

# Annual Report 2017



# Cassiopea at a glance

Cassiopea is a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products: the initial focus is on the topical treatment of acne, androgenic alopecia, (or AGA) and genital warts. 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"), and 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 establish Cassiopea as a pure-play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases.

## Key events in 2017

The phase III clinical trial program for **Winlevi**<sup>®</sup> is in the final stages of enrollment. Subjects 9 years or older with grade 3 or 4 on the acne IGA scale for facial acne have been treated with Winlevi<sup>®</sup> (1% cream or placebo twice a day for 12 weeks). By the end of the year, the two pivotal trials in 112 sites both in the US and Europe had enrolled a total of 1439 subjects. In the US/Europe long-term open label safety trial 604 subjects were enrolled in order to have the required 300 subjects treated for 6 months and 100 subjects treated for 12 months. The Phase 3 primary endpoints are the proportion of subjects with IGA scores of 0 (clear) or 1 (almost clear) and at least a two point reduction in the IGA in comparison to baseline, the absolute change from baseline in non-inflammatory lesion count and in inflammatory lesion count at week 12. We expect that top line data will be released in Q2 2018.

In June 2017, we began recruiting for the phase II dose ranging study for **Breezula**<sup>®</sup> in androgenic alopecia after we received German regulatory approval. This single 12 month dose ranging study calls for the enrollment of 400 male subjects aged 18–55, with mild to moderate androgenic alopecia. The 5 arms, each with 80 subjects, use different strength dosages ranging from 2.5%, 5%, 7.5%, vehicle twice a day and 7.5% once a day. The co-primary endpoints are the changes versus baseline in target area hair count in number of non-vellus hairs at month 12 and the

subjects' evaluation of treatment benefit via the hair growth assessment at month 12. The last subject was recruited at the beginning of December 2017. We plan to perform an interim analysis after 6 months and expect to be able to provide top line 6 month results in mid-2018 with full 12 month results expected in late 2018/early 2019.

After the encouraging results of the phase II proof of concept trial for **CB-06-01**, a novel antibiotic for the treatment of acne, it was decided to move ahead to produce a new GMP API batch, to optimize the formulation and then to conduct a formal Phase II Dose Ranging Program. The synthesis of the new API has been completed. The development of the new formulation is scheduled for H1 2018, after which the dose ranging plan will be developed.

The phase II proof of concept trial for **CB-06-02**, a novel integrin activator for the treatment of genital warts, in Israel testing 15% CB-06-02 once a day for up to 14 weeks against placebo in 60 subjects, completed enrollment in November 2017. The objective is the assessment of efficacy, safety and tolerability of CB-06-02 versus vehicle in the treatment of genital warts in women. Data will be published in H1 2018.

All operations were carried out within the **budgeted framework**. In 2017, Cassiopea spent EUR 14,545 thousand developing the clinical programs. At end of 2017, cash amounted to EUR 17,598 thousand, which is what had been originally planned.

## Cassiopea's pipeline

Product	Drug type	Preclinical	Phase			MA/ Expected Launch	Next Catalyst
			I	II	III		
<b>Winlevi®</b> Acne	Antiandrogen <b>NCE<sup>(1)</sup></b>				H1 2018	Q4 2019 Q1 2020	H1 2018 (Ph III data)
<b>Breezula®</b> Alopecia	Antiandrogen <b>NCE<sup>(1)</sup></b>			POC completed DR H2 2018	2019–20	2022	H1 2018 (Ph II DR interim analysis data)
<b>CB-06-01</b> Acne	Antibiotic <b>NCE</b>			POC completed DR 2019	2020–21	2022	H2 2019 (Ph II DR data)
<b>CB-06-02</b> HPV	Integrin activator <b>NCE</b>			POC 2017 DR 2019	2020–21	2022	H1 2018 (POC data)

<sup>1)</sup> Winlevi® and Breezula® are different formulations of the same NCE, for different indications.

POC = Proof of Concept | DR = Dose Ranging

## Key figures

EUR 1,000	31.12.2017	31.12.2016
<b>Income statement</b>		
Revenue	–	–
Other income	3,820	5,883
Cost of sales	–	–
R&D costs	(13,061)	(14,310)
SG&A costs	(1,484)	(2,026)
Operating result	(10,725)	(10,453)
Profit (loss) before taxes	(13,656)	(9,496)
Profit (loss) for the period	(13,656)	(9,496)
<b>Shares</b>		
Weighted average number shares	10,000,000	10,000,000
Basic earnings (loss) per share (in EUR)	(1.366)	(0.950)
<b>Statement of financial position</b>	<b>31.12.2017</b>	<b>31.12.2016</b>
Non-current assets	9,104	5,941
Cash and cash equivalents	17,598	33,656
Other current assets	1,767	2,328
Liabilities	2,115	2,776
Equity	26,354	39,149
Equity ratio	92.6%	93.4%

### Image concept

With this Annual Report, we provide you a carefully selected collection of color photography, showing various skin and hair types of several ethnicities. These images represent our mission to develop innovative new therapies for the treatment of skin diseases.



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# Dear Shareholder

It has been 2 ½ years since our IPO and we are pleased to inform you that we are performing according to the plan then presented. We are now entering a very exciting year for Cassiopea where the fruits of our work will be seen soon.

In 2017, we made substantial progress on each of our programs. We will announce key data sets in 2018: In H1 2018, the Phase 3 data for Winlevi®, the interim 6 month results for the Breezula® Dose Ranging Trial and the POC results for CB-06-02 will all be available. In late 2018/early 2019, the 12 month results for the Breezula® Dose Ranging Trial will be available.

By the end of 2017, the enrollment for the entire Phase 3 Program for Winlevi® was nearly complete. The two Phase 3 pivotal trials had enrolled a total of 1439 subjects trials in 112 sites in the US and Europe. The long-term open label safety trial had enrolled 604 patients and the pediatric trial is ongoing. The phase 3 data will be announced H1 2018.

The Breezula® androgenic alopecia Dose Ranging Study is being conducted in 6 specialized centers in Germany. The first subject was enrolled in June 2017 and the study closed at the beginning of December with 404 subjects enrolled. An interim analysis will be performed after 6 months to get an early view of the best dosing regimen. Top line 12 month results can be expected towards the end of 2018/early 2019.

You will recall that the results from our CB-06-01 proof of concept trial led us to conclude that the program warranted continued development provided that the formulation could be improved. We thus decided to move ahead to produce a new GMP API batch, optimize the formulation and then conduct a formal Phase II Dose Ranging Program. The new batch of API has been successfully developed and we expect to have the new formulation by the end of H1 2018 so that we can start planning the Dose Ranging Trial thereafter.

After our CB-06-02 licensor, BioMas, an Israeli company, ceased activity and consequently discontinued all work supervising the clinical trials in Israel, we needed to take total control ourselves. Completing recruitment

was tedious but at the beginning of December, we were able to announce that the trial had been closed after randomizing 68 subjects. Top line results should be available towards the end of Q1 2018.

Our service agreement with Cosmo Pharmaceuticals N.V., our largest shareholder, has proven invaluable to Cassiopea because it has allowed us to proceed on four different development programs simultaneously with tasks varying from API development, to new formulation development, to the management of several clinical trials, all with a very small operating staff basis. While this requires strong coordination efforts, it allows us to proceed with great expertise and minimal cost in developing the programs until we have the Winlevi® Phase 3 results.

2018 will be a pivotal year for Cassiopea as we move toward regulatory submission and pre-commercial activities for Winlevi®, further invest in the advancement of each of the other programs, and begin to build the infrastructure of the company. To that end, as originally envisioned during our IPO, we plan a follow-on capital raise or other financing event in H2 2018.

David Hale, Board Member, resigned in October because his other investments appeared to be entering a phase where there could be potential conflicts of interest. We thank him for his invaluable contribution to the company especially in its early phases. A replacement will be elected at the next General Shareholders meeting.

We thank all our shareholders and our employees, including the Cosmo Service team for their commitment to our Company and look forward to an exciting 2018.

Lainate, 27 February 2018



Jan E. de Vries  
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 as efficiently as possible.

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.

It is our intention to generate the full value of our products in the US market. The organizational expansion necessary for an integrated specialty pharma company will be executed when we have strong indications that our lead product will have a high likelihood of FDA approval.

According to widely-cited data, acne vulgaris is one of the most common skin conditions, affecting up to 50 million people in the US, of whom approximately 10 million suffer from moderate to-severe acne. It is estimated that approximately 85% of people in the US between the ages of 12 and 24 experience at least minor acne, and acne is the reason most cited for visits to the dermatologists by patients 14 to 45 years old. 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. Based on US IMS data, there were 25.2 million acne product prescriptions in 2016, 62% of which were for topical products. The major product classes predominantly used to treat acne have been available for over 30 years, and we believe that growth in this market recently has been significantly limited by a lack of innovation in new product development. According to Research & Markets, the global medical

dermatology market generated revenues of US\$ 20 billion in 2015 and is projected to grow by 7.7% p.a. well into the 2020's. Management's analysis of Symphony Health data indicates that the US acne market generated total sales of US\$ 5.9 billion in 2016, growing about 10% CAGR from 2012.

According to the International Society for Hair Restoration Surgery, 35 million men and 30 million women in the US suffer from hair loss from androgen induced alopecia. Yet global sales of drugs for androgenic alopecia are approximately US\$ 600 million, because most drugs currently in the androgenic alopecia market are off-patent and have low effectiveness and generic drug pricing. It is widely known that there is a large unsatisfied market demand among androgenic alopecia patients. With few drug options available, the global hair restoration surgery market has grown very quickly, amounting US\$ 4.2 billion in 2016, an increase of 64% since 2014 according to a 2017 survey by the International Society of Hair Restoration Surgery.

According to the Centers for Disease Control and Prevention, in the US approximately 14 million people are newly infected with Human Papillomavirus (HPV), the causative pathogen of anogenital warts, each year.

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 30 years. 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.

In addition, the fact that the US acne market is served by a relatively small, addressable number of practicing dermatologists, could allow a small and dedicated sales force to efficiently cover the customer base.

# Research and development

Product	Drug type	Preclinical	Phase			MA/ Expected Launch	Next Catalyst
			I	II	III		
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<b>CB-06-02</b> HPV	Integrin activator <b>NCE</b>			POC 2017 DR 2019	2020–21	2022	H1 2018 (POC data)

<sup>1)</sup> Winlevi® and Breezula® are different formulations of the same NCE, for different indications.

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## Winlevi®

Winlevi®, an NCE, is a topical antiandrogen, which penetrates the skin and displaces androgen from the androgen receptor of the sebaceous glands. This displacement helps prevent the cascade of events that leads to acne. Once in the bloodstream, Winlevi® metabolizes to cortexolone, a substance produced naturally by the human body, with no clinically relevant safety issues noted to date. If successful, with side effects similar to placebo, this would be the first topically applicable antiandrogen that treats acne. Winlevi®, if approved, would be a first-in-class medication with a novel mechanism of action and we expect that it will be able to both compete with and to complement existing acne therapies.

The Special Protocol Assessment for the phase III clinical trial program for Winlevi® was filed with the US FDA in April 2015 and was subsequently approved in July 2015. The phase III program for Winlevi® targeted the treatment of 1,400 subjects 9 years old or older, with moderate to severe acne with 1% cream applied twice daily for 12 weeks in 112 sites in both the US and Europe. At the end of the year, 1439 subjects had been enrolled and 939 subjects had completed

the 12 weeks of treatment. It is planned to release the Phase 3 data in H1 2018.

In addition to the phase III study, a long-term safety study is required by the FDA to determine the safety in at least 300 subjects for a total of six months of treatment and in at least 100 subjects treated for a total of twelve months. 604 subjects rolled over from the two acute studies, and by the end of the year, 199 subjects had completed the entire long-term treatment period.

By June 2016, centers were opened for another study, planned to complete characterization of the safety profile of Winlevi® in children aged 9–11 according to FDA requirements. This is an open label evaluation of the adrenal suppression potential of the product. The study calls for 24 evaluable subjects; at year-end 2017, 21 subjects had completed the study.

## Breezula®

Breezula® is a different formulation and a different strength of the same NCE in Winlevi®. In androgenic alopecia (AGA), high concentrations of dihydrotestosterone (DHT) at the hair follicle level shorten the hair cycle and gradually miniaturize scalp follicles

inducing them to produce progressively smaller, thinner hairs until they become unable to produce new hair. These DHT dependent effects are considered, in most cases, reversible, so that AGA could be susceptible to medical treatment with drugs such as Breezula® by blocking DHT interaction with the specific hair follicle androgen receptors. If successful, Breezula® would be the only topical antiandrogen approved for use in AGA and could be used in both men and women. We believe that Breezula® will not have the contraindications and safety warnings of the only other antiandrogen approved for the treatment of AGA, which is administered orally and indicated only for men. Breezula® does not interfere with the hormonal and, in particular, testosterone profile of patients; libido and sexual behavior are unaffected in clinical trials to date.

After the successful phase II trial, a Phase II Dose Ranging Study was planned in 400 AGA subjects to be treated for 12 months. This is Multicenter, Prospective, Randomized, Double-Blind, Vehicle-Controlled trial with 5 arms: Breezula® 2.5%, 5.0%, 7.5%, vehicle BID and Breezula® 7.5% QD is being conducted in 6 AGA specialized centers in Germany. The first subject was recruited in June 2017, by the beginning of December, when the enrollment was closed, 404 subjects had been recruited. An interim analysis is planned to be conducted in mid 2018.

#### **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 move ahead to produce a new GMP API batch, optimize the formulation and then conduct a formal Phase II Dose Ranging Program.

During 2017, the synthesis of the new API was completed. We are planning to develop a new improved formulation in 2018 and to begin preparation for the Phase 2 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 treatments.

The phase II proof of concept trial for CB-06-02 in Israel testing 15% CB-06-02 once a day for up to 14 weeks against placebo on 60 subjects suffered delays because BioMas ceased operations and consequently ceased supervising the clinical trials in Israel. After we took over these responsibilities, recruitment increased and recruitment reached the targeted 68 subjects. We expect to have top line data in H1 2018 after which a go no-go decision will be taken which would lead to further API manufacturing and formulation development.

# Patents and trademarks

## Patents granted in 2017

- \_ Two patents granted in Japan (CB-03-01 /01 crystalline forms/Winlevi® – expiry date 2028);
- \_ One patent granted in China (CB-03-01 /01 crystalline forms/Winlevi® – expiry date 2028);
- \_ Two patents granted in Canada (CB-03-01 /01 crystalline forms/Winlevi® – expiry date 2028);
- \_ One patent granted in the US (CB-06-02 – expiry date 2027).

## Notice of Allowance in 2017

- \_ One patent application allowed in the US (CB-03-01 Winlevi®/Breezula® – expiry date 2022);
- \_ One patent application allowed in Canada (CB-06-02 – expiry date 2025).

## Patent New Filings in 2017

- \_ One patent application in the US (CB-06-01 – continuation application);
- \_ PCT national phase entry (CB-03-11– Breezula®) in Australia, Brazil, Canada, China, Europe, India, Japan, South Korea, Mexico, Russia, US and South Africa.

## Trademarks Registered in 2017

- \_ Two trademarks registered in the US (Breezula®, word and logo);
- \_ One trademark registered in the US (Cassiopea® logo);
- \_ Two trademarks registered in the US (Winlevi®, word and logo).



# Scientific Advisory Board

In order to support the development of Cassiopea S.p.A. by providing advice on scientific and clinical development and product application, the Company established a Scientific Advisory Board. The Scientific Advisory Board comprises the following members:

## **James Leyden, MD**

Emeritus Professor of Dermatology, Department of Dermatology, University of Pennsylvania School of Medicine

Dr. James J. Leyden, M.D., has been a Professor Emeritus of Dermatology at the School of Medicine of the University of Pennsylvania in Philadelphia since 2002. Dr. Leyden has been involved in clinical research and care of patients for more than 30 years. Dr. Leyden's research interests encompass a wide range of clinical problems including bacterial and fungal infections, acne, aging and photoaging and developing methodologies for in-vivo evaluation of anti-microbial effects. More basic interests have included mechanisms of inflammation in acne, bacterial taxonomy and bacterial production of body odors. He has also been instrumental in the development, testing and commercialization of Retin-A, Accutane, Bactroban, Nizoral, Cleocin, Benzamycin, Benzaclin, Minocin and the use of bicarbonate to control body odor. He is internationally recognized for his contributions to the field of dermatology, particularly to the understanding of the pathophysiology, diagnosis, and treatment of acne and rosacea.

During his long career, he served on numerous boards and commissions: Consultant to the US Food and Drug Administration and the Federal Trade Commission, and to drug regulation agencies in England, Germany and Austria, Professor of Dermatology at the Hospital of the University of Pennsylvania in Philadelphia since 1983, Chairman of the Board of the dermatology foundation, member of the Executive Board of the dermatology foundation, numerous editorial boards and he is a Director of the American academy of Dermatology.

He received his medical degree from Perelman School of Medicine at the University of Pennsylvania and has been in practice for 49 years.

## **Diane Thiboutot, MD**

Professor of Dermatology Vice-Chair for Research for Dermatology Director of Clinical & Translational Science Research Education Penn State Hershey Dermatology

Dr. Diane Thiboutot is recognized for her research in the regulation of sebum production and the treatment of acne. She is Professor of Dermatology and Vice-Chair at the College of Medicine, Penn State Milton S. Hershey Medical Center and serves as a reviewer for the National Institute of Health (NIH) as well as several dermatology journals. Both in her practice and research, Dr. Thiboutot specializes in the care of patients with acne, rosacea, and hair disorders. In addition to serving as a reviewer for the National Institutes of Health and several dermatology journals, she has authored or co-authored many studies, articles, and book chapters relating to acne and hormone metabolism in the skin. She is also a frequent lecturer at medical conferences.

## **Ken Washenik, MD**

Ken Washenik, M.D., Ph.D., is the Chief Medical Officer and Medical Director of Bosley, the world's largest hair restoration practice and the past Chief Executive Officer of the Aderans Research Institute, a biotechnology firm involved in researching tissue engineered hair follicle neogenesis and cellular based hair restoration.

