COSMO Pharmaceuticals

ANNUAL REPORT & ACCOUNTS 2018

# CONTINUING OUR JOURNEY TO IMPROVE PATIENTS' LIVES

# DELIVER RESULTS + IMPROVE LIVES

**Cosmo is a pharmaceutical company with a specialised focus on gastroenterology and endoscopy. We develop and manufacture products which are distributed globally.**

OUR MISSION

# To improve people's lives by developing innovative treatments that address significant unmet clinical needs and improve clinical outcomes.

## Our clinical focus

Our development pipeline is focused on Bowel Diseases, Colon Infections and products to reduce the incidence of Colorectal Cancer (CRC) by increasing the detection rate of pre-cancerous lesions during colonoscopy.

Cosmo has also developed and launched a medical device to make the removal of these lesions safer and more efficient. Cosmo's strong links to the specialist physician community provide a continuous flow of information with which we develop new products.

## Proprietary technology

The Company's extensive galenic experience, which led to the development of the proprietary multi-matrix technology, MMX®, provides an excellent basis for the development of new, patentable, yet lower-risk products, manufactured at the company's own GMP-approved plant. Cosmo has a demonstrated ability to successfully identify unmet medical needs, manage the drug development process and obtain regulatory approval for new products. Cosmo then either licenses its approved products to partners with strong marketing and sales expertise or will market, sell and distribute its new products directly into selected markets.

## Our target therapies

Cosmo's therapeutic focus is on the oral and endoscopic treatment of colon diseases primarily Bowel Diseases and Colorectal Cancer (CRC) prevention. Our MMX® technology allows the delivery of active pharmaceutical ingredients into the lumen of the colon through tablets in a delayed and controlled way with the effect that the active pharmaceutical ingredients can be applied to the full length of the colon.

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**Certain Defined Terms**

In this report, unless otherwise specified, the terms 'we', 'our', 'us', 'the Company', 'the Group' and 'Cosmo' refer to Cosmo Pharmaceuticals N.V., together with its subsidiaries, or any one or more of them, as the context may require.

**Forward looking Statements**

This report contains certain 'forward-looking statements'. These forward-looking statements may include terms such as 'may,' 'will,' 'expect,' 'could,' 'should,' 'intend,' 'estimate,' 'anticipate,' 'believe,' 'remain,' 'target,' 'objective,' 'goal,' 'forecast,' 'projection,' 'outlook,' 'plan' or similar wording. Such forward-looking statements reflect the current views of the Management and are not guarantees of future performance and involve risks and uncertainties. Readers are cautioned that actual results may differ materially from those in the forward-looking statements as a result of various factors. Cosmo 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.

## Operating principles and activities

### Our Customers

Our customers are primarily our licensee partners and customers who we manufacture product for on a contract basis and, through our Aries Group, wholesale distributors and specialty distributors. During 2018 Cosmo's largest customer accounted for 26.7% (2017: 38.3%) of revenues and the second largest accounted for 26.5% (2017: 31.6%).

### Procurement

For the Company's contract manufacturing activities, active ingredients are either supplied by the client or purchased in the market from external Italian or international suppliers. All of the materials purchased are standard materials provided by a large number of sellers.

With reference to the Company's proprietary products, all active ingredients are from external suppliers. All active ingredients required are manufactured by more than one supplier. Generally, the Company negotiates with these suppliers in order to determine one preferred supplier at attractive prices and then holds certain inventory to prevent supply bottlenecks.

### Manufacturing

The Company has the ability to manufacture tablets, ointments and liquids. All of Cosmo's own MMX® products are manufactured in-house, at our FDA-approved plant, which is adjacent to the plant originally set up by Parke Davis. In order to monitor the production processes, the Company has its own analytics department. The Company does not manufacture unfinished products. All products are either packaged in bulk or final form at the Company's packaging line. It is the Company's intention to manufacture all of its own products in-house. The Company completed a new Methylene Blue MMX manufacturing facility in 2017 which was subsequently approved by the FDA.

### Sustainable practices

The Company is committed to operating in an environmentally and socially responsible manner and to the responsible management of manufacturing and non-manufacturing processes to reduce impacts on the environment. The Group continuously monitors compliance with applicable environmental, health and safety laws and regulations and the requirements of its permits and licenses and maintains programs that ensure that it:

- monitors the quality of the ambient air and the protection of the water resources;
- evaluates the site programs for the protection of the environment and the health and safety of employees and neighbours;
- manages the waste disposal in conformity with the local regulations;
- designs, constructs, maintains and manages its plant and systems in accordance with the best practices;
- communicates with the local community on safety and environmental matters in a timely and effective manner.

The Company is committed to a program of continual improvement in environmental, health and safety performance by making it an integral part of all its operations. As a pharmaceutical company, Cosmo is not directly obliged under REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances), a European Community regulation on chemicals and their safe use (EC 1907/2006), but constantly monitors its suppliers (i.e., labels and packaging materials) to assess their compliance to that regulation.

The Company impacts a large number of stakeholders and recognises the broader role which the Company plays. The Company is committed to developing mutually beneficial relationships with business partners and local communities.

## Operating principles and activities continued

### Quality management

The Group is committed to the development and manufacturing of products of high quality and to satisfy the expectations of its customers. The quality system implemented at Cosmo meets the requirements and the expectations of the European and U.S. health authorities (EMA and FDA) for the manufacturing of drug products. Pharmacopoeias, pharmaceutical directives and guidelines (i.e., those issued by ICH) help to maintain the quality system at a high standard level. The quality system is fully in compliance with the current Good Manufacturing Practice (GMP) and allows the production of drug products of defined quality.

The quality system at Cosmo's manufacturing plant is ISO 9000 certified. This certification, even if not required for the drug product manufacturing, demonstrates the Company's commitment to quality.

### Information Technology

Our IT Department is responsible for the strategic planning, oversight and direction of the IT infrastructure, resources and IT services within our Group. The IT Department works closely with management ensuring ongoing innovation and continuous improvement in our management information systems. SAP is our main ERP system and during the year several projects were completed which improved processes and resulted in greater efficiency.

### Health and safety

Cosmo constantly monitors its procedures and processes to ensure that the health and safety of all personnel working on site is protected and risk from accidents or incidents arising from site activities is minimised both on and off site.

From a job category perspective, employment at Cosmo can either be grouped into office activities, research and analysis activities or manufacturing activities. An initial medical test on hiring and an annual blood and urine test are performed for all managers, employees and workers and all males above 40 years are tested for PSA (Prostate Specific Antigen). For managers and employees working with a PC, eye and eyesight tests are made every two years and workstations are protected with blinds and properly positioned when exposed to natural light. With respect to research and analysis activities, strict policies were established together with the Italian Ministry of Health specifically with reference to the handling of dangerous substances. With reference to manufacturing activities primarily in the manufacturing, packaging and handling of pharmaceuticals, there are strict internal work flow processes intended to ensure that accidents are minimised. Insurance coverage is in place for accidents occurring off site.

# 2018 FINANCIAL HIGHLIGHTS

**€ 65.6 million**
2018 Revenue

**€ 16.6 million**
Operating Loss

**€ 18.1 million**
Loss After Tax

**€ 375.8 million**
Cash, bonds & fund investmests

**€ 27.5 million**
Manufacturing revenues for MMX® products

**€ 7.8 million**
Manufacturing revenues of generic products and specialty drugs

**€ 14.6 million**
Royalty Income

# KEY FIGURES

## Income statement

| EUR 1,000 | FY 2018 | FY 2017 |
|---|---|---|
| **Revenue** | **65,617** | **67,242** |
| Other income | 886 | 470 |
| Cost of sales | (22,058) | (21,988) |
| Research and development costs | (10,428) | (9,049) |
| Selling, general and administrative costs | (50,638) | (46,279) |
| **Net operating expenses** | **(82,238)** | **(76,846)** |
| **Operating loss** | **(16,621)** | **(9,604)** |
| Net financial income/expenses | 4,615 | (16,936) |
| Share of result of associates | (5,453) | (5,892) |
| **Loss before taxes** | **(17,459)** | **(32,432)** |
| **Loss after taxes for the period** | **(18,057)** | **(32,447)** |

## Shares

| EUR 1,000 | FY 2018 | FY 2017 |
|---|---|---|
| Weighted average number of shares | 15,005,414 | 14,809,753 |
| Earnings per share (in EUR) | (1.200) | (2.191) |

## Statement of financial position

| EUR 1,000 | 31 Dec 18 | 31 Dec 17 |
|---|---|---|
| Non-current assets | 251,519 | 300,668 |
| Cash and cash equivalents | 210,689 | 144,944 |
| Other current assets | 163,478 | 52,362 |
| Liabilities | 180,832 | 27,857 |
| Equity attributable to owners of the Company | 443,760 | 470,117 |
| Equity ratio (in %) | 71.1% | 94.4% |

# KEY EVENTS IN 2018

- Aemcolo™ New Drug Application seeking marketing authorisation for the treatment of Traveler's Diarrhoea approved by the FDA. The FDA granted Qualified Infectious Disease Product (QIDP) and together with New Chemical Entity (NCE) designation Aemcolo™ enjoys marketing exclusivity until 2028.
- Dr. Falk Pharma received approval via the European Decentralized Procedure for Relafalk (Rifamycin SV MMX) for the treatment of Travelers' Diarrhoea. This grants marketing authorisation in Germany, United Kingdom, Spain, Denmark, Greece, Finland, Hungary, Norway, Portugal, Poland, Sweden and Bulgaria.
- Aemcolo™ phase II proof of concept study in IBS-D progressed.
- Methylene Blue MMX NDA not approved by the FDA in current form. In March 2019 we announced that upon agrement with the FDA on a new trial design we intend to commence a comfirmatory phase III trial.
- Eleview® gross sales in the U.S. $10.9 million vs $2.1 million in 2017.
- License and supply agreement entered into with Pharmascience for Eleview®, Methylene Blue MMX, Aemcolo™ and Qolotag® for the territory of Canada.
- Eleview® agreement with FUJIFILM Europe B.V. expanded to South East Asia, Middle East, Africa, Australia and New Zealand. Under the agreement Cosmo to receive 45% of gross revenues.
- License and supply agreement entered into with EA Pharma for Methylene Blue MMX and Eleview® for the territories of Japan and South Korea.
- Our associate Cassiopea SpA, of which we own 45.09%, communicated a sequence of very good news including the successful phase III clinical trial outcome of its drug Winlevi® for the treatment of acne and the sucessful phase II clinical trial interim analysis of it drug Brezula® for the treatment of Androgenetic Alopecia.
- ICC Tribunal ruled that Bausch Health was not in breach of the Uceris® License Agreement.
- Generic of Lialda® launched in March in the U.S., Cosmo income down by 12.3% with reductions in the U.S. partially offset by increases in Japan and Europe.
- Generic of Uceris® launched in July in the U.S., net sales by our licensee Bausch Health reduced by 27.9% to US$96.7 million.
- Cortiment® net sales by our licensee Ferring increased by 12.1% to €15.1 million.
- Successfully placed €175 million senior convertible bonds due 2023 raising net proceeds of €163.4 million.

# Inflammatory Bowel Disease (IBD)

Inflammatory Bowel Disease (IBD) is a chronic inflammatory condition that affects the gastrointestinal tract causing a number of distressing symptoms such as bleeding, diarrhoea, abdominal pain and weight loss. The main disease categories are Ulcerative Colitis and Crohn's Disease, both of which can have a significant adverse impact on the quality of life of an individual.

It is estimated that over 1 million people in the U.S. and 2.5 million people in Europe have IBD.

The goal of treatment of IBD is to induce and maintain remission of symptoms and mucosal inflammation in order to provide an improved quality of life. There are a number of treatment options available that range from nonpharmacological treatments, such as dietary, to pharmacological treatments and surgery. No precise cause of the disease has been found but scientists and gastroenterologists commonly believe that IBD results from a combination of genetic and environmental factors.

For More Info Visit Website

## Characterisation of disease

Ulcerative Colitis causes inflammation of the lining of the large intestine. The disease originates in the rectum-sigma and spreads to affect various segments of the colon up to the entire colon.

Crohn's Disease is a patchy, transmural inflammation that can affect any part of the gastrointestinal tract. It is thus much more disparately distributed than Ulcerative Colitis.

The symptoms of Crohn's Disease and Ulcerative Colitis vary from patient to patient depending on the level of disease severity and may change over time because of the chronic, relapsing nature of the diseases; most patients experience periods of disease activity and remission. As IBD is a chronic disease, most patients are required to take medication over the course of a lifetime making consistent compliance with drug regimens an important factor.

In terms of severity, gastroenterologists tend to split the patient population into three different categories (mild, moderate and severe) and prescribe medication accordingly. It is commonly believed that 45–55% of the patients have a mild form of the disease, 30–35% a moderate form. Around 30% of patients that have mild to moderate Ulcerative Colitis will be in the acute phase, 70% in remission.

## Disease treatment

Given the chronic nature of the disease and the desire to minimise side effects, the classic treatment strategy has been for the gastroenterologist to start treatment using the mildest form of medication. If a pharmaceutical product then proves to be ineffective, a step up to a more effective but usually more toxic product is made. More recently, there has been a move by some gastroenterologists towards adopting a top-down approach meaning that the use of aggressive therapies such as AntiTNF therapies is started early on. This, however, makes the therapy considerably more expensive per patient and could expose the patient to higher, unnecessary adverse side effects.

Cosmo believes that there is growing consensus in the medical community that infections play an important role in onset and maintenance of IBD. The Company believes that more than 30% of all IBD patients could be better treated if they received anti-infectives concurrently with their IBD medication. Given that IBD is a chronic disease, it is a considerable challenge for the pharmaceutical industry to develop anti-infectives that can be applied frequently without incurring problems associated with resistance.

Treatment with 5-ASAs for the mild to moderate form of the disease includes oral dosage forms (primarily tablets), enemas and suppositories. Corticosteroids are delivered in tablets and enemas and treatment with immunosuppressants is primarily with tablets with selective injected applications. Biologics have, to date, all required intravenous or subcutaneous injections. This means that the active pharmaceutical ingredient acts in different forms. Tablets, enemas and suppositories develop their effect primarily topically but they have the disadvantage that they do not consistently reach the site of inflammation, while injections only act systemically and thus also reach many parts of the body that do not require treatment.

Datamonitor forecasts the seven major IBD markets will grow to US$8.7 billion by 2021. IBD sales grew steeply in the seven major markets which Datamonitor attributes to a combination of uptake of drugs, price increases and the earlier treatment of patients with expensive biologics, particularly in those who have Fistulizing Disease and bad prognostic features of disease.

# Colorectal Cancer (CRC)

Colon cancer is cancer of the large intestine (colon), rectal cancer affects the last part of the colon, together they are referred to as colorectal cancer (CRC). Colorectal cancer arises from adenomas that grow in the colon. Not all adenomas become cancer but all colon and rectal cancers start from adenomas. Epidemiologists estimate that, at birth, every person has a 5 % chance of developing colorectal cancer during their lifetime.

Globally it is estimated that each year over 1.4 million people are diagnosed with colorectal cancer and at least 694,000 people die from the disease.

The risk of CRC increases with age and screening with a colonoscopy is recommended starting at the age of 50. According to the World Health Organization colorectal cancer is one of the most common cancers in men and women representing almost 10% of cancer incidence globally.

Survival rates vary significantly depending on the stage at which CRC is diagnosed. According to the National Cancer Institute in the U.S. the 5-Year Relative Survival rate for Localised CRC (confined to the primary site) is 90.1% compared to 13.5% for Distant CRC (cancer has metastasised).

It is estimated that 75-90 % of colorectal cancer could be prevented through the early detection and removal of pre-cancerous polyps.

The most effective tool to detect and remove pre-cancerous polyps is a colonoscopy. We estimate that 33 million colonoscopies are carried out in the U.S. and EU on an annual basis.

In clinical practice adenoma detection rate (ADR) is the percentage of patients aged 50 and over undergoing a first-time screening colonoscopy who have one or more conventional adenomas detected and removed. ADR is a key quality indicator for colonoscopy, a high ADR is associated with a low post colonoscopy CRC therefore increasing ADR is key to reducing the incidence of CRC.

**For More Info Visit Website**

**1.4 Million**
Patients diagnosed P.A.

**75%-90%**
Estimated prevention rate through early detection

# Products in Clinical Development

### Aemcolo™- IBS-D
A new formulation to treat colonic infections and IBS-D. The application of MMX® technology to rifamycin SV allows the antibiotic to be delivered directly into the colon, avoiding unwanted systemic side effects. Phase II proof of concept study in IBS-D underway.

Read more on pages 13 - 15

### Remimazolam
A new sedation agent to be used in all procedural sedations, including colonoscopies, safer and faster than available alternatives.

Read more on page 18

### Qolotag®
Qolotag® is a new product, which allows for a faster and better enhancement of detection of small lesions or dysplasias during sigmoidoscopy.

Read more on page 21

### Methylene Blue MMX
A new diagnostic drug to improve pre-cancerous and cancerous lesion detection during colonoscopy.

Read more on page 16

# Marketed Products

### Eleview®
A new medical device approved in U.S. and EU to remove colonic lesions more safely and quickly.

Read more on page 17

### Aemcolo™- TD
The first GI antibiotic with MMX® technology. Aemcolo™ is indicated for the treatment of travelers' diarrhoea (TD) by the FDA. The application of MMX® technology to rifamycin SV allows the antibiotic to be delivered directly into the colon, avoiding unwanted systemic side effects.

Read more on pages 13 - 15

### Lialda®
Lialda® is a once-daily mesalamine tablet approved to help get active, mild to moderate Ulcerative Colitis into remission.

### Uceris®
Uceris®/Cortiment® tablets are a prescription corticosteroid medicine used to help get active, mild to moderate ulcerative colitis under control (induce remission) and may help relieve the symptoms of Ulcerative Colitis.

Read more on page 19

## Aemcolo™

Aemcolo™ is a new pharmaceutical product employing rifamycin SV engineered with the MMX® technology.

The application of MMX® technology to rifamycin SV allows the antibiotic to be delivered directly into the colon, avoiding unwanted effects on the beneficial bacterial flora living in the upper portions of the gastrointestinal tract. The specific dissolution profile of Aemcolo™ tablets increases the colonic disposition of the antibiotic so that an optimised intestinal concentration is achieved thus abating its systemic absorption in the small intestine

### Approval of Aemcolo™ by the FDA for the treatment of Travelers' Diarrhoea

In November 2018 the FDA approved Aemcolo™ for the treatment of Travelers' Diarrhoea caused by non-invasive strains of Escherichia coli in adults.

In October 2017, the FDA granted Qualified Infectious Disease Product (QIDP) and Fast Track designations for Aemcolo™. With the QIDP designation, intended for antibacterial or antifungal drugs that treat serious or life-threatening infections, together with new chemical entity (NCE) designation, Aemcolo™ enjoys marketing exclusivity until 2028.

### Rifamycin SV MMX marketing Authorisation in Europe

Rifamycin SV MMX is licensed to Dr. Falk Pharma for Europe and other territories.

In November 2018 Dr. Falk Pharma received approval via the European Decentralized Procedure for Relafalk (Rifamycin SV MMX) for the treatment of Travelers' Diarrhoea. This grants marketing authorisation in Germany, United Kingdom, Spain, Denmark, Greece, Finland, Hungary, Norway, Portugal, Poland, Sweden and Bulgaria.

**FDA APPROVAL**

Approved for treatment of Travelers' Diarrhoea in U.S.

**MARKETING EXCLUSIVITY IN U.S. UNTIL 2028**

Enjoys marketing exclusivity until 2028 in U.S.under QIDP and NCE designations

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## Aemcolo™ – cont.

### Aemcolo™ phase III clinical trials for Traveler's Diarrhoea

Phase III clinical trials in traveler's diarrhoea were completed in the U.S. and E.U. Aemcolo™ underwent two pivotal trials, with different designs. The first one, performed by Santarus, showed Aemcolo™ superiority vs. placebo (p-value = 0.0008). The second one performed by Dr. Falk Pharma, showed Rifamycin SV MMX non-inferiority vs. Ciprofloxacin (= Cipro, the current standard of care in Traveler's Diarrhoea).

The details of the successful Aemcolo™ phase III clinical trial were announced in November 2016. Aemcolo™ attained the primary endpoint also in this second trial with a Hazard Ratio ≤ 0.764 and a p-value = 0.0018. The Clinical Cure Rate (percentage of patients showing clinical symptoms remission) of Aemcolo™ was 85.0% vs. 84.8% Cipro.

Aemcolo™ has shown a very good efficacy in eradicating the whole E. coli bacteria family (65.9% vs. 63.7% Cipro) and a very similar failure rate to Cipro (14.8 vs. 15.2 Cipro).

The main parameter to show efficacy in Traveler's Diarrhoea is TLUS (Time to Last Unformed Stools). Aemcolo™ TLUS in the patients that completed treatment according to protocol was equivalent to Cipro, 33.3 hrs. vs. 32.8 hrs.

In terms of Microbiological Cure Rate, in the patients that had at least one isolated microorganism, the efficacy was also equivalent to Cipro, 49.24% vs. 49.60%.

Aemcolo™ was administered to more than 600 patients in phase III and was optimally tolerated, with only 5.5% of adverse events possibly drug-related.

### Aemcolo™ phase II clinical trial for IBS-D

In 2017 we commenced a phase II clinical trial for Aemcolo™ for a second indication for diarrhoea-predominant irritable bowel syndrome (IBS-D) with first patient randomised in December 2017. The trial was progressed in 2018 and recruitment is ongoing. This phase II trial if successful would pave the way for future phase III trials for this second IBS-D indication. Should the Company successfully conclude all clinical trial phases this would provide the data for a new indication for Aemcolo™ for the IBS-D market.

**PHASE III**

trial for TD completed and announced November 2016

**PHASE II**

IBS-D trial underway

**PHASE II**

trial for uncomplicated diverticulitis completed by Dr. Falk

Continues on next page >>

## Aemcolo™ – cont.

### Rifamycin SV MMX phase II clinical trial for Uncomplicated Diverticulitis

Approximately 60% of all persons that are older than 60 have diverticulae. When diverticulae get inflamed and infected, serious complications can occur. The phase II trial comparing two doses of Rifamycin SV MMX (400mg BID, 600mg TID & placebo) in Acute Uncomplicated Diverticulitis sponsored by our partner Dr. Falk Pharma has been completed. A full analysis of the results is ongoing in collaboration with Dr. Falk.

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## Methylene Blue MMX

The results of our Methylene Blue MMX pivotal phase III study were announced in November 2016.

The primary endpoint was attained identifying 17.71% more patients with adenomas or carcinomas were identified when the patients took Methylene Blue MMX prior to the endoscopy procedure compared to Standard of Care White Light colonoscopy with High Definition endoscopes.

