharmaceuticals N.V., under a stock option plan, has granted 21,333 options to certain employees of the Company. The cost of these options in Cassiopea financial statements for H1 2021, determined on the basis of the fair value of the option, is equal to EUR 72 thousand (EUR 77 thousand in H1 2020).

On 12 December 2018, Cosmo Pharmaceuticals N.V. granted the Company a committed unsecured term loan facility of EUR 10 million, subsequently extended to EUR 20 million, on the following terms:

- the loan shall expire on 31 December 2021, but may be repaid in advance by the Company
- the Company shall pay a signing fee of 0.5%
- the interest rate will be 10% per annum for the drawn amount and 2% commitment fee will be payable on undrawn amount
- signing fee, interests and commitment fee will be paid at the repayment date

As at 30 June 2021, the loan facility was fully drawn by the Company, and after the EUR 14,000 thousand settled-off in 2020 Cassiopea capital increase, Company's debt to Cosmo Pharmaceuticals N.V. is equal to EUR 6,226 thousand of which EUR 6,000 million relates to the loan facility and EUR 226 thousand relates to interests and commitment fee.

## 21 Fair value measurement

IFRS 13 establishes a hierarchy that categorizes into three levels the inputs to the valuation techniques used to measure fair value by giving the highest priority to quoted prices (unadjusted) in active markets for identical assets and liabilities (level 1 inputs) and the lowest priority to unobservable inputs (level 3 inputs). In some cases, the inputs used to measure the fair value of an asset or a liability might be categorized within different levels of the fair value hierarchy. In those cases, the fair value measurement is categorized in its entirety in the same level of the fair value hierarchy at the lowest level input that is significant to the entire measurement.

Levels used in the hierarchy are as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets and liabilities that the Company can access at the measurement date.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the assets or liabilities, either directly or indirectly.
- Level 3 inputs are unobservable inputs for the assets and liabilities.

### Assets and liabilities that are measured at fair value on a recurring basis

As at 30 June 2021 and 31 December 2020, there are no assets and liabilities measured at fair value on a recurring basis.

### Assets and liabilities not measured at fair value on a recurring basis

This table shows the comparison of fair values versus carrying amounts of financial assets and liabilities:

EUR 1,000	As at 30 June 2021		As at 31 December 2020	
	Carrying amount	Fair value	Carrying amount	Fair value
Cash and cash equivalents	1,796	1,796	2,646	2,646
<b>Total Assets</b>	<b>1,796</b>	<b>1,796</b>	<b>2,646</b>	<b>2,646</b>
Cosmo Pharmaceuticals N.V. unsecured loan	(6,226)	(6,226)	(64)	(64)
Financial lease liabilities	(4)	(4)	(6)	(6)
Trade payables	(2,246)	(2,246)	(2,839)	(2,839)
<b>Total Liabilities</b>	<b>(8,476)</b>	<b>(8,476)</b>	<b>(2,909)</b>	<b>(2,909)</b>
Unrecognised (loss) gain	–	–	–	–

The carrying amount of Cash and cash equivalents, which consist primarily of bank current accounts, approximates fair value.

For Cosmo Pharmaceuticals N.V. unsecured credit facility and financial lease liabilities, the carrying amount approximates the fair value calculated based on the present value of future principal and interest cash flows, discounted at the interest market rate at the reporting date.

For Trade payables for which the present value of future cash flows does not differ significantly from carrying value, we assume that carrying value is a reasonable approximation of the fair value.



## 22 Subsequent events

On 26 July 2021 the Company announced, the signing of License and Supply Agreements for Winlevi® (clascoterone cream 1%) in the US and Canada with Sun Pharmaceutical Industries Ltd (NSE: SUNPHARMA).

Under the terms of the above referred agreements, Sun Pharma will have the exclusive right to commercialize Winlevi® in the United States 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 the HSR (Hart–Scott–Rodino Antitrust Improvements Act of 1976) waiting period.

Winlevi® is expected to be available in the US in Q4 2021.

Lainate, 28 July 2021

On behalf of the Board of Directors of Cassiopea S.p.A.