Dr. Washenik is the immediate past President and a Board member of the North American Hair Research Society and Vice Chair of the Board of Trustees of the Hair Foundation. He is also on the Board of the International Society of Hair Restoration Surgery and the Cicatricial Alopecia Research Foundation as well as a member of the American Academy of Dermatology and the medical honor society, Alpha Omega Alpha. He is a Diplomate of the American Board of Dermatology and a member of the Dermatological

Society of Greater New York and the Los Angeles Metropolitan Dermatological Society.

The former director of the Dermatopharmacology Unit at the New York University School of Medicine, Dr. Washenik continues to serve as a clinical investigator and faculty member in the Department of Dermatology. Dr. Washenik, a well-known national and international lecturer, has presented many seminars on hair growth and loss, dermatopharmacology and dermatology-related issues. His Ph.D. is in Cell Biology and focused on hormone metabolism.

Dr. Washenik has published numerous scientific and medical articles in peer review journals including Endocrinology, Journal of the American Academy of Dermatology, Archives of Dermatology, The Lancet and The New England Journal of Medicine.

#### **Jonathan Wilkin, MD \***

Founding director of the Division of Dermatology and Dental Products at the US Food and Drug Administration from March 1994 to October 2005 and was a member of the FDA's Dermatology Drugs Advisory Committee. Dr. Wilkin is a fellow of the American Academy of Dermatology and the American College of Physicians, a member of the American Dermatological Association, and board certified by both the American Board of Dermatology and the American Board of Clinical Pharmacology. He has remained active in regulatory matters, of American Academy of Dermatology's Ad Hoc Task Force on Academy's Efforts with the FDA. He served as Director, Dermatology Division and Professor of Medicine and Pharmacology Departments, of The Ohio State University. He served as Chief of Dermatology section, Hunter Holmes McGuire Veterans Administration Medical Center in Richmond, Virginia. Dr. Wilkin served as the Chairman of the medical advisory board for the National Rosacea Society from 1998 to 2012.

\* resigned as per July 2017

Dr. Wilkin received his BA and MS in zoology from Ohio State University in Columbus, followed by his medical degree from the Ohio State University College of Medicine.

#### **Andrea Zaenglein, MD pediatric Dermatologist**

Professor of Dermatology and Pediatric Dermatology, Penn State Hershey Dermatology, Hershey, PA since 2013. From 2007 to 2013 she was Associate Professor of Dermatology and Pediatrics at Penn State College of Medicine / Milton S. Hershey Medical Center, from 2001 to 2007 she was Assistant Professor of Dermatology and Pediatrics at Penn State College of Medicine / Milton S. Hershey Medical Center, from 1999 to 2000 she had a Pediatric Dermatology Fellowship at NYU Hospital and Bellevue Hospital, New York, from 1997 to 2001 she was a Dermatology Resident at MCP Hahnemann University Hospitals, Philadelphia and from 1996 to 1997 she had an Internal Medicine Internship at George Washington University Hospital, Washington DC.

She is a member of the American Academy of Dermatology, the Society for Pediatric Dermatology, the American acne and Rosacea Society, the American Academy of Pediatrics, and the International Society for the Study of Vascular Anomalies.

She has been the principal investigator in 11 completed funded research projects and is currently the principal investigator in 3 ongoing funded research projects, has been lecturer in 104 events, has published more than 60 articles in scientific journals and book chapters in 17 books. Dr Zaenglein received her BA in English Literature at the University of South Carolina in Columbia in 1990, and her Doctor of Medicine at the Pennsylvania State University College of Medicine, Hershey in 1996.

# Corporate governance

The Company is a stock corporation, Società per Azioni, (S.p.A.), organized under the laws of Italy and listed on the SIX Swiss Exchange. The share capital amounts to EUR 10,000 thousand represented by 10,000,000 shares each with a nominal value of EUR 1.00.

## Corporate governance model

The Company has adopted the corporate governance model called “monistic model” which is ruled by Articles 2409 *sexiesdecies* and following of the Italian Civil Code. The shareholders’ meeting appoints the Board of Directors (Consiglio di Amministrazione), which has the responsibility to manage the Company. The Board of Directors appoints a controlling body (Management Control Committee – Comitato per il Controllo sulla Gestione) from among its members. The shareholders’ meeting must also appoint an external auditing body.

According to the corporate governance model the Company has adopted the structure of an S.p.A. (Joint Stock Corporation), that is in the responsibility of the Board of Directors. The Board of Directors may delegate its authority to the Executive Committee and/or to the Chief Executive Officer (CEO). The Board of Directors determines the duration of the term and the powers of the CEO. The CEO’s functions include coordination and supervision. The Company does not adopt the model of a board of statutory auditors, but has chosen to designate appropriate Directors with respective qualifications to allow not to adopt such model.

The general policies and the management of the Company are the responsibility of the Board of Directors, which are:

- 1) Appoint of its members as CEO of the company;
- 2) Assign powers among the members of the BoD;
- 3) Approve budget and strategic plans and supervise the management performance vs the budget;
- 4) establish the strategic, accounting, organizational and financing policies

In particular, the Board of Directors approved the 2017 budget in relation with the clinical trials. The management was delegated to operate in the expenses limits as set forth in the 2017 Budget and to manage and supervise the clinical trials and operations according to the approved plans.

During 2017, the Board of Directors and the management control committee have verified that the managements operated in the full respect of budget limits. The same procedure occurred in December 2017 in respect of 2018 budget.

Pursuant to the Company’s Articles of Association ([www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx](http://www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx)) the members of the Board of Directors are elected by the shareholders at the annual shareholders’ meeting, for a term established by the shareholders, but not to exceed three financial years. The mandate of the current Directors will end with the shareholders meeting approving the financial statements as of the fiscal year 2017 to be held in 2018. The Company’s Articles of Association establish a slate voting system for the election of the members of the Board of Directors. According to this system, each shareholder can present or concur to the presentation of just one list and each candidate can present himself in just one list, under sanction of ineligibility; each shareholder is entitled to vote for just one list. The candidates within a list shall be listed with progressive numbers. Each list shall contain a number of candidates not higher than the number of members of the Board to be elected. According to the Article of Association, shareholders who own, alone or together with other shareholders, at least 2.5% of the share capital are entitled to present a list, providing evidence of ownership of the required amount of shares at the latest ten days prior to the scheduled date for the shareholders’ meeting on first call. The Company’s Articles of Association provide that one Director (the one which is listed as first) is appointed from the list which has obtained the second highest



number of votes. This last provision entitles minority shareholders to appoint one minority director. Pursuant to the Company's Articles of Association, at least three directors shall fulfil the independence requirements provided for the Auditors by sect. 2399 of the Italian Civil Code.

For the purpose of this provision, a director shall not be deemed independent if he/she:

(i) falls within section 2382 of the civil code (provisions on ineligibility); (ii) is a spouse, relative or the like up to the fourth degree of kinship of the directors of the Company, is a spouse, relative and the like up to the fourth degree of kinship of the directors of the companies controlled by the Company, of the companies it is controlled by and of those subject to common control; (iii) is linked to the Company, the companies it controls, the companies it is controlled by and those subject to common control or to directors of the Company or persons referred to 91 above sub (ii) by self-employment or employee relationships or by other relationships of an economic or professional nature that might compromise their independence. The Articles of Association also provide that, if the director registered with the national register of auditors (Registro dei Revisori Contabili) is not elected from the list which obtains the highest number of votes, the director registered with the national register of auditors shall be the first candidate listed on the minority list fulfilling this requirement, even if he is not the first on the list.

The members of the Board of Directors may be re-elected for consecutive terms, except the independent directors that cannot be appointed for more than two tenures. There is no age limitation for board members. See "The Board of Directors".

Only in case the shareholders' meeting has not elected the Chairman (as a rule, the role of the Chairman is always granted to the first listed candidate on the list that obtained the most votes), the Board of Directors

elects the Chairman, the Deputy Chairman of the Board (which is optional), and the CEO from among the members of the board.

Pursuant to the Articles of Association, the Board of Directors has full power over the management of the Company, except for actions reserved by the law to meetings of the shareholders.

Under Italian law, directors may be removed from office at any time by the shareholders in ordinary meetings. If removed without valid reasons, such directors may have a claim for damages against the Company, but may not stay in office. Directors may resign at any time by written notice to the Board of Directors and to the Chairman of the Board of Statutory Auditors. The Board of Directors must appoint substitute directors to fill vacancies arising from removals or resignations, subject to the approval of the Board of Statutory Auditors. Substitute directors serve until the following general meeting of shareholders.

Board of Directors meetings are called by the Chairman (or in his absence, by the eldest of the Deputy Chairmen) or by the CEO by written notice, highlighting the matters to be discussed, sent at least three days (or in cases of urgency, at least one day) before the date of the meeting. A minimum of two members of the Board of Directors or one of the Statutory Auditors may request the Chairman or the CEO to call a meeting, in such case the Chairman or the CEO are obligated to call the meeting. The minimum quorum required to validly hold Board meetings is a majority of the Directors in office. Directors may attend meetings via telephone conference or videoconference provided that all participants can be identified and that they are all able to follow the discussion and intervene in real time, in relation to the issues in discussion. Pursuant to the Company's Articles of Association, meetings of the Board of Directors are chaired by the Chairman of the Board of Directors or, if the Chairman of the Board is absent or otherwise unable to act, by the Deputy

Chairman. If the Chairman and the Deputy Chairman are absent or otherwise unable to act, the meeting is presided by the CEO or by the eldest director among those present at the meeting. Resolutions are adopted by the majority votes of the Directors present at the meeting.

The Chairman of the Board of Directors is the legal representative of the Company. However, if the Chairman is absent or otherwise unable to act, each Deputy Chairman may also act on the Company's behalf within the limits prescribed by the Board of Directors. The Board of Directors may from time to time appoint the General Manager or one or more Deputy General Managers or confer powers on executives or an attorney of the Company to represent the Company, determining the scope and exercise of such powers on appointment.

According to section 2391 of the Italian Civil Code, each director must inform the other directors of any interest he has on his behalf or on behalf of third persons in a specific transaction of the company, specifying the nature, the terms, the origin and the relevance of his interest. If the conflicted party is the CEO, he must abstain from executing the transaction and must refer the transaction to the board. In such circumstances, the resolution of the board of directors must adequately justify the reasons and the convenience for the company to execute the transaction. In the event of non-compliance with these provisions or if the resolution of the board or of the executive committee is adopted with the determining vote of the conflicted director, the resolution, if it may cause harm to the company, may be challenged by the directors and by the board of auditors within 90 days from the date of its adoption. The person who consented to the resolution having been provided with the relevant information cannot challenge it. In any case the rights acquired by third parties in good faith, on the basis of acts made in execution of the resolution, cannot be challenged. The director is liable for

damages caused to the company by his action or omission. The director is also liable for the damages suffered by the company in case the director uses, for his own benefit or for the benefit of third parties, data, information or business opportunities obtained in connection with his appointment.

According to section 2409 octiesdecies of the Italian Civil Code and the Articles of Association, the Management Control Committee is appointed by the Board of Directors among its members. The members of the Management Control Committee cannot be less than three. The Management Control Committee is formed by Board members who fulfill the requirements of independence according to section 2409 septiesdecies of the Italian Civil Code. For the purpose of this provision, a member of the Management Committee shall not be deemed independent if he/she: (i) falls within section 2382 of the Italian civil code (provisions on ineligibility); (ii) is a spouse, relative or the like up to the fourth degree of kinship of the directors of the Company, is a spouse, relative and the like up to the fourth degree of kinship of the directors of the companies controlled by the Company, of the companies it is controlled by and of those subject to common control; (iii) is linked to the Company, the companies it controls, the companies it is controlled by and those subject to common control or to directors of the Company or persons referred to above sub (ii) by self-employment or employee relationships or by other relationships of an economic or professional nature that might compromise their independence.

According to the Articles of Association ([www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx](http://www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx)) at least three directors shall fulfil the independence requirements. As listed on pages 26–31, four members of the five Board Members fulfilled the independence requirements starting 2017. In October 2017, David Hale notified the Company that a company in which he was a major investor had decided to proceed on activities

that could potentially conflict with the interests of Cassiopea, so he immediately tendered his resignation as Board Member of Cassiopea.

At least one of the members of the Management Control Committee must be selected among statutory auditors registered with the national register of auditors (Registro dei Revisori Contabili).

None of the members of the Management Control Committee can be a member of the executive committee – if appointed – and no powers or specific offices can be delegated to a member of the management control committee. In any case the members of the Management Control Committee cannot perform, even de facto, functions relating to the management of the company's business or the companies which control it or is under control by it. The Management Control Committee elects its chairman among its members, by an absolute majority of the latter.

The Management Control Committee exercise its functions according to the provisions of sect. 2409 octiesdecies of the Italian Civil Code, namely: (i) it monitors the adequacy of the company's organizational structure, of the internal auditing system and on the administrative and accounting system as well as on its capacity to correctly represent the acts of the management; (ii) it performs the additional functions assigned to it by the Board of Directors with specific reference to the relationship with the persons entrusted with the statutory accounting audit.

The annual remuneration of the members of the Management Control Committee must be determined by the shareholders' meeting upon appointment of the members of the Management Control Committee, for the entire duration of their term of office. This remuneration was decided at the beginning of their 3 year term on 27 May 2015.

The members of the Management Control Committee can attend to meetings by means of audio-video-

conference or teleconference, in accordance to what is provided by the by-laws with reference to the Board of Directors' meetings.

According to section 2409 octiesdecies of the Italian Civil Code and the Articles of Association, if shareholders representing 5% of the capital stock file a complaint, the Management Control Committee must investigate the facts reported in the complaint without delay. The Members of Management Control Committee may, individually, ask other directors information, also with reference to the subsidiaries, on the performance of the business or on particular transactions. They can ask for the same information directly to the management and control bodies. The information has to be provided to all members of the Management Control Committee. The members of the Management Control Committee may, individually, ask the President to call the Committee, specifying the subjects to be discussed. The meeting must be called without delay, unless there are reasons that prevent the meeting to be called, which should be promptly illustrated to the Committee during the next meeting. The member of the Management Control Committee may, upon notice to the Chairman of the Board of Directors, call the Board of Directors or the executive committee and avails oneself of employees of the company for the performance of its functions. The powers to call meetings and request collaboration may also be exercised individually by each member of the Committee. The Management Control Committee, or a member of it who has a specific mandate, may, at any time, carry out inspections and controls and exchange information with the corresponding bodies of subsidiaries with reference to the administration and control systems and general business trends.

In listed companies, the auditing of the accounts must be executed by an external independent auditing company, which must be enrolled in the Registro dei Revisori Contabili.

The Articles of Association of the Company can be found on the Company's web site under the following link: <http://www.cassiopea.com/investor-relations/corporate-governance/articles-of-association.aspx>

### Major shareholders

Cosmo Pharmaceuticals N.V., Amsterdam, is the Company's main shareholder holding 4,508,987 shares or 45.09% of all outstanding shares at year end 2017. Furthermore, Cosmo Holding S.a.r.l. holds 753,445 shares or 7.53%.

At year end 2017, UBS Fund Management (Switzerland) AG was reported as holding 565,511 shares respectively 5.66% of the shares of the Company; Heinrich Herz AG/Logistable SA was reported as holding 409,000 shares respectively 4.09% of the shares of the Company and LB Swiss Investment AG was reported as holding 305,000 shares respectively 3.05% of the shares of the Company.

### Capital structure

#### Share capital

The Company was incorporated by its founding shareholder Cosmo Pharmaceuticals on 29 July 2013 in the form of a limited liability company (Società a responsabilità limitata) under the name of Cosmo Dermatos S.r.l. with a capital of EUR 100,000. The Company was registered with the commercial register of Milan at no. 08338370961 and REA MI-2018773 as of 30 July 2013. The Company's current registered address is Via C. Colombo 1, Lainate, Milan.

The Company, on 14 April 2015, was transformed into a joint stock corporation (S.p.A., or società per azioni). On the same date, the nominal value of the common shares was set into EUR 1 per share.

On 27 May 2015, its share capital was increased to nominal EUR 10,000,000, with the issue of 9,900,000 new common shares with a nominal value of EUR 1 each reserved to the existing shareholders for the purpose of the Initial Public Offering concluded in July 2015.

Also on 27 May 2015, the shareholders' meeting resolved to delegate to the Board of Directors to increase the share capital of EUR 10,000,000 by issuing 500,000 new common shares with a nominal value of EUR 1 each to service an employee stock option plan ("ESOP") according to terms to be set by the Board of Directors after completion of the Offering. The authority delegated to the Board of Directors has to be executed by 27 May 2020 the latest.

Except for the authorization with respect to the ESOP, the Company has no conditional capital, no authorized share capital and no unit or profit-sharing certificates outstanding.

As per 31 December 2017, the share capital is composed of 10,000,000 shares, each with a nominal value of EUR 1. The share capital is fully paid up. The shares are issued in book entry form according to Italian law. No share certificates have been issued and share certificates will not be available for physical delivery. Shares are centralized in the central security depository system managed by Monte Titoli.

As at 31 December 2017, the Company does not own any treasury shares.

### Stock option plans

The extraordinary shareholders' meeting of 27 May 2015 authorized the Board of Directors to increase the capital by a nominal amount of EUR 500,000 by issuing 500,000 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 3 December 2015, the Board of Directors granted a total of 140,000 options of which:

- \_ 49,800 with a vesting period of 1 year, expiring on 3 December 2021 and an exercise price of CHF 34 ("Option series 1a")
- \_ 46,600 with a vesting period of 2 years, expiring on 3 December 2022 and an exercise price of CHF 34 ("Option series 1b")

\_43,600 with a vesting period of 3 years, expiring on 3 December 2023 and an exercise price of CHF 34 ("Option series 1c")

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 14.45 per option ("Option series 1a"), of CHF 19.28 per option ("Option series 1b") and of CHF 22.56 per option ("Option series 1c").

On 23 February 2016, the Board of Directors granted a total of 20,000 options of which:

- \_6,800 with a vesting period of 1 year, expiring on 23 February 2022 and an exercise price of CHF 34 ("Option series 2a")
- \_6,700 with a vesting period of 2 years, expiring on 23 February 2023 and an exercise price of CHF 34 ("Option series 2b")
- \_6,500 with a vesting period of 3 years, expiring on 23 February 2024 and an exercise price of CHF 34 ("Option series 2c")

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 11.28 per option ("Option series 2a"), of CHF 15.87 per option ("Option series 2b") and of CHF 18.98 per option ("Option series 2c").