In the phase III clinical trial, the false positive rate (an important secondary endpoint) in the Methylene Blue MMX arm was lower than in the WLHD. In the Methylene Blue MMX arm 356 subjects out of 485 subjects had an excision. 83 of these subjects (23.3%) were false positives. In the WLHD arm 326 out of 479 subjects had an excision and 97 of these subjects (29.7%) were false positives.

**16 MILLION**

colonoscopies performed P.A. in the U.S.

**17.71%**

improvement in adenoma detection rate

A new diagnostic drug to improve pre-cancerous and cancerous lesion detection during colonoscopies.

Our New Drug Application (NDA) for Methylene Blue MMX was submitted to the U.S. Food and Drug Administration (FDA) in July 2017.

On 23 May 2018 we announced that we had received a Complete Response Letter ("CRL") from the FDA in which the FDA stated that it had determined that it could not approve the NDA in form and while the outcome of the phase III trial had translated in a statistically significant outcome, the outcome was not sufficiently "robust". The FDA recommended that we provide confirmation of effectiveness with a second phase III trial.

On 25 July 2018 the Type A meeting took place with the FDA Medical Imaging Division.

On September 13 2018 we announced that we had received the minutes of the Type A meeting which stated that while some issues had been resolved some disagreement remained with the review division. We also announced that we would pursue the Formal Dispute Resolution process and file an appeal above the Medical Imaging Division level to the Office of Drug Evaluation IV (ODE IV) in the Center for Drug Evaluation and Research (CDER).

On 1 November 2018 we announced that notwithstanding that the FDA had recognised that the Methylene Blue MMX phase III trial had met both the primary and key secondary endpoints under the terms of the Special Protocol Assessment for the trial, the appeal to the ODE IV had been denied.

On 21 December 2018 we announced that we were i n the process of filing a new appeal to the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER).

On 12 March 2019 we announced that the FDA had denied our appeal to OND, CDER. The FDA have advised that a confirmatory phase III trial is required to approve Methylene Blue MMX. Upon agreement with the FDA on a new trial design we will commence a confirmatory phase III trial.

In February 2019 we filed a Marketing Authorisation Application for Methylene Blue MMX 200mg tablets with the European Medicines Agency.

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## Eleview®

Eleview® is an injectable composition, patented by Cosmo, intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers or other gastrointestinal mucosal lesions prior to excision with a snare or other endoscopic device.

Eleview® provides an immediate and long-lasting cushion that holds for up to 45 minutes. Eleview® is designed to decrease the time needed to completely resect a lesion. Eleview® requires less volume to create submucosal cushions compared to saline, it reduces the number of reinjections required compared to saline and reduces piecemeal excisions compared to saline.

Eleview® contains methylene blue which increases visibility of target lesion margins. The improved margin visualisation helps to decrease the risk of damage to the external muscular layer, incomplete resections and of leaving residual adenoma tissue.

Eleview® is classified as a class II medical device in the U.S. and Europe. Eleview® was launched in the U.S. in May 2017 and is the only commercially available device approved by the FDA for the removal of polyps and lesions in the colon.

Cosmo has a co-promotion agreement with Olympus in the U.S. and established a distribution agreement with Fujifilm for Europe and South Africa and since March 2018 for South East Asia, Middle East, Africa, Australia and New Zealand.

A new medical device approved in U.S. and EU to remove colonic lesions more safely and quickly.

**IMPROVES**

visibility of target lesion margins

**DECREASES**

risk of intestinal perforation

**45 MINS**

cushion hold

**DECREASES**

time to resect and volume to inject

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## Remimazolam

Remimazolam is a fast-acting intravenous benzodiazepine agent in-licensed by Cosmo from PAION AG. Cosmo holds an exclusive right to develop and commercialise Remimazolam in the U.S.

In the human body, remimazolam is rapidly metabolised to an inactive metabolite by tissue esterases and is not metabolised by cytochrome-dependent hepatic pathways. Like other benzodiazepines, Remimazolam can be reversed with flumazenil to rapidly terminate sedation and anesthesia if necessary.

During 2017 PAION AG announced positive headline data in a remimazolam U.S. clinical safety trial of high risk (ASA III/IV) patients, the efficacy and efficiency gains were comparable to the first pivotal Phase III trial in colonoscopy patients.

Positive headline results were also announced by PAION AG during 2017 in a U.S. phase III trial for procedural sedation in patients undergoing bronchoscopy.

The trial achieved the primary endpoint and therefore we expect to submit an NDA for Remimazolam to the FDA in Q1 2019.

A new sedation agent to be used in all procedural sedations, including colonoscopies, safer and faster than available alternatives.

**REDUCES**

time to reach sedation

**REDUCES**

time back to normal

**PHASE III**

trials successfully completed in colonoscopy and bronchoscopy

**Q1 2019**

filing of NDA with FDA expected

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## Uceris®/Cortiment®

Uceris®/Cortiment® is an oral tablet formulation which delivers budesonide directly to the lumen of the colon.

Budesonide is a corticosteroid that acts as an anti-inflammatory pharmaceutical product.

The specific pharmaceutical product dissolution profile increases the colonic specific bio-availability of budesonide and reduces the pre-colonic systemic absorption.

The intended reduction of systemic absorption reduces side effects associated with pharmaceutical product treatment while the intended delivery to the colon enables the product to be especially effective in the treatment of proximal and distal Ulcerative Colitis.

Uceris®/Cortiment® tablets are a prescription corticosteroid medicine used to help get active, mild to moderate ulcerative colitis under control (induce remission) and may help relieve the symptoms of Ulcerative Colitis.

Through the application of our MMX® technology to budesonide, an off-patent corticosteroid, Cosmo has developed a treatment which is more effective than existing 5-ASA applications and less toxic than classical corticosteroid applications.

Uceris® is licenced to Bausch Health in the U.S. In July 2018 the FDA approved a generic version of Uceris®. Nothwithstanding that a patent infringement case is ongoing in appeal Teva launched the generic at risk.

Cosmo will continue to defend and enforce it's Uceris® patent rights and if the generic is found to have infringed our patent rights in appeal this would expose Teva to significant damages.

Cortiment® is licensed to Ferring in the Rest of World.

**US$96.7M**

Uceris® net sales in 2018 by Bausch Health

**€17.5M**

Royalty and Manufacturing income in 2018

**US$134.2M**

Uceris® net sales in 2017 by Bausch Health

**€25.7M**

Royalty and Manufacturing income in 2017

**€15.1M**

Cortiment® net sales in 2018 by Ferring

**€3.9M**

Royalty and Manufacturing income in 2018

**€13.5M**

Cortiment® net sales in 2017 by Ferring

**€3.4M**

Royalty and Manufacturing income in 2017

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## Lialda®

Lialda®/Mezavant®/Mesavancol® is an oral tablet formulation to deliver mesalazine directly into the lumen of the colon using our MMX® technology. The specific pharmaceutical product dissolution profile increases the colonic specific disposition of mesalazine, reduces the pre-colonic systematic absorption and allows the product to be especially effective for the treatment of both proximal and distal Ulcerative Colitis.

The application of the MMX® technology reduces the number of tablets which patients taking mesalazine in non-acute phases have to take to approximately two tablets a day, and to three to four tablets per day during acute phases of Ulcerative Colitis. The reduction in the number of tablets required compared to the standard oral administration of mesalazine results in an increase in medication adherence.

Lialda® is a once-daily mesalamine approved to help get active, mild to moderate Ulcerative Colitis into remission.

In 2018 a generic of Lialda® was launched in the U.S. market and this adversely impacted on our income.

Lialda® is a once-daily mesalamine approved to help get active, mild to moderate Ulcerative Colitis into remission

**€20.7M**

Manufacturing and Royalty income in 2018

**€25.2M**

Manufacturing and Royalty income in 2017

Continues on next page >>

## Qolotag®

Qolotag® is single use enema formulation developed by Cosmo composed of a liquid emulsion made with a special polymer and dyed with methylene blue.

Qolotag® cleanses the sigmoid colon and the rectum prior to sigmoidoscopy and simultaneously stains the rectal mucosa enhancing the tissues' structure.

This improves the visualisation of the lesions and the diagnosis of dysplasias and bowel diseases during the procedure.

Qolotag® is classified as a medical device, is approved for marketing in the EU and carries the CE mark.

Qolotag® is a new product, which allows for a faster and better enhancement of detection of small lesions or dysplasias during sigmoidoscopies

QOLOTAG®

is approved for marketing in the E.U. and carries the CE mark

Continues on next page >>

# DIRECTORS' REPORT

**Mauro S. Ajani**
Chairman

**Alessandro Della Chà**
CEO

Dear Shareholder

2018 presented many challenges for Cosmo.

Our first antibiotic Aemcolo™ was approved by the FDA and in EU under the brand name Relafalk, whilst Eleview® performed according to our expectations.

In the meantime, the FDA did not approve Methylene Blue MMX NDA, notwithstanding the Special Protocol Assessment agreement and the excellent trial results.

Further, while the franchise of Lialda® has grown in Japan and in the EU and that of Cortiment® (Uceris®) all over the world, generics were launched in the US competing with both Lialda® and Uceris®.

## Methylene Blue MMX

In May we received a Complete Response Letter (CRL) from the FDA in relation to our Methylene Blue MMX NDA. In the CRL the FDA stated that it had determined that it could not approve the NDA in its present form. The CRL did not raise any safety or manufacturing concerns but stated that, although the phase III trial has translated in a statistically significant outcome, the outcome was not sufficiently "robust" and recommended a second phase III trial to provide confirmation of effectiveness. In June we submitted a Type A Meeting Request and Briefing Document to the FDA.

On the 25th July a Type A meeting took place with the FDA Medical Imaging Division and on 13 September following the receipt of the minutes of the meeting we communicated that while some issues had been resolved some disagreement remained with the review division. We announced that we would purse the Formal Dispute Resolution process and file an appeal above the Medical Imaging Division level to the Office of Drug Evaluation IV in the Centre for Drug Evaluation and Research.

In November we announced that notwithstanding that the FDA had recognised that Methylene Blue MMX phase III trial had met both the primary and key secondary endpoints under the terms of the Special Protocol Assessment for the trial, the appeal to the ODE IV had been denied with the FDA continuing to recommend a second phase III trial.

In December we filed a new appeal to the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). A meeting took place with the FDA on 18 January 2019 and on 12 March 2019 we announced that the FDA Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) had denied our last appeal.

While stating again that the completed phase III clinical trial has been successful and statistically significant, the FDA concluded that a phase III confirmatory trial is needed to approve the drug since Methylene Blue MMX is not intended to cure a disease but help the prevention of colorectal cancer and will likely be taken by millions of patients undergoing colonoscopy.

We believe that the time spent with the Agency in discussing the dispute resolution has been very helpful in clarifying the underlying issues. We have thus decided that there was no reason to pursue further appeals as we concluded the Agency had made up its mind in a final form. Nonetheless, because of all that has been learned in the dispute resolution process, we believe we know now how to present a new clinical plan encompassing different endpoints that will take into account all excellent findings of the completed phase III. Upon agreement with the FDA on a new trial design we will immediately start a confirmatory phase III trial.

Separately, in February 2019 we filed a Marketing Authorisation Application for Methylene Blue MMX 200mg tablets with the European Medicines Agency.

### Financial Performance
In 2018 our revenues were €65.6 million, a reduction of 2.5% versus 2017, net operating expenses increased by 7% to €82.2 million and our operating loss was €16.6 million.

In 2018 the operating costs associated with our U.S. operation were €33.7 million while revenue generated from Eleview® sales was €6.8 million.

Following the unexpected set-back in relation to obtaining approval from the FDA for Methylene Blue MMX we have reviewd our cost structure. At the beginning of 2019 we have taken steps to reduce the cost base of our Aries organisation and we expect to achieve cost savings of €15.0 million compared to 2018.

### Pharmascience Agreement
In February we entered into a license and supply agreement for Eleview®, Methylene Blue MMX, Aemcolo™ and Qolotag® for the territory of Canada with Pharmascience, the fourth largest Company in Canada by number of prescriptions. The agreement included an up-front payment of CA$5 million as well as additional commercial milestones based on reaching certain net sales thresholds and high double-digit royalties. Submissions have been made by Pharmascience to Health Canada for Methylene Blue MMX and Eleview®, the review of both is ongoing with approval expected in the third quarter of 2019.

### Fujifilm Agreement
In March we expanded our exclusive distribution agreement for Eleview® with FUJIFILM Europe B.V. beyond Europe and South Africa to South East Asia, Middle East, Africa, Australia and New Zealand. FUJIFILM are planning market launch in the second half of 2018 and Cosmo will receive 45% of gross revenues under the terms of the agreement.

### EA Pharma Agreement
Also in March, Cosmo entered into a license and supply agreement for Methylene Blue MMX and Eleview® with EA Pharma for the territories of Japan and South Korea. Cosmo received an upfront payment and will receive additional development and commercial milestone payments upon reaching certain annual net sales thresholds plus royalties once the products are approved.

### Lialda®/Mezavant®
A generic version of Lialda® was launched in the U.S. in March, as a result our Lialda® income reduced from €25.2 million to €20.7 million. Income from the U.S. reduced from €13 million to €3 million although this was partially off-set by an increase in Europe where income increased by 18% to €9 million and in Japan where manufacturing income increased from €0.6 million to €3.7 million and royalty income increased from €0.5 million to €1.6 million.

### Uceris®/Cortiment®
A generic of Uceris® was launched in July in the U.S., an authorised generic of Uceris® was also launched by Bausch Health however net sales of both Uceris® and the authorised generic by Bausch Health reduced by 28% to US$96.7 million and our royalty and manufacturing income reduced from €25.7 million to €17.5 million.

Disappointingly, in April the ICC Arbitral Tribunal ruled that Bausch Health was not in breach of the Uceris® License Agreement notwithstanding our claims.

Cortiment® net sales by our licensee Ferring increase by 12.1% to €15.1 million and our royalty and manufacturing income increased by 13% to €3.9 million.

### Eleview®
Eleview® revenue was €6.8 million compared to €1.6 million in 2017.

### Aemcolo™
In November the FDA approved Aemcolo™ (Rifamycin SV MMX) for the treatment of Travelers' Diarrhoea caused by non-invasive strains of Escherichia coli in adults. Aemcolo™ enjoys marketing exclusivity until to 2028 with the QIDP and the NCE designations.

Dr. Falk Pharma received approval via the European Decentralized Procedure for Relafalk (Rifamycin SV MMX) for the treatment of Travelers' Diarrhoea. This grants marketing Authorisation in Germany, United Kingdom, Spain, Denmark, Greece, Finland, Hungary, Norway, Portugal, Poland, Sweden and Bulgaria.

In parallel, our Aemcolo™ phase II proof of concept study in IBS-D is progressing, the trial is open in Belgium, Italy, Spain and Germany and recruitment is ongoing.

### Remimazolam
A pre-NDA meeting for Remimazolam took place with the FDA on 12 July, the preparation of the NDA submission package is ongoing with filing of the NDA expected by the end of Q1 2019.

### Development Pipeline
Our development pipeline continues to progress for several other drug products and devices in development stages.

### Cassiopea SpA
Our associate Cassiopea SpA, of which we own 45.09%, communicated a sequence of very good news including the successful Phase III clinical trial outcome of its drug Winlevi® for the treatment of acne and the sucessful phase II clinical trial interim analysis of its drug Brezula® for the treatment of Androgenetic Alopecia. As at 27 March 2019, Cosmo's stake in Cassiopea had a market value of €184.5 million compared to €134.2 million as at 31 December 2017.

### Convertible Bonds due 2023
In November we successfully placed €175 million senior unsecured convertible bonds due 2023 raising net proceeds of €163.4 million. The annual coupon is 2.5% and maturity is five years, so we believe we have raised capital at very appealing conditions. Even more importantly, the essential feature of the bond is that we are entitled to reimburse it, if we elect to do so, using up to 2.4 million Cosmo shares (which is a feature normally reserved to much larger issuer). This was especially crafted in order to reduce as much as possible the risk for the issuer.

### Our people
We thank our employees for their continued hard work, professionalism, dedication and focus on quality and our Board of Directors for their advice and oversight.

### Key priorities for 2019 and beyond
Our primary focus for the remainder of 2019 and beyond will be to progress the tasks to bring Aemcolo™ and Remimazolam to market, progress our product pipeline, restructure our U.S. organisation in order to make it cost efficient, reach an understanding with the FDA in relation to the new confirmatory phase III trial for Methylene Blue MMX and hopefully commence the trial.

We thank you, our shareholders, for your continued support and we look forward to updating you on Cosmo's developments.

Dublin, Ireland, 28 March 2019

**Mauro S. Ajani**
Chairman

**Alessandro Della Chà**
CEO

# OUR STRATEGY

## Cosmo's therapeutic focus is on the oral and endoscopic treatment of colon diseases.

Our strategy is built on innovation, improving clinical outcomes, improving patient safety and meeting unmet medical needs.

Cosmo develops pharmaceutical products based on its know-how. The Company's proprietary MMX® technology allows the delivery of active pharmaceutical ingredients into the lumen of the colon throughout the full length of the colon.

We aim to improve the safety profile and efficacy of molecules that are already on the market, or to make them more patient or user friendly.

Cosmo has a demonstrated ability to successfully identify unmet medical needs, manage the drug development process and obtain regulatory approval for new products.

Historically, we have exclusively licensed our products and our licensee partners have sold, marketed and distributed our products.

In 2017 we launched Eleview® directly in the U.S. market with our own marketing and sales organisation.

We will continue to license our products to established partners into other markets as appropriate.

We have a risk-averse financial approach, we believe that pursuing strategic objectives in the context of low levels of financial risk provides the greatest likelihood of generating value for shareholders.

Ensuring that adequate cash reserves are in place is a key strategic priority for us and maintaining low levels of financial risk allows us to quickly react to opportunities as they arise.

Careful cash management has enabled the implementation of our strategic objectives with the Company's own financial resources.

Our overriding objective is to achieve superior long-term returns for shareholders.

## Business performance against strategic objectives

| Strategic priority | Metrics | Performance | Comments |
|---|---|---|---|
| Market, sell and distribute our products in the U.S. | Sale of own products to end customer | Achieved Eleview® revenue of €6.8 million in 2018 | |
| Advance clinical pipeline | Obtain regulatory approval for Methylene Blue MMX | Discussions ongoing with the FDA in relation to Methylene Blue MMX approval | Methylene Blue MMX significantly improves ADR identifying 17.71% more patients with adenomas or carcinomas compared with high definition white light endoscopy, which is the current highest standard of care |
| | Obtain regulatory approval for Aemcolo™ | Aemcolo™ New Drug Application seeking marketing authorisation for the treatment of Traveler's Diarrhoea approved by the FDA. The FDA granted Qualified Infectious Disease Product (QIDP) and together with new chemical entity (NCE) designation Aemcolo™ enjoys marketing exclusivity until 2028.<br><br>Dr. Falk Pharma received approval via the European Decentralized Procedure for Relafalk (Rifamycin SV MMX) for the treatment of Travelers' Diarrhoea. | |
| | Bring Remimazolam to market | NDA filing with FDA expected by end of Q1 2019 | |
| Replenishment of pipeline | Rifamycin SV MMX IBS-D | Proof of Concept phase II clinical trial in IBS-D underway | Trial will be progressed in 2019 |
| | Development of AntiTNF MMX | Biobetter identified, industrial scale | Trial will be progressed in 2019 |
| Adequate cash and liquid investment reserve | Adequate level of cash plus liquid investment reserve | Cash and cash equivalents, bonds and investments of €375.8 million at 31 December 2018 | Cash and liquid investments to finance entire development of pipeline and strategic plans |
| Partners | Revenue derived from partners | Ferring, the licensee for Cortiment®, continuing to grow sales | Net sales increased by 12.1% to €15.1 million in 2018 |

## Income Statement

Revenue for the year ended 31 December 2018 was €65,617 thousand (2017: €67,242 thousand) and loss before taxes was €17,459 thousand (2017: Loss before tax €32,432 thousand.

Net operating expenses increased by €5,392 thousand to €82,238 thousand of which:

- S,G&A costs increased to €50,638 thousand (2017: €46,279 thousand) mainly as a result of an increase in costs in our U.S. organisation.
- Cost of sales increased to €22,058 thousand (2017: €21,988 thousand) as a result of an increase in raw material costs and production labour costs.
- Research and Development costs increased to €10,428 thousand (2017: €9,049 thousand).

Net financial income/(expense) was net income of €4,615 thousand (2017: net expense €16,936 thousand) which mainly relates to a foreign exchange gain due to the movement in the Euro/US$ exchange rate over the period.

Share of result of associates relates to the Company's 45.09% stake in Cassiopea, the Group's share of Cassiopea's losses was €5,453 thousand (2017: €5,892 thousand).

Loss before taxes was €17,459 thousand (2017: €32,432 thousand).

Income tax expenses were €598 thousand (2017: €15 thousand) in the period.

The loss for the period was €18,057 thousand (2017: Loss of €32,447 thousand).

| EUR 1,000 | FY 2018 | FY 2017 |
|---|---|---|
| **Revenue** | **65,617** | **67,242** |
| Net operating expenses | (82,238) | (76,846) |
| **Operating loss** | **(16,621)** | **(9,604)** |
| Net financial income/(expense) | 4,615 | (16,936) |
| Share of result of associates | (5,453) | (5,892) |
| **Loss before taxes** | **(17,459)** | **(32,432)** |
| Income tax expenses | (598) | (15) |
| **Loss for the period** | **(18,057)** | **(32,447)** |

## Revenue

### Lialda®/Mezavant®/Mesavancol®

Lialda®/Mezavant®/Mesavancol® revenue reduced by €4,511 thousand to €20,707 thousand. The reduction in revenue was due mainly to the launch of a generic version of Lialda® in the U.S. in March 2018.

U.S. manufacturing income reduced from €12,957 thousand to €3,028 thousand was partially offset by an increase in royalty and manufacturing income for Mesavancol® for Japan which increased from €1,129 thousand to €5,327 thousand and an increase in manufacturing income for Europe which increased from €7,629 thousand to €9,001 thousand.

### Uceris®

Uceris® revenue decreased by €8,192 thousand to €17,530 thousand as a result of the launch of a generic version of Uceris® in July 2018, net sales by Valeant reduced to US$ 96.7 million (2017: US$ 134.2 million).

### Cortiment®

Cortiment® manufacturing and royalty revenue increased from €3,412 thousand to €3,868 thousand a result of higher net sales by our partner Ferring which increased 12.1% from €13,476 thousand to €15,105 thousand. In 2017 a milestone of €1,000 thousand was received and this did not reoccur in 2018.

### Eleview®

Eleview® income was €6,760 thousand representing an increase of €5,192 thousand compared to 2017.