Pierpaolo Guzzo  
Chairman

# Information for Investors

## Capital structure

EUR 1,000	30.06.2021
Total equity	9,845
Share capital	10,750
Reserves	26,963
Profit (Loss) for the period	(6,165)
Number of registered shares	10,750,000
Nominal value per share (in EUR)	1.00

Major shareholders	No. of shares	% of share capital
Cosmo Pharmaceuticals N.V.	5,005,066	46.56%
Cosmo Holding S.a.r.l.	809,953	7.53%
Herz / Logistable Group	504,432	4.69%
LB Swiss Investment	410,522	3.82%

## Share price data

CHF	Price	Date
First trading day close	37.30	01.07.2015
H1 2021 lowest	43.10	01.04.2021
H1 2021 highest	51.40	08.02.2021
H1 2021 last trading date close	45.50	30.06.2021
Market capitalization (in CHF million)	489.12	30.06.2021

## Share earnings

EUR	30.06.2021
Basic earnings (loss) per share	(0.573)

## Stock exchange information

Listing	SIX Swiss Exchange, Main Board
Security ID	SKIN
ISIN	IT0005108359
Swiss security number (Valor)	28 252 872
Number of shares	10,750,000

## Research coverage

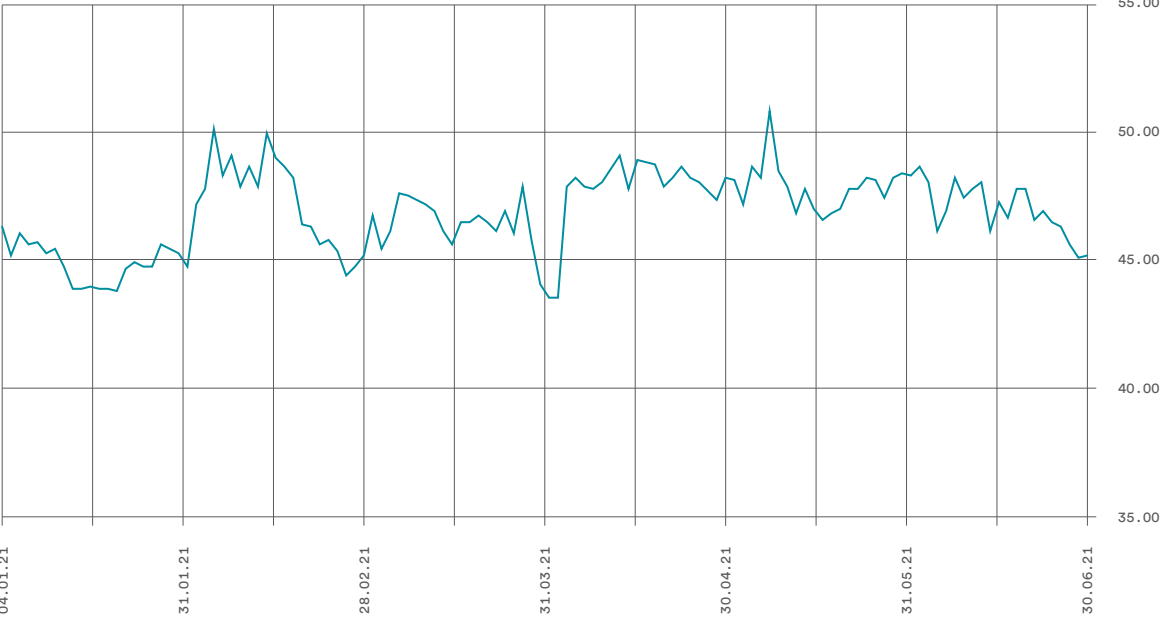
Jefferies International	Peter Welford	Phone: +44 20 702 986 68
valuationLab AG	Bob Pooler	Phone: +41 79 652 67 68
Credit Suisse, EMEA Equity Research Switzerland	Barbora Blaha	Phone: +41 44 334 60 54
HC Wainwright	Raghuram Selvaraju	Phone: +1 212 916 39 66
Research Partners AG	Paul Verbraecken	Phone +41 44 533 40 30