On 23 February 2017, the Board of Directors granted a total of 12,000 options of which:

- \_4,100 with a vesting period of 1 year, expiring on 23 February 2023 and an exercise price of CHF 34 ("Option series 3a")
- \_4,000 with a vesting period of 2 years, expiring on 23 February 2024 and an exercise price of CHF 34 ("Option series 3b")
- \_3,900 with a vesting period of 3 years, expiring on 23 February 2025 and an exercise price of CHF 34 ("Option series 3c")

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 11.59 per option ("Option series 3a"), of CHF 15.84 per option ("Option series 3b") and of CHF 18.84 per option ("Option series 3c").

On 14 November 2017, the Board of Directors granted a total of 70,000 options of which

- \_24,400 with a vesting period of 1 year, expiring on 14 November 2023 and an exercise price of CHF 34 ("Option series 4a")
- \_24,300 with a vesting period of 2 years, expiring on 14 November 2024 and an exercise price of CHF 34 ("Option series 4b")
- \_21,300 with a vesting period of 3 years, expiring on 14 November 2025 and an exercise price of CHF 34 ("Option series 4c")

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 10.46 per option ("Option series 4a"), of CHF 14.32 per option ("Option series 4b") and of CHF 17.11 per option ("Option series 4c").

In the year 2017, 20,000 options were forfeited. Considering also the options forfeited in the previous years, 187,000 options of the total option program of 500,000 options are outstanding.

Italian law does not foresee the creation of conditional capital for stock option plans. The share capital will thus not be increased until such time when the option holders execute their options.

### **Transfer of shares and disclosure of principal shareholders**

The transfer of shares is affected by corresponding entry in securities accounts, which record the transfer of financial instruments opened with authorized financial

intermediaries and in accordance with the applicable law. Upon registration of the transfer and upon request of the shareholder, the financial intermediaries shall inform the Company of the transfer of shares, and the Company shall update the shareholders' register in accordance with Italian law. A shareholder may ask for his registration at any time.

The Company has been advised that, as an Italian company listed in Switzerland, it and its shareholders may not have the protection of either Italian or Swiss laws and regulations governing disclosure of significant shareholdings. However, each shareholder (as defined in the Articles of Association) who directly, indirectly or beneficially has voting or investment power in the Company is required by the Articles of Association to comply with the laws, rules and regulations.

### **Share purchases by the Company**

The Company has a market-making agreement with a well-known bank. The Company does not have any authorization to repurchase shares.

At year-end the Company had no owned shares on its books.

### **Shareholders' rights**

Each share carries one vote. Holders of the shares are entitled to attend and vote at shareholders' meetings on the basis of one vote for each share held, although shares held in breach of certain provisions of applicable law and/or the Company's Articles of Association may not be voted.

According to the Italian law, Shareholders representing at least 2.5% of the issued and outstanding share capital are entitled to put issues on the agenda of the meeting, provided that their request is filed at least within five days from the publication of the notice of call.

In addition, even in absence of notice, a meeting will be deemed duly convened if shareholders representing

100% of the share capital, together with the majority of directors and members of the Board of Statutory Auditors, are present at the meeting. In this case, shareholders attending may object to discussions of matters on which they have not been sufficiently informed.

Since 1 May 2013, foreign companies listed in Switzerland are subject to the Swiss takeover provisions as regulated under SESTA (Swiss Exchange Take Over Act) and SESTO (Swiss Exchange Take Over Ordinance).

The Articles of Association also require investors in the shares to notify the Company of certain acquisitions and dispositions of shares.

To attend a meeting, the owners of shares are required to instruct any relevant authorized intermediary with which their accounts are held to provide to the Company admission certificates or notice.

The Company's shareholders may appoint proxies in writing. Proxies are valid only for single meetings (including, however, the first, second and subsequent calls). General proxies can be released only by companies, associations, foundations or other legal entities or institutions, and only to their own employees.

Directors, Independent Auditors and employees of the Company or of its subsidiaries, or a subsidiary itself, may not act as proxies for shareholders. A shareholder may also appoint another shareholder to represent it at shareholders' meetings.

No voting rights restriction, statutory group clauses and rules on granting exceptions exist.

### **Dividends, allocation of annual net profits and other financial rights**

The board does not intend to propose the distribution of a dividend before the Company generates solid revenues and profits.

### **Pre-emptive rights**

New issues of shares, whether shares or other classes of share capital, are authorized by a resolution of the shareholders passed at an extraordinary meeting. Pursuant to Italian law, holders of ordinary shares are entitled to subscribe for new issue of shares, debt instruments convertible into shares and any other warrants, rights or options entitling the holder to acquire shares, in each case in proportion to their respective shareholdings.

### **Information policy**

Cassiopea S.p.A. is committed to a clear, transparent, consistent and nonselective disclosure of material information. In accordance with the Italian and the SIX Swiss Exchange rules, Cassiopea S.p.A. provides complete and detailed information in annual and half-year reports and regularly updates its website [www.cassiopea.com](http://www.cassiopea.com)

The Company publishes additional information on important events.

The Company has formulated a corporate commitment to keep its investors fully apprised of the Company's developments. The Chairman, CEO, CFO and Head of Investor Relations are responsible for communication with the financial community. The Company adheres strictly to the ad hoc publicity rules of the SIX Swiss Exchange and has issued all press releases to a wide range of international agencies as required by the SIX Swiss Exchange. In selective cases such as the presentation of annual report and the half-year report, the Company has also invited shareholders and the financial press to conference calls and selective news events.

To extent the law or the Articles of Association do not require a written personal notice, all announcements prescribed by law and other notices to the shareholders are therefore validly made through publication in a daily newspaper (chosen alternately between

Il Corriere della Sera, La Repubblica, Il Sole 24 Ore, the Financial Times and the Neue Zürcher Zeitung) as provided in the Articles of Association. In the event the publication in an Italian newspaper is not possible under applicable Italian law, the Company shall publish notice of call and other announcements in the Italian Official Gazette (Gazzetta Ufficiale). Notice shall also be published as required by the listing rules of the SWX Swiss Exchange.

A notice of a shareholders' meeting generally specifies two meeting dates (calls) and may specify three calls for extraordinary meetings.

Notices are also to be published as required by the listing rules of the SIX Swiss Exchange.

### **The Board of Directors**

The general policies and the management of the Company are the responsibility of the Board of Directors, which establishes the strategic, accounting, organizational and financing policies and appoints, recalls and supervises the members of the management. The Board of Directors may delegate its authority to the Executive management and/or to the Chief Executive Officer (CEO). Furthermore, the Board of Directors is responsible for the preparation of annual reports, organization and preparation of shareholders' meetings and carrying out shareholders' resolutions.

The Company's current Articles of Association ([www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx](http://www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx)) provide for a Board of Directors of at least 3 and no more than 9 members; in addition section 13, second paragraph, of the Company's Articles of Association provides for the Board of Directors to consist of five members until the shareholders' meeting's approval of the financial statements as of the fiscal year 2017. Note that resolutions concerning the amendment of such provision of the Articles of Association before the shareholders' meeting's approval of the financial statements

as of the fiscal year 2017 requires a favorable vote of 60% of the share capital.

The Company's Board of Directors is currently composed of four members, each of them being elected for a term of 3 fiscal years and re-eligible to successive terms following the above-mentioned Italian civil code rules. The mandates of the current Directors will terminate with the shareholders' meeting approving the financial statements as of the fiscal year 2017, to be held in 2018, but they may be re-elected so that their mandates will continue for another three fiscal years. As stated above, members of the Company's Board of Directors may be removed by resolution of the shareholders' meeting. However the independent board members may not be elected for more than two consecutive terms.

The Company's Articles of Association establish a slate voting system for the election of the members of the Board of Directors. According to this system, each shareholder can present or concur to the presentation of just one list and each candidate can present himself in just one list, under sanction of ineligibility; each shareholder is entitled to vote for just one list. The candidates on each list shall be listed with progressive numbers. Each list shall contain a number of candidates not higher than the total number of members of the Board to be elected. According to the Article of Association ([www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx](http://www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx)), shareholders who own, alone or together with other shareholders, at least 2.5% of the share capital are entitled to present a list, providing evidence of ownership of the required amount of shares at the latest ten days prior to the scheduled date for the shareholders' meeting on first call. The Company's Articles of Association provide that one Director (the one which is listed as first) is appointed from the list which has obtained the second highest number of votes. This last provision entitles minority shareholders to one board member to represent their interests See also

"Description of the Company's Capital Structure and Shares – Minority shareholders' rights".

Pursuant to the Company's Articles of Association ([www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx](http://www.cassiopea/investor-relations/corporate-governance/articles-of-association.aspx)), at least three directors shall fulfil the independence requirements provided for the Auditors by sect. 2399 of the Italian Civil Code. For the purpose of this provision, a director shall not be deemed independent if he/she: (i) falls within section 2382 of the civil code (provisions on ineligibility); (ii) is a spouse, relative or the like up to the fourth degree of kinship of the directors of the Company, is a spouse, relative and the like up to the fourth degree of kinship of the directors of the companies controlled by the Company, of the companies it is controlled by and of those subject to common control; (iii) is linked to the Company, the companies it controls, the companies it is controlled by and those subject to common control or to directors of the Company or persons referred to above sub (ii) by self-employment or employee relationships or by other relationships of an economic or professional nature that might compromise their independence.

As listed on pages 27–31, four members of the five Board Members fulfilled the independence requirements starting 2017. In October 2017, David Hale notified the Company that a company in which he was a major investor had decided to proceed on activities that could potentially conflict with the interests of Cassiopea, so he immediately tendered his resignation as Board Member of Cassiopea.

Should one or more Directors terminate their office, they shall be substituted pursuant to section 2386 of the Italian Civil Code<sup>1</sup>, without regards to the list wherefrom the director comes. In case the majority of the Directors terminate the office, for resignation or other causes, the entire Board shall be considered as terminated and a shareholders' meeting shall be called for the appointment of a new Board.








Following the resignation of David Hale as board member in October 2017, the board internally decided only to reallocate its tasks given that the terms of all the board members end per the date of the shareholders meeting 2017,

The Articles of Association also provide that, if the director registered with the national register of auditors (Registro dei Revisori Contabili) is not elected from the list which obtains the highest number of votes, the director registered with the national register of auditors shall be the first candidate listed on the minority list fulfilling this requirement, even if he is not the first on the list.

At the Extraordinary Shareholders' Meeting held on 27 May 2015, the new Board of Directors was appointed for a three-year period, eligible to successive terms following Italian civil code rules. The Board of Directors consists of four nonexecutive members and one executive Director. The Management of the Company is in the responsibility of the Board of Directors.

In 2017, five meetings of the new Board of Directors took place each one lasting approximately 3 hours.

<sup>1</sup> Section 2386 of the Italian Civil Code provides that if one or more (but not the majority of the Directors) terminate their office, the board shall co-opt one or more new director; Directors co-opted by the Board of Directors shall remain in office until the next shareholders' meeting, which will then replace the director leaving office.

	<b>Name/current position</b>	<b>Member since</b>	<b>Relevant external positions</b>
	Jan E. de Vries Nonexecutive Director; Chairman	2015	CEO and Board member, AIMM Therapeutics Amsterdam, The Netherlands Member Scientific Advisory Board, Anaptys, La Jolla
	Øyvind Bjordal Nonexecutive Director	2015	Managing Director and Head of Lincoln International, Switzerland
	Pierpaolo Guzzo Nonexecutive Director	2015	CEO EQValue, Rome, Italy Board member of Smartika S.p.A. Board member of Sistan Sgr Board member of Femi S.p.A. Statutory Auditor of: Elco Group S.p.A. (Chairman) Zeis Excelsa S.p.A. (Chairman) CAM S.p.A. (Chairman) Aloiq Wind Italia S.r.l. (Chairman) 3 TI Progetti S.p.A. (Chairman) LFK S.p.A. Geico S.p.A. Elco S.p.A. Lux Vide S.p.A. Filmauro S.p.A.
	David Hale Nonexecutive Director (resigned as per October 2017)	2015	Chairman & CEO of Hale BioPharma Ventures LLC Chairman of the Board of Biocept Inc (NASDAQ) and Connatus Pharmaceuticals Inc (NASDAQ) Board member of: Colorescience Inc (private) MD Rejuvena Inc (private) Clarify Medical Inc (private) Recross Medica Inc (private) Dermata Therapeutics Inc (private) Agility Clinical (private) Neurelis Inc (private) Adigica Health Inc (private) Neurana Inc (private)
	Diana Harbort Executive Director; CEO	2015	

Except for Diana Harbort, none of the board members was part of senior management of the Company nor any of its subsidiaries in the three financial years preceding the period under review and none has significant business connections with the Company or any of its subsidiaries.

None of the board members had any activities in governing and supervisory bodies of important Swiss companies.

None of the board members had any official functions or political posts in Italy or Switzerland.

### **Jan E. de Vries**

Dr. de Vries, born 1946, Dutch citizen, has been the Chairman of Cassiopea S.p.A. since 2015. Dr. de Vries was not part of senior management of Cassiopea in the three financial years preceding the period under review and neither he nor any of the companies he is on the board of have significant business connections with Cassiopea. Dr. de Vries has a) no activities in governing or supervising bodies of important Swiss and foreign organisations, institutions and foundations under private and public law, b) no permanent management and consultancy functions for important Swiss nor foreign interest groups; c) no official functions nor political posts

He has more than 30 years of experience in drug discovery and development both in biotech and large pharmaceutical companies. He is currently the CEO of AIMM–Therapeutics, Amsterdam. Prior to that Dr. de Vries was VP and Head of the Novartis Research Institutes for Biomedical Research in Basel, Switzerland. From 1997–2007, he was the Head of the Novartis Research Institute in Vienna and Global Head of the Disease Area Autoimmunity, Transplantation and Inflammation (including Dermatology) in Basel. At Novartis Dr. de Vries led the discovery and early development of four marketed drugs: Elidel, Ilaris, Gilenya and Consentyx.

Dr. de Vries joined Novartis from the DNAX Research Institute for Molecular Biological Research, owned by Schering–Plough (now Merck), in Palo Alto in California where he was Director of the Human

Immunology Department and did pioneering studies on the biological functions of cytokines and their receptors. Before that, he was co-director of the Schering-Plough Institute for Immunological Research in Lyon, France.

Prior to joining industry Dr. de Vries held various academic positions with increasing responsibilities at the Netherlands Cancer Institute in Amsterdam, where he was Head of the Immunology Department.

Dr. de Vries holds a MSc. degree in biochemistry from the University of Utrecht, the Netherlands, a PhD in immunology from the University of Amsterdam and did his post-doctoral studies at the University of California San Diego.

### **Øyvind Bjordal**

Norwegian (born 1966), has been a Board Member of Cassiopea S.p.A. since 2015. Mr. Bjordal was not part of senior management of Cassiopea in the three financial years preceding the period under review and neither he nor any of the companies he is in have significant business connections with Cassiopea. Mr. Bjordal has a) no activities in governing or supervising bodies of important Swiss and foreign organisations, institutions and foundations under private and public law, b) no permanent management and consultancy functions for important Swiss nor foreign interest groups; c) no official functions nor political posts

Mr Bjordal is Managing Director and Head of Switzerland of Lincoln International. He manages key client relationships, leads deal teams and is responsible for marketing Lincoln International's services to Swiss based companies, in Switzerland and globally.

Prior to joining Lincoln International in 2014 to launch the Swiss operations, Mr. Bjordal worked as a Managing Director / Partner with a corporate finance advisory team since its foundation in 1999, covering the Swiss mid-cap market. The team based in Zurich was initially with Andersen / EY, before continuing with Sal. Oppenheim and most recently Leonardo & Co. where he was also co-leading the pan-European Consumer & Retail team.

After completing his studies and working in the finance area for a global industrial firm, he started his investment banking career at UBS in 1994 where he worked on transactions throughout Europe, including several privatization assignments in the telecoms sector.

Mr. Bjordal graduated in Business Administration at the University of Fribourg in Switzerland in 1990 and holds an MBA degree.

### **Pierpaolo Guzzo**

Italian (born 1968), has been a Board Member and Chairman of the Management Control Committee of Cassiopea S.p.A. since 2015. Mr. Guzzo was not part of senior management of Cassiopea in the three financial years preceding the period under review and neither he nor any of the companies he is in have significant business connections with Cassiopea. Mr. Guzzo has a) no activities in governing or supervising bodies of important Swiss and foreign organisations, institutions and foundations under private and public law, b) no permanent management and consultancy functions for important Swiss nor foreign interest groups; c) no official functions nor political posts

He has been the CEO of EQValue, an Italian M&A and business advisory boutique since 2008. In his role he manages all of the key client relationships and leads deal teams.

After completing his studies, Mr. Guzzo started his career in 1993 at Arthur Andersen, where he worked for both the audit and the business consulting areas. In 1996, he joined the M&A Team of SOFIPA, an Italian Merchant Bank. In 1998, he joined the private equity team of ABN AMRO in Italy, where he served as Investment Manager. In 2000, he joined, as Director, PM & Partners S.p.A., a EUR 200 million private equity fund focused on Italian companies.

He graduated in Business Administration at the University of Rome "La Sapienza" in 1991, qualified as a CPA – Certified Public Accountant ("Dottore Commercialista") in 1993 and as an External Auditor ("Revisore Contabile") in 1997.