### Licence fees, up-front fees and milestones

Licence fees, up-front fees and milestones income of €5,705 thousand (2017: €1,500 thousand) includes CAD$5,000 thousand (€3,205 thousand) relating to a licence and supply agreement for Eleview®, Methylene Blue MMX, Qolotag® and Aemcolo™ with Pharmascience for the Canadian territory, a milestone fee of €1,000 thousand for Aemcolo™ relating to a license and supply agreement for the Italian territory and €1,500 thousand relating to a license agreement with EA Pharma for Japan for Eleview®.

### Generic products and specialty drugs

Income from manufacturing of generics decreased by 5.9% to €7,775 thousand (2017: €8,261 thousand).

| EUR 1,000 | FY 2018 | % of revenue | FY 2017 | % of revenue |
|---|---|---|---|---|
| Manufacturing on behalf of third parties: | | | | |
| Manufacturing of generic products and speciality drugs | 7,775 | 11.9 | 8,261 | 12.3 |
| Manufacturing of MMX® products | 27,515 | 41.9 | 36,315 | 54.0 |
| Related services | 2,280 | 3.5 | 722 | 1.1 |
| Other revenues from sales | 945 | 1.4 | 805 | 1.2 |
| Marketed products – Eleview® | 6,759 | 10.3 | 1,568 | 2.3 |
| Licence fees, up-front fees and milestones | 5,705 | 8.7 | 1,500 | 2.2 |
| Royalties | 14,638 | 22.3 | 18,071 | 26.9 |
| **Total revenue** | **65,617** | **100.0** | **67,242** | **100.0** |

| | Year ended 31 December | | Year ended 31 December | |
|---|---|---|---|---|
| EUR 1,000 | FY 2018 | % of revenue | FY 2017 | % of revenue |
| Own products | 54,617 | 83.2 | 57,454 | 85.4 |
| Third-party products | 11,000 | 16.8 | 9,788 | 14.6 |
| **Total revenue** | **65,617** | **100.0** | **67,242** | **100.0** |

Revenue related to own products, which includes manufacturing of MMX® products, license fees, up-front fees and royalties, represents 83.2% (2017: 85.4%) of total revenue.

## Net operating expenses

| EUR 1,000 | FY 2018 | % of revenue | FY 2017 | % of revenue |
|---|---|---|---|---|
| Other income | 886 | 1.4 | 470 | 0.7 |
| Cost of sales | (22,058) | (33.6) | (21,988) | (32.7) |
| Research and development costs | (10,428) | (15.9) | (9,049) | (13.5) |
| Selling, general and administrative costs | (50,638) | (77.2) | (46,279) | (68.8) |
| **Total net operating expenses** | **(82,238)** | **(125.3)** | **(76,846)** | **(114.3)** |

## Operating expenses as per nature

| EUR 1,000 | FY 2018 | % of revenue | FY 2017 | % of revenue |
|---|---|---|---|---|
| Other income | 886 | 1.4 | 470 | 0.7 |
| Changes in inventories of finished goods and wip | 84 | 0.1 | 919 | 1.4 |
| Raw materials and consumables used | (6,304) | (9.6) | (8,163) | (12.1) |
| Personnel expenses | (38,565) | (58.8) | (35,990) | (53.5) |
| Outsourced preclinical and clinical trial costs | (2,545) | (3.9) | (740) | (1.1) |
| Other operating expenses | (31,310) | (47.7) | (29,802) | (44.3) |
| Depreciation and amortisation | (4,484) | (6.8) | (3,540) | (5.3) |
| **Total net operating expenses** | **(82,238)** | **(125.3)** | **(76,846)** | **(114.3)** |

### Raw materials and consumables used

Expenditure on raw materials, consumables used and changes in inventory reduced by €1,024 thousand to €6,220 thousand.

### Personnel expenses

Personnel expenses increased by €2,575 thousand to €38,565 thousand due to the full year impact of the hiring of marketing and sales personnel in the U.S. in 2017.

The average number of employees in the Group in 2018 was 302 (2017: 275.5) and as at 31 December 2018 a total of 306 (2017: 301) people were employed in the Group.

The average staff numbers for the year ended 31 December 2018 was as follows:

| No. of people | FY 2018 | FY 2017 |
|---|---|---|
| Managers | 18.5 | 18.0 |
| Junior managers | 63.0 | 51.5 |
| Employees | 130.5 | 114.5 |
| Workers | 90.0 | 91.5 |
| **Total average number** | **302.0** | **275.5** |

The number of staff by function as at 31 December 2018 was as follows:

| Employees by function | As at 31 December | | As at 31 December | |
|---|---|---|---|---|
| | FY 2018 | % | FY 2017 | % |
| Research & Development | 60 | 20.0 | 40 | 13.3 |
| Production & Logistics | 133 | 43.0 | 142 | 47.2 |
| Selling, General, Adm. & Finance, IT and others | 113 | 37.0 | 119 | 39.5 |
| **Total** | **306** | **100.0** | **301** | **100.0** |

### Outsourced preclinical and clinical trial costs

Outsourced pre-clinical and clinical trial costs were €2,545 thousand (2017: €740 thousand) and related mainly to the Aemcolo™ IBS-D Phase II trial.

### Other operating expenses

Other operating expenses increased by 5.1% to EUR 31,310 thousand and include advertising and marketing costs of €9,901 thousand (2017: €9,477 thousand), external consultancy services of €7,636 thousand (2017: €5,531 thousand), operating lease expenses of €1,942 thousand (2017: €1,682 thousand) maintenance costs of €1,715 thousand (2017: €1,826 thousand), utility costs of €1,537 thousand (2017: €1,487 thousand) patent related costs of €927 thousand (2017: €1,730 thousand) and other operating costs of €1,035 thousand (2017: €1,172 thousand).

### Depreciation and amortisation

Depreciation and amortisation of other intangible assets increased by €944 thousand to €4,484 thousand.

## Financial income and expenses

| EUR 1,000 | FY 2018 | FY 2017 |
|---|---|---|
| **Financial income:** | | |
| Interest received on listed bonds and securities at FVOCI | 1,449 | 2,333 |
| Interest received on cash and cash equivalents | 748 | 642 |
| Gain on sale of listed bonds and securities at FVOCI | 145 | 437 |
| Gain on investments in funds mandatorily at FVTPL | 414 | – |
| Foreign exchange gains | 5,350 | 331 |
| Movement in loss allowance on financial investments at FVOCI | 21 | – |
| Other | – | 41 |
| **Total financial Income** | **8,127** | **3,784** |
| | | |
| **Financial expenses:** | | |
| Interest on bank overdraft/advance on invoices at amortised cost | (8) | (9) |
| Interest on medium and long term bank loan at amortised cost | (25) | (29) |
| Interest on financial lease payables at amortised cost | (32) | (41) |
| Interest on convertible bond at amortised cost | (582) | – |
| Impairment loss on financial assets available for sale | – | (24) |
| Loss on sale of listed bonds and securities at FVOCI | (1,806) | (1,858) |
| Loss on investments in funds mandatorily at FVTPL | (353) | – |
| Foreign exchange losses | (308) | (18,724) |
| Other | (398) | (35) |
| **Total financial expenses** | **(3,512)** | **(20,720)** |
| **Net financial income/(expense)** | **4,615** | **(16,936)** |

Financial income was €8,127 thousand (2017: €3,784 thousand) and mainly includes foreign exchange gains of €5,350 thousand (2017: €331 thousand) and interest received on listed bonds and securities of €1,449 thousand (2017: €2,333 thousand), interest received on cash and cash equivalents of €748 thousand (2017: €642 thousand), gains on the sale of listed bonds and securities at FVOCI €145 thousand (2017: €437 thousand) and gains on investments in funds at FVTPL €414 thousand (2017: Nil).

Financial expenses of €3,512 thousand (2017: €20,720 thousand) includes losses on the sale of listed bonds and securities at FVOCI of €1,806 thousand (2017: 1,858 thousand), interest on convertible bond €582 thousand (2017: Nil), loss on investments in funds FVTPL €353 thousand (2017: Nil) and foreign exchange losses of €308 thousand (2017: €18,724 thousand).

### Income tax expenses

Income taxes in the period were €598 thousand (2017: €15 thousand).

### Net Profit After Tax

Net loss for the period was €18,057 thousand (2017: Net loss €32,447 thousand).

## Assets

### Non-current assets

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Property, plant and equipment | 28,616 | 30,152 |
| Goodwill | 1,439 | 109 |
| Other intangible assets | 35,524 | 28,525 |
| Investments in associates | 130,402 | 135,742 |
| Financial assets | 41,855 | 93,811 |
| Deferred tax assets | 11,724 | 10,456 |
| Other non-current receivables | 1,959 | 1,873 |
| **Total non-current assets** | **251,519** | **300,668** |

### Property, plant and equipment

Property, plant and equipment primarily consists of the real estate property in Lainate (industrial plant, laboratories and offices), inclusive of surrounding land and of the equipment in the plant that is used for the manufacturing of MMX® tablets. During 2018, an investment of €1,898 thousand (2017: €12,289 thousand) was made in property, plant and equipment.

## Goodwill

The increase in Goodwill relates to the acquisition of Linkverse in July 2018, through the purchase of shares and a capital increase Cosmo increased its shareholding from 30% to 60%. Previously Cosmo's shareholding was held as an equity investment carried at cost of €300k.

## Other intangible assets

Other intangible assets as at 31 December 2018 consist of:

- Patents and rights of €3,866 thousand (2017: €3,820 thousand).
- Capitalised Remimazolam license costs of €10,000 thousand (2017: €10,000 thousand) in relation to the license agreement signed with PAION AG.
- Capitalised development costs of €21,563 thousand (2017: €14,705 thousand).
- Assets under construction of €95 thousand (2017: Nil)

## Capitalised development costs of €21,563 thousand (2017: €14,705 thousand) consists of:

- Methylene Blue MMX (CB-17-01) €9,835 thousand (2017: €9,464 thousand)
- Aemcolo™ (CB-01-11) €7,540 thousand (2017: €3,197 thousand)
- Eleview® (CB-17-04) €1,512 thousand (2017: €1,607 thousand)
- Remimazolam (CB-07-01) €2,676 thousand (2017: €437 thousand)

The development projects are progressing in line with the technical and economic plan and after review, Management confirms the recoverability of the relevant capitalised costs, based on probable future economic benefits.

## Investment in associates

Investments in Associates consists of the Group's 45.09 % interest in Cassiopea S.p.A (4,508,987 shares) which was listed on the SIX Swiss Exchange on 1 July 2015.

## Non-current financial assets

Non-current financial assets of €41,855 thousand (2017: €93,811 thousand) includes the Group's investments in funds and bonds of €26,330 thousand (2017: €74,459 thousand) and €15,525 thousand (2017: €19,352 thousand) relating to shareholdings in AIMM Therapeutics, PAION AG and VolitionRX and other investments.

## Deferred tax assets

Deferred tax assets of €11,724 thousand (2017: €10,456 thousand) consist mainly of losses carried forward related to our Aries Group, losses on the sale of financial investments measured at FVOCI and tax assets related to certain intercompany transactions.

## Current assets

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Inventories | 3,937 | 3,241 |
| Trade receivables | 12,762 | 13,190 |
| Current tax assets | 5,231 | 2,972 |
| Other receivables and other assets | 2,801 | 5,200 |
| Current financial assets | 138,747 | 27,759 |
| Cash and cash equivalents | 210,689 | 144,944 |
| **Total current assets** | **374,167** | **197,306** |

## Current financial assets

Current financial assets of €138,747 thousand (2017: €27,759 thousand) consist of the current element of the Group's investments in funds and bonds.

## Cash and cash equivalents

Cash and cash equivalents were €210,689 thousand (2017: €144,944 thousand) as at 31 December 2018.

## Equity and liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Share capital | 3,910 | 3,910 |
| Share premium | 84,448 | 84,448 |
| Other reserves | 47,845 | 47,845 |
| Treasury shares | (18,353) | – |
| Stock option plan reserve | 19,299 | 9,597 |
| Fair value reserve | (56) | 3,894 |
| Equity component of convertible bond | 7,011 | – |
| Employee benefits actuarial gains/losses reserve | (163) | (155) |
| Currency translation reserve | (197) | 958 |
| Retained earnings | 318,023 | 352,067 |
| Loss for the period | (18,007) | (32,447) |
| **Equity attributable to owners of the company** | **443,760** | **470,117** |
| **Non-controlling interests** | **1,094** | – |
| **Total equity** | **444,854** | **470,117** |

As at 31 December 2018, Cosmo Pharmaceuticals had 15,037,483 (2017: 15,037,483) shares issued, fully subscribed and paid up, each share with a nominal value of EUR 0.26.

As at 31 December 2018, Equity attributable to owners of the company was €443,760 thousand (2017: €470,117 thousand).

### Non-current liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Interest-bearing loans and borrowings | 157,623 | 3,827 |
| Employee benefits | 365 | 318 |
| Deferred tax liabilities | 7,499 | 4,280 |
| **Total non-current liabilities** | **165,487** | **8,425** |

Interest bearing loans and borrowings of €157,623 thousand (2017: €3,827 thousand) consist of the convertible bond - liability component of €154,322 thousand (2017: Nil), financial lease liabilities of €2,217 thousand (2017: €2,616 thousand) and bank loans of €1,084 thousand (2017: €1,211 thousand).

### Current liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Interest-bearing loans and borrowings | 527 | 649 |
| Trade payables | 8,806 | 11,328 |
| Current tax liabilities | 424 | 1,538 |
| Other current liabilities | 5,588 | 5,917 |
| **Total current liabilities** | **15,345** | **19,432** |

As at 31 December 2018 current liabilities were €15,345 thousand (2017: €19,432 thousand) and include trade payables of €8,806 thousand (2017: €11,328 thousand), other current liabilities of €5,588 thousand (2017: €5,917 thousand) and interest bearing loans and borrowings of €527 thousand (2017: €649 thousand).

## Cashflow

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Loss for the period before tax | (17,459) | (32,432) |
| Income taxes paid (net) | (4,156) | (9,051) |
| Adjustment for non-monetary item | 14,906 | 33,376 |
| Change in net working capital | (3,455) | (1,321) |
| **Net cash flows from operating activities** | **(10,164)** | **(9,428)** |
| Investments in property, plant and equipment | (1,898) | (12,289) |
| Investments in other intangible assets | (7,774) | (9,746) |
| Disposals of property, plant and equipment | 28 | 36 |
| Net (outflows)/inflows from the investment in/ disposal of financial assets | (64,851) | (5,619) |
| Interest received | 2,793 | 3,889 |
| Net cash flow due to Linkverse acquisition | (79) | – |
| **Cash flows from investing activities** | **(71,781)** | **(23,729)** |
| Repayments of interest-bearing loans and borrowings | (665) | (854) |
| Change in other non-current receivables | – | (173) |
| Purchase of treasury shares | (18,353) | – |
| Sale of treasury shares | – | 47,290 |
| Capital increase/Stock option exercise | – | 48,963 |
| Dividends paid | – | (22,556) |
| Issue of convertible bond | 166,250 | – |
| Transaction costs related to loans and borrowings | (2,841) | – |
| **Cash flows from financing activities** | **144,391** | **72,670** |
| **Net increase/(decrease) in cash and cash equivalents** | **62,446** | **39,513** |
| **Cash and cash equivalents at the beginning of the year** | **144,944** | **117,649** |
| **Net foreign exchange differences** | **3,299** | **(12,218)** |
| **Total cash and cash equivalents at the end of the year** | **210,689** | **144,944** |

The net cash outflow from operating activities was €10,164 thousand (2017: €9,428 thousand). Income taxes paid during the period were €4,156 thousand (2017: €9,051 thousand) and working capital outflows during the year were €3,455 thousand (2017: €1,321 thousand).

Investment in property, plant and equipment was €1,898 thousand (2017: €12,289 thousand).

Investment in other intangible assets of €7,774 thousand (2017: €9,746 thousand) relates to capitalised development costs mainly associated with Methylene Blue MMX, Aemcolo™ and Remimazolam.

Net outflows related to investment in/disposal of financial assets available for sale were €64,851 thousand (2017: €5,619 thousand).

Interest of €2,793 thousand (2017: €3,889 thousand) was received in the period.

The Company purchased 201,770 treasury shares in 2018 resulting in an outflow of €18,353 thousand. In 2017 the Company sold 315,447 treasury shares generating an inflow of €47,290 thousand.

The Company raised net proceeds of €163,409 thousand (2017: Nil) during the period though the issue of a convertible bond.

No dividends were paid during 2018, in 2017 dividends of €22,556 thousand were paid.

The net increase in cash and cash equivalents during 2018 was €62,446 thousand (2017: €39,513 thousand)

## Patents and licenses

Patents and other intellectual property rights are important to our business. Cosmo has been pursuing a double-cover selective country patent strategy. Our intellectual property rights have material value and we have act to protect them. A global MMX® patent protecting the platform technology has been filed and granted in practically all major countries and deriving product patents have been filed and received in most of the countries. In selective cases the Company subsequently, files process and use patents. In 2017 the Cosmo patent portfolio was further strengthened worldwide by the following patent-related activities:

### Patents granted in 2018

- **CB-17-04 Eleview®** two patents were granted in the United States with one patent expiring in November 2034 and one patent expiring in January 2035. One patent was granted in Australia with expiry in November 2034 and one patent was granted in Russia with expiry in November 2034.
- **CB-01-02 Uceris®** five patents were granted in the USA with three patents expiring in June 2020 and two patents expiring in September 2031. One ADD ON patent was granted in Russia, expiry in February 2033.
- **CB-17-01 Methylene Blue MMX** one patent was granted in Australia, Japan and Russia with expiry in September 2033.
- **CB-07-01/02** (under PAION AG license) one patent was granted in the USA with expiry in July 2027.
- **CB-07-01/03** (under PAION AG license) one patent was granted in the USA with expiry in September 2030.
- **CB-07-01/04** (under PAION AG license) one patent was granted in the USA with expiry in March 2034.
- **CB-07-01/06** (under PAION AG license) one patent was granted in the USA with expiry in November 2031.
- **CB-07-01/06** (under PAION AG license) one patent was granted in the USA with expiry in November 2031.
- **CB-16-01/01** one patent was granted in Canada with expiry in July 2031.
- **CB-03-10** one patent was granted in Europe with expiry in October 2035.

### Notice of Allowance 2018

- **CB-17-04 Eleview®** one patent application allowed in Russia.
- **CB-07-01/06** (under PAION AG license) one patent application allowed in the USA.
- **CB-01-02 Uceris®** one patent application allowed in the USA.
- **CB-03-10** one patent application was allowed in the USA.
- **CB-03-06** one patent application was allowed in the USA.
- **CB-17-01 Methylene Blue MMX** one patent application was allowed in Canada, one patent application was allowed in Europe and one patent application was allowed in Mexico.

### New Patent Filings 2018

- **CB-17-04 Eleview®** one patent application in the USA was filed.
- **CB-01-02 Uceris®** six patent applications were filed in the USA.
- **CB-17-01 Methylene Blue MMX** one patent applications was filed in the USA. One divisional application was filed in New Zealand.
- **CB-17-01/03** one international (PCT) patent application was filed.
- **CB-03-10** one divisional application was filed in the USA, one divisional application was filed in Europe and a further application was filed in Brazil.
- **CB-07-01/02** (under PAION AG license) one patent application was filed in the USA.
- **CB-07-01/04** (under PAION AG license) one patent application was filed in the USA.
- **CB-07-01/06** (under PAION AG license) two patent applications were filed in the USA.
- **CB-07-01/08** (under PAION AG license) one patent application was filed in the USA.
- **CB-01-12** one international (PCT) patent application was filed.
- **CB-01-23** one international (PCT) patent application was filed.
- **CB-01-18** one international (PCT) patent application including Argentina was filed.

### Trademark Registrations 2017

- **Methylene Blue MMX** (word) one trademark registration in the USA and two in Europe.
- **Methylene Blue MMX** (word and device in colour) one trademark registration in the USA.
- **Qolotag®** (word) one trademark registration in the USA.
- **Qolotag®** (word and device in colour) one trademark registration in the USA.
- **MMX®** (word) one trademark registration in Taiwan.
- **Aries** (device in colour) one trademark registration in the U.S.
- **Aries** (icon) one trademark registration in the USA.

# RISK MANAGEMENT

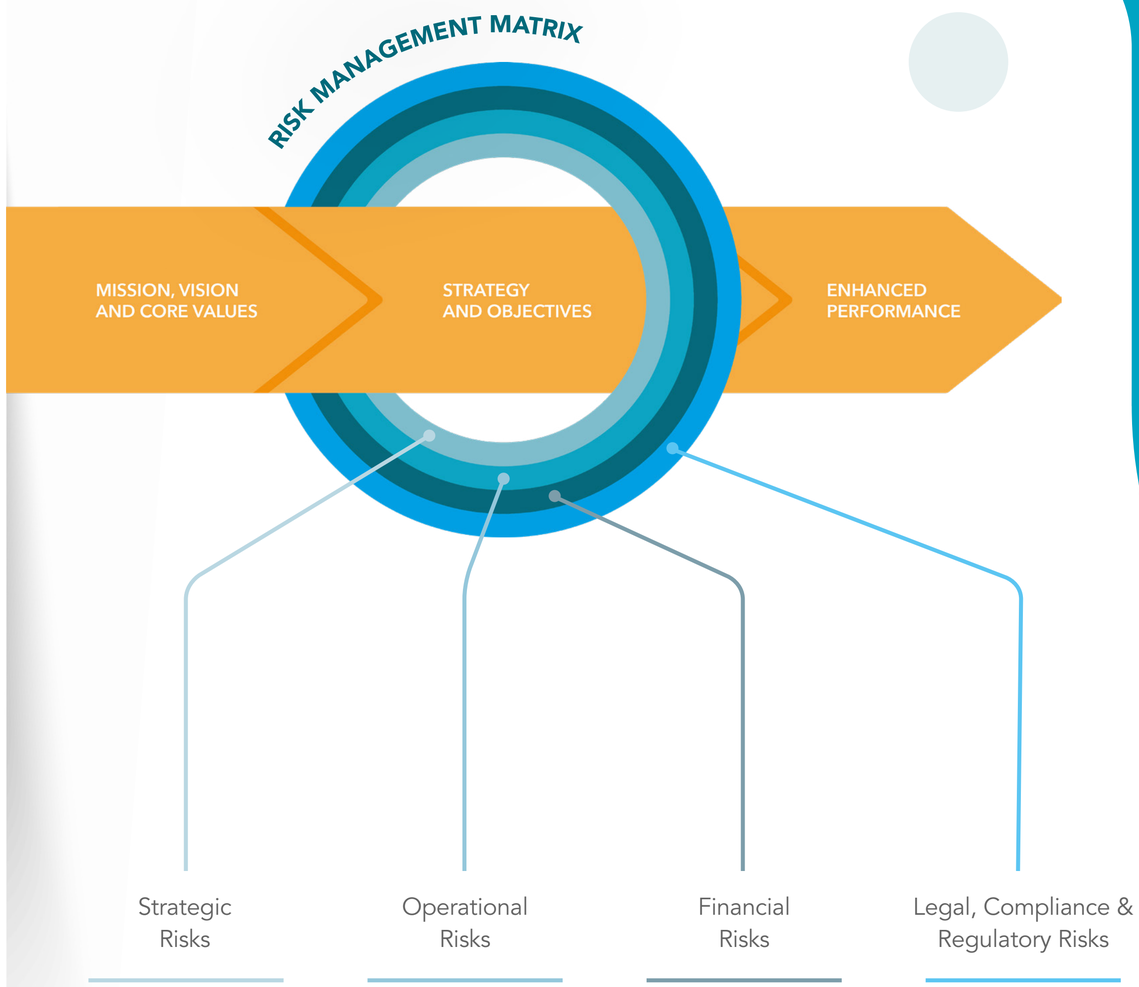
The Board is responsible for determining Cosmo's risk tolerance and for ensuring that systems of risk management and internal control are in place. To this end the Board has implemented a comprehensive risk management framework in order to assure that the internal processes are adequate, the financial reporting is reliable, the assets of the Company are protected and all laws and regulations are complied with.