## Calendar

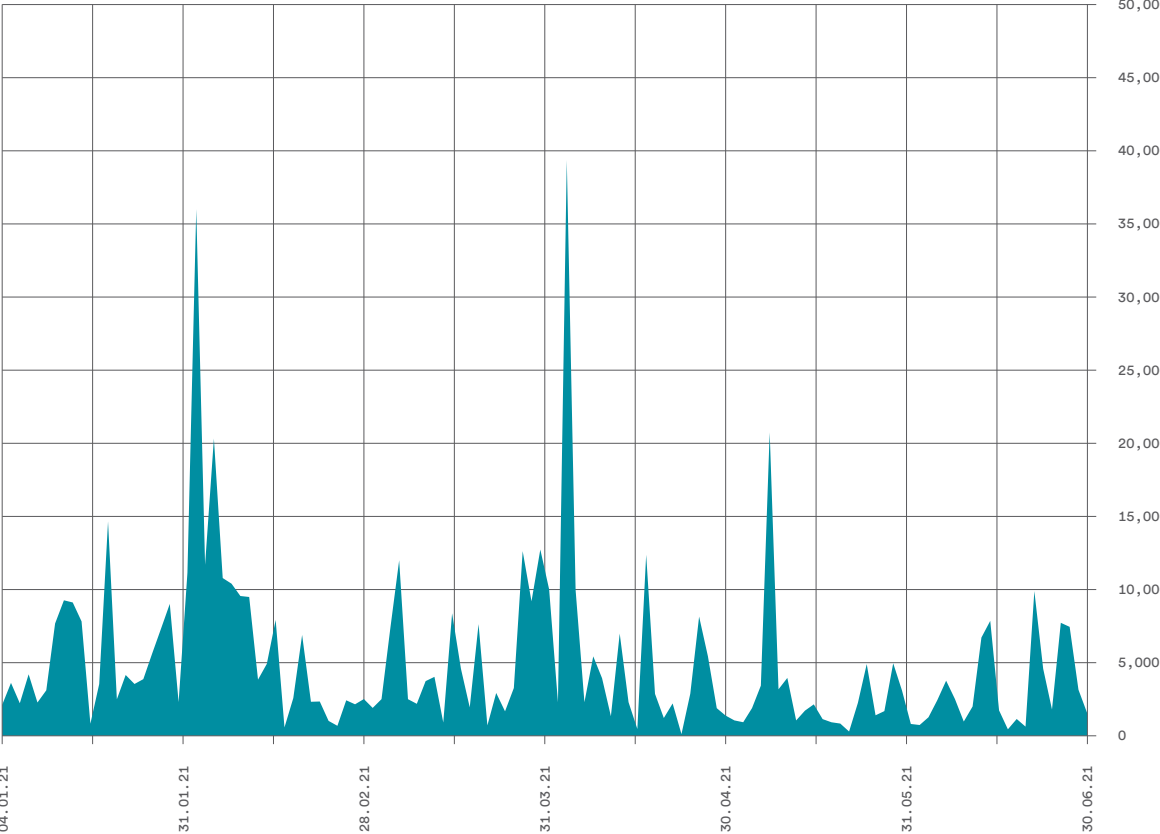
Jefferies Global Healthcare Conference	London, 16–18 November 2021
Credit Suisse Swiss Equity Conference	Zurich, Mid-November 2021
Annual Report 2021	February 2022

Share price

CHF



Trading volumes



## Contacts and Addresses

Cassiopea S.p.A.  
Via Cristoforo Colombo 1  
I-20045 Lainate  
Phone: +39 02 868 911 24  
[www.cassiopea.com](http://www.cassiopea.com)

Investor and public relations  
Diana Harbort,  
CEO and Head of Investor Relations  
Phone: +39 02 868 911 24  
[dharbort@cassiopea.com](mailto:dharbort@cassiopea.com)

Publications and further information  
[investor.relations@cassiopea.com](mailto:investor.relations@cassiopea.com)

### Imprint

© 2021 Cassiopea S.p.A.  
Phone: +39 02 868 911 24

Concept: IRF Reputation AG, Zurich  
Graphic design: TGG Hafen Senn Stieger, St. Gallen