### **David Hale \***

American (born 1949), was a Board Member of Cassiopea S.p.A. from 2015 to 19 October 2017 when he resigned because of possible conflicts of interest. Mr. Hale was not part of senior management of Cassiopea in the three financial years preceding the period under review and he does not have significant business connections with Cassiopea. Mr. Hale had a) no activities in governing or supervising bodies of important Swiss and foreign organisations, institutions and foundations under private and public law, b) no permanent management and consultancy functions for important Swiss nor foreign interest groups; c) no official functions nor political posts

He is also Chairman and CEO of Hale BioPharma Ventures, Chairman of Biocept Inc (NASDAQ) a cancer diagnostic company and Conatus Pharmaceuticals Inc, (NASDAQ) a liver disease company. He was Chairman of Santarus prior to its sale to Salix Pharmaceuticals in 2014, Chairman of SkinMedica prior to its sale to Allergan in 2012, Chairman of Microment prior to its sale to Amgen in 2012, Chairman of Somaxon Pharmaceuticals prior to its sale to Pernisx in 2013 and Crisi Medical Systems prior to its sale to Becton-Dickinson in 2015. He co-founded CancerVax in 2000 and served as its President and CEO until its merger with Microment in 2006. From 1997 to 2000, he was President and CEO of Women First HealthCare. From 1987 to 1995, he was co-founder and Chairman of Viagene when the company was acquired by Chiron and from 1987 to 1997 he was Chairman, President and CEO of Gensia which merged with Sicom to become Gensia Sicom and then was acquired by Teva Pharmaceuticals. From 1982 to 1987, he was first COO, then President and then CEO of Hybritech when it was acquired by Eli Lilly. From 1980 to 1988, he was VP and General Manager of BBL Microbiology Systems, a division of Becton Dickinson and from 1971 to 1980 he held various marketing and sales management positions with Ortho Pharmaceutical Corporation and J&J Derm, both divisions of Johnson and Johnson.

Mr. Hale received his Bachelor of Arts degree from Jacksonville State University in Biology & Chemistry.

\* resigned as per October 2017

## **Diana Harbort**

American (born 1966), has been CEO and Board Member of Cassiopea S.p.A. since 2015. Diana Harbort is also CEO of Cassiopea since 2015. Ms. Harbort has a) no activities in governing or supervising bodies of important Swiss and foreign organisations, institutions and foundations under private and public law, b) no permanent management and consultancy functions for important Swiss nor foreign interest groups; c) no official functions nor political posts

She was the VP Corporate Development and Head of Business Development of Medicis, the largest independent specialty pharma company focusing on skin diseases, a company she joined in 1998, up until its acquisition by Valeant in 2012. From 1989 to 1998, she was at Abbott Laboratories, initially in a management professional development program, then production planning specialist, marketing product manager and business development manager.

Diana Harbort has a BBA of the University of Wisconsin Whitewater (1989) and a MBA from J.L. Kellogg Graduate School of Management, Northwestern University in 1998.

## **Board Committees**

### **The Management Control Committee**

The Management Control Committee includes the functions usually assigned to the audit committees in other jurisdictions. For a description of its responsibilities, see "Board of Directors, Management and Independent Auditors – General". The Management Control Committee is composed of Pierpaolo Guzzo, (Chairman), Jan de Vries, and Øyvind Bjordal. The Management Control Committee did not call upon any external consultants to help it deal with any of the issues addressed.

In 2017, 5 meetings, each lasting between one and three hours, of the Management Control Committee took place.

### **Nomination and Compensation Committee**

The Board of Directors has established a Nomination and Compensation Committee, which provides

recommendations to the full board and enacts guidelines for selecting candidates for the election to the Board of Directors in the event one or more directors is replaced pursuant to section 2386 of the Italian civil code. It also enacts guidelines for the appointment of senior management and makes arrangements to select such candidates. Further, it assists the Board of Directors in compensation related matters, including matters related to the Company's stock option plan. No formal compensation criteria have been defined; compensation proposals are entirely at the discretion of the Committee. The Nomination and Compensation Committee provides recommendations on and policies for the compensation of the members of the Board of Directors, the management and other employees.

The Nomination and Compensation Committee is composed of Jan E. de Vries (Chairman), and Øyvind Bjordal. In 2017, the Nomination & Compensation Committee met two times, for one hour each to discuss and approve the hiring and compensation of Alessandro Mazzetti and to discuss the compensation necessary for the extension of the agreements (post ending on 30 June 2017 of their original commitments stipulated in the IPO) with the CSO Luigi Moro and CFO Hans Christoph Tanner. It did not call upon any external consultants to help it deal with any of the issues addressed.

Neither the Management Control nor the Nomination & Compensation Committee have decision making authority. They report their findings to the full board, which then takes the necessary decisions.

### **Executive Management**

The Management is responsible for the operational management of Cassiopea S.p.A. in line with the instructions issued by the Board of Directors. The Board has decided to pursue a strategy wherein there is extreme focus on developing the existing product pipeline as efficiently as possible. To this end, the effective Executive Management Team is very small and where possible, the activities are outsourced. The Executive Management consists of persons with extensive experience in dermatology and in managing the various dermatology activities.

The table below shows the Company's senior managers' names and position within the Company (the "Management"):

<b>Name</b>	<b>Position</b>
Diana Harbort	CEO
Alessandro Mazzetti	Chief Medical Officer (as of 1 January 2017)
Luigi Moro	CSO
Marco Pasero	Chief Operating Officer
Hans Christoph Tanner	CFO; Head of IR
Marco Lecchi	Finance Director

**Diana Harbort**, American (born 1966), Chief Executive Officer of Cassiopea. See "The Board of Directors".

**Alessandro Mazzetti**, Italian (born 1952), since 1 January 2017 Chief Medical Officer and from 1 April 2014 to 31 December 2016 Chief Medical Officer of Cosmo Pharmaceutical. He has extensive experience in clinical trials having managed clinical trials at Smith Kline Beecham (1993–1996) and RBM Serono (1996–2001). Thereafter he worked as a consultant and advisor, amongst other to Cosmo. He graduated in Medicine and surgery from Florence University in 1980.

**Luigi Moro**, Italian (born 1951), Chief Scientific Officer. He has been Chief Scientific Officer of Cosmo since 2001. He graduated in chemistry and pharmacology at the University of Milan, Italy. He began his career in 1976 with Farmitalia – Carlo Erba, working on discovery/preclinical phase technological projects and the development of new drug administration systems, with particular concentration on anticancer drugs. From 1985 to 1988, with Recordati Industria Chimica e Farmaceutica S.p.A., he collaborated on the direction of technological projects of the parent company and in the definition of drug delivery systems developed by the subsidiary company Pharmetrix, a Californian

company specializing in the application of polymer membranes and control systems for problems relating to the controlled administration of drugs. He was appointed manager of the pharmaceutical technology laboratories of Poli Industria Chimica S.p.A. in 1988 and from 1990 to 1995, he coordinated that company's research activities and industrial applications in the pharmaceutical, synthesis and fermentation sector. In 1996, he became manager of industrial development, responsible for the identification of the technical resources and facilities for the industrial implementation of development projects. He is the author of numerous scientific publications and papers and inventor of numerous international technology patents. He joined Cosmo in 1999.

**Marco Pasero**, Italian (born 1966) Chief Operating Officer since 2015. He completed his studies in Economy and Commerce at the State University of Pavia in 1993 and got his accreditation as a commercialista in 2001 and as official auditor in 2002. Since 2002 he has been developing his activities as a "commercialista". He is the President of Adras S.p.A and the Sindaco of Ahsi S.p.A, Italiana Valorizzazioni Immobiliari S.r.l., and the Sindaco supplente of Carini SA, Atmos Venture S.p.A and Residenze Porta Nuova S.r.l. as well as Amministratore Unico of ARthos S.r.l., Soara Immobiliare S.r.l., Edil Mite, Vetabbia, Primal Wear Europe S.r.l., Sunnergy Group S.p.A, Pike S.r.l., La Casa del Bosco S.r.l., 20 Votes, S.r.l.

**Hans Christoph Tanner**, Swiss (born 1951), Chief Financial Officer and Head of Investor Relations, has been the CFO of Cassiopea since 2015. He is a Board Member and Head of Transactions at Cosmo Pharmaceuticals N.V. He is also a member of the board of directors or advisory board (Beirat) of DKSH AG (SIX: DKSH), Private Equity Holding AG (SIX: PEH), Paion AG (XETRA:PA8), CureVac AG, Tuebingen, Qvanteq AG and Joimax GmbH. From 1998 to 2001, he was a partner of Dr. Ernst Mueller-Moehl and co-founder of the 20 Minutes group of newspapers,

founded A&A Active Investor, a SIX listed investment company. From 1992 to 1998, he was the head of corporate finance & capital markets of UBS in Zurich and from 1976 to 1991 he had various functions in the Corporate Banking Department of UBS in Zurich, Madrid and Los Angeles. Dr. Tanner has a PhD in economics and diploma as an economist from the University of St. Gallen.

**Marco Lecchi**, Italian (born 1964), Finance Director. Head of Internal Audit of Cosmo Pharmaceuticals, he joined the Group in 2001; from 1999 to 2001 he worked as director of administration of Gianfranco Ferrè S.p.A. and its subsidiary GF Manufacturing S.r.l., and from 1992 to 1999 he worked at an international audit firm. In 1999, he gained admittance to the Official Register of Public Auditors. Marco Lecchi obtained his degree in economics and business administration, specializing in financial administration, from the Bocconi University in Milan, Italy.

All the members of the Management have their business address at the registered office of the Company.

### Service agreements

The Company has entered into Service Agreements with Cosmo Pharmaceuticals N.V. as well as with its subsidiary, Cosmo S.p.A .

### Services Agreement with Cosmo Pharmaceuticals N.V.

On 13 May 2015, the Company entered into a services agreement with Cosmo Pharmaceuticals N.V. Pursuant to this agreement, Cosmo Pharmaceuticals N.V. provides the Company with the services of its Chief Financial Officer, Hans Christoph Tanner, and its Chief Scientific Officer (CSO), Luigi Moro. The services provided under this agreement will not exceed 30% of their respective available working time and Cosmo provided the Company the services of the CSO and the CFO at no cost. The agreement had an original term of two years from the date of the IPO (1 July 2015). Upon

the expiry of the agreement, having obtained the consent of Cosmo Pharmaceuticals N.V. and of the two interested managers, the Nomination and Compensation Committee recommended and the Board approved the extension of their mandates for another two years. At the Board of Director of the Company held in November 2017, it was resolved to award to the two managers, Luigi Moro (CSO) and Hans Christoph Tanner (CFO), each 20,000 options to subscribe to Cassiopea shares; furthermore the Board resolve to award 10,000 options to Marco Lecchi (Finance director), Head of Internal Audit of Cosmo Pharmaceuticals.

### Services Agreement with Cosmo S.p.A.

On 5 June 2015, the Company entered into a services agreement with Cosmo S.p.A. Pursuant to this agreement, Cosmo S.p.A. provides the Company with general administrative services, regulatory services and clinical lots manufacturing and lab testing services. Cosmo S.p.A. is to perform these services on demand.

Cosmo S.p.A., will charge the Company for the use of its personnel at an agreed hourly rate equal to its own labor cost plus a 10% margin. Similarly, Cosmo S.p.A. will charge the Company for direct costs incurred in connection with its services, such as the cost of laboratory materials, at cost plus a 10% margin. In addition, the Company will pay Cosmo S.p.A. an annual reservation fee in the amount of EUR 200 thousand, subject to certain adjustments, to cover the provision of on-demand office space and indirect costs which cannot be separately identified, such as utilities, general services, IT assistance, phone lines and internet access.

The services agreement with Cosmo S.p.A. is for a term of three years. The Company is entitled to terminate the agreement with two months' prior notice at any time and at no cost. Cosmo S.p.A. has no right to terminate the agreement prior to the end of its term.

## Compensation, shareholdings and loans

### Compensation of Board of Directors

EUR

<b>Board of Directors</b>	<b>Function</b>	<b>Base compensation</b>	<b>Additional compensation</b>	<b>Stock options</b>	<b>Total compensation</b>
Jan E. de Vries	Nonexecutive, Chairman	35,256	–	98,983	134,239
David Hale *	Nonexecutive, Independent director	28,488	2,711 **	82,718	113,917
Øyvind Bjordal	Nonexecutive, Independent director	35,256	3,388 **	45,391	84,035
Pierpaolo Guzzo	Nonexecutive, Independent director	35,256	3,388 **	45,391	84,035
Diana Harbort	Executive, CEO	176,279	–	251,165	427,444
<b>Total</b>		<b>310,535</b>	<b>9,487</b>	<b>523,648</b>	<b>843,670</b>

\* resigned as per October 2017

\*\* compensation Management Control Committee

### Compensation for Management

The compensation of the members of Senior Management is proposed by the CEO and reviewed annually by the Compensation Committee of the Board of Directors who then requests the approval by the full Board of Directors. The compensation policy of Cassiopea is based on the following:

- The compensation consists of base salary, cash bonuses and stock-based remuneration.
- To distribute bonuses only if the Company is profitable.

Here below the compensation for the year 2017:

EUR

<b>Executive Management</b>	<b>No of members</b>	<b>Base compensation</b>	<b>Cash bonus</b>	<b>Fringe benefits</b>	<b>Stock options</b>	<b>Total compensation</b>
Executive Management ***	5 members	142,595	7,000	8,880	176,743	335,218
highest paid of 5 members		118,595	7,000	8,880	86,951	221,426

\*\*\* excluding CEO



## Stock option

Below the situation at year-end 2017:

Nonexecutive Members of the Board	Outstanding as at 1 January 2017	Granted	in 2017			Outstanding as at 31 December 2017
			Forfeited	Exercised	Expired	
Jan E. de Vries	20,000	-	-	-	-	20,000
David Hale*	20,000	-	(20,000)	-	-	-
Øyvind Bjordal	10,000	-	-	-	-	10,000
Pierpaolo Guzzo	10,000	-	-	-	-	10,000
	<b>60,000</b>	<b>-</b>	<b>(20,000)</b>	<b>-</b>	<b>-</b>	<b>40,000</b>
Of which exercisable	<b>22,000</b>					<b>28,000</b>
* resigned as per October 2017						
Executive Members of the Board and Members of Management detailed if allocation exceeds 5,000 options	Outstanding as at 1 January 2017	Granted	in 2017			Outstanding as at 31 December 2017
			Forfeited	Exercised	Expired	
Diana Harbort	50,000	-	-	-	-	50,000
Marco Pasero	10,000	-	-	-	-	10,000
Alessandro Mazzetti	-	30,000	-	-	-	30,000
Hans Christoph Tanner	-	20,000	-	-	-	20,000
Luigi Moro	-	20,000	-	-	-	20,000
Marco Lecchi	-	10,000	-	-	-	10,000
	<b>60,000</b>	<b>80,000</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>140,000</b>
Of which exercisable	<b>20,800</b>					<b>40,400</b>

### **Loans granted by the Company to Members of the Board of Directors or the Management**

The Company has not granted any loans or guarantees to any Member of the Board of Directors, the Board of Statutory Auditors or members of the Management.

### **Independent Auditors**

#### **Duration of the mandate and term of office of the Independent Auditors**

The Independent Auditors BDO Italia S.p.A. was appointed in April 2015 for the audit of the financial statements 2015 and such appointment shall expire with the approval of the 31 December 2017 financial statements. Mr. Carlo Consonni is the partner in charge for the report of the independent auditors. Auditor's honorariums for the audit of 2017 financial statements amounted to EUR 12 thousand.

In 2017, the auditor's perform additional services for the R&D tax credit and for the VAT conformity confirmation: the honorarium amounted to EUR 9 thousand.



# Financial review

## Income results

EUR 1,000

	Year ended 31 December		Change	% change
	2017	2016		
<b>Revenue</b>	-	-	-	-
Other income	3,820	5,883	(2,063)	-35.1%
Cost of sales	-	-	-	-
Research and development costs	(13,061)	(14,310)	1,249	-8.7%
Selling, general and administrative costs	(1,484)	(2,026)	542	-26.8%
<b>Net operating expenses</b>	<b>(10,725)</b>	<b>(10,453)</b>	<b>(272)</b>	<b>2.6%</b>
<b>Operating result</b>	<b>(10,725)</b>	<b>(10,453)</b>	<b>(272)</b>	<b>2.6%</b>
Financial income	484	1,245	(761)	-61.1%
Financial expenses	(3,415)	(288)	(3,127)	1085.8%
<b>Profit (loss) before taxes</b>	<b>(13,656)</b>	<b>(9,496)</b>	<b>(4,160)</b>	<b>43.8%</b>
Income tax expenses	-	-	-	-
<b>Profit (loss) for the year</b>	<b>(13,656)</b>	<b>(9,496)</b>	<b>(4,160)</b>	<b>43.8%</b>

## Revenue

The Company has no approved products, does not market any third-party products and did not enter into any licensing agreements for any of the products under development, so it had no operating revenues in 2017 and 2016.

## Net Operating expenses

Net operating expenses slightly increased from EUR 10,453 thousand to EUR 10,725 thousand: the decrease in the Research and development costs (EUR -1,249 thousand) and in the Selling, general and administrative costs (EUR -542 thousand) was partially offset by the reduction of the tax credit included in other income (EUR -2,063 thousand).

## Operating expenses as per nature

EUR 1,000

Other income	3,820
Raw materials and consumables used	(736)
Personnel expenses	(1,374)
Outsourced preclinical and clinical trial costs	(10,116)
Other operating expenses	(2,289)
Depreciation and amortization	(30)
<b>Total net operating expenses</b>	<b>(10,725)</b>

### Year ended 31 December

	2017	2016	Change	% change
Other income	3,820	5,883	(2,063)	-35.1%
Raw materials and consumables used	(736)	(375)	(361)	96.3%
Personnel expenses	(1,374)	(1,974)	600	-30.4%
Outsourced preclinical and clinical trial costs	(10,116)	(11,363)	1,247	-11.0%
Other operating expenses	(2,289)	(2,599)	310	-11.9%
Depreciation and amortization	(30)	(25)	(5)	20.0%
<b>Total net operating expenses</b>	<b>(10,725)</b>	<b>(10,453)</b>	<b>(272)</b>	<b>2.6%</b>

Other income entirely refers to the tax credit of EUR 3,820 thousand (EUR 5,883 thousand in 2016) for research and development pursuant to the Ministerial Decree of 27 May 2015. Said law provides for the grant of a tax credit to all companies investing in research and development activities with effect from the tax year 2015 to 2019. Income arising from such tax credit has been recognized only starting from 2016, when the Italian Tax Office, following a tax ruling requested by the Company, made it clear that also Phase III clinical trial costs, contrary to common interpretation, may be considered eligible for the tax credit.

Broken down by nature, the bulk of the operating expenses were outsourced preclinical and clinical trial costs which decreased from EUR 11,363 thousand to EUR 10,116 thousand (-11.0%).