The Group's risk management framework is designed to identify, evaluate and mitigate risks. Risks identified through our risk management framework are categorised, prioritised and assigned to a separate person who is required to continually monitor, evaluate and report on the risk(s) for which they are responsible.

Risks are classified into risks that can be managed by appropriate in-house action or risks that cannot be managed by internal action. All the risks that cannot be met by internal action are then split into risks that can be insured and those that cannot be reasonably insured and must be borne as business risks.

## Risk Factors

The following sets out certain important risk factors associated with the business that have been identified through the Company's risk management and control systems.



# STRATEGIC RISKS

Strategic risk relates to the Company's future business plans and strategies and includes risks associated with the environment in which we operate, intellectual property and risks including the demand for our products, competitive threats, information technology and public policy.

### Generic Competition and Intellectual property rights

All Pharmaceutical companies face generic competition when their products lose patent or other intellectual property protection. The Company takes active measures to protect its patents, trademarks and other intellectual property and to extend product life cycles. The Company has a dedicated patent department headed by its Chief Patent Counsel which manages its intellectual property assets and supported with the services of specialist intellectual property law firms based in the countries where we primarily operate.

### Research and Development and new product development

The future growth of our business is dependent on our ability to develop new products that address unmet medical needs and are accepted by patients and physicians. New products must also be reimbursed by payers. The process to develop new products is costly and can take considerable time. At each stage in the development of new products obstacles may be encountered.There is no guarantee that clinical endpoints will be attained or regulatory approval obtained forcing us to abandon a product.

The Company has a demonstrated track record of successfully concluding clinical trials and developing products which meet unmet clinical needs. The unique characteristics of our MMX® technology has enabled us to develop new products using chemical entities that are already on the market. We initially focused on Inflammatory Bowel Disease but our most recent products have been developed by focusing on unmet needs in the treatment of colon diseases and we believe that this provides ample new product development opportunity. Where possible we seek to improve the safety profile, efficacy or make more patient or user-friendly molecules that are already on the market in order to reduce new product development risk.

### Commercial success of our products

The Company ability to grow depends on the commercial success of our products. The success of our products could be impacted by several factors beyond our control including new competing products, pricing pressures, loss of intellectual property protection and changes in physician prescribing habits. Where we license our products to partners we rely on them to market, sell and distribute our products. In future where we choose to sell our products directly into selected markets the timing and rate of commercial acceptance or our products cannot be guaranteed. Should we fail to achieve our commercial goals or fail to do so within the time frame we have set ourselves it could have a material adverse impact on result of operations, our business or our financial condition.

### Pricing and reimbursement

The commercial success of our products depends on our ability and the ability of our partners to establish appropriate reimbursement for our products. Across the world, governments and payers continue to seek ways to reduce expenditure in the face of rising healthcare costs.

We believe that our focus on quality and on developing products which improve clinical outcomes and patient safety positions us to achieve the appropriate reimbursement for our products.

# OPERATIONAL RISKS

Operational risks are those which relate to our systems, people, processes and external events which affect our business and include manufacturing, supply chain, product safety and performance, information management and data protection and security, human resources and reputation.

### Manufacturing of finished products and supply of raw materials

Any issue with our manufacturing processes could have serious consequences for the health of patients and damage our reputation. Our manufacturing facilities are subject to strict regulatory requirements. If we fail to meet our regulatory requirements there is a risk that we would have to temporarily suspend or cease production. Any interruption to the supply chain of our raw materials could impair the supply of our products and consequently damage sales. The manufacturing process at the Company's manufacturing facility in Lainate, Milan is controlled with respect to raw materials, process parameters and final product quality. The controls are in accordance with procedures which comply with the provisions of Good Manufacturing Practices (GMP). The FDA has certified the Company for the production of Lialda® and Uceris® tablets for the U.S. market.

### Continuity of Supply

The supply chain for our products is subject to regulatory requirements. Any failure on our part, or failure on the part of our partners, to meet supply chain regulatory requirements could disrupt the supply chain and result in product shortages and loss of revenue.

### IT security, data and information systems

We are dependent on information technology infrastructure and systems. The loss of sensitive or confidential information and /or other security breaches or data leakages could have an adverse effect on our financial position or financial results. Our use of IT systems at times involves gathering personal information relating to patients, customers, vendors, employees and others. A breach of our systems or any other failure to protect personal information held on our systems could expose the personal information to unauthorised persons. Any such breach could result in liability and reputational damage.

The Company has committed and continues to commit significant management focus and resources to the protection of its data and information technology systems.

### Human Resources

The Company relies on recruiting and retaining highly skilled employees to meet its strategic objectives. The Company faces competition for highly qualified personnel from other companies and organisations and the supply of people with the necessary skills may be limited. If the Company is unable to retain key individuals or recruit new employees with the necessary skills and experience the implementation of the Company's strategic objectives could be adversely impacted and as a consequence the Company's financial performance or financial position could be adversely impacted. The Company seeks to ensure that remuneration packages are competitive with the market and has an ESOP and a bonus scheme in place for management and an Employee Incentive Plan for other employees.

# FINANCIAL RISKS

The Group is exposed to various financial risks in normal course of business. The principle financial risks to which it is exposed include credit risks related to the creditworthiness of its customers and counterparties of investment portfolio, with which it invests surplus cash funds, liquidity risks associated with the availability of sufficient capital resources, foreign currency risks, including both translation and transaction risk, and interest rate risk.

The Group measures and manages financial risks in accordance with Group Policy. The Board of Directors have overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identity and analyse the risks faced by the Group, to set appropriate risk limits, controls and to monitor risks and adherence limit. The Audit Committee of the Board periodically reviews the policies and adequacy of the risk management framework in regards to the risk faced by the Group.

## Credit Risk

The Group has a credit risk exposure in respect of the creditworthiness of its customers. The Group has series of long-standing customers and has established on-going monitoring for risk of credit deterioration. Credit risk for new customers is managed by ensuring strict credit procedures. For instance, in the event where a new customer credit rating is not available, the customer is required to provide bank reference. If the Company is unable to reach sufficient comfort over the creditworthiness the Company will transact based on prepayment basis only.

Credit risk exposure also exists in relation to the investment by the Group in financial assets and the cash which the Group places on deposit with financial institutions. The Group actively manages these risks by investing in financial assets and placing deposits with financial institutions in accordance with strict credit risk management policies and controls as specified by the Group's Board of Directors. The Group's cash and cash equivalents as at 31 December 2018 was held on deposit with banks whose FITCH credit rating ranged from BB- to A.

## Liquidity Risk

The Group's primary objectives in managing liquidity is to ensure:

- adequate resources to fund its continued operations
- availability of sufficient resources to sustain future development and growth of the business
- maintain sufficient resources to mitigate risks and unforeseen events which may arise.

The Group manages risks associated with liquidity by investing its cash in short-term deposits and short term financial investments which can be readily realised into cash. Where the Group has entered into long-term financial investment obligations, the maturity dates are spread out evenly in order to attain the most effective rate of liquidity.

## Currency Risk

The Group is subject to a number of foreign currency risks for transactions that are denominated in a currency other than its functional currency (euro) and given the global nature of its operations. The Group is subject to increased exposure to fluctuation in exchange rates between U.S. dollar and euro due to its expansion in operations into the U.S. Market. The Group manages its foreign exchange exposures with natural hedging and effective management of foreign currency cash inflows and outflows.

## Interest Rate Risk

The Group is exposed to interest rate risk in respect of its cash and cash equivalents, investment in financial assets, bank loans and financial leases with variable interest rates. There were no material hedging activities, such as interest rate swaps, utilised during the financial period under review. Except for a very small level of debt our interest rate exposure is restricted to our investments. We primarily invest in fixed rate instruments with maturities varying according to our liquidity needs. This process is overseen by an investment committee and implemented by an external expert investment manager. More information on financial risks is provided in note 35 of the consolidated financial statements.

# LEGAL, COMPLIANCE & REGULATORY RISKS

Legal, Compliance and Regulatory risks relate to the legal and regulatory environment within which we operate.

**Laws and regulations governing the sale and marketing of our products**

Where we have licensed our products the responsibility to comply with law and regulations governing the sale of our products rests with our licensees. Any failure on the part of our licensees to comply with laws and regulations governing the marketing and selling of our products could impact on our revenues and profitability.

For products, which we market and sell directly, any failure on our part to comply with laws and regulations governing the sales and marketing of our products could impact on our revenues and profitability.

**Regulatory approval for new products and approvals for new indications for existing products**

Our future commercial success depends on gaining regulatory approval for new products and obtaining approvals for existing products for new indications. The Company outsources certain tasks required as part of the approval process. The Company takes commercially reasonable steps to ensure that we engage with quality outsource partners. However, notwithstanding the steps which we take there is no guarantee that regulatory approval will obtained for new products or new indications for existing products.

**Tax**

We operate in a number of tax jurisdictions and are taxed accordingly. The OECD has proposed a number of tax law changes under its Base Erosion and Profit Shifting (BEPS) Action Plans. We have taken steps and continue to take steps to be in compliance with the evolving tax initiatives. Such tax law changes could require us to adapt our tax structure, increase our effective tax rate and adversely affect our financial performance.

## Sustainable practices

The Company is committed to operating in an environmentally and socially responsible manner and to the responsible management of manufacturing and non-manufacturing processes to reduce impacts on the environment. The Group continuously monitors compliance with applicable environmental, health and safety laws and regulations and the requirements of its permits and licenses and maintains programs that ensure that it:

- monitors the quality of the ambient air and the protection of the water resources;
- evaluates the site programs for the protection of the environment and the health and safety of employees and neighbours;
- manages the waste disposal in conformity with the local regulations;
- designs, constructs, maintains and manages its plant and systems in accordance with the best practices;
- communicates with the local community on safety and environmental matters in a timely and effective manner.

The Company is committed to a program of continual improvement in environmental, health and safety performance by making it an integral part of all its operations. As a pharmaceutical company, Cosmo is not directly obliged under REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances), a European Community regulation on chemicals and their safe use (EC 1907/2006), but constantly monitors its suppliers (i.e. labels and packaging materials) to assess their compliance to that regulation. The Company impacts a large number of stakeholders and recognises the broader role which the Company plays. The Company is committed to developing mutually beneficial relationships with business partners and local communities.

## Quality management

The Group is committed to the development and manufacturing of products of high quality and to satisfy the expectations of its customers. The quality system implemented at Cosmo meets the requirements and the expectations of the European and U.S. health authorities (EMA and FDA) for the manufacturing of drug products. Pharmacopoeias, pharmaceutical directives and guidelines (i.e., those issued by ICH) help to maintain the quality system at a high standard.

The quality system is fully in compliance with the current Good Manufacturing Practice (GMP) and allows the production of drug products of defined quality. The quality system at Cosmo's manufacturing plant is ISO 9000 certified. This certification, even if not required for the drug product manufacturing, demonstrates the Company's commitment to quality.

## Code of conduct

Cosmo recognises the need for our employees, consultants and contractors to always act with integrity. The Company and has a code of conduct which sets high standards and guides employees to make right decisions. Cosmo is committed to complying with applicable l aws, regulations and licensing requirements set down but recognised national and international authorities.

## Health and safety

Cosmo constantly monitors its procedures and processes to ensure that the health and safety of all personnel working on site is protected and risk from accidents or incidents arising from site activities is minimised both on and off site.

From a job category perspective, employment at Cosmo can either be grouped into office activities, research and analysis activities or manufacturing activities. An initial medical test on hiring and an annual blood and urine test are performed for all managers, employees and workers and all males above 40 years are tested for PSA (Prostate Specific Antigen). For managers and employees working with a PC, eye and eyesight tests are made every two years and workstations are protected with blinds and properly positioned when exposed to natural light. With respect to research and analysis activities, strict policies were established together with the Italian Ministry of Health specifically with reference to the handling of dangerous substances. With reference to manufacturing activities primarily in the manufacturing, packaging and handling of pharmaceuticals, there are strict internal work flow processes intended to ensure that accidents are minimised. Insurance coverage is in place for accidents occurring off site.

# COMPENSATION POLICY AND PERFORMACE MANAGEMENT

## Compensation Policy and Performance management

Cosmo aims to attract and retain highly skilled people and seeks to ensure that remuneration packages are competitive with the market. Pursuant to Dutch law, the non-executive directors of the Board are authorised to determine the remuneration of the executive directors.

The Compensation Committee provides recommendations on and policies in relation to the compensation of the Members of the Board of Directors in accordance with the Company's remuneration policy.

The remuneration policy of the Company is based on the following:

- Compensation consists of base salary, cash bonus and, where applicable, stock-based compensation.
- Certain medical and Insurance coverage.
- Company cars for senior executives.

Bonus and Share Option Incentive arrangements are as follows:

### Employee Incentive Plan

An employee incentive plan is in place for employees and junior managers to provide an incentive to achieve overall corporate objectives to enhance shareholder value, to reward employees for the achievement of corporate goals, to encourage teamwork across all disciplines. The Employee Incentive Plan provides for an award of up to 6% of an employee's annual base compensation depending on the achievement of corporate goals. The achievement of corporate goals is determined by the Company's Compensation Committee.

In addition to the employee incentive plan, an additional bonus payment of one month's salary was paid in 2018 to all employees.

### Profit Driven Bonus Plan

A Profit Driven Bonus Plan is in place for members of Senior Management and certain senior employees. The Profit Driven Bonus plan was approved by the Board for three years from 2017 to 2019 and provides for a pool of up to 7% of annual operating profits above a hurdle of €20.0 million. The CEO makes a proposal to the Compensation Committee in relation to the allocation of the Profit Driven Bonus plan based on the individual contribution of each person during the year to the achievement of the Company's goals.

### Share Option Plans

Some Share Option Plans are in place for members of the Board, members of Senior Management and certain senior employees.

## Cross border legal merger

In March 2016 Cosmo Pharmaceuticals S.A. incorporated Cosmo Pharmaceuticals N.V., a fully owned public company organised and existing under the laws of the Netherlands, having its corporate seat in Amsterdam, the Netherlands, with office address and its seat of management in Dublin, Ireland, registered with the Dutch Trade Register of the Chamber of Commerce under number 65617738 ('Cosmo' or the 'Company'). On 7 April 2016, the Board of Directors of Cosmo Pharmaceuticals S.A. approved the cross-border legal merger (the 'Merger') of Cosmo Pharmaceuticals S.A. into its 100 percent owned direct subsidiary Cosmo and on 12 May 2016 the shareholders of Cosmo Pharmaceuticals S.A. approved the Merger. The Merger became effective on 17 May 2016. As of such date, the Company became the ultimate parent company of the Group and its shares obtained a listing on SIX Swiss Exchange.

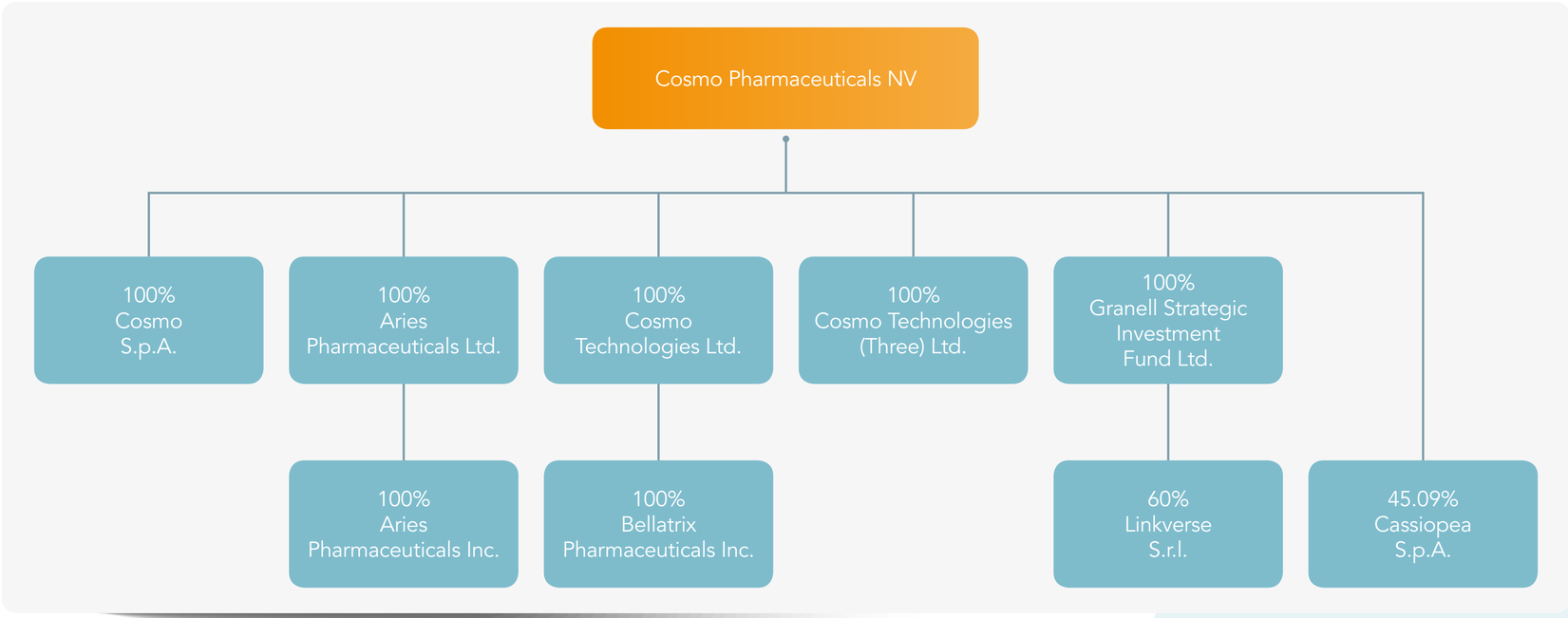
## Share capital and listing

The Company's authorised capital amounts to €18,744,677.64 and is divided into 36,047,457 ordinary shares, each with a nominal value of €0.26 and 36,047,457 preferred shares, each with a nominal value of €0.26. As at 31 December 2018 14,835,713 ordinary shares were outstanding and fully paid. Cosmo shares are listed on the SIX Swiss Exchange (SIX: COPN) with ISIN number NL0011832936.

## Cosmo Group structure

Cosmo has the following subsidiaries: (i) Cosmo S.p.A.; (ii) Aries Pharmaceuticals Ltd. (which owns 100 percent of the shares in Aries Pharmaceuticals Inc.); (iii) Cosmo Technologies Ltd. (which owns 100 percent of the shares in Bellatrix Pharmaceuticals Inc.); (iv) Cosmo Technologies (Three) Ltd.; and (v) Granell Strategic Investment Fund Ltd. (which owns 60% of Linkverse S.r.l.). The aforementioned companies together with Cosmo's 45.09 % shareholding in its associate Cassiopea S.p.A., form the Cosmo Group of companies of which Cosmo is the ultimate parent company (the 'Cosmo Group').

The Cosmo Group is organised according to the organisation structure as follows. Each of the Cosmo Group entities has its own Board of Directors.



### Authorisation to purchase own shares

The Shareholders' Meeting may authorise the Company to acquire fully paid-up shares in the Company's share capital if certain conditions as set out in the Company's articles of association have been met. An Authorisation by the Shareholders' Meeting will be valid for a maximum of eighteen months and shall stipulate the number of shares that may be acquired, how the shares may be acquired and the upper and lower limit of the acquisition price. The Authorisation of the Shareholders' Meeting as referred to above is not required in the event the Company acquires any shares listed on a stock exchange in order to transfer such shares to employees of the Company or to a Group company pursuant to a plan applicable to such employees. The Board of Directors has been authorised by the Shareholders' Meeting on 30 May 2018 to acquire fully paid up shares in the share capital of the Company up to a maximum of 10% of the ordinary shares included in the authorised capital for a period of eighteen months. As at 31 of December 2018 the Company held 201,770 treasury shares.

### 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 authorised 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 Dutch law. A shareholder may ask for his registration at any time.

The Company has been advised that, since it is a Dutch company listed in Switzerland, it and its shareholders may not have the protection of either Dutch or Swiss laws and regulations governing disclosure of significant shareholdings.

# CORPORATE GOVERNANCE - BOARD OF DIRECTORS

The Board of Directors consists of five non-executive members and two executive members. The Management of the Group falls under the responsibility of the Board of Directors.

| **Name** | Mauro S. Ajani | Alessandro Della Chà | Chris Tanner | Dieter A. Enkelmann | Maria Grazia Roncarolo | Kevin Donovan | Eimear Cowhey |
|---|---|---|---|---|---|---|---|
| **Position** | Non-executive Director; Chairman | Executive Director; CEO | Executive Director; Head of Transactions Office | Non-executive Director | Non-executive Director | Non-executive director | Non-executive Director, |
| **Member since** | 2006 | 2006 | 2006 | 2006 | 2012 | 2016 | 2017 |
| **Relevant external position** | | | • Board member and head of Audit Committee of DKSH AG (SIX: DKSH), Zurich<br>• Board member and Head of Compensation Committee of Private Equity Holding AG, Zug (SIX: PEHN)<br>• Board member of Qvanteq AG, Zurich<br>• Board member (Beirat) of Joimax GmbH, Karlsruhe<br>• CFO and Head of Investor Relations Cassiopea | • Chief Financial Officer and member of the executive management board of Julius Baer Group Ltd. (SIX: BAER.S) | • Professor of Pediatrics and Co-Director of Stanford Institute for Stem Cell Biology and Regenerative Medicine | • Fellow of the Institute of Chartered Accountants in Ireland<br>• Member of the Institute of Directors | • Serves as a non-executive independent chairperson, director and committee member of investment funds and management boards in Ireland, England and Luxembourg of promoters including:<br>- UBS<br>- Morgan Stanley<br>- GMO<br>- HSBC<br>- Artisan<br>- Mcquarie<br>- Generation<br>- John Hancock/ Manulife<br>- Nuveen<br>- Guggenheim<br>- BMO |
| | For full bio please visit our website. | For full bio please visit our website. | For full bio please visit our website. | For full bio please visit our website. | For full bio please visit our website. | For full bio please visit our website. | For full bio please visit our website. |

# CORPORATE GOVERNANCE - BOARD COMMITTEES

## Compensation Committee

The Compensation Committee assists the Board of Directors in compensation related matters, including matters related to the Company's stock option plan. The Compensation Committee provides recommendations on and polices for the compensation of the Members of the Board of Directors in accordance with the Company's remuneration policy, the Management and other employees. It is composed solely of non-executive members of the Board of Directors and is chaired by Kevin Donovan. Maria Grazia Roncarolo and Dieter A. Enkelmann are additional members.