Within the outsourced preclinical and clinical expense, the development of CB-03-01 Winlevi® was by far the most important cost factor representing the 85.4% of the total. However, it decreased from EUR 10,257 thousand to EUR 8,639 thousand whilst outsourced preclinical and clinical trial costs for CB-03-11 Breezula® increased from EUR 777 thousand to EUR 1,378 thousand; in 2017 no outsourced preclinical and clinical activities have been performed for the new acne antibiotic CB-06-01 while CB-06-02, the genital warts product, decreased from EUR 130 thousand to EUR 99 thousand.

Raw materials and consumables necessary for the development of these projects increased from EUR 375 thousand to EUR 736 thousand.

Personnel expenses decreased from EUR 1,974 thousand to EUR 1,374 thousand (-30.4%) mainly due to the less average number of employees (9 in 2017 vs 10.5 in 2016).

Other operating expenses decreased by 11.9% from EUR 2,599 thousand to EUR 2,289 thousand mainly due to the reduction in the R&D and Regulatory services provided by Cosmo Spa and for the reduction in the nonexecutive directors cost for the ESOP partially offset by the increase in the cost for R&D consultancies costs.

### Financial income and Expenses

Following the 2015 capital increase by EUR 49,900 thousand, the bulk of the funds were converted to US\$. Financial expenses mainly consists of foreign exchange losses on cash and cash equivalents.

### Income tax expenses

In 2017 and 2016, the Company did not recognize deferred tax assets relating to the loss before income tax due to the uncertainty of the availability of future tax profits against which such an asset may be offset.

## Assets

EUR 1,000

	As at 31 December			
	2017	2016	Change	% change
<b>Assets</b>				
Non-current assets				
Property, plant and equipment	2	2	–	0.0%
Other intangible assets	409	356	53	14.9%
Tax receivables	8,693	5,583	3,110	55.7%
<b>Total non-current assets</b>	<b>9,104</b>	<b>5,941</b>	<b>3,163</b>	<b>53.2%</b>
Current assets				
Current tax assets	312	313	(1)	–0.3%
Other receivables and other assets	1,455	2,015	(560)	–27.8%
Cash and cash equivalents	17,598	33,656	(16,058)	–47.7%
<b>Total current assets</b>	<b>19,365</b>	<b>35,984</b>	<b>(16,619)</b>	<b>–46.2%</b>
<b>Total assets</b>	<b>28,469</b>	<b>41,925</b>	<b>(13,456)</b>	<b>–32.1%</b>

As at 31 December 2017, 68.0% of all assets were current assets, the bulk of which is represented by cash and cash equivalents for EUR 17,598 thousand decreasing by EUR 16,058 thousand due to the loss of the year.

Other receivables and other assets decreased by EUR 560 thousand to EUR 1,455 thousand and mainly include prepaid expenses and VAT receivables.

Non-current assets increased from EUR 5,941 thousand to EUR 9,104 thousand mainly for the increase in the non-current tax receivable (EUR 8,693 thousand at the end of 2017) in relation to the tax credit for research and development pursuant to Ministerial Decree of 27 May 2015.

## Equity and liabilities

EUR 1,000

	As at 31 December		Change	% change
	2017	2016		
<b>Equity</b>				
Share capital	10,000	10,000	-	0.0%
Share premium	28,172	37,380	(9,208)	-24.6%
Capital contribution	122	-	122	n/a
Stock option plan reserve	1,716	1,265	451	35.7%
Profit/(Loss) for the year	(13,656)	(9,496)	(4,160)	43.8%
<b>Total equity</b>	<b>26,354</b>	<b>39,149</b>	<b>(12,795)</b>	<b>-32.7%</b>
<b>Liabilities</b>				
<b>Total non-current liabilities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>n/a</b>
<b>Current liabilities</b>				
Trade payables	2,012	2,739	(727)	-26.5%
Current tax liabilities	26	16	10	62.5%
Other current liabilities	77	21	56	266.7%
<b>Total current liabilities</b>	<b>2,115</b>	<b>2,776</b>	<b>(661)</b>	<b>-23.8%</b>
<b>Total liabilities</b>	<b>2,115</b>	<b>2,776</b>	<b>(661)</b>	<b>-23.8%</b>
<b>Total equity and liabilities</b>	<b>28,469</b>	<b>41,925</b>	<b>(13,456)</b>	<b>-32.1%</b>

Equity decreased from EUR 39,149 thousand to EUR 26,354 thousand mainly because of the 2017 loss.

The Company has no non-current liabilities.

Trade payables decreased from EUR 2,739 thousand to EUR 2,012 thousand. These payables were incurred mainly for services in conjunction with the clinical trials.

# Financial statements

## Income Statement

EUR 1,000

	Notes	Year ended 31 December	
		2017	2016
<b>Revenue</b>		-	-
Other income		3,820	5,883
Cost of sales		-	-
Research and development costs		(13,061)	(14,310)
Selling, general and administrative costs		(1,484)	(2,026)
<b>Net operating expenses</b>	4	<b>(10,725)</b>	<b>(10,453)</b>
<b>Operating result</b>		<b>(10,725)</b>	<b>(10,453)</b>
Financial income	5	484	1,245
Financial expenses	5	(3,415)	(288)
<b>Profit (loss) before taxes</b>		<b>(13,656)</b>	<b>(9,496)</b>
Income tax expenses	6	-	-
<b>Profit (loss) for the year</b>		<b>(13,656)</b>	<b>(9,496)</b>
<b>Earnings (loss) per share</b>		EUR	EUR
Basic	7	(1.366)	(0.950)
Diluted	7	(1.366)	(0.950)

## Statement of Comprehensive Income

EUR 1,000

	Notes	Year ended 31 December	
		2017	2016
<b>Profit (loss) for the year (A)</b>		<b>(13,656)</b>	<b>(9,496)</b>
Total other comprehensive income that will not be reclassified subsequently to profit or loss, net of tax (B1)		-	-
Total other comprehensive income that will be reclassified subsequently to profit or loss, net of tax (B2)		-	-
<b>Total other comprehensive income, net of tax (B)=(B1+B2)</b>		<b>-</b>	<b>-</b>
<b>Total comprehensive income (A)+(B)</b>		<b>(13,656)</b>	<b>(9,496)</b>

The notes form an integral part of the Statutory financial statements.



## Statement of Financial Position

EUR 1,000

	Notes	As at 31 December	
		2017	2016
<b>Assets</b>			
Non-current assets			
Property, plant and equipment		2	2
Other intangible assets	8	409	356
Tax receivables	9	8,693	5,583
<b>Total non-current assets</b>		<b>9,104</b>	<b>5,941</b>
Current assets			
Current tax assets	10	312	313
Other receivables and other assets	11	1,455	2,015
Cash and cash equivalents	12	17,598	33,656
<b>Total current assets</b>		<b>19,365</b>	<b>35,984</b>
<b>Total assets</b>		<b>28,469</b>	<b>41,925</b>
<b>Equity</b>			
Share capital		10,000	10,000
Share premium		28,172	37,380
Capital contribution		122	–
Stock option plan reserve		1,716	1,265
Profit/(Loss) for the year		(13,656)	(9,496)
<b>Total equity</b>	13	<b>26,354</b>	<b>39,149</b>
<b>Liabilities</b>			
<b>Total non-current liabilities</b>			
–			
Current liabilities			
Trade payables	14	2,012	2,739
Current tax liabilities	15	26	16
Other current liabilities	16	77	21
<b>Total current liabilities</b>		<b>2,115</b>	<b>2,776</b>
<b>Total liabilities</b>		<b>2,115</b>	<b>2,776</b>
<b>Total equity and liabilities</b>		<b>28,469</b>	<b>41,925</b>

The notes form an integral part of the Statutory financial statements.

## Cash Flow Statement

EUR 1,000

	Notes	As at 31 December	
		2017	2016
<b>Profit (loss) before taxes</b>		<b>(13,656)</b>	<b>(9,496)</b>
Tax credit R&D costs	4	(3,820)	(5,883)
R&D credit offset		710	-
Depreciation and amortization	4	30	25
Share payment based expenses	17	861	1,464
Unrealised foreign exchange (gain) losses on cash and cash equivalents		2,366	(1,005)
		<b>(13,509)</b>	<b>(14,895)</b>
Change in trade payables		(727)	104
Change in other receivables and other assets		560	(532)
Change in other current liabilities		56	17
Change in current tax assets		1	(5)
Change in current tax liabilities		10	-
<b>Cash flows from operating activities</b>		<b>(13,609)</b>	<b>(15,311)</b>
Investments in property, plant and equipment		-	(1)
Investments in other intangible assets	8	(83)	(150)
<b>Cash flows from investing activities</b>		<b>(83)</b>	<b>(151)</b>
<b>Cash flows from financing activities</b>		<b>-</b>	<b>-</b>
<b>Unrealised foreign exchange gain (losses) on cash and cash equivalents</b>		<b>(2,366)</b>	<b>1,005</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>		<b>(16,058)</b>	<b>(14,457)</b>
<b>Cash and cash equivalents at the beginning of the year</b>	12	<b>33,656</b>	<b>48,113</b>
<b>Cash and cash equivalents at the end of the year</b>	12	<b>17,598</b>	<b>33,656</b>
Cash at hand		-	-
Bank accounts		17,598	33,656
Advances on invoices and bank overdraft		-	-
<b>Total cash and cash equivalents at the end of the year</b>	12	<b>17,598</b>	<b>33,656</b>

The notes form an integral part of the Statutory financial statements.

## Statement of Changes in Equity

EUR 1,000	Number of Shares	Share capital	Share premium	Extraordinary reserve	Capital contribution	Stock option plan reserve	Retained earnings	Total
<b>Net equity as at 1 January 2016</b>	<b>10,000,000</b>	<b>10,000</b>	<b>40,000</b>	<b>3,526</b>	<b>-</b>	<b>106</b>	<b>(6,451)</b>	<b>47,181</b>
Allocation of prior year result			(2,925)	(3,526)			6,451	-
Cost for stock options						1,464		1,464
Forfeited stock options			305			(305)		-
Total comprehensive income for the year							(9,496)	(9,496)
<b>Net equity as at 31 December 2016</b>	<b>10,000,000</b>	<b>10,000</b>	<b>37,380</b>	<b>-</b>	<b>-</b>	<b>1,265</b>	<b>(9,496)</b>	<b>39,149</b>

EUR 1,000	Number of Shares	Share capital	Share premium	Extraordinary reserve	Capital contribution	Stock option plan reserve	Retained earnings	Total
<b>Net equity as at 1 January 2017</b>	<b>10,000,000</b>	<b>10,000</b>	<b>37,380</b>	<b>-</b>	<b>-</b>	<b>1,265</b>	<b>(9,496)</b>	<b>39,149</b>
Allocation of prior year result			(9,496)				9,496	-
Cost for stock options					122	739		861
Forfeited stock options			288			(288)		-
Total comprehensive income for the year							(13,656)	(13,656)
<b>Net equity as at 31 December 2017</b>	<b>10,000,000</b>	<b>10,000</b>	<b>28,172</b>	<b>-</b>	<b>122</b>	<b>1,716</b>	<b>(13,656)</b>	<b>26,354</b>

The notes form an integral part of the Statutory financial statements.

# Notes to the financial statements

## 1 General information

### The company and its core business

Cassiopea S.p.A. ("Cassiopea" or the "Company") is a company established and domiciled in Italy. The address of the registered office is Via Cristoforo Colombo 1, Lainate (MI), Italy.

Cassiopea is a clinical-stage specialty pharmaceutical company focused on developing and commercializing innovative and differentiated medical dermatology products: the initial focus is on the topical treatment of acne, androgenic alopecia, (or AGA), and genital warts. 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"), and target unmet medical needs and 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 establish Cassiopea as a pure play, fully integrated company whose mission is to identify, develop and commercialize treatments for skin diseases.

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

- \_ Winlevi®, which is being developed as first-in-class antiandrogen for the topical treatment of acne;
- \_ Breezula®, which is being developed as the first antiandrogen for the topical treatment of androgenic 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 31 December 2017 was equal to CHF 348,000,000.

## 2 Basis of preparation

The 2017 financial statements together with the notes thereto (the "Annual Report 2017") were authorized for issuance on 27 February 2018 and 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).

The accounting principles and policies used in preparation of the financial statements are consistent with those used in the Financial statements for the year ended 31 December 2016, except as otherwise stated under "New accounting standard and IFRIC interpretations" in the following paragraphs.

Cassiopea's financial statements and notes are prepared and expressed in thousands of euros, except where otherwise stated, rounding the amounts to the nearest thousand.

## 3 Basis of accounting

### 3.1 Classification criteria

The financial statements and related classification criteria adopted for the preparation of the Company's Financial statements are based on the option allowed by IAS1 – Presentation of financial statements:

- \_ the statement of financial position has been prepared presenting asset and liabilities as current and non-current;
- \_ the income statement presents a classification based on the function of expenses ("cost of sales method");

- \_ the statement of comprehensive income includes other changes in equity related to non-owner transactions as well as the profit/loss of the year;
- \_ the statements of cash flows present cash flows from operating activities using the indirect method;
- \_ the statement of changes in equity includes all the changes in equity.

### 3.2 Measurement criteria

The financial statements have been prepared using the historical cost criterion, except where it is mandatory to measure financial assets and liabilities at fair value.

The Company, since it was incorporated, has sustained losses mainly because of the massive research and clinical development costs incurred for its products and its business plans project that further operating losses will be incurred at least until one of its products is launched for sale or out-licensed.

The financial statements have been prepared on a going concern basis as the financial resources made available by the shareholders were considered adequate to meet the cash requirements projected in the business plans. The Company's current cash position, considering the level of spending planned in the management's budget to conclude the Winlevi® Phase 3, will allow it to meet its obligations as they fall due for a period of at least 12 months from the date of signing the financial statements. If the Company moves toward regulatory submission and pre-commercial activities for Winlevi®, and begins to build the company's infrastructure, further funding, as originally plan, will be required through a capital raise or other financing event.

### 3.3 Accounting policies

The accounting policies adopted are consistent with those of the previous financial year, as no new IFRS or IFRIC interpretations that became effective on 1 January 2017 are relevant for the Company's operations.

### Standards, amendments and interpretations effective from 1 January 2017 but not applicable to the Company

The following new standards and amendments, which were effective from 1 January 2017, were adopted by the Company. The adoption of these amendments had no effect on the Financial Statements.

- \_ Amendments to IAS 12 – Income Taxes that clarify how to account for deferred tax assets related to debt instruments measured at fair value.
- \_ Amendments to IAS 7 – Statement of Cash Flows introducing additional disclosures that will enable users of financial statements to evaluate changes in liabilities arising from financing activities.
- \_ Amendments to IFRS 12 – Disclosure of Interests in Other Entities

### Accounting principles, amendments and interpretations not yet applicable and not early adopted by the Company

- \_ IFRS 15 – Revenue from contracts with customers ("IFRS 15"), which was issued by the IASB in May 2014 and amended in September 2015. The standard requires a company to recognize revenue upon transfer of control of goods or services to a customer at an amount that reflects the consideration it expects to receive using a five-step process. The new standard also requires additional disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. The standard is effective for annual periods beginning on or after 1 January 2018, and requires either a full or modified retrospective application. Considering that the Company has not operating revenues, the new standard will not impact the financials of the Company.

- \_ In July 2014, the IASB issued IFRS 9 – Financial Instruments. The improvements introduced by the new standard includes a logical approach for classification and measurement of financial instruments driven by cash flow characteristics and the business model in which an asset is held,

a single “expected loss” impairment model for financial assets and a substantially reformed approach for hedge accounting. The standard is effective, retrospectively with limited exceptions, for annual periods beginning on or after 1 January 2018 with earlier application permitted. Considering the financial assets and liabilities of the Company, the new standard will not have impact on the Company.

In January 2016, the IASB issued IFRS 16 – Leases. The new standard has developed a new approach to lease accounting that require a lessee to recognize assets and liabilities for the rights and obligations created by the lease. The standard replaces IAS 17 Leases and is effective for annual periods beginning on or after 1 January 2019. Early application is permitted for companies that also apply IFRS 15 Revenue from Contracts with Customers.

In June 2016, the IASB issued amendment to IFRS 2 Share-based Payment in relation to the classification and measurement of share-based payment transactions. The amendments are intended to eliminate diversity in practice in three main areas: the effects of vesting conditions on the measurement of a cash-settled share-based payment transaction, the classification of a share-based payment transaction with net settlement features for withholding tax obligations, the accounting where a modification to the terms and conditions of a share-based payment transaction changes its classification from cash-settled to equity-settled. The amendments are effective from 1 January 2018, with earlier adoption permitted.

In September 2016, the IASB published “Applying IFRS 9, Financial Instruments with IFRS 4, Insurance Contracts” (Amendments to IFRS 4). The amendments provide two options for entities that issue insurance contracts within the scope of IFRS 4: (i) an option that permits entities to reclassify, from profit or loss to other comprehensive income, some of the income or expenses

arising from designated financial assets (the “overlay approach”) and (ii) an optional temporary exemption from applying IFRS 9 for entities whose predominant activity is issuing contracts within the scope of IFRS 4 (the “deferral approach”). An entity would apply the overlay approach retrospectively to qualifying financial assets when it first applies IFRS 9. An entity would apply the deferral approach for annual periods beginning on or after 1 January 2018. The deferral can only be used for the three years following 1 January 2018. The application of both approaches is optional and an entity is permitted to stop applying them before the new insurance contracts standard is applied.

In December 2016, the IASB issued Annual Improvements to IFRS Standards 2014–2016 Cycle which included amendments to IAS 28 – Investments in Associates and Joint Ventures (effective date of 1 January 2018). The amendments clarify, correct or remove redundant wording in the related IFRS Standard.

In December 2016, the IASB issued IFRIC Interpretation 22 – Foreign Currency Transactions and Advance Consideration which addresses the exchange rate to use in transactions that involve advance consideration paid or received in a foreign currency. The interpretation is effective 1 January 2018.

In June 2017, the IASB issued IFRIC 23 “Uncertainty over Income Tax Treatments” to clarify the accounting for uncertainties in income taxes. The interpretation addresses the determination of taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates, when there is uncertainty over income tax treatments under IAS 12. The interpretation is applicable to annual reporting periods beginning on or after 1 January 2019.

In October 2017, the IASB issued Prepayment Features with Negative Compensation (Amendments to IFRS 9), allowing companies to measure

particular prepayable financial assets with so-called negative compensation at amortized cost or at fair value through other comprehensive income if a specified condition is met, instead of at fair value through profit or loss, effective January 1, 2019.

In October 2017, the IASB issued Long-term interests in associates and joint ventures (Amendments to IAS 28), clarifying that companies account for long-term interests in an associate or joint venture to which the equity method is not applied using IFRS 9, effective January 1, 2019.

In December 2017, the IASB issued the Annual Improvements to IFRSs 2015–2017, a series of amendments to IFRSs in response to issues raised mainly on IFRS 3 – Business Combinations, which clarifies that a company remeasure its previously held interest in a joint operation when it obtains control of the business, on IFRS 11 – Joint Arrangements, a company does not remeasure its previously held interest in a joint operation when it obtains joint control of the business, on IAS 12 – Income Taxes, which clarifies that all income tax consequences of dividends (i.e. distribution of profits) should be recognized in profit or loss, regardless of how the tax arises, and on IAS 23 – Borrowing Costs, which clarifies that a company treats as part of general borrowing any borrowing originally made to develop an asset when the asset is ready for its intended use or sale. The effective date of the amendments is January 1, 2019.

In February 2018, the IASB issued Plan Amendment, Curtailment or Settlement (Amendments to IAS 19) which specifies how companies determine pension expenses when changes to a defined benefit pension plan occur. IAS 19 Employee Benefits specifies how a company accounts for a defined benefit plan. When a change to a plan—an amendment, curtailment or settlement—takes place, IAS 19 requires a company to remeasure its net defined benefit liability or asset. The amendments require a company to use the updated assumptions from

this remeasurement to determine current service cost and net interest for the remainder of the reporting period after the change to the plan. The amendments are effective on or after 1 January 2019.

### **Summary of significant accounting policies and practices**

The most significant accounting policies and measurement criteria applied to prepare the financial statements are summarized below.

#### **Property, plant and equipment**

Property, plant and equipment are stated at cost including related expenses, less accumulated depreciation and impairment losses.

Depreciation is recognized starting from the month in which the asset is available for use or potentially able to provide the economic benefits associated therewith on a systematic basis, whereby the assets are depreciated over their useful lives or, in the event of disposal, until their final month of use.

For assets disposed of during the year, depreciation is calculated for the period in which the asset was available for use, excluding assets purchased during the year.

Residual amounts, useful lives and the depreciation methods are reviewed at the end of every accounting period.

The depreciation rates applied to the items of property, plant and equipment are the following:

Other tangible assets – office equipment electronics:  
5 years

#### **Other intangible assets**

Other intangible assets are recognized as assets where it is probable that the use of the asset will generate future economic benefits and where the costs of the asset can be determined reliably. Other intangible assets that are acquired by the Company are stated at cost less accumulated amortization (see below) and impairment losses, if any.

Subsequent expenditures on capitalized intangible assets are capitalized only when they increase the future economic benefits embodied in the specific assets to which they relate. All other expenditure is expensed as incurred.

Other intangible assets with definite useful lives are amortized on a straight-line basis over their useful lives, being the estimated period over which the Company will use the assets. Other intangible assets are amortized from the date they are available for use.

Residual amounts, useful lives and the amortization methods are reviewed at the end of every accounting period. The estimated useful lives are as follows:

- \_ Patents and rights 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 15.6 years).
- \_ Expenditures on research activities, undertaken with the prospect of gaining new technical knowledge and understanding, are recognized in the income statements as an expense as incurred.

Development costs are capitalized as an intangible asset if all of the following criteria are met:

- \_ the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- \_ the intention to complete the intangible asset and use or sell it;
- \_ the ability to use or sell the intangible asset;
- \_ the asset will generate probable future economic benefits and demonstrate the existence of a market or the usefulness of the intangible asset if it is to be used internally;
- \_ the availability of adequate technical, financial and other resources to complete the development and to use or sell it;
- \_ the ability to measure reliably the expenditure attributable to the intangible asset during its development.

Following initial recognition of the development expenditure as an intangible asset, the cost model is applied requiring the intangible asset to be carried at cost, less any accumulated amortization and accumulated impairment losses. The intangible

asset is amortized on a straight-line basis over the period of its expected benefit, starting from the date of full commercial use of the product. During the period of development, the asset is tested for impairment annually.

If specific events indicate that impairment of an item of intangible asset may have taken place, the item's recoverability is assessed by comparing its carrying amount with its recoverable amount.

### **Foreign currency transactions**

Transactions in foreign currency are translated into Euros using the exchange rate ruling on the transaction date. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated into Euros at the foreign exchange rate ruling at that date. Foreign exchange differences arising on translation are recognized in the income statement. Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currencies that are stated at fair value are translated into Euros at foreign exchange rates ruling at the dates the fair value was determined.

### **Trade and other receivables and payables**

Trade and other receivables are stated at amortized cost net of impairment losses. The impairment loss is calculated on the basis of recovery assessments by analysing each receivable considered unlikely to be collected and the overall risk of non-recovery of the receivables. When the payment of the sum due is postponed beyond normal credit terms offered to customers, it is necessary to discount the receivable.

Trade and other payables are measured at amortized cost which reflects the effective interest rate in the income statement and represents the rate used to discount the expected future cash flows to the carrying value of the assets to which they relate.

They are included in current assets or liabilities, except for maturities greater than 12 months after the balance sheet date.



### **Cash and cash equivalents**

Cash and cash equivalents comprises cash balances and call deposits. Cash equivalents are short-term and highly liquid investments, mainly time deposits, that are readily convertible to known amounts of cash, are subject to risk of fluctuations and have an original maturity of no more than three months.

### **Employee benefits**

Obligations for contributions to defined contribution pension plans are recognized as an expense in the income statement as incurred.

### **Forms of remuneration involving participation in stock capital (stock option plans)**

The Company grants additional benefits to the Board and senior management and key employees through stock option plans. Pursuant to IFRS 2, "Share-based payment", these plans represent a form of remuneration for the beneficiaries. The cost is equal to the fair value as calculated on the date the option rights are granted and is recorded in the income statement on a straight-line basis over the vesting period, i.e., the date between the date the stock option plan was granted and the date the rights matured. The corresponding entry is made directly to shareholders' equity. Changes in fair value after the grant date do not have an effect on the initial valuation. At each balance sheet date, the Company revises its estimate of the number of options that are expected to become exercisable.

It recognizes the impact of the revision to original estimates, if any, in the income statements, with a corresponding adjustment to equity. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium when the options are exercised.

### **Revenue and cost recognition**

Revenue, income, costs and charges are recorded net of discounts and allowances.

Revenues from licensing contracts for non-refundable up-front fees, in situations where no further performance

obligation exists, are recognized on the earlier of when payments are received or collection is assured. Up-front fees related to future performance obligations are either spread over the duration of such obligations or part of the revenue provisioned therefore. Where continuing significant involvement is required in the form of support, revenues are recognized over the relevant period.

Revenues from licensing contracts for milestones are recognized in the period the outcome can be estimated reliably, which is in general when the milestone is successfully achieved, which is determined when the funding party agrees that the required results stipulated in the agreement have been met.

Government grant income is recognized when it is reasonably certain that it will be received. This takes place when the grant is approved by the relevant public sector bodies. This income is recognized based on the costs actually incurred.

Expenditures on research activities, undertaken with the prospect of gaining new technical knowledge and understanding, as well as development costs not capitalized, are recognized in the income statement as an expense as incurred. Since inception, all research and development costs have been treated as expenses

### **Income tax**

The tax charge for the period is determined on the basis of prevailing laws and regulations. Taxes on income are recognized in the income statement except to the extent that they relate to items directly charged or credited to equity, in which case the related income tax effect is recognized in equity.

Deferred tax assets and liabilities are determined on the basis of all the temporary differences between the carrying amount of an asset or liability in the statement of financial position and its corresponding tax basis. Deferred tax assets resulting from unused tax losses and temporary differences are recognized to the extent that it is probable that future taxable profit will be available against which they can be utilized.

Current and deferred income taxes and liabilities are offset when there is a legally enforceable right to offset. Deferred tax assets and liabilities are measured at the substantively enacted tax rates that are expected to apply to taxable income in the periods in which temporary differences will be reversed.

### **Earnings per share**

Basic earnings per share are calculated dividing the net profit (loss) attributable to the owners of ordinary shares in the Company (the numerator) by the weighted average number of ordinary shares in issue (the denominator) during the year.

Diluted earnings per share is calculated by adjusting the net profit attributable to owners of ordinary shares and the weighted average number of ordinary shares during the year to take account of all potential ordinary shares with a diluting effect. A potential ordinary share is a financial instrument or other contract that could give its owner the right to obtain ordinary shares.

### **3.4 Critical accounting estimates, assumptions and judgments**

The preparation of the 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. Such estimates and assumptions are based on accumulated experience and on other factors deemed to be appropriate in the calculation of the carrying amounts of assets and liabilities that cannot be measured on the basis of other sources. Revisions to accounting estimates are recognized in the period in which the estimate is revised and any future period affected.

Accounting estimates that require the more subjective judgment of the Management in making assumptions or estimates regarding the effects of matters that are inherently uncertain and for which changes in conditions may significantly affect the results reported in the financial statements, are reported below.

### **Deferred tax assets**

The Company has a considerable amount of tax losses carried forward that allow for the recognition of deferred tax assets. Deferred tax assets are recognized only to the extent that it is probable that future taxable profits will be available against which the asset can be utilized, determined on the basis of future results forecasts.

### **Share-based compensation expenses**

The Company has granted stock options to some of its employees and Directors. Since there is no market for trading stock options, the Management must use a fair-value method to value the stock options. Fair-value methods require the Management to make several assumptions, the most significant of which are the selection of a fair value model, stock price volatility and the average life of an option. The fair value of the stock options is determined separately by an external appraiser. Estimates have been based on Company history or market data where appropriate. There is no certainty that the results of a fair-value method would be the value at which the stock options would be traded for cash. Should different assumptions be used, the expenditure recognized could be different. Additional information is reported in "Accounting policies – Employee benefits – Forms of remuneration involving participation in stock capital (stock option plans)."

#### 4 Net operating expenses

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

EUR 1,000	Year ended 31 December	
	2017	2016
Other income	3,820	5,883
Raw materials and consumables used	(736)	(375)
Personnel expenses	(1,374)	(1,974)
Outsourced preclinical and clinical trial costs	(10,116)	(11,363)
Other operating expenses	(2,289)	(2,599)
Depreciation and amortization	(30)	(25)
<b>Total net operating expenses</b>	<b>(10,725)</b>	<b>(10,453)</b>

#### Other income

Other income entirely refers to the tax credit of EUR 3,820 thousand (EUR 5,883 thousand in 2016) for research and development pursuant to Ministerial Decree of 27 May 2015, implementing Law No. 190 of 23 December 2014 (2015 Stability Law). Said law provides for the grant of a tax credit to all companies investing in research and development activities with effect from the tax year 2015 to 2019. Income arising from such tax credit has been recognized only starting from 2016 (in 2016 EUR 1,501 thousand included in EUR 5,883 thousand, refers to 2015 costs for R&D

activities), when the Italian Tax Office, following a tax ruling requested by the Company, made it clear that also Phase III clinical trial costs, contrary to common interpretation, may be considered eligible for the tax credit. The R&D tax credit is calculated every year as a percentage of the increase in the R&D expenses in comparison with the average R&D costs for the period 2012–2014. The R&D tax credit can be used to offset income/regional taxes and social security contributions in the payment form (Modello F24) since the year following that ongoing when expenses were borne.

#### Raw materials and consumables used

The item "Raw materials and consumables used" comprises the following:

EUR 1,000	Year ended 31 December	
	2017	2016
Purchase of consumables	1	1
Purchase of laboratory supplies and materials for clinical trial	735	374
<b>Total raw materials and consumables used</b>	<b>736</b>	<b>375</b>

#### Personnel expenses

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

EUR 1,000	Year ended 31 December	
	2017	2016
Salaries and wages	658	1,057
Social security contributions	101	23
Employee benefits	18	4
Stock options	588	890
Other costs	9	–
<b>Total personnel expenses</b>	<b>1,374</b>	<b>1,974</b>

In 2017, the expense for the value of employees' and executives Directors' services exchanged for stock options amounted to EUR 588 thousand (EUR 890 thousand in 2016) and it refers to the cost accounted in relation to the options granted by the Board of Directors in the period 2015–2017 and to the options granted

by Cosmo Pharmaceuticals N.V. (see note 17, "Share-based payments").

The average numbers of the entire staff for the years ended 31 December 2017 and 2016 are the following:

No. of people	Year ended 31 December	
	2017	2016
Managers *	5.0	4.5
Junior managers	4.0	6.0
<b>Total average number</b>	<b>9.0</b>	<b>10.5</b>

The entire staff as at 31 December 2017 and 2016 is shown by category here below:

No. of people	Year ended 31 December	
	2017	2016
Managers *	6	5
Junior managers	4	6
<b>Total number</b>	<b>10</b>	<b>11</b>

\*Includes the managers provided by Cosmo Pharmaceuticals N.V. as for service agreement (see note 18 "Related parties transactions")

In addition, the companies of the Cosmo Pharmaceuticals N.V. group provide the services for research & development, regulatory, secretarial, and accounting services at

a cost determined in the Services Agreement (see note 18 "Related parties transactions").

### Outsourced preclinical and clinical trial costs

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

EUR 1,000	Year ended 31 December	
	2017	2016
CB-03-01 Winlevi®	8,639	10,257
CB-03-11 Breezula®	1,378	777
CB-06-01	–	199
CB-06-02	99	130
<b>Outsourced preclinical and clinical trials costs</b>	<b>10,116</b>	<b>11,363</b>

## Other operating expenses

Other operating expenses comprises the following:

EUR 1,000	Year ended 31 December	
	2017	2016
Service costs	2,275	2,594
Operating lease expenses	9	–
Other operating costs	5	5
<b>Total other operating expenses</b>	<b>2,289</b>	<b>2,599</b>

“Service costs” mainly comprises costs for professional and consultancy services (i.e., scientific and administrative services), cost for the maintenance of the patent, and costs for the investor relations activities.

Service costs in 2017 also include EUR 273 thousand (EUR 574 thousand in 2016) for the Stock Option Plan to the nonexecutive directors and it refers to the cost accounted in relation to the options granted by the Board of Directors on 3 December 2015.

EUR 1,000	Year ended 31 December	
	2017	2016
External consultancy services	481	378
Patent costs	173	144
Investor relations and web site maintenance	162	161
Technical assistance	5	4
Utilities, telephone, internet	10	8
Insurance	143	147
Nonexecutive directors	134	145
Stock options nonexecutive directors	273	574
Management control committee	10	12
Auditing	12	12
Advertising and marketing costs	18	6
Freight and customs	54	58
Travel expenses	141	107
External laboratory services	134	91
R&D and Regulatory services	517	739
Other costs	8	8
<b>Total service costs</b>	<b>2,275</b>	<b>2,594</b>

In the period ended 31 December 2017, the Company has been charged by Cosmo S.p.A. and by Bellatrix Inc. (subsidiaries of Cosmo Pharmaceuticals N.V.) for an amount of EUR 465 thousand and EUR 52 thousand respectively (EUR 720 thousand and EUR 19 thousand in 2016) for Research/Development/Regulatory services.

In 2017, the Company has been charged by Cosmo S.p.A. for secretarial and accounting services for an amount of EUR 138 thousand, included in External consultancy services (EUR 130 thousand in 2016).

## Depreciation and amortization

The item comprises the following:

EUR 1,000	Year ended 31 December	
	2017	2016
Depreciation of property, plant and equipment	–	1
Amortization of other intangible assets	30	24
<b>Total depreciation and amortization</b>	<b>30</b>	<b>25</b>

## 5 Financial income/expenses

The item comprises the following:

EUR 1,000	Year ended 31 December	
	2017	2016
Financial income:		
Other	484	1,245
<b>Total financial income</b>	<b>484</b>	<b>1,245</b>
Financial expenses:		
Other	3,415	288
<b>Total financial expenses</b>	<b>3,415</b>	<b>288</b>
<b>Financial income (expense), net</b>	<b>(2,931)</b>	<b>957</b>

Other financial income as at 31 December 2017 includes EUR 217 thousand for foreign exchange differences (EUR 1,033 thousand in 2016) and EUR 266 thousand for interest received on cash and cash equivalents (EUR 210 thousand in 2016); financial expenses mainly includes foreign exchange differences.

## 6 Income tax expenses

On the tax losses and on the Italian fiscal relief "ACE" (Aiuto alla crescita economica) for 2017 and 2016 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.

The reconciliation between theoretical income taxes determined on the basis of the tax rates applicable and the income taxes reported in the financial statements for the year ended 31 December 2017 and 2016 is as follows:

EUR 1,000	As at 31 December	
	2017	2016
<b>Profit before taxes</b>	<b>(13,656)</b>	<b>(9,496)</b>
Nominal Tax rate - Ires	24.00%	27.50%
Nominal Tax rate - Irap	3.90%	3.90%
<b>Total theoretical income taxes</b>	<b>(3,810)</b>	<b>(2,982)</b>
Permanent difference relating to ACE	(101)	(446)
Permanent difference R&D tax credit	(1,066)	(1,847)
Tax effect of other permanent differences	(6)	3
Unrecognised theoretical tax benefit for tax loss carryforwards (a)	4,301	4,134
Unrecognised theoretical tax benefit for change nominal rate Ires (b)	0	538
Unrecognised theoretical tax benefit for tax loss for Irap tax	682	600
<b>Current and deferred income tax recognised in the financial statements</b>	<b>0</b>	<b>0</b>

Notes:

(a) Due to uncertainty for the taxable profit in the foreseeable future, no deferred tax asset calculated for tax loss carryforwards

(b) Starting from 1 January 2017 the Italian tax laws lowered the IRES rate from 27.5% to 24%

According to the amended article 84 of the Italian TUIR, the losses can be carried forward indefinitely, but a quantitative limit for the use of tax losses is introduced, up to 80% of the income realized in the subsequent years. The quantitative limit of 80%

does not apply to losses that arose in the first three years from the establishment of the Company.