Two meetings of the Compensation Committee took place in 2018.

## Nomination Committee

The Board of Directors established a Nomination Committee, which enacts guidelines for selecting candidates for the election to the Board of Directors in accordance with Dutch law. It also enacts guidelines for the appointment of the members of the Executive Management and makes arrangements to select such candidates. The Nomination Committee is composed solely of non-executive members of the Board of Directors and is chaired by Kevin Donovan, Maria Grazia Roncarolo and Dieter A. Enkelmann are additional members. Under Dutch law the appointment of Board Members is inalienably reserved to shareholders and is therefore not an area of responsibility of the Nomination Committee.

One meeting of the Nomination Committee took place in 2018.

## Audit Committee

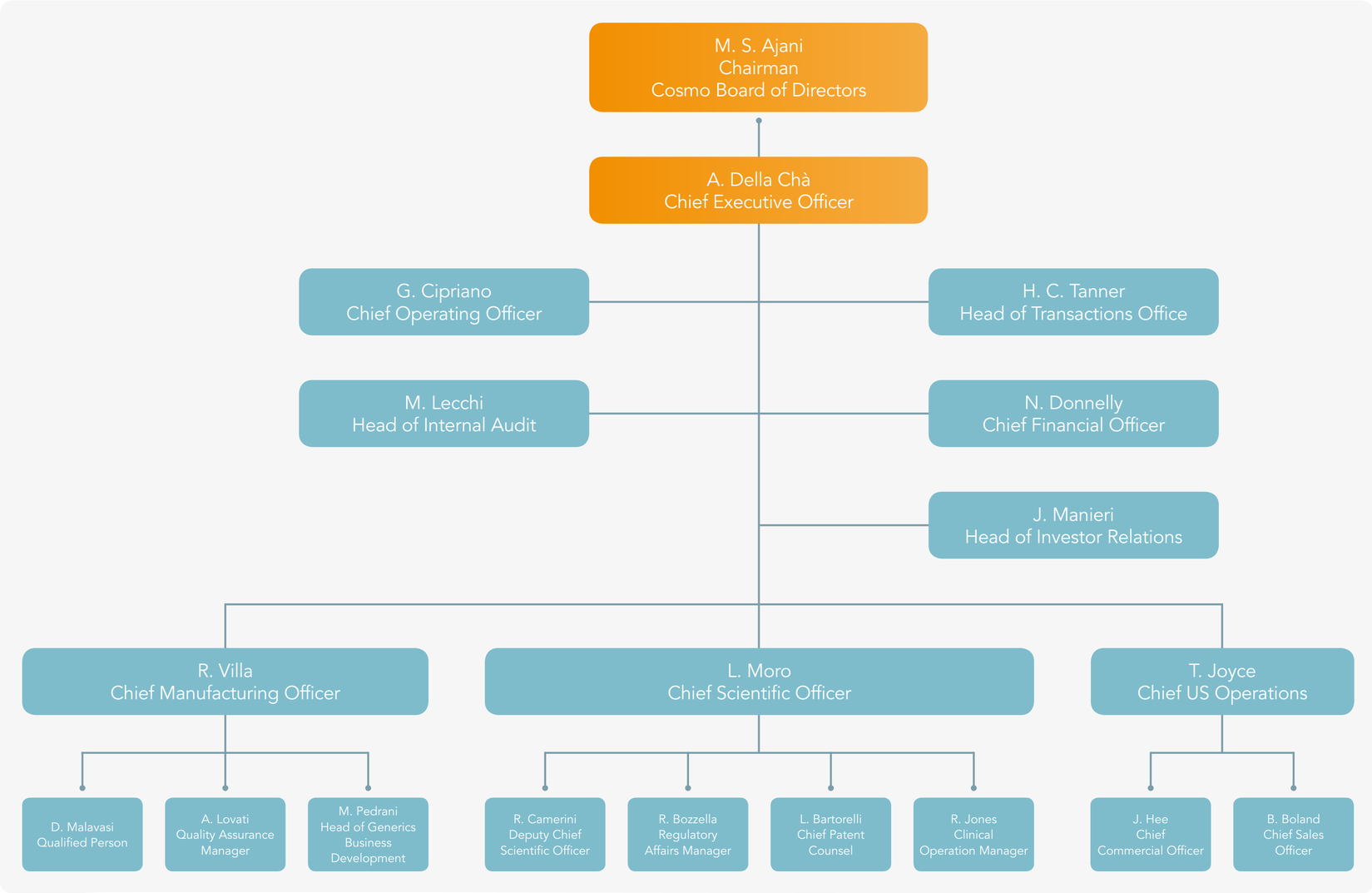
The Audit Committee evaluates the performance of the external audit and the effectiveness of the internal control and risk management processes.

Additionally, the Audit Committee reviews, together with the Chief Financial Officer and separately as the case may be, with the head of the external audit, the individual and consolidated financial statements as well as the interim statements intended for publication. It advises the Board of Directors as to whether the individual and consolidated financial statements can be presented to the Shareholders' Meeting. The Audit Committee assesses the performance and the fees charged by the external auditors and ascertains their independence. It examines the compatibility of the auditing responsibilities with any consulting mandates. The Audit Committee is comprised solely of non-executive members and is chaired by Dieter A. Enkelmann, Kevin Donovan and Eimear Cowhey are additional members.

Four meetings of the Audit Committee took place in 2018. In the reporting year, the auditors attended two meetings with the Audit Committee to provide status updates on audit matters.

## Executive Management

The Executive Management is responsible for the operational management of Cosmo in line with the instructions issued by the Board of Directors. Cosmo has grown based on a strong, focused Executive Management team encompassing skills across the spectrum of disciplines required for an emerging specialty pharmaceutical company. The Company has an internationally experienced and entrepreneurial Executive Management Team of pharmaceutical industry executives and recognised experts in their field with diverse backgrounds and complementary skills in research, development, regulation, manufacturing, sales, marketing and finance.



## Biographies

### Luisa Bartorelli – Chief Patent Counsel

Italian (born 1972), Luisa joined Cosmo on 1 February 2014. Luisa is an Italian Patent Agent and European Patent Attorney admitted before UIBM, EPO, WIPO, UAMI (design models) and a patent attorney in San Marino (USBM). Luisa is on the Board of IP Consultants and in the AIDB (Association of Italian Information Professionals).

### Blake Boland – Chief Sales Officer of Aries Pharmaceuticals Inc.

American (born 1960), Blake joined Cosmo in October 2016. He has more than 25 years of proven sales leadership experience in large corporate and emerging biopharmaceutical start-up environments. Previously, he served as Vice President of Sales at Santarus Inc., where he developed and led a national sales team, from company start-up, through all growth stages and the company's ultimate US$ 2.6 billion sale in 2014.

### Roberta Bozzella – Regulatory Affairs Manager

Italian (born 1974), Roberta joined the Group in 2002 and is responsible for the regulatory activities of the pipeline development projects. She graduated in pharmaceutical chemistry from the University of Milan, Italy, and holds a master in regulatory affairs from the University of Pavia, Italy.

### Giuseppe Cipriano – Chief Operating Officer

Italian (born 1957), Chief Operating Officer since 2001. From 1996 to 2001 he was managing director of Gianfranco Ferre S.p.A. and Gianfranco Ferre US Holding, the well-known fashion group. From 1990 to 1996 he was the managing director of Cordara S.p.A. and Ecor Impianti S.r.l., companies in the field of commercialisation of oil products and related services. From 1982 to 1990 he was a vice president (vicedirettore) in the Public Administration Inland Revenue Department in Milan, Italy.

### Alessandro Della Chà – Chief Executive Officer

Italian (born 1963), has been a Board Member of Cosmo since 2006 and CEO since the 27th of March 2014. From 1988 to the 27th of March 2014, he was senior partner at Studio Legale Edoardo Ricci e Associati, Milan, where he specialised in company law, mergers and acquisitions. From 1987 to 1988 he was assistant of the central director for corporate matters at Fininvest Group. From 1994 to 1998 he was director of II.PP.A.B. Milan (formerly ECA), a charitable institution owning hospitals and specialised in elderly care.

Mr. Della Chà has a degree in law from the University of Milan, Italy, and an LL.M. in European Union commercial law from the University of Leicester, United Kingdom. He is a lecturer in conferences and seminars held by universities and institutions on commercial and company law issues.

### Roberto Camerini – Deputy Chief Scientific Officer

Italian (born 1963), Roberto joined Cosmo in 2018 He graduated summa cum laude in Medicine and Surgery at the University of Rome, Italy and Post-graduated in Liver and Metabolic Diseases at University of Rome, Italy. He began his career in 1991 with Abbott SpA working in the Medical Department on the development of new antibiotics and other compounds. From 1993 to 1998 he served in Serono SpA as Clinical Project Leader for the development of Interferon beta in Multiple Sclerosis and Medical Manager for the Growth & Metabolism area. In 1998 he moved to Sigma-tau SpA where he covered several positions up to Head of Clinical Research with the worldwide responsibility for the clinical development of Sigma-tau R&D pipeline. In 2015 he was appointed as Pre-clinical and Clinical R&D Director in Alfa Wassermann SpA and then with the same position in Alfasigma SpA until 2018 when he joined Cosmo. He served as member of the Board of Directors of Sciclone Pharmaceutical Inc. from 2009 to 2011 and is Co-founder and member of the Board of Directors of Nibit Foundation (Italian Network of Tumor Biotherapy). He has significant experience in the Immunology/ Oncology, Gastroenterology/Hepatology, Neurology and Metabolic therapeutic areas.

### Niall Donnelly – Chief Financial Officer

Irish (born 1972), has been Chief Financial Officer of Cosmo Pharmaceuticals N.V. since June 2016. Niall is an experienced senior executive with over twenty years' experience across a number of sectors including acute healthcare, information technology, FMCG in privately owned, multinational and PLC environments. He is a member of the Chartered Institute of Management Accountants.

### Jon Hee – Chief Commercial Officer of Aries Pharmaceutical Inc

American (born 1958), Jon joined in October 2006 and is an executive leader specialising in establishing and scaling commercial operations to successfully launch new biopharmaceutical companies and products. He has helped create two multi-billion-dollar companies in the biopharmaceutical industry, taking them from pre-commercial planning to commercial build out, product launch and lifecycle management.

### Richard Jones – Clinical Operations Manager

British (born 1969), Richard joined the Group in February 2006 and is responsible for overseeing the interface of the Group with CROs in charge of conducting the clinical trials. Before he joined the Group, he held a position with Nabi Biopharmaceuticals Europe as a clinical project manager.

### Tom Joyce – Chief US Operations

American (born 1960), Tom joined the Group in July 2016. He has over three decades of strategic and operational leadership experience building effective commercial organisations and launching new products.

## Biographies continued

### Marco Lecchi – Head of Internal Audit

Italian (born 1964), Marco joined the Group in 2001. Prior to joining Cosmo he worked as director of administration of Gianfranco Ferre 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.

### Andrea Lovati – Quality Assurance Manager

Italian (born 1967), Andrea has held this post since 1999. From 1997 to 1999 he was responsible for quality control of labs in Cosmo. Prior to joining Cosmo he was responsible for quality control in a chemical lab in Parke Davis S.p.A.

### Davide Malavasi – Qualified Person

Italian (born 1972), Davide has held this post, a requirement under Italian law, since September 2001. He joined Cosmo in 2003. From 2007 to 2011 he was Production Manager. From January 2006 to December 2006 he was Production Assistant of Cosmo and from 2003 to 2005 he was a Quality Control Assistant for Cosmo. He holds a degree in chemistry and pharmaceutical technology.

### John Manieri – Head of Investor Relations and Investment Committee

Swiss (born 1972), John joined the Group in 2017. Prior to joining Cosmo, John was Managing Director and Head of Products, Healthcare Funds and Mandates at Bellevue Asset Management. He joined Bellevue Asset Management in 2015 following its acquisition of Adamant Biomedical Investments. Responsible for various investment vehicles, he won the Lipper Fund Award with the BB Adamant Global Medtech and Services Share class AA 2017 for the Best Equity Sector Healthcare Fund over 3 years.

### Luigi Moro – Chief Scientific Officer

Italian (born 1951), Luigi joined the Group in 1999 with over 40 years' experience in the field. 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.

### Massimo Pedrani – Head of Business Development

Italian (born 1954), Massimo joined the Group in 2001. He began his career as a researcher in the galenical laboratory of Midy S.p.A. (Sanofi Group) in 1981 and then worked as responsible for the pharmaceutical development department in Pierrel S.p.A. from 1983 to 1987. He then joined Farmitalia – Carlo Erba (Erbamont Group) as supervisor of external research institutes and head of the industrial galenics laboratories until 1992. During 1992 to 1996, he was the managing director of the Italian subsidiary of Applied Analytical Industries Inc., a US company operating in the pharmaceutical research and services sector. Since 1997, he has worked as a pharmaceutical business development and regulatory affairs consultant through his own company, Emmepi Pharma SAS.

### Chris Tanner – Head of Transaction Office

Swiss (born 1951), has been a Board Member of Cosmo since 2006. From 2006 to June 2016 Dr. Tanner was Chief Financial Officer and Head of Investor Relations of Cosmo and is currently Head of Transactions Office of Cosmo.

He has a diploma in economics and a PhD in economics from the University of St.Gallen. He joined UBS in 1977, in 1985 he became a member of the global credit committee and from 1987 to 1992 was the head of corporate banking in Asia, Australia and Africa as well as Southern Europe. In 1992 he became head of corporate finance and capital markets at UBS in Zurich. In 1998, one year after UBS's merger with SBC, he left to become a partner of Dr. Ernst Müller-Möhl, cofounded the '20 Minuten' group of newspapers and founded A&A Active Investor, a listed investment company. From 2002 to 2006 he was a corporate finance adviser and participated in numerous fund raisings amongst other for the private placement of Cosmo Holding S.p.A.

He is a Board Member and head of the audit committee of DKSH AG (SIX: DKSH), a market expansion company, a Board Member and head of the Compensation Committee of Private Equity Holding AG, (SIX: PEH) a private equity investment company, a Board member of PAION AG (ETR:PA8), Board member and Head of the Audit Committee of CureVac AG, Tübingen, a biotech company, Beirat of Joimax GmbH, Karlsruhe, a medtech company, and Board Member of Qvanteq AG, Zurich, a medtech start-up company, Board member of FARa AG, a wood trading company and member of the Evaluation Board of Wyss Zurich.

None of the companies that Dr. Tanner is a major shareholder of or is a Board Member of has any business activities with the Company.

### Roberto Villa – Chief Manufacturing Officer

Italian (born 1943), he joined Cosmo when it was established, and is responsible for the supervision of all industrial, logistic and quality aspects of its production facilities. Mr. Villa has significant experience in multinational pharmaceutical companies. He began his career as a laboratory analyst, and was promoted to Production Manager, Head of Development Laboratories and to the Head of Quality Control and Quality Assurance Laboratories. Given the experience acquired in various pharmaceutical sectors, he was appointed as Chief Manufacturing Officer of Cosmo S.p.A. and is responsible for the supervision of all industrial, logistic and quality aspects of its production facilities.

## Compensation Governance

The compensation of the Board of Directors is set in accordance with the remuneration policy of the Company adopted by the Shareholders Meeting on 24 May 2017 ('Remuneration Policy'). The objective of the Remuneration Policy is to provide a compensation structure that allows the Company to attract and retain the most highly qualified executives and to motivate them to achieve business and financial objectives which create value for shareholders.

Pursuant to Dutch law, the Compensation Committee consisting of independent non-executive Directors is authorised to determine the remuneration of the executive directors of the Board in accordance with the Remuneration Policy.

The Compensation Committee comprises Kevin Donovan, Maria Grazia Roncarolo, Dieter A. Enkelmann and is chaired by Kevin Donovan.

Two meetings of the Compensation Committee took place in 2018.

## Compensation of Board of Directors

The Board of Directors compensation recognised in the Income Statement 2018 including stock based compensation is as follows:

EUR

| Board of Directors | Function | Base compensation | Additional compensation | Cash bonus | Fringe benefits | Stock options | Total compensation |
|---|---|---|---|---|---|---|---|
| Mauro Ajani | Chairman | 30,000 | 370,000 | – | – | 1,092,022 | 1,492,022 |
| Alessandro della Cha | member, executive CEO | 30,000 | 570,000 | – | – | 1,092,022 | 1,692,022 |
| Dieter Enkelmann | member, non executive | 30,000 | – | – | – | 124,803 | 154,803 |
| Hans Christoph Tanner | member, executive Head of TO | 30,000 | 162,000 | – | – | 624,013 | 816,013 |
| Maria Grazia Roncarolo | member, non executive | 30,000 | – | – | – | 124,803 | 154,803 |
| Kevin Donovan | member, non executive | 30,000 | – | – | – | 124,803 | 154,803 |
| Eimear Cowhey | member, non executive | 30,000 | – | – | – | 130,156 | 160,156 |
| **Total** | | **210,000** | **1,102,000** | – | **–** | **3,312,620** | **4,624,620** |

## Compensation of Executive Management Including Executive Directors

EUR

| Executive Management | No of members | Base compensation | Cash bonus | Fringe benefits | Stock options | Total compensation |
|---|---|---|---|---|---|---|
| Executive Management | 16 members* | 2,859,692 | 170,512 | 111,579 | 4,268,851 | 7,410,634 |
| Highest paid of 16 members | | 380,874 | 93,314 | 23,134 | 1,080,969 | 1,578,291 |

* Excluding Chairman, CEO and Head of TO

## Compensation Policy and Performance management

Cosmo aims to attract and retain highly skilled people and seeks to ensure that remuneration packages are competitive with the market.

The remuneration policy of the Company is based on the following:

- Compensation consisting of base salary, cash bonus.
- Stock based compensation, where applicable.
- Certain medical and insurance coverage.
- Company cars for senior executives.

Cosmo aims to provide a total compensation which is competitive compared to compensation paid by comparable companies in order to attract, retain and motivate qualified executives, which reinforces the Company's performance driven culture; and which ensures that management and shareholders' interests are aligned.

The remuneration structure for executives consists of a fixed component and a variable component based on short and long-term performance.

The Company believes that its remuneration structure promotes the interests of the company in the short and the long-term and is designed to encourage the executives to act in the best interests of the Company.

In determining the level and structure of the remuneration of each of the Executives, the Compensation Committee will take into account, among other things, the Company's financial and operational results and other business objectives.

The total remuneration package and the different elements of remuneration of the executives are benchmarked periodically against those prevailing in a peer group of companies.

### Fixed component

The primary objective of the base salary (the fixed part of the annual cash compensation) for executives is to attract and retain highly qualified and experienced senior executives. The Company's policy is to periodically benchmark comparable salaries paid to executives with similar experience by comparable companies.

### Variable components

Executives are also eligible to receive variable cash compensation in accordance to the Profit Driven Bonus Plan.

### Short Term Incentive – Profit Driven Bonus Plan

With the cash-based incentive, 7% of the overall operating profits of the Company, on a yearly consolidated basis, above the threshold of € 20,000,000 (twenty million) is put into a pool ('Profit Pool'). The main objective of the Profit Pool is to incentivise the entire management team, including the Executives. The Profit Pool will be discretionarily allocated by the Compensation Committee and by the Board, provided that the CEO and the Chairman (Non-Executive) are both entitled to 20% each of such Profit Pool. This incentive is to ensure that the entire management team including the Executives have a simple objective being the achievement of a yearly profit of at least €20,000,000 (twenty million).

### Long Term Incentives – Share Performance based Incentives

The primary objective of the share performance based incentive is to creating a long term incentive based on shareholder value. For such purposes the Company has an ESOP in which the Executives and Non-Executives also participate. The ESOP, which conditions have been adopted by the general meeting of shareholders on May 24, 2017, has a term of three years and Executives will be granted the right to subscribe for ordinary shares (het recht op het nemen van een aandeel) or acquire shares, once the options have been vested, for a period of three years. This equity based incentive helps to align the interests of Executive with the interests of shareholders.

### Other benefits

Executives may also be entitled to customary fringe benefits such as personal use of company car and medical insurance. The Compensation Committee may grant other benefits to the Executives in particular circumstances.

### Stock option plan of Cosmo Pharmaceuticals N.V.

Cosmo Pharmaceuticals N.V. has an ESOP ("Cosmo N.V. ESOP") plan in which Executives and Non-Executives participate. The Cosmo N.V. ESOP, which conditions have been adopted by the general meeting of shareholders on 24 May 2017, has a term of three years and Executives and Non-Executives have been granted the right to subscribe for ordinary shares or acquire shares for a period of three years once the options have vested.

This equity-based award helps to align the Executives' interests with those of shareholders.

As at 31 December 2018 the stock option of Cosmo Pharmaceuticals N.V. was as follows:

| Non-executive Members of the Board | Outstanding as at 1 January 2018 | Granted | Forfeited | Exercised | Expired | Outstanding as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Dieter Enkelmann | 32,000 | – | – | – | – | 32,000 |
| Maria Grazia Roncarolo | 16,000 | – | – | – | – | 16,000 |
| Kevin Donovan | 16,000 | – | – | – | – | 16,000 |
| Eimear Cowhey | 16,000 | – | – | – | – | 16,000 |
| **Total** | **80,000** | – | **–** | – | **–** | **80,000** |
| **Of which exercisable** | **–** | | | | | **16,000** |

| | | In 2018 | | | | |
|---|---|---|---|---|---|---|
| Executive Members of the Board and Members of Management detailed if allocation exceeds 50,000 options | Outstanding as at 1 January 2018 | Granted | Forfeited | Exercised | Expired | Outstanding as at 31 December 2018 |
| Mauro Ajani | 140,000 | – | – | – | – | 140,000 |
| Alessandro della Cha | 140,000 | – | – | – | – | 140,000 |
| Hans Christoph Tanner | 80,000 | – | – | – | – | 80,000 |
| Guiseppe Cipriano | 80,000 | – | – | – | – | 80,000 |
| Luigi Moro | 80,000 | – | – | – | – | 80,000 |
| Other management | 204,300 | 24,000 | – | – | – | 228,300 |
| **Total** | **724,300** | **24,000** | **–** | – | **–** | **748,300** |
| **Of which exercisable** | **–** | **–** | **–** | **–** | **–** | **–** |

As at 31 December 2018 16,000 of the outstanding options were vested.