A summary of tax incurred since inception and the related gross and net deferred tax assets is provided in the following table:

EUR 1,000	Tax losses Carryforward	%	Deferred tax assets	Quantitative limit
Created in first 3 year from the establishment	–	24.00%	–	100% of income in subsequent years
Created in the following years	43,140	24.00%	10,354	80% of income in subsequent years
	<b>43,140</b>		<b>10,354</b>	

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

Basic earnings (loss) per shares are calculated by dividing the net profit (loss) for the year attributable to ordinary shareholders by the weighted average

number of shares outstanding during the year. Basic earnings (loss) per share are as follows:

	Year ended 31 December	
	2017	2016
Net profit (loss) attributable to Shareholders (in EUR 1,000)	(13,656)	(9,496)
Weighted average number shares	10,000,000	10,000,000
<b>Basic earnings (loss) per share (in EUR)</b>	<b>(1.366)</b>	<b>(0.950)</b>

Diluted earnings (loss) per share are calculated by dividing the net profit for the year attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year, 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 Other intangible assets

"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 15.6 years).

EUR 1,000	Patents and rights	Total
<b>Net book value as at 1 January 2016</b>	<b>230</b>	<b>230</b>
Additions of the year	150	150
Amortization charge for the year	(24)	(24)
<b>Net book value as at 31 December 2016</b>	<b>356</b>	<b>356</b>
Additions of the year	83	83
Amortization charge for the year	(30)	(30)
<b>Net book value as at 31 December 2017</b>	<b>409</b>	<b>409</b>

## 9 Tax receivables (non current)

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Tax credit R&D costs	8,693	5,583
<b>Total tax receivables</b>	<b>8,693</b>	<b>5,583</b>

Tax receivables refer to the non-current amount of the tax credit for research and development pursuant to Ministerial Decree of 27 May 2015, implementing

Law No. 190 of 23 December 2014 (2015 Stability Law) (see note 4, "Net operating expenses" – Other income).



## 10 Current tax assets

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Advance payments of income taxes	12	13
Tax credit R&D costs	300	300
<b>Total current tax assets</b>	<b>312</b>	<b>313</b>

Tax credit R&D costs refers to the current amount of tax credit for research and development pursuant to Ministerial Decree of 27 May 2015, that will be offset against social security contributions and withholdings tax in the course of the 2018.

## 11 Other receivables and other assets

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
VAT receivables	892	1,118
Prepaid expenses	396	665
Other prepaid	167	232
<b>Total other receivables and other assets</b>	<b>1,455</b>	<b>2,015</b>

## 12 Cash and cash equivalents

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Cash at hand	-	-
Bank accounts	17,598	33,656
<b>Total cash and cash equivalents</b>	<b>17,598</b>	<b>33,656</b>

"Bank accounts" include availability on current bank accounts and short-term "time deposit" bank contracts. Part of the availability is held in US\$ and in particular

as at 31 December 2017 the amount includes US\$ 20,598 thousand equal to EUR 17,175 thousand at 31 December 2017 exchange rate.

### 13 Total shareholders' equity

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Share capital	10,000	10,000
Share premium	28,172	37,380
Capital contribution	122	–
Stock option plan reserve	1,716	1,265
Profit/(Loss) for the year	(13,656)	(9,496)
<b>Total equity</b>	<b>26,354</b>	<b>39,149</b>

#### Share capital

As at 31 December 2017 and 2016, Cassiopea S.p.A. had 10,000,000 shares issued, fully subscribed and paid up, each share with a nominal value of EUR 1.00, for a total share capital of EUR 10,000 thousand.

#### Share premium

"Share premium" refers to the proceeds from April 2015 capital increase, partially reduced in relation to the allocation of the 2015 and 2016 losses.

#### Capital contribution

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

#### Stock option plan reserve

In 2017, the expense for the stock options allocated in the period 2015–2017, amounted to EUR 739 thousand of which EUR 466 thousand for management and personnel and EUR 273 thousand for nonexecutive Directors (In 2016 EUR 890 thousand and EUR 574 thousand respectively). The decrease of EUR 288 thousand refers to the stock option forfeited in 2017.

### 14 Trade payables

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Trade payables	1,956	2,482
Trade payables related company	56	257
<b>Total trade payables</b>	<b>2,012</b>	<b>2,739</b>

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

## 15 Current tax liabilities

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Withholding tax for employees	16	4
Withholding tax for consultants	10	12
<b>Total current tax liabilities</b>	<b>26</b>	<b>16</b>

## 16 Other current liabilities

The item comprises the following:

EUR 1,000	As at 31 December	
	2017	2016
Social security payables	23	4
Other liabilities	54	17
<b>Total other current liabilities</b>	<b>77</b>	<b>21</b>

## 17 Share-based payment

The extraordinary shareholders' meeting of 27 May 2015 authorized the Board of Directors to increase the capital by a nominal amount of EUR 500,000 by issuing 500,000 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 3 December 2015, the Board of Directors granted a total of 140,000 options of which:

- \_ 49,800 with a vesting period of 1 year, expiring on 3 December 2021 and an exercise price of CHF 34 ("Option series 1a")
- \_ 46,600 with a vesting period of 2 years, expiring on 3 December 2022 and an exercise price of CHF 34 ("Option series 1b")
- \_ 43,600 with a vesting period of 3 years, expiring on 3 December 2023 and an exercise price of CHF 34 ("Option series 1c")

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 14.45 per option ("Option series 1a"), of CHF 19.28 per option ("Option series 1b") and of CHF 22.56 per option ("Option series 1c").

On 23 February 2016, the Board of Directors granted a total of 20,000 options of which:

- \_ 6,800 with a vesting period of 1 year, expiring on 23 February 2022 and an exercise price of CHF 34 ("Option series 2a")
- \_ 6,700 with a vesting period of 2 years, expiring on 23 February 2023 and an exercise price of CHF 34 ("Option series 2b")
- \_ 6,500 with a vesting period of 3 years, expiring on 23 February 2024 and an exercise price of CHF 34 ("Option series 2c")

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 11.28 per option ("Option series 2a"), of CHF 15.87 per option ("Option series 2b") and of CHF 18.98 per option ("Option series 2c").

On 23 February 2017, the Board of Directors granted a total of 12,000 options of which:

- \_ 4,100 with a vesting period of 1 year, expiring on 23 February 2023 and an exercise price of CHF 34 ("Option series 3a")

\_ 4,000 with a vesting period of 2 years, expiring on 23 February 2024 and an exercise price of CHF 34 ("Option series 3b")

\_ 3,900 with a vesting period of 3 years, expiring on 23 February 2025 and an exercise price of CHF 34 ("Option series 3c")

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 11.59 per option ("Option series 3a"), of CHF 15.84 per option ("Option series 3b") and of CHF 18.84 per option ("Option series 3c").

On 14 November 2017, the Board of Directors granted a total of 70,000 options of which

\_ 24,400 with a vesting period of 1 year, expiring on 14 November 2023 and an exercise price of CHF 34 ("Option series 4a")

\_ 24,300 with a vesting period of 2 years, expiring on 14 November 2024 and an exercise price of CHF 34 ("Option series 4b")

\_ 21,300 with a vesting period of 3 years, expiring on 14 November 2025 and an exercise price of CHF 34 ("Option series 4c")

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 10.46 per option ("Option series 4a"), of CHF 14.32 per option ("Option series 4b") and of CHF 17.11 per option ("Option series 4c").

In the year 2017 20,000 options were forfeited. Thus 187,000 options of the total option program of 500,000 options are allocated.

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

In 2017, in relation to the "Option series 1a,b,c", "Option series 2a,b,c", "Option series 3a,b,c" and to the "Option series 4a,b,c" the expense for the value of employees' and Directors' services exchanged for stock options amounted to EUR 739 thousand of which EUR 466 thousand for management and personnel and EUR 273 thousand for nonexecutive Directors. In the year 2017 20,000 options were forfeited.

Option series	Number	Grant date	Vesting date	Expiry date	Exercise price	Fair value of the option at the grant date
					CHF	CHF
1a) Issued 3 December 2015	49,800	03/12/2015	03/12/2016	03/12/2021	34.00	14.45
1b) Issued 3 December 2015	46,600	03/12/2015	03/12/2017	03/12/2022	34.00	19.28
1c) Issued 3 December 2015	43,600	03/12/2015	03/12/2018	03/12/2023	34.00	22.56
2a) Issued 23 February 2016	6,800	23/02/2016	23/02/2017	23/02/2022	34.00	11.28
2b) Issued 23 February 2016	6,700	23/02/2016	23/02/2018	23/02/2023	34.00	15.87
2c) Issued 23 February 2016	6,500	23/02/2016	23/02/2019	23/02/2024	34.00	18.98
3a) Issued 23 February 2017	4,100	23/02/2017	23/02/2018	23/02/2023	34.00	11.59
3b) Issued 23 February 2017	4,000	23/02/2017	23/02/2019	23/02/2024	34.00	15.84
3c) Issued 23 February 2017	3,900	23/02/2017	23/02/2020	23/02/2025	34.00	18.84
4a) Issued 14 November 2017	24,400	14/11/2017	14/11/2018	14/11/2023	34.00	10.46
4b) Issued 14 November 2017	24,300	14/11/2017	14/11/2019	14/11/2024	34.00	14.32
4c) Issued 14 November 2017	21,300	14/11/2017	14/11/2020	14/11/2025	34.00	17.11

<b>Share options</b>	<b>Number</b>	<b>Weighted average exercise price</b>
		CHF
<b>Outstanding as at 1 January 2016</b>	<b>140,000</b>	<b>34.00</b>
Exercisable as at 1 January 2016	–	–
Granted during the period	20,000	34.00
Forfeited during the period	(35,000)	34.00
Exercised during the period	–	–
Expired during the period	–	–
<b>Outstanding as at 31 December 2016</b>	<b>125,000</b>	<b>34.00</b>
Exercisable as at 31 December 2016	42,800	34.00
Granted during the period	82,000	34.00
Forfeited during the period	(20,000)	34.00
Exercised during the period	–	–
Expired during the period	–	–
<b>Outstanding as at 31 December 2017</b>	<b>187,000</b>	<b>34.00</b>
Exercisable as at 31 December 2017	70,100	34.00

The share options outstanding at the end of the financial year had an exercise price of CHF 34,00 and a weighted average remaining contractual life of 5.7 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%
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%
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%
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%
Option life	1,826 days	1,827 days	1,826 days
Risk-free interest rate	0.33%	0.49%	0.65%

## 18 Related-parties transactions

In the period ended 31 December 2017 the Company has been charged by Cosmo S.p.A., under a service agreement, and by Bellatrix Inc. (subsidiaries of Cosmo Pharmaceuticals N.V.) for an amount of EUR 465 thousand and EUR 52 thousand respectively (EUR 720 thousand and EUR 19 thousand in 2016) for Research/Development/Regulatory services.

In 2017 the Company has been charged by Cosmo S.p.A., under a service agreement, for secretarial and accounting services for an amount of EUR 138 thousand (EUR 130 thousand in 2016).

Starting from May 2015, Cosmo Pharmaceuticals N.V. provides Cassiopea with the services of its Chief Financial Officer, and its Chief Scientific Officer. The services provided under this agreement will not exceed 30% of their respective available working time. Cosmo provides Cassiopea these services to at no cost. At the Board of Director of the Company held in November 2017, it was resolved to award to the two

managers, Luigi Moro (CSO) and Hans Christoph Tanner (CFO), each 20,000 options to subscribe to Cassiopea shares; furthermore the Board resolve to award 10,000 options to Marco Lecchi (Finance director), Head of Internal Audit of Cosmo Pharmaceuticals N.V. The cost to the Company, for the services of the three managers of Cosmo Pharmaceuticals N.V., determined on the basis of the fair value of the option, is equal to EUR 44 thousand.

In 2017, Cosmo Pharmaceuticals N.V., under a stock option plan, has granted options to some employees of the Company. The cost to the Company, determined on the basis of the fair value of the option, is equal to EUR 122 thousand.

### Key Management personnel compensation

Key Management personnel consist of the Board of Directors and the Executive Management; the table below shows the compensation recognized in the profit and loss statement 2017.

EUR

Board of Directors	Function	Base compensation	Additional compensation	Stock options	Total compensation
Jan E. de Vries	Nonexecutive, Chairman	35,256	–	98,983	134,239
David Hale *	Nonexecutive, Independent director	28,488	2,711**	82,718	113,917
Øyvind Bjordal	Nonexecutive, Independent director	35,256	3,388**	45,391	84,035
Pierpaolo Guzzo	Nonexecutive, Independent director	35,256	3,388**	45,391	84,035
Diana Harbort	Executive, CEO	176,279	–	251,165	427,444
<b>Total</b>		<b>310,535</b>	<b>9,487</b>	<b>523,648</b>	<b>843,670</b>

\* resigned as per October 2017

\*\* compensation Management Control Committee

EUR

Executive Management	No of members	Base compensation	Cash bonus	Fringe benefits	Stock options	Total compensation
Executive Management ***	5 members	142,595	7,000	8,880	176,743	335,218
highest paid of 5 members		118,595	7,000	8,880	86,951	221,426

\*\*\* excluding CEO



## 19 Financial risk management objectives and policies

### Financial risk management

Cassiopea's financial assets, mainly cash and cash equivalents, are managed by the Management Control Committee of the Company's Board of Directors.

The major risks arising from the Cassiopea's financial instruments are credit risk, liquidity risk and market risk (primarily interest rate risk and foreign currency risk). The Management Control Committee periodically reviews the policies for managing each of the above-mentioned risks.

To illustrate the correlation between the financial instruments and the related risk exposure, a description of the policies and the measures adopted by the Company to manage its financial risk exposure is provided here below.

### Credit risk

Credit risk is the risk of financial loss to Cassiopea if a counterparty to a financial instrument fails to meet its contractual obligations. It arises mainly from the Cassiopea's cash and cash equivalents.

The counterparties of financial instruments are chosen based on the Cassiopea Management Control Committee estimate on their reliability.

### Liquidity risk

Cassiopea's approach to managing liquidity is to ensure, as far as possible, that it will always have sufficient liquidity to meet its liabilities when due, under both normal and stressed conditions, without incurring unacceptable losses or risking damages to the Cassiopea's reputation.

To this end, the Company has invested its cash in short-term deposits.

Cassiopea rates managing the liquidity risk as more important than optimizing investment income.

### Market risk

Market risk is the risk that changes in market prices, such as foreign exchange rates and interest rates prices, will affect Cassiopea's income/cost or the value of its holdings of financial instruments. The objective of market risk management is to manage and control the market risk exposures within acceptable parameters, while optimizing the return on risk.

### Interest rate risk

Cassiopea's exposure to the risk of changes in market interest rates relates to Cassiopea's cash in bank deposits and equivalent investments, therefore no material-hedging activities (such as interest rate swaps) were used during the period under review.

### Foreign currency risk

Cassiopea is exposed to currency risk on revenues and costs that are denominated in a currency other than its functional currency (EUR).

Cassiopea intends to work with natural hedges where possible, matching foreign currency inflows with out-flows.

Where this is not possible, foreign currency advice from renowned experts will be sought, and a decision will then be made to either run the currency risk or to hedge it.

### Capital management

Cassiopea's capital management objectives are focused on safeguarding Cassiopea's capacity to safely execute the business plan of the Company. To this end, Cassiopea does not plan to rely on debt to finance any of its longer-term capital requirements and will not strive to maintain an optimal capital structure until its income streams reach a high level of predictability.

With reference to the supplemental disclosures required by IFRS 7, the comments below supply details about the measures and mechanisms implemented by the Company to manage its exposure to financial risks.

### Classes of financial instruments

The table below shows the financial assets and liabilities, as required by IFRS 7 within the framework of the different categories contemplated by IAS 39, resulting on 31 December 2017 and 2016.

	Carrying amount	
	As at 31 December	
EUR 1,000	2017	2016
Cash and cash equivalents	17,598	33,656
Trade payables	(2,012)	(2,739)

## Information and financial risk analysis

### Liquidity risk

The liquidity risk is the risk that the Company will encounter difficulty in meeting future obligations with respect to financial liabilities, after considering the Company's cash and cash equivalents' availability. The risk analysis is aimed at quantifying, on the basis of contractual maturity, the cash flow in relation to the reimbursement of the Company's financial liabilities as of 31 December 2017 and 2016 as much as they are considered significant for the purpose of liquidity risk.

### Market risk

The actual exposure to such sources of risk is illustrated as of 31 December 2017 and 2016, along with the possible balance sheet impact of the risk factor's plausible variations.

### Interest rate risk and sensitivity analysis

The table below provides an indication of the impact on the profit before tax of a parallel  $\pm 50$  basis-point shift of the rate curve estimated as of 31 December 2017 and 2016. The analysis was carried out by assuming that the other variables remained constant.

EUR 1,000	Profit or (loss)	
	50 bp increase	50 bp decrease
Cash and cash equivalents	126	(126)
<b>Cash flow sensitivity</b>	<b>126</b>	<b>(126)</b>

EUR 1,000	Profit or (loss)	
	50 bp increase	50 bp decrease
Cash and cash equivalents	199	(199)
<b>Cash flow sensitivity</b>	<b>199</b>	<b>(199)</b>

### Foreign currency risk and sensitivity analysis

The Company is exposed to currency risk on costs that are denominated in a currency other than the functional currency of the Company (EUR).

It is the Company's policy to primarily maintain its cash and cash equivalents in US\$ due to the business plan that foresees costs mainly denominated in US\$.

At the present time, no hedges are in place for the excess of US\$ outflows, but the Company regularly reviews this position.

A 10% strengthening of the euro against the US\$ would have resulted in a loss decrease of EUR 543 thousand and EUR 779 thousand as at 31 December 2017 and 2016 respectively. A 10% weakening of the euro against the US\$ as at 31 December 2017 and 2016 would have had the opposite effect, for the equal amount shown above.

Furthermore, in relation to the cash held in US\$ at the end of 2017, a 5% strengthening of the US\$ against the euro would have resulted in a loss decrease of EUR 859 thousand. A 5% weakening of the US dollar against the euro would have had the opposite effect, for the equal amount shown above.

## 20 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 31 December 2017 and 2016, 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 31 December 2017		As at 31 December 2016	
	Carrying amount	Fair value	Carrying amount	Fair value
Cash and cash equivalents	17,598	17,598	33,656	33,656
<b>Total Assets</b>	<b>17,598</b>	<b>17,598</b>	<b>33,656</b>	<b>33,656</b>
Unrecognised (loss) gain	-	-	-	-
Trade payables	(2,012)	(2,012)	(2,739)	(2,739)
<b>Total Liabilities</b>	<b>(2,012)</b>	<b>(2,012)</b>	<b>(2,739)</b>	<b>(2,739)</b>
Unrecognised (loss) gain	-	-	-	-

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

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.

## 21 Subsequent events

No significant events occurred subsequently the year ended 31 December 2017.

Lainate, 27 February 2018

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



Jan E. de Vries  
Chairman

# Auditor report



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## INDEPENDENT AUDITOR'S REPORT

To the Shareholders and Board of Cassiopea S.p.A.

### Report on the Audit of the Financial Statements 2017

#### Opinion

We have audited the financial statements of Cassiopea S.p.A. (the Company), which comprise the statement of financial position as at 31 December 2017, the income statement and statement of comprehensive income, statement of changes in equity, and statement of cash flows for the year then ended, and notes to the financial statements comprising a summary of significant accounting policies.

In our opinion the enclosed financial statements, give a true and fair view of the financial position of Cassiopea S.p.A. as at 31 December, 2017, and of its result and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union.

#### Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Statements* section of our report.

We are independent of the Company in accordance with the International Ethics Standards Board for Accountants' *Code of Ethics for Professional Accountants (IESBA Code)* and we have fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Bari, Bergamo, Bologna, Brescia, Cagliari, Firenze, Genova, Milano, Napoli, Novara, Padova, Palermo, Pescara, Potenza, Roma, Torino, Treviso, Trieste, Verona, Vicenza

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#### R&D TAX CREDIT RECOGNITION

The company recognizes tax receivables related to the tax credit for research and development pursuant to the Italian Law that provides for the grant of a tax credit to all companies investing in research and development activities with effect in the tax year from 2015 to 2019.

Income arising from such tax credit has been recognized starting from 2016, when the Italian Tax Office, following a tax ruling requested by the Company, made it clear that also Phase III clinical trial costs may be considered eligible for the tax credit. The R&D tax credit is calculated every year as a percentage of the increase in the R&D expenses in comparison with the average R&D costs for the period 2012-2014.

During the year, the company recorded other income from R&D tax credit amounting to EUR 3,820 thousand as disclose in note 4 (Net operating expenses - Other income). At the end of the year tax receivable amount to EUR 8,993 of which EUR 8,693 classified non current as disclose in note 9 (Tax Receivable non current) and EUR 300 thousand classified current as disclose in note 10 (Current tax assets).

We focus on this area because the significance of this tax credit R&D costs in the financial statements.

#### AUDIT APPROACH

We obtained an understanding of the relevant Company process to determine the R&D tax credit recognition pursuant the Italian Ministerial Decree of May 27, 2015 and related updating.

We performed substantive procedure for R&D tax credit including reconciliation of R&D costs to supporting documents of services rendered and authorized purchase contract for the year 2017. We have performed detailed testing on the calculation as a percentage of the increase in the R&D expenses in comparison with the average R&D costs for the period 2012-2014, in agreement with the regulation.

We assessed the assumptions regarding R&D costs by nature, the accuracy of costs considered in the valuation and the computation of the amount applying the percentage provided by the Decree above mentioned.

We have also assessed the accuracy and completeness of the company's disclosure in the financial statements relating to R&D tax credit.

#### Other Information included in the annual report

The Board is responsible for the preparation of the other information included in the annual report. Next to the financial statements and our auditor's report thereon, the annual report consists of other information including: Cassiopea at a glance, the letter to shareholders, corporate governance, and other information for investors.

Our opinion on the financial statements does not cover the other information in the annual report and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.



## Responsibilities for the Financial Statements

The Board is responsible for the preparation and fair presentation of the financial statements in accordance with International Financial Reporting Standards (IFRS's) as adopted by European Union, and for such internal control as the Board determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board is responsible for assessing the Company's ability to continue as a going concern. Based on the financial reporting framework mentioned, the Board should prepare the financial statement using the going concern basis of accounting unless the Board either intend to liquidate the Company or to cease operations, or has no realistic alternative but to do so. The Board should disclose, as applicable, events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

Those charged with governance are responsible for overseeing the Company's financial reporting process.

## Auditor's Responsibilities for the Audit of the Financial Statements

Our objective is to plan and perform the audit assignment in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion and reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the International Standards on Auditing (ISAs) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists,



we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not mentioning it is in the public interest.

Milan, 27 February 2018

BDO Italia S.p.A.  
  
Carlo Consonni  
Partner

# Information for investors

## Capital structure

EUR 1,000	31.12.2017
Total equity	26,354
Share capital	10,000
Reserves	30,010
Profit (Loss) for the period	(13,656)
Number of registered shares	10,000,000
Nominal value per share (in EUR)	1.00

## Stock exchange information

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

## Research coverage

Major shareholders	No. of shares	% of share capital
Cosmo Pharmaceuticals N.V.	4,508,987	45.09%
Cosmo Holding S.a.r.l.	753,445	7.53%
UBS Fund Management (Switzerland) AG	565,511	5.66%
Herz/Logitable group	409,000	4.09%
LB Swiss Investment	305,000	3.05%

Jefferies International	Peter Welford	Phone: +44 20 702 986 68
Valuation Labs for Bank am Bellevue	Bob Pooler	Phone: +41 44 267 72 85

## Share price data

CHF	Price	Date
First trading day close	37.30	01.07.2015
2017 lowest	29.05	05.01.2017
2017 highest	35.70	14.07.2017
2017 last trading date	34.80	29.12.2017
Market capitalization (in CHF million)	348.00	31.12.2017

## Calendar

### Key reporting dates

2018 Half Year Report – July 2018

### Jefferies' 2018 Global Healthcare Conference

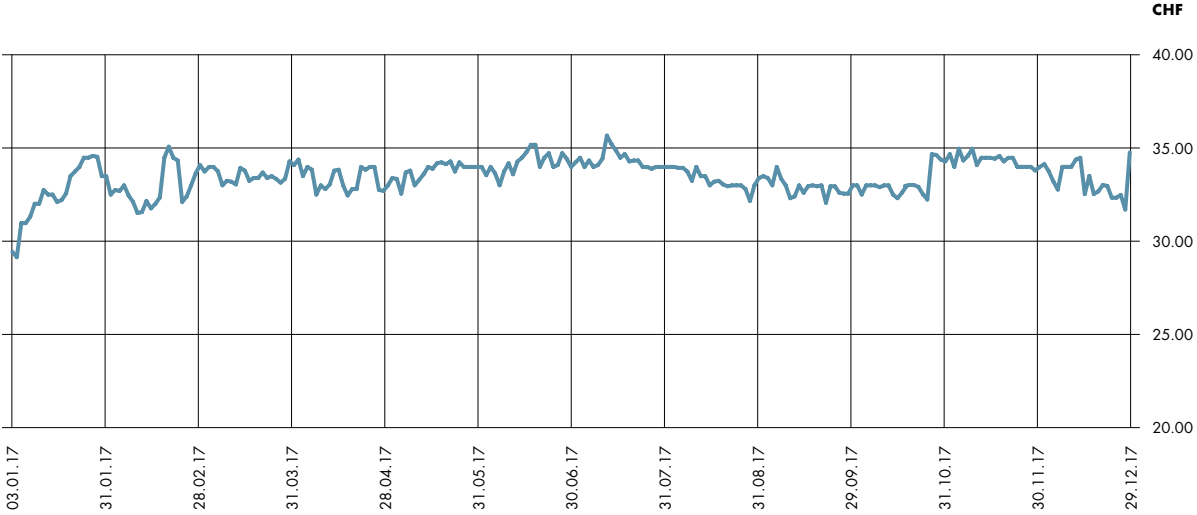
New York, 5–8 June, 2018

## Share earnings

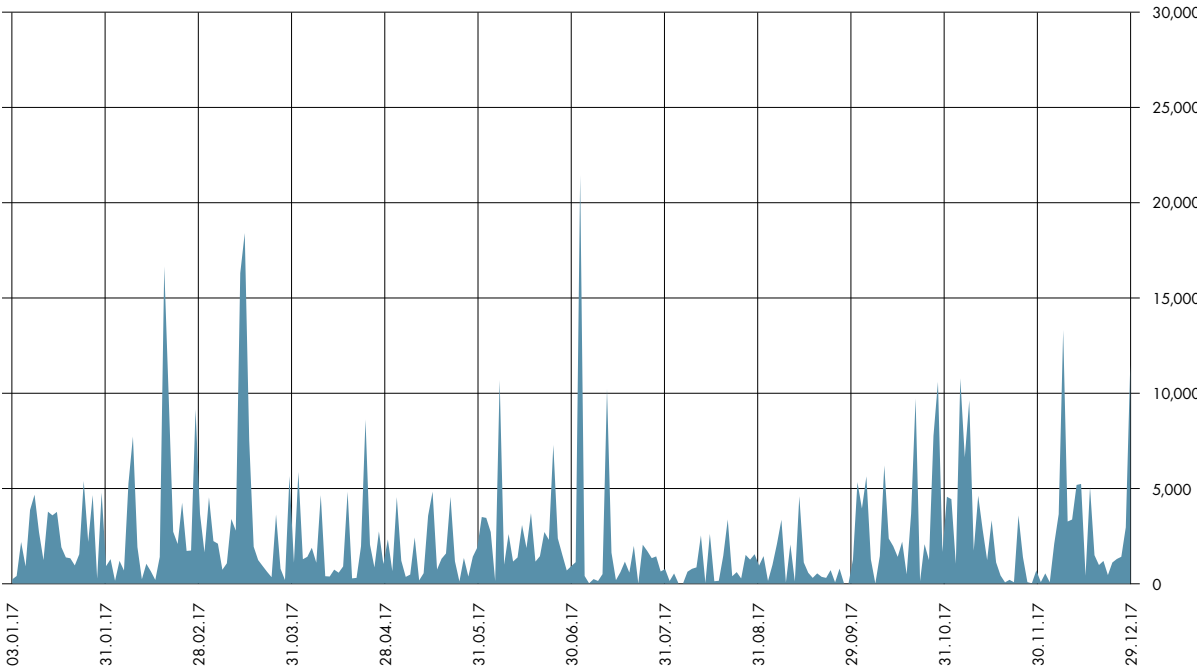
EUR	31.12.2017
Basic earnings (loss) per share	(1.366)



Share price



Trading volumes





# Glossary

## **505 (b)2**

Refers to a section of the FDA act which allows a new drug approval application (NDA) that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This allows the filing avoiding lengthy, costly and in many cases repetitive preclinical trials. Drugs approved under 505 (b)2 generally get 3 or 5 years market exclusivity.

## **Abbreviated NDA (ANDA)**

Is for a proposed drug that is identical to a reference listed drug. The proponent must prove its bioequivalence. Drugs approved under an ANDA only get exclusivity of 180 days.

## **Acne**

Skin disorder characterized by inflammation as a result of overactivity of the sebaceous glands.

## **Acute**

Disease or its symptoms that could be suddenly, severe but of short duration.

## **AGA**

Androgenic alopecia.

## **Alopecia**

Hair follicle disease that cause partial or complete absence of hair.

## **Androgens**

Male sex hormones.

## **Antibiotic**

Drug that kills bacteria or prevents them from multiplying.

## **API**

Active Principle Ingredient.

## **AUC (area under the curve)**

Term used in pharmacokinetic studies as measure of systemic absorption.

## **Autoimmune**

A condition in which the body produces antibodies to its own tissue.

## **Bacteria**

Single-celled microorganisms that can exist independently or dependently upon another organism for life. They can cause infection and are usually treated with antibiotics.

## **BfArM**

Bundesinstitut für Arzneimittel und Medizinprodukte: the German Federal Institute for Drugs and Medical Devices.

## **Chronic**

Lasting a long time.

## **Clinical need**

Therapeutic need not covered by drugs that are currently marketed.

## **Clinical phase I**

Phase I trials are the first stage of drug testing on human subjects.

## **Clinical phase II**

Once the initial safety of therapy has been confirmed in phase I trials, phase II trials are performed on larger groups (20–200) and are designed to assess clinical efficacy of the therapy, as well as to continue safety assessment on a larger group of patients.

## **Clinical phase III**

Phase III studies are randomized controlled trials on large patient groups ( $\geq 200$ , depending on the condition) and are aimed at producing a definitive assessment of the efficacy of the new therapy, sometimes in comparison with current "gold standard" treatment.

## **Clinical trial**

A meticulously controlled test of a drug/device/medical strategy candidate on humans, to explore its safety and efficacy.

**C<sub>max</sub>**

Maximum drug concentration reached in a body fluid, usually plasma or blood.

**Compliance**

Compliance with the therapeutic regime imposed by the prescribing doctor.

**C.P.O.**

Contract Pharmaceutical Organization, a company that carries out services in the pharmaceutical sector on behalf of third parties.

**C.R.O.**

Contract Research Organization, a company that carries out research and/or development activities in the pharmaceutical sector on behalf of third parties.

**Cytokines**

Any class of substances that are secreted by cells of the immune system.

**DHT**

Dihydrotestosterone.

**Dose-finding study**

A clinical study designed to determine the efficacy and safety of different doses to help in the identification of the most efficacious and well-tolerated dose.

**Double-blind study**

A clinical trial design in which neither the participating individuals nor the study staff know which participants are receiving the experimental drug and which are receiving placebo or another active ingredient (comparator).

**Drug delivery system**

A technology or method that is able to control the time and the extent of the release of a drug.

**Efficacy**

The ability of a drug to control or cure an illness.

**EMA**

European Medicines Agency.

**Endogenous**

Produced or synthesized within the organism.

**Enzyme**

A molecule that includes the conversion of one chemical substance to another.

**Epidemiology**

Analysis of cause, pattern, effect of a disease in populations.

**EPO**

European Patent Office.

**Ethical drugs**

Prescription drugs used for treatment of serious diseases.

**ESOP**

Employee Stock Option Plan.

**Excipient**

An inert substance used as a diluent or vehicle for a drug.

**FDA**

Food and Drug Administration, the US government agency that governs the entry and monitoring of products on the market.

**FPI**

First Patient In.

**Galenic**

Galenic formulation deals with the principles of preparing and compounding medicines in order to optimize their absorption.

**GMP**

Good Manufacturing Practice.

**Generic drugs**

Drugs equivalent to brand drugs.

**Hirsutism**

Excessive growth of thick hair in women, with a male pattern.

**HGA**

Hair Growth Assessment.

**ICH**

The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**IGA**

Investigator Global Assessment.

**Infection**

A condition resulting from the presence of bacteria or other microorganisms in the body.

**Inflammation**

Swelling, reddening, heat and/or pain produced in the area of the body as a result of irritation, injury or infection.

**Investigational New Drug Application (IND)**

Once the drug has been screened for pharmacological activity and acute toxicity potential in animals, the sponsor must next test its therapeutic potential for humans. At that point the molecule changes legal status under the FDA act and becomes a new drug subject to specific requirements of the drug regulatory system. An Investigator IND is submitted by the party who both initiates and conducts an investigation and under whose immediate direction the investigational drug is administered or dispensed. Technically the IND is the means through which a sponsor obtains the authority to transport an investigational drug across state lines for clinical trial purposes. Once the IND is submitted, the sponsor must wait for 30 days before initiating clinical trials.

**In vitro**

In an artificial environment, referring to a process or reaction occurring therein, as in a test tube or culture media.

**Lesions**

A lesion is any abnormal tissue found on or in an organism, usually damaged by disease or trauma.

**Lipophilic**

The property of a chemical compound to dissolve in fats, oils, lipids, and nonpolar solvents.

**LPO**

Last Patient Out.

**Mechanism of action**

The manner by which a drug exerts its activity.

**NCE**

New Chemical Entity, chemical structure that is not part of existing technical know-how.

**NDA**

The New Drug Application, a procedure through which drug sponsors formally propose that the FDA approves a new pharmaceutical for sale and marketing in the US.

**Off-label**

The use of a drug for a medical condition other than for which it was officially approved and marketed.

**Onset of action**

The length of time it takes for a medicine to start to work.

**Open-label**

A study in which all parties (patient, physician and study coordinator) are informed of the drug and dose being administered.

**Orphan diseases**

Diseases characterized by a limited incidence in the population, generally fewer than five cases per 10,000, and for which there are currently no valid therapies available.

**Orphan drug**

Drug intended to cure orphan diseases.

**OTC drugs**

Over-the-counter drugs are medicines that may be sold without the prescription of a medical professional, in contrast to prescription drugs.

**Pharmaceutical manufacturing plant**

Facilities for the manufacturing of drugs, subject to authorization by specific health authorities.

**Pharmacokinetic**

The process by which a drug is absorbed, distributed, metabolized and eliminated by the body.

**Pharmacokinetic parameters**

Measures related to drug absorption and elimination rates that are useful to evaluate the behavior of the drugs after administration to a living organism (such as C<sub>max</sub>, T<sub>max</sub>, AUC, etc.).

**Pivotal study**

Usually a phase III study that presents the data that the governmental agencies responsible for approving the marketing of pharmaceutical products (e.g., the FDA and the EMEA) use to decide whether or not to approve a drug.

**Placebo**

Drug with no active ingredients.

**Proof-of-concept study**

Phase IIa clinical trials, usually conducted within the target patient group, to determine whether the considerable resources necessary to complete drug development should be invested.

**Prophylaxis**

A method to prevent a disease.

**Randomized/Randomization**

The procedures ensuring that the subjects are equally and randomly distributed to treatment or control groups.

**REACH**

Registration, Evaluation, Authorization and Restriction of Chemical substances.

**Receptor**

A protein complex located inside or on the wall of the cells characterized by selective binding of a specific substance.

**Registration**

Authorization required to market a drug.

**Seborrhea**

A skin disease characterized by increase of sebum associated or not to inflammation.

**Technology platform**

Technology applied to various molecules generating certain products.

**Tmax (time to maximum concentration)**

Term used in pharmacokinetic studies to indicate the time after administration when the maximum concentration in a body fluid is obtained.

**TAHC**

Target Area Hair Counts.



### **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 warranties 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.



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