Cosmo Pharmaceuticals N.V. Outstanding Share Options at 31 December 2018

| Option series | Number | Grant date | Vesting date | Expiry date | Exercise price CHF | Fair value of the option at the grant date CHF |
|---|---|---|---|---|---|---|
| Option series 3 – issued 26 March 2014 | 2,000 | 26/03/2014 | 26/03/2017 | 26/03/2020 | 100.36 | 24.20 |
| Option series 4 – issued 26 March 2014 | 16,000 | 26/03/2014 | 26/03/2017 | 26/03/2020 | 79.64 | 35.01 |
| Option series 5 – issued 28 July 2016 | 43,000 | 28/07/2016 | 28/07/2019 | 28/07/2022 | 159.00 | 27.37 |
| Option series 6 – issued 11 April 2017 | 830,300 | 11/04/2017 | 11/04/2020 | 11/04/2023 | 154.90 | 25.05 |
| Option series 7 – issued 31 May 2017 | 16,000 | 31/05/2017 | 31/05/2020 | 31/05/2023 | 163.00 | 26.62 |
| Option series 8 - issued 3 December 2018 | 24,000 | 03/12/2018 | 03/12/2021 | 03/12/2024 | 120.20 | 13.18 |
| **Outstanding as at 31 December 2018** | **931,300** | | | | | |

| | 2018 | | 2017 | |
|---|---|---|---|---|
| EUR | Number | Weighted average exercise price | Number | Weighted average exercise price |
| **Outstanding as at 1 January** | **909,300** | **153.79** | **679,500** | **89.19** |
| Granted during the period | 24,000 | 120.20 | 848,300 | 155.05 |
| Forfeited during the period | (2,000) | 154.90 | – | – |
| Exercised during the period | – | – | (618,500) | 84.55 |
| Expired during the period | – | – | – | – |
| **Outstanding as at 31 December** | **931,300** | **152.92** | **909,300** | **153.79** |
| Exercisable as at 31 December | 18,000 | 81.94 | 18.000 | 81.94 |

The share options outstanding at 31 December 2018 had a weighted average exercise price of CHF 152.92 and a weighted average remaining contractual life of 4.2 years.

**Stock option plan of Aries Pharmaceuticals Ltd.**

Aries Pharmaceutical Ltd. is a 100% subsidiary of Cosmo Pharmaceuticals N.V. Aries Pharmaceuticals Ltd. has an issued share capital of 100,000,000 ordinary shares of EUR 0.0001 each.

On 22 July 2016 the board of Aries Pharmaceuticals Ltd. established a share option program that entitles certain employees of Aries Pharmaceuticals Ltd. and it's subsidiary Aries Pharmaceuticals Inc. to purchase shares in Aries Pharmaceuticals Ltd. During 2018 the Board of Directors granted 708,620 options and 653,604 options were forfeited.

As at 31 December 2018 the stock option plan of Aries Pharmaceuticals Ltd. was as follows:

| | | In 2018 | | | | |
|---|---|---|---|---|---|---|
| **Executives and Members of Management detailed if allocation exceeds 200,000 options** | **Outstanding as at 1 January 2018** | **Granted** | **Forfeited** | **Exercised** | **Expired** | **Outstanding as at 31 December 2018** |
| Tom Joyce | 3,100,000 | – | – | – | – | 3,100,000 |
| John Hee | 720,000 | 45,000 | – | – | – | 765,000 |
| Blake Boland | 286,000 | 30,750 | – | – | – | 316,750 |
| | **4,106,000** | **75,750** | **–** | **–** | **–** | **4,181,750** |
| Of which exercisable | **–** | **–** | **–** | **–** | **–** | **2,053,000** |

As at 31 December 2018 2,090,250 of the outstanding options were vested.

Aries Pharmaceuticals Ltd. Outstanding Share Options at 31 December 2018

| Option series | Number Outstanding | Grant date | Vesting date | Expiry date | Exercise price EUR | Fair value of the option at the grant date EUR |
|---|---|---|---|---|---|---|
| 1a) Issued 28 July 2016 | 1,550,000 | 28/07/2016 | 28/07/2018 | 27/07/2023 | 5.00 | 1.117 |
| 1b) Issued 28 July 2016 | 775,000 | 28/07/2016 | 28/07/2019 | 27/07/2023 | 5.00 | 1.252 |
| 1c) Issued 28 July 2016 | 775,000 | 28/07/2016 | 28/07/2020 | 27/07/2023 | 5.00 | 1.365 |
| 2a) Issued 31 October 2016 | 540,250 | 31/10/2016 | 31/10/2018 | 30/10/2023 | 5.00 | 1.124 |
| 2b) Issued 31 October 2016 | 270,125 | 31/10/2016 | 31/10/2019 | 30/10/2023 | 5.00 | 1.263 |
| 2c) Issued 31 October 2016 | 270,125 | 31/10/2016 | 31/10/2020 | 30/10/2023 | 5.00 | 1.378 |
| 3a) Issued 1 January 2017 | 123,200 | 01/01/2017 | 01/01/2019 | 31/12/2023 | 9.00 | 2.029 |
| 3b) Issued 1 January 2017 | 61,600 | 01/01/2017 | 01/01/2020 | 31/12/2023 | 9.00 | 2.282 |
| 3c) Issued 1 January 2017 | 61,600 | 01/01/2017 | 01/01/2021 | 31/12/2023 | 9.00 | 2.491 |
| 4a) Issued 31 March 2017 | 434,750 | 31/03/2017 | 31/03/2019 | 30/03/2024 | 9.00 | 2.038 |
| 4b) Issued 31 March 2017 | 217,375 | 31/03/2017 | 31/03/2020 | 30/03/2024 | 9.00 | 2.294 |
| 4c) Issued 31 March 2017 | 217,375 | 31/03/2017 | 31/03/2021 | 30/03/2024 | 9.00 | 2.506 |
| 5a) Issued 30 May 2017 | 86,750 | 30/05/2017 | 30/05/2019 | 29/05/2024 | 9.00 | 1.755 |
| 5b) Issued 30 May 2017 | 43,375 | 30/05/2017 | 30/05/2020 | 29/05/2024 | 9.00 | 1.948 |
| 5c) Issued 30 May 2017 | 43,375 | 30/05/2017 | 30/05/2021 | 29/05/2024 | 9.00 | 2.116 |
| 7a) Issued 25 October 2017 | 18,750 | 25/10/2017 | 25/10/2019 | 24/10/2024 | 9.00 | 1.753 |
| 7b) Issued 25 October 2017 | 9,375 | 25/10/2017 | 25/10/2020 | 24/10/2024 | 9.00 | 1.950 |
| 7c) Issued 25 October 2017 | 9,375 | 25/10/2017 | 25/10/2021 | 24/10/2024 | 9.00 | 2.121 |
| 9a) Issued 2 January 2018 | 33,553 | 02/01/2018 | 02/01/2020 | 01/01/2025 | 10.24 | 2.000 |
| 9b) Issued 2 January 2018 | 16,787 | 02/01/2018 | 02/01/2021 | 01/01/2025 | 10.24 | 2.227 |
| 9c) Issued 2 January 2018 | 16,766 | 02/01/2018 | 02/01/2022 | 01/01/2025 | 10.24 | 2.414 |
| 10) Issued 2 January 2018 | 146,125 | 02/01/2018 | 02/01/2019 | 01/01/2025 | 10.24 | 1.727 |
| 11a) Issued 22 March 2018 | 76,801 | 22/03/2018 | 22/03/2020 | 21/03/2025 | 10.04 | 1.972 |
| 11b) Issued 22 March 2018 | 38,401 | 22/03/2018 | 22/03/2021 | 21/03/2025 | 10.04 | 2.199 |
| 11c) Issued 22 March 2018 | 38,400 | 22/03/2018 | 22/03/2022 | 21/03/2025 | 10.04 | 2.395 |
| 12) Issued 22 March 2018 | 165,625 | 22/03/2018 | 22/03/2019 | 21/03/2025 | 10.04 | 1.698 |

### Loans granted by the Cosmo Group to Members of the Board of Directors or the Management

No company within the Cosmo Group, including the Company, has granted any loans or guarantees to any Member of the Board of Directors or members of the Executive Management.

| Option series | Number Outstanding | Grant date | Vesting date | Expiry date | Exercise price EUR | Fair value of the option at the grant date EUR |
|---|---|---|---|---|---|---|
| 13a) Issued 4 July 2018 | 25,600 | 04/07/2018 | 04/07/2020 | 03/07/2025 | 5.00 | 0.981 |
| 13b) Issued 4 July 2018 | 12,800 | 04/07/2018 | 04/07/2021 | 03/07/2025 | 5.00 | 1.093 |
| 13c) Issued 4 July 2018 | 12,800 | 04/07/2018 | 04/07/2022 | 03/07/2025 | 5.00 | 1.190 |
| 14) Issued 4 July 2018 | 22,250 | 04/07/2018 | 04/07/2019 | 03/07/2025 | 5.00 | 0.826 |
| 15a) Issued 19 September 2018 | 1,200 | 19/09/2018 | 19/09/2020 | 18/09/2025 | 5.00 | 0.985 |
| 15b) Issued 19 September 2018 | 600 | 19/09/2018 | 19/09/2021 | 18/09/2025 | 5.00 | 1.100 |
| 15c) Issued 19 September 2018 | 600 | 19/09/2018 | 19/09/2022 | 18/09/2025 | 5.00 | 1.198 |
| 16a) Issued 12 November 2018 | 19,350 | 12/11/2018 | 12/11/2020 | 11/11/2025 | 5.00 | 0.985 |
| 16b) Issued 12 November 2018 | 9,675 | 12/11/2018 | 12/11/2021 | 11/11/2025 | 5.00 | 1.098 |
| 16c) Issued 12 November 2018 | 9,675 | 12/11/2018 | 12/11/2022 | 11/11/2025 | 5.00 | 1.197 |
| 17) Issued 12 November 2018 | 7,500 | 12/11/2018 | 12/11/2020 | 11/11/2025 | 5.00 | 0.849 |
| **Outstanding as at 31 December 2018** | **6,006,716** | | | | | |

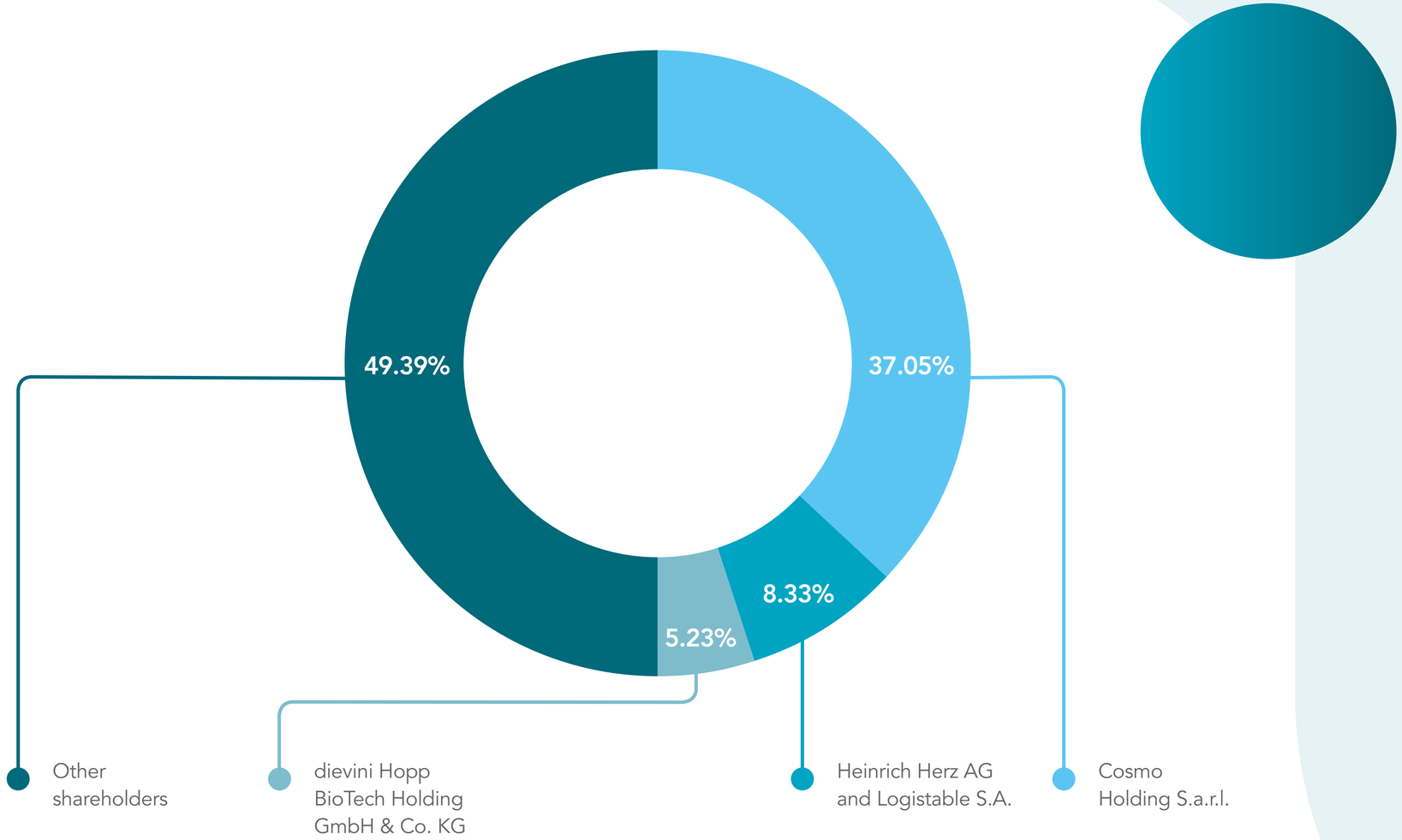
| | 2018 | | 2017 | |
|---|---|---|---|---|
| EUR | Number | Weighted average exercise price | Number | Weighted average exercise price |
| **Outstanding as at 1 January** | **5,951,700** | **6.20** | **4,180,500** | **5.00** |
| Granted during the period | 708,620 | 9.20 | 1,771,200 | 9.02 |
| Forfeited during the period | (653,604) | 9.15 | – | – |
| Exercised during the period | – | – | – | – |
| Expired during the period | – | – | – | – |
| **Outstanding as at 31 December** | **6,006,716** | **6.23** | **5,951,700** | **6.20** |
| Exercisable as at 31 December | 2,090,250 | 5.00 | – | – |

The share options outstanding at the end of 2018 had a weighted average exercise price of €6.23 and a weighted average remaining contractual life of 4.9 years.

# MAJOR SHAREHOLDERS

At 31 December 2018 Cosmo Holding S.a.r.l., a Luxembourg company controlled by Mauro S. Ajani, the Chairman of the Company, held 5,571,209 or 37.05 % of the shares in the Company.

Heinrich Herz AG and Logistable S.A., a related company, held 1,252,984 or 8.33 % of the shares in the Company. Dievini/Hopp BioTech Holding GmbH & Co. KG, the investment company of Dietmar Hopp and his family, held 786,361 or 5.23 % of the shares in the Company.



## Shareholders Meeting

The Company's shareholders are only entitled to attend the general meeting in person or be represented by a person holding a written proxy, to address the Shareholders' Meeting and to vote at the Shareholders' Meeting, if the shareholder has lodged documentary evidence to the Board of Directors of his voting rights. For these purposes, the Board of Directors shall set a record date on the twenty-eighth day before the general meeting by which date the shareholder must register as such in a register (or one of more parts thereof) designated by the Board of Directors. The registration process is described in the notice for the general meeting. At the Shareholders Meeting, each share entitles its holder to one vote. Unless another majority is prescribed under Dutch law or in the articles of association, resolutions of the Shareholders' Meeting shall be adopted by an absolute majority of votes cast.

One or more shareholders of the Company, entitled to make such request according to the law, may request the Board of Directors in writing to include items for the meeting in the agenda, at least sixty days before the date on which the meeting is convened. No valid resolutions can be adopted at a general meeting of the Company's shareholders in respect of subjects which are not mentioned in the agenda.

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). Since the introduction of these rules, Cosmo Holding S.a.r.l notified that it was subscribing to the opting-out option.

## Dividends, allocation of annual net profits

The Board of Directors may determine that all or part of the Company's profits shall be added to the reserves. Any remaining profits shall be at the disposal of the Shareholders' Meeting, who may resolve to distribute such profits as dividends.

If the Company has issued preferred shares, then out of the profits remaining after reservation, if any, first a dividend shall be distributed on the preferred shares of (a) a percentage equal to the higher of twelve (12) months LIBOR as published by the ICE Benchmark Administration Limited or twelve (12) months EURIBOR as published by European Money Markets Institute, and (b) a premium to be determined by the Board of Directors in line with market conditions on the date the preferred shares were first issued. However, if preferred shares have been paid-up from the Company's distributable part of the equity, then no dividend shall be distributed on the preferred shares until three (3) years after the first issuance of such preferred shares. After three years, a total dividend of one thousand euro (€1,000) will be paid on the preferred shares to be divided pro rata on all issued preferred shares. Any remaining profits shall be at the disposal of the Shareholders' Meeting and can be distributed as dividends to the shareholders or added to the reserves, albeit that the holders of preferred shares shall not be entitled to any further distributions.

The Company may only make distributions to the shareholders and other persons who are entitled to profits that qualify for distribution if the Company's equity is in excess of the paid and called-up portion of the share capital increased by the reserves that must be set aside under the provisions of the law.

Dividends are payable on the date specified by the shareholders' resolution at the annual meeting on the account of each shareholder through the relevant intermediaries.

## Pre-emptive rights

In accordance with Dutch laws, each holder of ordinary shares has a pre-emptive right in case of issuance by the Company of additional ordinary shares, except in the following instances:(i) the shares are paid for in kind, for example the contribution of shares in another listed company; (ii) when shares are issued to employees of the Company or to employees of a Group company; or (iii) the pre-emptive right is limited or excluded. In the Company's articles of association, it is included that the Board of Directors shall be irrevocably authorised to limit or exclude pre-emptive rights on any issue of shares for a period of 5 years as of the Merger becoming effective.

# INDEPENDENT AUDITORS

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

The Shareholders' Meeting elected BDO Audit & Assurance B.V., the Netherlands as independent auditor of the Company for the audit of the financial statements as at 31 December 2017 and as at 31 December 2018. BDO Audit & Assurance B.V. have been auditors of the Company since 2016 with Mr. Jeroen Van Erve acting as it lead partner also since 2016.

The following fees were charged by BDO Audit & Assurance BV to the company, its subsidiaries and other consolidated companies, as referred to in Section 2:382a (1) and (2) of the Netherlands Civil Code.

## Audit Fees

BDO audit fees for 2018, including audit fees for the controlled companies, amounted to €318 thousand (2017: €233 thousand).

| | BDO Audit & Assurance BV | | Other BDO network | | Total BDO | |
|---|---|---|---|---|---|---|
| | **2018** | 2017 | **2018** | 2017 | **2018** | 2017 |
| Audit of the financial statements | 182 | 133 | 136 | 100 | 318 | 233 |
| Other audit engagements | | – | | – | | – |
| Tax-related advisory services | | – | | – | | – |
| Other non-audit services | | – | | – | | – |
| | **182** | **133** | **136** | **100** | **318** | **233** |

## Defense measures

The Stichting Preferred Shares Cosmo Pharmaceuticals (the 'Foundation') was established on 17 May 2016. By virtue of the Company's articles of association, 36,047,457 preferred shares can be issued. In addition, the Company's articles of association provide the Board of Directors with the authority to issue and the right to subscribe for 36,047,457 preferred shares for a period of eighteen (18) months.

Under a call option agreement entered into during 2016 between the Foundation and the Company, the Foundation has the right to acquire a maximum number of shares as equals 100% of the Company's issued ordinary share capital immediately prior to the exercise of the call option, minus one share. This will entitle the Foundation to 50% minus one vote of the total voting rights after the issuance of such preferred shares, assuming the Foundation has exercised the call option in full.

The objectives and purpose of the Foundation are to promote the interests of the Company, the enterprise affiliated with it and all stakeholders involved, resisting, among other things, as much as possible all influences which could threaten the continuity, independency or identity of the same.

The Foundation shall exercise the voting rights attached to the preferred shares issued to the Foundation, independently and at its sole discretion, in accordance with its objectives and purpose.

The Foundation did not acquire any preferred shares in 2018.

The board of the Foundation consists of the following members: (i) Gerald Herz, (ii) Maurizio Baldassarini and (iii) Dieter A. Enkelmann. The Foundation is an independent legal entity within the meaning of the Dutch Act on Financial Supervision (Wet op het financieel toezicht).

### Information and control instruments vis-à-vis the Board of Directors

The Board of Directors is currently scheduled to meet at least four times a year plus a budget meeting plus a meeting to discuss and approve the financial statements. Further meetings will be called as required.

The Board of Directors has set a series of benchmarks and parameters to track the financial, scientific, product, and production development of the Company. These benchmarks and parameters are regularly reviewed.

### Information policy

Cosmo is committed to a clear, transparent, consistent and nonselective disclosure of material information. In accordance with Dutch law and the SIX Swiss Exchange rules, Cosmo provides complete and detailed information in annual and half-year reports. 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 the half-year report, the Company has also invited shareholders and the financial press to conference calls and selective news events.

### Dutch Corporate Governance Code

Cosmo is subject to various corporate governance requirements and best practice provisions such as (i) the Swiss Code of Best Practice for Corporate Governance; (ii) the SIX Swiss Exchange Directive on Information relation to Corporate Governance; and (iii) the revised Dutch Corporate Governance Code which became effective on 1 January 2018 ('Code').

As a Dutch company listed on the SIX Swiss Exchange, Cosmo is subject to the Code and is required to disclose in its statutory annual report, filed in the Netherlands, whether or not it complies with the provisions of the Code. If the Company does not comply with the Code, it must state the reasons in connection therewith in its annual report.

The Company has decided not to apply the Code at this point in time. The reasons for the Company not applying the Code in respect of its 2018 annual accounts are that (i) the Company is listed on the SIX Swiss Exchange with most of its investors residing outside the Netherlands; (ii) the Company's business focus is very international and outside of the Netherlands and (iii) as SIX investors are more familiar with Swiss Governance rules than the Code the Company complies with the Swiss Code of Best Practice for Corporate Governance, which can be found at www.economiesuisse.ch, and the SIX Swiss Exchange Directive on Market Information, which can be found at. www.six-swiss-exchange.com.

The Board of Directors acknowledges the importance of good corporate governance, including those rules as reflected in the Code. Therefore, the Company intends to continue to monitor the developments in corporate governance to consider whether or not it shall apply the principles and best practice provisions of the Code in the future.

## Other Disclosures

a) The rules governing the appointment and dismissal of members of the Board of Directors are stated in the Articles of Association of the Company. The General Meeting shall appoint the directors. The directors are appointed for a period to be determined by the General Meeting with a maximum of three (3) years starting on the day after the day of the General Meeting on which they are appointed and ending on the day of the subsequent annual General Meeting that will be held in the year following the year of their appointment. Directors may immediately be reappointed. The General Meeting may at any time suspend or remove any director. A resolution to remove or suspend a director may be passed by an absolute majority of the votes cast. The Board of Directors may also suspend any executive director. If a director is suspended, the General Meeting shall within three months of the date on which suspension has taken effect resolve either to dismiss such director, or to terminate or continue the suspension, failing which the suspension shall lapse. A resolution to continue the suspension may be adopted only once and in such event the suspension may be continued for a maximum period of three months commencing on the day the General Meeting has adopted the resolution to continue the suspension. If within the period of continued suspension, the General Meeting has not resolved either to dismiss the director concerned or to terminate the suspension, the suspension shall lapse.

A director who has been suspended shall be given the opportunity to account for his actions at the General Meeting.

b) The general powers of the Board of Directors are stated in the Articles of Association of the Company.

Shares shall be issued pursuant to a resolution passed by the General Meeting, upon the proposal of the Board of Directors containing the price and further terms and conditions of the issue. The General Meeting may resolve to designate the Board of Directors, for a fixed period not exceeding five years, as the body authorised to issue shares. When the Board of Directors is so designated, it must be specified in the resolution passed by the General Meeting, how many shares may be issued and further conditions may be laid down. The designation may be renewed each time for a period not exceeding five years. No designation made pursuant to a resolution passed by the General Meeting may be cancelled, unless cancellation of such designation was explicitly permitted in the applicable designation. For as long as the Board of Directors is designated, the General Meeting shall not have this power.

For a period of eighteen (18) months from the thirtieth day of May two thousand eighteen the Board of Directors has been authorised to:

(i) issue – and grant subscription rights to – ordinary shares up to a maximum nominal sum of ten percent (10%) and, in the event of a merger, an acquisition or a strategic alliance to increase this Authorisation by a maximum of a further ten percent (10%) of the ordinary shares included in the authorised capital;
(ii) issue ordinary shares up to a maximum nominal sum of ten percent (10%) of the ordinary shares included in the authorised capital, which shares shall be issued for the execution of the Company's employee stock ownership plan for directors, employees, co-workers and administrators of the Company or a Group Company; and
(iii) issue preferred shares or to grant the right to subscribe for preferred shares up to the maximum number as provided for in article 4.1 of the Company's articles of association.

c) Any member of the board who has an interest in a related party transaction which is under discussion by the board must abstain from this discussion and abstain from any vote on the approval of the related party transaction under discussion.

# RESPONSIBILITIES IN RESPECT TO THE ANNUAL REPORT

In accordance with Section 5:25c, paragraph 2 of the Dutch Financial Supervision Act, the Board of Directors of the Company hereby declare that, to the best of their knowledge:

- the annual financial statements for the financial year 2018 give a true and fair view of the assets, liabilities, financial position and profit or loss of the Company and its consolidated entities;
- the Directors Report provides a true and fair view of the position of the company and its related entities whose financial information has been consolidated in the annual financial statements as at the balance sheet date 31 December 2018 and of their state of affairs during the financial year 2018;
- the Directors Report describes the principal risks that the Company and the Group faces.

Dublin, Ireland, 28 March 2019
The Board of Directors

Mauro Ajani
Alessandro Della Chà
Hans Christoph Tanner
Dieter Enkelmann
Maria Grazia Roncarolo
Kevin Donovan
Eimear Cowhey

# FINANCIAL STATEMENTS

## Consolidated income statement

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 (restated note 5) |
|---|---|---|---|
| **Revenue** | 6 | **65,617** | **67,242** |
| Other income | | 886 | 470 |
| Cost of sales | | (22,058) | (21,988) |
| Research and development costs | | (10,428) | (9,049) |
| Selling, general and administrative costs | | (50,638) | (46,279) |
| **Net operating expenses** | 7 | **(82,238)** | **(76,846)** |
| **Operating loss** | | **(16,621)** | **(9,604)** |
| Financial income | | 8,127 | 3,784 |
| Financial expenses | | (3,512) | (20,720) |
| **Net financial income/(expense)** | 8 | **4,615** | **(16,936)** |
| Share of result of associate | 15 | (5,453) | (5,892) |
| **Loss before taxes** | | **(17,459)** | **(32,432)** |
| Income tax expenses | 9 | (598) | (15) |
| **Loss for the period** | | **(18,057)** | **(32,447)** |
| | | | |
| **Loss attributable to:** | | | |
| Owners of the company | | (18,007) | (32,447) |
| Non-controlling interest | 24 | (50) | – |
| | | | |
| **Earnings per share** | | EUR | EUR |
| Basic | 10 | (1.200) | (2.191) |
| Diluted | 10 | (1.200) | (2.191) |

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

## Consolidated statement of other comprehensive income

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 |
|---|---|---|---|
| **Loss for the period (A)** | | **(18,057)** | **(32,447)** |
| **Other comprehensive income** | | | |
| ***Items that will not be reclassified subsequently to profit or loss*** | | | |
| Losses on equity instruments measured at FVOCI | | (3,529) | – |
| Remeasurement of defined benefit liability | 26 | (7) | 18 |
| Income tax | 9 | 266 | (4) |
| **Total items that will not be reclassified subsequently to profit or loss (B1)** | | **(3,270)** | **14** |
| ***Items that may be reclassified subsequently to profit or loss*** | | | |
| Losses on debt securities measured at FVOCI | | (1,174) | – |
| Losses on disposal of debt securities measured at FVOCI reclassified to profit or loss | | 917 | – |
| Losses on fair value of available for sale financial assets | | – | (672) |
| Losses on disposal of available for sale financial assets reclassified to profit or loss | | – | 1,216 |
| Remeasurement to fair value of pre-existing interest in an acquiree | 13 | (52) | – |
| Exchange differences on translating foreign operations | | (1,155) | 840 |
| Income tax | 9 | 86 | 293 |
| **Total items that may be reclassified subsequently to profit or loss (B2)** | | **(1,378)** | **1,677** |
| **Total other comprehensive (loss)/income, net of tax (B1)+(B2)=(B)** | | **(4,648)** | **1,691** |
| **Total comprehensive income (A)+(B)** | | **(22,705)** | **(30,756)** |
| | | | |
| **Total comprehensive income attributable to:** | | | |
| Owners of the company | | (22,655) | (30,756) |
| Non-controlling interest | 24 | (50) | – |

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

## Consolidated statement of financial position

| EUR 1,000 | Notes | As at 31 December 2018 | 2017 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Property, plant and equipment | 11 | 28,616 | 30,152 |
| Goodwill | 12 | 1,439 | 109 |
| Other intangible assets | 14 | 35,524 | 28,525 |
| Investments in associates | 15 | 130,402 | 135,742 |
| Financial assets | 16 | 41,855 | 93,811 |
| Deferred tax assets | 17 | 11,724 | 10,456 |
| Other non-current receivables | | 1,959 | 1,873 |
| **Total non-current assets** | | **251,519** | **300,668** |
| **Current assets** | | | |
| Inventories | 18 | 3,937 | 3,241 |
| Trade receivables | 19 | 12,762 | 13,190 |
| Current tax and other tax assets | 20 | 5,231 | 2,972 |
| Other receivables and other assets | 21 | 2,801 | 5,200 |
| Current financial assets | 16 | 138,747 | 27,759 |
| Cash and cash equivalents | 22 | 210,689 | 144,944 |
| **Total current assets** | | **374,167** | **197,306** |
| **TOTAL ASSETS** | | **625,686** | **497,974** |

| EUR 1,000 | Notes | As at 31 December 2018 | 2017 |
|---|---|---|---|
| **EQUITY** | | | |
| Share capital | | 3,910 | 3,910 |
| Share premium | | 84,448 | 84,448 |
| Reserves | | 55,386 | 62,139 |
| Retained earnings | | 300,016 | 319,620 |
| **Equity attributable to owners of the company** | | **443,760** | **470,117** |
| Non-controlling interests | | 1,094 | – |
| **TOTAL EQUITY** | 23 | **444,854** | **470,117** |
| **LIABILITIES** | | | |
| **Non-current liabilities** | | | |
| Interest-bearing loans and borrowings | 25 | 157,623 | 3,827 |
| Employee benefits | 26 | 365 | 318 |
| Deferred tax liabilities | 27 | 7,499 | 4,280 |
| **Total non-current liabilities** | | **165,487** | **8,425** |
| Interest-bearing loans and borrowings | 25 | 527 | 649 |
| Trade payables | 28 | 8,806 | 11,328 |
| Current tax and other tax liabilities | 29 | 424 | 1,538 |
| Other current liabilities | 30 | 5,588 | 5,917 |
| **Total current liabilities** | | **15,345** | **19,432** |
| **TOTAL LIABILITIES** | | **180,832** | **27,857** |
| **TOTAL EQUITY AND LIABILITIES** | | **625,686** | **497,974** |

The notes form an integral part of the consolidated financial statements

## Consolidated cash flow statement

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 (restated note 5) |
|---|---|---|---|
| **Loss for the period before tax** | | **(17,459)** | **(32,432)** |
| **Adjustments for:** | | | |
| Depreciation and amortisation | 7 | 4,484 | 3,540 |
| Patent write-off | 7 | 41 | – |
| Movement in employee benefits/pension provision | | (12) | (72) |
| Share based payment expenses | | 9,589 | 9,446 |
| Financial expense on subsidised loans at amortised cost | 25 | 17 | 21 |
| Net interest income recognised in profit or loss | | (1,615) | (2,975) |
| Loss on financial investments | | 1,579 | 1,445 |
| Share of result of associate Cassiopea | 15 | 5,453 | 5,892 |
| Net unrealised foreign exchange differences | | (4,630) | 16,079 |
| **Operating cash outflow before changes in working capital** | | **(2,553)** | **944** |
| | | | |
| Change in inventories | | (696) | (937) |
| Change in trade receivables | | 628 | 1,778 |
| Change in trade payables | | (2,675) | 5,255 |
| Change in other receivables and other assets | | 2,350 | (4,201) |
| Change in other liabilities | | (1,132) | (3,198) |
| Change in other tax assets | | (1,963) | – |
| Change in other tax liabilities | | 33 | (18) |
| **Cash flows from operating activities** | | **(6,008)** | **(377)** |
| Income taxes paid (net) | | (4,156) | (9,051) |
| **Net cash from operating activities** | | **(10,164)** | **(9,428)** |
| Investments in property, plant and equipment | 11 | (1,898) | (12,289) |
| Investments in other intangible assets | 14 | (7,774) | (9,746) |
| Disposals of property, plant and equipment | 11 | 28 | 36 |
| Investments in financial assets | | (176,022) | (68,358) |
| Disposal of financial assets | | 111,171 | 62,739 |
| Interest received | | 2,793 | 3,889 |
| Net cash flow due to Linkverse acquisition | | (79) | – |
| **Cash flows from investing activities** | | **(71,781)** | **(23,729)** |
| | | | |
| Repayments of interest-bearing loans and borrowings | 25 | (665) | (854) |
| Change in other non-current receivables | | – | (173) |
| Purchase of treasury share | 23 | (18,353) | – |
| Sale of treasury share | | – | 47,290 |
| Capital increase/Stock option exercise | | – | 48,963 |
| Dividends paid | | – | (22,556) |
| Issue of convertible bond | 25 | 166,250 | – |
| Transaction costs related to loans and borrowings | 25 | (2,841) | – |
| **Cash flows from financing activities** | | **144,391** | **72,670** |
| | | | |
| **Net increase in cash and cash equivalents** | | **62,446** | **39,513** |
| **Cash and cash equivalents at the beginning of the period** | | **144,944** | **117,649** |
| Net foreign exchange differences | | 3,299 | (12,218) |
| **Cash and cash equivalents at the end of the period** | | **210,689** | **144,944** |
| Cash at hand | | 15 | 14 |
| Bank accounts | | 210,674 | 144,930 |
| **Total cash and cash equivalents at the end of the period** | 22 | **210,689** | **144,944** |

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

## Consolidated statement of changes in equity

| | Attributable to owners of the Company | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EUR 1,000 | Number of shares | Share capital | Share premium | Other reserves | Treasury shares | Stock option plan reserve | Fair value reserve | Employee benefits actuarial gains/losses reserve | Currency translation reserve | Retained earnings | Total | Non-controlling interests | Total Equity |
| | (n) | | | | | | | | | | | | |
| **Net equity as at 1 January 2017** | ***14,418,983*** | **3,749** | **–** | **47,845** | **(28,073)** | **16,457** | **3,057** | **(169)** | **118** | **372,562** | **415,546** | **12** | **415,558** |
| Total comprehensive income for the period | | | | | | | | | | | | | |
| Loss for the period | | | | | | | | | | (32,447) | (32,447) | * | (32,447) |
| Other comprehensive income for the period | | | | | | | 837 | 14 | 840 | | 1,691 | | 1,691 |
| **Total comprehensive income for the period** | | **–** | **–** | **–** | **–** | **–** | **837** | **14** | **840** | **(32,447)** | **(30,756)** | * | **(30,756)** |
| Transactions with owners of the company | | | | | | | | | | | | | |
| Dividends payment | | | | | | | | | | (22,556) | (22,556) | | (22,556) |
| Capital increase/stock option exercise | 618,500 | 161 | 65,231 | | | (16,429) | | | | | 48,963 | | 48,963 |
| Personnel cost for stock options | | | | | | 9,569 | | | | 2,061 | 11,630 | | 11,630 |
| Sale of treasury shares | | | 19,217 | | 28,073 | | | | | | 47,290 | | 47,290 |
| Subsidiary dissolution | | | | | | | | | | | – | (12) | (12) |
| **Total transactions with owners of the Company** | | **161** | **84,448** | **–** | **28,073** | **(6,860)** | **–** | **–** | **–** | **(20,495)** | **85,327** | **(12)** | **85,315** |
| **Net equity as at 31 December 2017** | ***15,037,483*** | **3,910** | **84,448** | **47,845** | **–** | **9,597** | **3,894** | **(155)** | **958** | **319,620** | **470,117** | **–** | **470,117** |

* Less than EUR 1 thousand

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

## Consolidated statement of changes in equity

| | | Attributable to owners of the Company | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EUR 1,000 | Number of shares | Share capital | Share premium | Other reserves | Treasury shares | Stock option plan reserve | Fair value reserve | Equity component of convertible bond | Employee benefits actuarial gains/losses reserve | Currency translation reserve | Retained earnings | Total | Non-controlling interests | Total Equity |
| | (n) | | | | | | | | | | | | | |
| **Net equity as at 31 December 2017** | ***15,037,483*** | **3,910** | **84,448** | **47,845** | **–** | **9,597** | **3,894** | **–** | **(155)** | **958** | **319,620** | **470,117** | **–** | **470,117** |
| Impact of the adoption of IFRS 9 | | | | | | | (464) | – | | | 464 | | | – |
| **Net equity as at 1 January 2018** | ***15,037,483*** | **3,910** | **84,448** | **47,845** | **–** | **9,597** | **3,430** | **–** | **(155)** | **958** | **320,084** | **470,117** | **–** | **470,117** |
| Total comprehensive income for the period | | | | | | | | | | | | | | |
| Loss for the period | | | | | | | | | | | (18,007) | (18,007) | (50) | (18,057) |
| Other comprehensive income for the period | | | | | | | (3,487) | | (6) | (1,155) | | (4,648) | | (4,648) |
| **Total comprehensive income for the period** | | **–** | **–** | **–** | **–** | **–** | **(3,487)** | **–** | **(6)** | **(1,155)** | **(18,007)** | **(22,655)** | **(50)** | **(22,705)** |
| Transactions with owners of the company | | | | | | | | | | | | | | |
| Personnel cost for stock options | | | | | | 9,702 | | | | | (2,061) | 7,641 | | 7,641 |
| Purchase of treasury shares | | | | | (18,353) | | | | | | | (18,353) | | (18,353) |
| Issue of convertible bond | | | | | | | | 7,011 | | | | 7,011 | | 7,011 |
| Acquisition of subsidiary with NCI | | | | | | | 1 | | (2) | | | (1) | 1,144 | 1,143 |
| **Total transactions with owners of the Company** | | **–** | **–** | **–** | **(18,353)** | **9,702** | **1** | **7,011** | **(2)** | **–** | **(2,061)** | **(3,702)** | **1,144** | **(2,558)** |
| **Net equity as at 31 December 2018** | ***15,037,483*** | **3,910** | **84,448** | **47,845** | **(18,353)** | **19,299** | **(56)** | **7,011** | **(163)** | **(197)** | **300,016** | **443,760** | **1,094** | **444,854** |

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

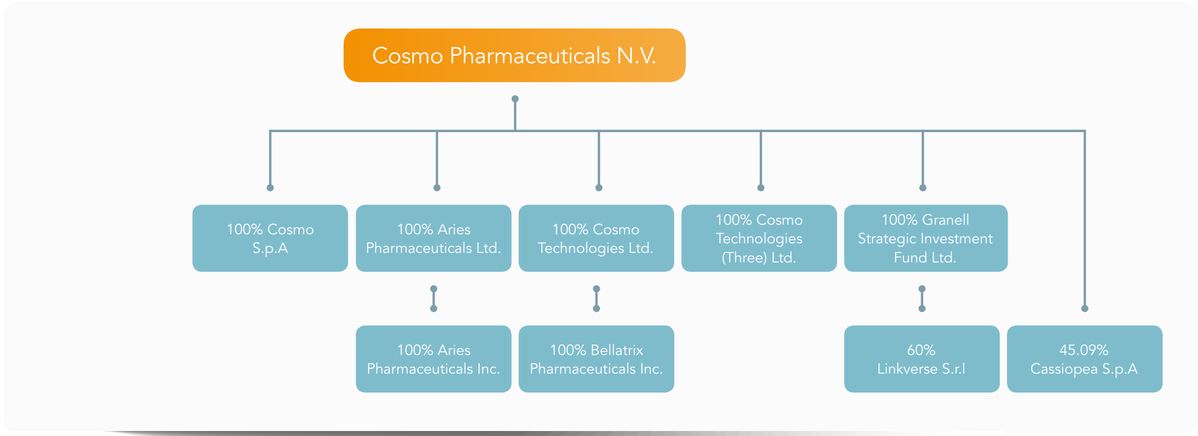
## 1 General information

Cosmo Pharmaceuticals N.V. with its subsidiaries, ('Cosmo' or 'Cosmo Pharmaceuticals' or 'Company' or 'Group') is a specialty pharmaceutical company registered in the Netherlands with its seat of management at Riverside II, Sir John Rogerson's Quay, Dublin, Ireland, and listed on the SIX Swiss Exchange (SIX: COPN), the Company has a Swiss branch located in Lugano, Switzerland. The Company is registered at the Dutch trade register under number 65617738.

Cosmo is a pharmaceutical company with a specialised focus on gastroenterology and endoscopy. We develop and manufacture products which are distributed globally. Our mission is to improve people's lives by developing innovative treatments that address unmet clinical needs and improve clinical outcomes.

Since 12 March 2007, Cosmo Pharmaceuticals' shares have been publicly listed on the Swiss Stock Exchange (SIX: COPN). The Company's stock market capitalisation as at 31 December 2018 was equal to CHF 1,321,794,756, EUR 1,172,947,694.

### Group structure as of 31 December 2018:




During 2018, Cristoforo Colombo Real Estate S.r.l. merged with Cosmo S.p.A. and a controlling interest in Linkverse S.r.l. was acquired. Cassiopea S.p.A. is an associate – refer to note 15 Investment in associates

## 2 Basis of preparation

### Authorisation of Consolidated Financial Statements and compliance with International Financial Reporting Standards

The Consolidated Financial Statements, together with notes thereto of Cosmo Pharmaceuticals, at 31 December 2018 were authorised for issuance by the Board of Directors on 28 March 2019 and have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the European Union (EU-IFRS) and part 9 of Book 2 of the Dutch Civil Code. The designation 'IFRS' also includes International Accounting Standards (IAS) as well as all interpretations of the IFRS Interpretations Committee (IFRIC).

### Basis of Preparation

These financial statements comprise the Company and its subsidiaries. The Consolidated Financial Statements are prepared under the historical cost method, modified as required for the measurement of certain financial instruments, as well as on a going concern basis. In this respect, the Group's assessment is that no material uncertainties exist about its ability to continue as a going concern.

The consolidated financial statements are presented in thousands of euro unless stated otherwise, rounding the amounts to the nearest thousand. Euro is the functional currency of the company and also the presentation currency for the Group's financial reporting.

For presentation of the Consolidated Income Statement, the Group uses a classification based on the function of expenses, rather than based on their nature, as it is more representative of the format used for internal reporting and management purposes and is consistent with international practice in the pharmaceuticals sector. The statement of financial position has been prepared presenting asset and liabilities as current and non-current; the statements of cash flows present cash flows from operating activities using the indirect method and the statement of changes in equity includes all the changes in equity.

## 3 Changes in accounting policies

### New standards, interpretations and amendments effective from 1 January 2018

The Group has initially applied IFRS 15 (see A) and IFRS 9 (see B) from 1 January 2018. A number of other new standards are also effective from 1 January 2018 but they do not have a material effect on the Group's financial statements.

Due to the transition methods chosen by the Group in applying these standards, comparative information throughout these financial statements has not been restated to reflect the requirements of the new standards.

The effect of initially applying these standards is attributed to an increase in impairment losses recognised on financial assets.

**A. IFRS 15 Revenue from Contracts with Customers**

The Group implemented the new standard IFRS 15 Revenue from Contracts with Customers as of 1 January 2018. The new standard amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces IAS 18 Revenue and IAS 11 Construction contracts and related interpretations.

The Group has adopted IFRS 15 using the cumulative effect method with the effect of initially applying this standard recognised at the date of initial application (i.e. 1 January 2018). Accordingly, the information presented for 2017 has not been restated – i.e. it is presented, as previously reported, under IAS 18, IAS 11 and related interpretations. Additionally, the disclosure requirements in IFRS 15 have not generally been applied to comparative information.

The was no material impact of transition to IFRS 15 on retained earnings at 1 January 2018, the Group's statement of financial position as at 31 December 2018 and its statement of profit or loss, OCI and cash flows for the year then ended.

## 3 Changes in accounting policies continued

### New standards, interpretations and amendments effective from 1 January 2018 continued

**A. IFRS 15 Revenue from Contracts with Customers** continued

The details of the significant accounting policies and the nature of the changes to previous accounting policies in relation to the Group's various revenue streams are set out below:

| Type of product/service | Revenue recognition under IFRS 15 (applicable from 1 January 2018) | Revenue recognition under IAS 18 (applicable before 1 January 2018) | Nature of change in accounting policy |
|---|---|---|---|
| Manufacturing on behalf of third parties | Sales from the manufacture of generic, specialty drugs, MMX® products and related services where control transfers to our customers and our performance obligations are satisfied at the time of shipment to or receipt of the products by the customer or when the services are performed. Invoices are generated and revenue is recognised at that point in time. Invoices are usually payable within 30 days. | Revenue from the sale of goods is recognised in the income statement when the significant risks and rewards of ownership have been transferred to the buyer or when the services are performed. | The adoption of IFRS 15 did not significantly change the timing or amount of revenue recognised under these arrangements. |
| Marketed products – Eleview® | Marketed products – Eleview® sales are derived from the sale of the device Eleview® directly in the US market through distributors. Revenue is recognised on receipt of the product by the distributor as control, as indicated under IFRS 15, is deemed to have transferred. Invoices are generated and revenue is recognised at that point in time. Invoices are usually payable within 30 days.<br><br>Where the consideration promised in a contract includes variable consideration, the amount of consideration to which the Company will be entitled is estimated only to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur when the uncertainty associated with the variable consideration is resolved.<br><br>For contracts that permit a right of return, under IFRS 15 revenue is recognised to the extent that it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. Therefore, the amount of revenue recognised is adjusted for expected returns, which are estimated based on historical data. This is applied to the amounts invoiced, also considering the amount of returned products to be destroyed versus products that can be placed back in inventory for resale. Where shipments are made on a re-sale or return basis, without sufficient historical experience for estimating sales returns, revenue is only recorded when there is evidence of consumption or when the right of return has expired. In these circumstances, a refund liability and a right to recover returned goods asset are recognised. | Revenue from the sale of goods is recognised in the income statement when the significant risks and rewards of ownership have been transferred to the buyer. No revenue is recognised if there are significant uncertainties regarding recovery of the consideration due, associated costs or the possible return of goods cannot be estimated reliably and there is no continuing management involvement with the goods. | The adoption of IFRS 15 did not significantly change the timing or amount of revenue recognised under these arrangements. |

## 3 Changes in accounting policies continued

### New standards, interpretations and amendments effective from 1 January 2018 continued

#### A. IFRS 15 Revenue from Contracts with Customers continued

| Type of product/service | Revenue recognition under IFRS 15 (applicable from 1 January 2018) | Revenue recognition under IAS 18 (applicable before 1 January 2018) | Nature of change in accounting policy |
|---|---|---|---|
| Licence fees, up-front fees and milestones | These licence agreements are accounted for as a right to use IP. The performance obligation to transfer the licenses to the counterparty to the agreement (the licensee) has been satisfied, revenue is recognised at the point in time when the upfront payment is received or when the milestone criteria is highly probable to be met. Milestone criteria refer to events such as NDA acceptance or approval, marketing authorisation of the product in the territory, sales targets, etc. Invoices are issued according to contractual terms and are usually payable within 30 days. | Revenues from licensing contracts for non-refundable up-front fees, in situations where no further performance obligation exists, are recognised on the earlier of when payments are received or at the inception of the license period. Revenue in relation to up-front fees related to future performance obligations are recognised as such obligations are fulfilled. Where continuing significant involvement is required in the form of support, revenues are recognised over the relevant period.<br><br>Revenues from licensing contracts for milestones are recognised 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. | The adoption of IFRS 15 did not significantly change the timing or amount of revenue recognised under these arrangements. |
| Royalties | Royalty income relates to the out-licensing of intellectual property (IP). These are sales-based royalties and revenue is recognised based on the customer's subsequent sales. Invoices are issued quarterly and are usually payable within 30 days. | Income from royalties is recognised on an accrual basis and represents income earned as a percentage of product sales, in accordance with the terms of the relevant agreement. | The adoption of IFRS 15 did it change accounting for these royalty arrangements, as the standard's royalty exception is applied for IP licenses. |

## 3 Changes in accounting policies continued

### New standards, interpretations and amendments effective from 1 January 2018 continued

**B. IFRS 9 Financial Instruments**

IFRS 9 sets out requirements for recognising and measuring financial assets, financial liabilities and some contracts to buy or sell non-financial items. This standard replaces IAS 39 Financial Instruments: Recognition and Measurement.

In particular, it amends the previous guidance in two main areas;

- The classification and measurement of financial assets, which is driven by cash flow characteristics and the business model in which an asset is held;
- The accounting for impairment of financial assets through the introduction of an 'expected credit loss' impairment model, replacing the incurred loss method under IAS 39.

In accordance with the transitional provisions in IFRS 9, the Group did not restate prior periods. Comparative figures have not been restated for the classification and measurement provisions of the standard, including impairment, and continue to be reported under the accounting standards in effect for periods prior to 1 January 2018. The impact of adoption on our Consolidated Financial Statements was not material.

The following table summarizes the impact, net of tax, of transition to IFRS 9 on the opening balance of reserves and retained earnings.

| EUR 1,000 | |
|---|---|
| **Fair value reserve** | |
| Recognition of expected credit losses under IFRS 9 for debt securities measured at FVOCI | 54 |
| Reclassification of unrealised gain on investment in funds measured at FVTPL | (746) |
| Related tax | 228 |
| **Restated at 31 December 2017** | **(464)** |
| **Retained earnings** | |
| Recognition of expected credit losses under IFRS 9 for debt securities measured at FVOCI | (54) |
| Reclassification of unrealised gain on investment in funds measured at FVTPL | 746 |
| Related tax | (228) |
| **Restated at 31 December 2017** | **464** |

### Financial assets and liabilities

Financial assets primarily include trade and other receivables, cash and cash equivalents, investments in other companies, investments in funds and debt securities that represent temporary investments of available funds and do not satisfy the requirements for being classified as cash equivalents. Financial liabilities primarily consist of debt, trade payables and other liabilities. The classification of financial liabilities under IFRS 9 is unchanged compared with the previous accounting requirements under IAS 39.

The details of new significant accounting policies and the nature and effect of the changes to previous accounting policies are set out below.

#### i Classification and measurement of financial assets and financial liabilities

IFRS 9 largely retains the existing requirements in IAS 39 for the classification and measurement of financial liabilities. However, it eliminates the previous IAS 39 categories for financial assets of held to maturity, loans and receivables and available for sale. IFRS 9 contains three principal classification categories for financial assets: measured at amortised cost, FVOCI and FVTPL. The classification of financial assets under IFRS 9 is generally based on the business model in which a financial asset is managed and its contractual cash flow characteristics.

The adoption of IFRS 9 has not had a significant effect on the Group's accounting policies related to financial liabilities.

For an explanation of how the Group classifies and measures financial instruments and accounts for related gains and losses under IFRS 9, see accounting policy in note 4(F)(ii).

The following table and the accompanying notes below explain the original measurement categories under IAS 39 and the new measurement categories under IFRS 9 for each class of the Group's financial assets and financial liabilities as at 1 January 2018.

## 3 Changes in accounting policies continued

### New standards, interpretations and amendments effective from 1 January 2018 continued

### B. IFRS 9 Financial Instruments continued

| Financial statement line item | Note | Original classification under IAS 39 | Original carrying amount under IAS 39 | New carrying amount under IFRS 9 | New classification under IFRS 9 | Financial statement line item |
|---|---|---|---|---|---|---|
| **Non-current financial assets** | | | | | | |
| Financial assets available for sale | (a) | Cost (AFS) | 2,894 | 2,894 | FVOCI – equity instrument | Equity instruments measured at FVOCI |
| Financial assets available for sale | (a) | FVOCI (AFS) | 16,458 | 16,458 | FVOCI – equity instrument | Equity instruments measured at FVOCI |
| Other financial assets available for sale – investment securities | (b) | FVOCI (AFS) | 74,459 | 74,459 | FVOCI – debt instrument | Debt securities measured at FVOCI |
| Other non-current receivables | (c) | Loans and receivables | 1,873 | 1,873 | Amortised cost | Other non-current receivables |
| **Current financial assets** | | | | | | |
| Other financial assets available for sale – investment securities | (b) | FVOCI (AFS) | 27,759 | 12,388 | FVOCI – debt instrument | Debt securities measured at FVOCI |
| | (d) | | | 15,371 | Mandatorily at FVTPL | Investment in funds measured at FVTPL |
| Trade receivables | (c) | Loans and receivables | 13,190 | 13,190 | Amortised cost | Trade receivables |
| Other receivables and other assets | (c) | Loans and receivables | 56 | 56 | Amortised cost | Other receivables and other assets |
| Cash and cash equivalents | (e) | Loans and receivables | 144,944 | 144,944 | Amortised cost | Cash and cash equivalents |
| **Total financial assets** | | | **281,633** | **281,633** | | |

**(a)** Investments in other companies are measured at fair value. The Group may irrevocably elect to present subsequent changes in the investment's fair value in Other comprehensive income (OCI) upon the initial recognition of an equity investment that is not held to sell. This election is made on an investment-by-investment basis. Generally, any dividends from these investments are recognised in 'Other income' when the Group's right to receive payment is established. Other net gains and losses are recognised in OCI and will not be reclassified to the Consolidated Income Statement in subsequent periods. Impairment losses (and the reversal of impairment losses) on equity investments measured at FVOCI are not reported separately from other changes in fair value in OCI.

**(b)** The corporate debt securities categorized as available-for-sale under IAS 39 are held by Group treasury in a separate portfolio to provide interest income, but may be sold to meet liquidity requirements arising in the normal course of business. The Group considers that these securities are held within a business model whose objective is achieved both by collecting contractual cash flows and by selling securities. The corporate debt securities mature in one to five years and the contractual terms of these financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding. These assets have therefore been classified as financial assets at FVOCI under IFRS 9.

**(c)** Trade and other receivables and other non-current receivables that were classified as loans and receivables under IAS 39 are now classified at amortized cost.

**(d)** Investments in funds were categorized as available-for-sale under IAS 39. The portfolio is managed by an investment manager, who actively buys and sells instruments within the portfolio to generate short-term profits. These assets have been classified as financial assets at FVTPL under IFRS 9.

**(e)** Cash and cash equivalents include cash at banks and short-term deposits that are readily convertible into cash with original maturities of six months or less at the date of purchase. Cash and cash equivalents are subject to an insignificant risk of changes in value and consist of balances across various financial institutions. Cash at banks and other cash equivalents are measured at amortised cost.

## 3 Changes in accounting policies continued

### New standards, interpretations and amendments effective from 1 January 2018 continued

**B. IFRS 9 Financial Instruments** continued

ii Impairment of financial assets

Impact of the new impairment model

The Group has determined that the application of IFRS 9's impairment requirements at 1 January 2018 results in an additional impairment allowance as follows:

| EUR 1,000 | |
|---|---|
| **Loss allowance at 31 December 2017 under IAS 39** | **32** |
| Additional impairment recognised at 1 January 2018 on: | |
| Debt securities measured at FVOCI | 54 |
| **Loss allowance at 1 January 2018 under IFRS 9** | **86** |

The debt securities at FVOCI held by the Group are considered to have low credit risk, and the loss allowance recognised during the period was therefore limited to 12 months expected losses. The credit risk on debt securities at FVOCI has not increased significantly since initial recognition. Management consider 'low credit risk' for listed bonds to be an investment grade credit rating with at least one major rating agency.

Cosmo concludes that its trade receivables do not include a significant financing component because they are due within 0-30 days of the invoice date. Hence, the Group apply the simplified approach and recognise lifetime ECLs on trade receivables. The Group has experienced no instances of trade receivables written-off / bad debts to date. The Group assesses that there are no factors specific to our customers or general economic conditions, in both the current as well as the forecast direction, of conditions at the reporting date that are indicative of potential material credit losses.

### Standards, amendments and interpretations issued but not yet effective

A number of new standards are effective for annual periods beginning after 1 January 2018 and earlier application is permitted; however, the Group has not early adopted the new or amended standards in preparing these consolidated financial statements.

Of those standards that are not yet effective, IFRS 16 is expected to have a material impact on the Group's financial statements in the period of initial application.

**C. IFRS 16 Leases**

The Group is required to adopt IFRS 16 Leases from 1 January 2019. The Group has assessed the estimated impact that initial application of IFRS 16 will have on its consolidated financial statements, as described below. The actual impacts of adopting the standard on 1 January 2019 may change because the new accounting policies are subject to change until the Group presents its first financial statements that include the date of initial application. IFRS 16 introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognises a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are recognition exemptions for short-term leases and leases of low-value items. Lessor accounting remains similar to the current standard, i.e. lessors continue to classify leases as finance or operating leases.

IFRS 16 replaces existing leases guidance, including IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases – Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease.

The Group will recognise new assets and liabilities for its operating leases of office buildings and company cars. The nature of expenses related to those leases will now change because the Group will recognise a depreciation charge for right-of-use assets and interest expense on lease liabilities. Previously, the Group recognised operating lease expense on a straight-line basis over the term of the lease, and recognised assets and liabilities only to the extent that there was a timing difference between actual lease payments and the expense recognised.

No significant impact is expected for the Group's finance leases.

Based on the information currently available, the Group estimates that it will recognise additional lease liabilities of €4,308 thousand and a right-of-use asset of €3,976 thousand as at 1 January 2019.

**D. Other standards**

The following amended standards and interpretations are not expected to have a significant impact on the Group's consolidated financial statements.

- IFRIC 23 Uncertainty over Tax Treatments.
- Prepayment Features with Negative Compensation (Amendments to IFRS 9).
- Long-term Interests in Associates and Joint Ventures (Amendments to IAS 28).
- Plan Amendment, Curtailment or Settlement (Amendments to IAS 19).
- Annual Improvements to IFRS Standards 2015–2017 Cycle – various standards.
- Amendments to References to Conceptual Framework in IFRS Standards.
- IFRS 17 Insurance Contracts.

## 4 Accounting policies

The major accounting policies adopted are detailed below.

### A. Principles of consolidation

#### i Business combinations

Business combinations are accounted for using the acquisition method of accounting. The consideration transferred in a business combination is measured at fair value at the date of acquisition. This consideration includes the cash paid plus the fair value at the date of exchange of assets given, liabilities incurred or assumed and equity instruments issued by the Group. The fair value of the consideration transferred also includes contingent consideration arrangements at fair value. Any subsequent changes in the fair value of the contingent consideration are recognised in profit or loss. Directly attributable acquisition-related costs are expensed in the current period and reported within general and administration expenses. At the date of acquisition, the Group recognises the identifiable assets acquired, the liabilities assumed and any non-controlling interest in the acquired business. Any goodwill that arises is tested annually for impairment. Any gain on a bargain purchase is recognised in profit or loss immediately.

#### ii Subsidiaries

Subsidiaries are entities over which the Group has control. Control is achieved when the Group has power over the investee, when it is exposed to, or has rights to, variable returns from its involvement with the investee, and has the ability to use its power over the investee to affect the amount of the investor's returns. Subsidiaries are consolidated on a line by line basis from the date on which control is achieved by the Group. The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

The Group recognises a non-controlling interest in the acquiree on a transaction-by-transaction basis, either at fair value or at the non-controlling interest's share of the recognised amounts of the acquiree's identifiable net assets. Net profit or loss and each component of Other comprehensive income/(loss) are attributed to Equity attributable to owners of the parent and to non-controlling interest.

Total comprehensive income/(loss) of subsidiaries is attributed to Equity attributable to the owners of the parent and to the non-controlling interest even if this results in a deficit balance in non-controlling interest. Changes in the Group's ownership interests in a subsidiary that do not result in the Group losing control over the subsidiary are accounted for as an equity transaction. The carrying amounts of the Equity attributable to owners of the parent and non-controlling interests are adjusted to reflect the changes in their relative interests in the subsidiary.

Any difference between the carrying amount of the non-controlling interests and the fair value of the consideration paid or received in the transaction is recognised directly in the Equity attributable to the owners of the parent.

Subsidiaries are deconsolidated from the date on which control ceases. When the Group ceases to have control over a subsidiary, it de-recognises the assets (including any goodwill) and liabilities of the subsidiary at their carrying amounts at the date when control is lost, and de-recognises the carrying amount of non-controlling interests in the former subsidiary at the same date and recognises the fair value of any consideration received from the transaction. Any retained interest in the former subsidiary is remeasured to its fair value at the date when control is lost. This fair value is the initial carrying amount for the purposes of subsequent accounting for the retained interest as an associate, or financial asset. In addition, any amounts previously recognised in Other comprehensive income/(loss) in respect of that entity are accounted for as if the Group had directly disposed of the related assets or liabilities. This may mean that amounts previously recognised in Other comprehensive income/(loss) are reclassified to the Consolidated income statement or transferred directly to retained earnings as required by other IFRS.

Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

#### iii Interests in Associates

An associate is an entity over which the Group has significant influence. Significant influence is the power to participate in the financial and operating policy decisions of the investees but does not have control over those policies.

Associates are accounted for using the equity method of accounting from the date on which significant influence is obtained. On acquisition of the investment, any excess of the cost of the investment and the Group's share of the net fair value of the investee's identifiable assets and liabilities is recognised as goodwill and is included in the carrying amount of the investment. Any excess of the Group's share of the net fair value of the investee's identifiable assets and liabilities over the cost of the investment is included as income in the determination of the Group's share of the investee's profit or loss in the acquisition period.

Under the equity method, the investments are initially recognised at cost, and adjusted thereafter to recognise the Group's share of the profit or loss and Other comprehensive income/(loss) of the investee.

The Group's share of the investee's profit or loss is recognised in the Consolidated income statement.

**4 Accounting policies** continued

**A. Principles of consolidation** continued

**iii Interests in Associates** continued

Distributions received from an investee reduce the carrying amount of the investment. Post-acquisition movements in Other comprehensive income/(loss) are recognised in Other comprehensive income/(loss) with a corresponding adjustment to the carrying amount of the investment.

Unrealised gains on transactions between the Group and associates are eliminated to the extent of the Group's interest in the associate. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred.

When the Group's share of the losses of associate exceeds the Group's interest in that associate, the Group discontinues recognising its share of further losses. Additional losses are provided for, and a liability is recognised, only to the extent that the Group has incurred legal or constructive obligations or made payments on behalf of associate.

The Group discontinues the use of the equity method from the date when the investment ceases to be an associate or when it is classified as held for sale.

**iv Transactions eliminated in consolidation**

All intra-group balances and transactions and any unrealised gains and losses arising from intragroup transactions are eliminated in preparing the Consolidated financial statements.

Unrealised gains and losses arising from transactions with associates are eliminated to the extent of the Group's interest in those entities.

Unrealised losses are eliminated in the same way as unrealised gains, but only to the extent that there is no evidence of impairment.

**B. Foreign currency**

**i Foreign currency transactions**

The functional currency of the Group's entities is the currency of their primary economic environment.

In individual companies, transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated at the exchange rate prevailing at that date. Exchange differences arising on the settlement of monetary items or on reporting monetary items at rates different from those at which they were initially recorded during the period or in previous financial statements, are recognised in the Consolidated 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 at exchange rates at the date the fair value was determined.

**ii Consolidation of foreign entities**

All assets and liabilities of foreign consolidated companies with a functional currency other than the Euro are translated using the closing rates at the date of the Consolidated statement of financial position.

Income and expenses are translated into euro at the average exchange rate for the period.

Translation differences resulting from the application of this method are classified as Other comprehensive income/(loss) until the disposal of the investment. Average exchange rates for the period are used to translate the cash flows of foreign subsidiaries in preparing the Consolidated statement of cash flows.

Goodwill, assets acquired and liabilities assumed arising from the acquisition of entities with a functional currency other than the Euro are recognised in the Consolidated financial statements in the functional currency and translated at the exchange rate at the acquisition date. These balances are translated at subsequent balance sheet dates at the relevant exchange rate.

**4 Accounting policies** continued

**C. Property, plant and equipment**

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

The cost of self-constructed assets includes the cost of materials, direct labour, the initial estimate, where relevant, of the costs of dismantling and removing the items and restoring the site on which they are located, and an appropriate proportion of production overheads.

Subsequent expenditures are capitalised only if they increase the future economic benefits embodied in the related item of property, plant and equipment. All other expenditures are expensed as incurred.

Property, plant and equipment that are being constructed or developed for future use are classified as Assets under construction and stated at cost until construction is complete, at which time they are reclassified as property, plant and equipment.

Where parts of an item of property, plant and equipment have different useful lives, they are separately identified and depreciated on the basis of their estimated useful lives (component approach).

The cost of replacing part of an item is recognised in the carrying amount of an item of property, plant and equipment when that cost is incurred if it is probable that the future economic benefits embodied in the item will flow to the Group and the cost of the item can be measured reliably. The residual carrying amount of the replaced component is recognised in the income statement as an expense. All other costs are recognised in the income statement as an expense as incurred. Financial expenses related to the purchase of such assets are recognised in the income statement.

Depreciation is recognised 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 as follows:

| | |
|---|---|
| Buildings – owned buildings | 33 years |
| Buildings – leasehold-improvements | At the lower of the useful life of the improvement and the residual term of the lease |
| Plant and machinery – general | 10 years |
| Plant and machinery – specific | 8 years |
| Industrial and commercial equipment | 3 years |
| Other tangible assets – office equipment – electronics | 5 years |
| Other tangible assets – office equipment – furniture | 8 years |
| Other tangible – assets – means of internal -transportation | 5 years |

Appurtenance land related to own buildings or purchased through finance leases is stated separately and is not depreciated.

Improvements to third-party assets are classified under property, plant and equipment depending on the nature of the asset to which it refers. The depreciation period is based on the lower of the asset's remaining useful life and the residual duration of the lease of the principal asset.

If specific events indicate that impairment of an item of property, plant and equipment may have taken place, the item's recoverability is assessed by comparing its carrying amount with its recoverable amount, represented by the higher of the fair value net of disposal costs and value in use, as defined in the paragraph Impairment of property, plant and equipment and intangible assets.

Assets held under finance leases, which provide the Group with substantially all the risks and rewards of ownership, are recognised as assets of the Group at their fair value or, if lower, at the present value of the minimum lease payments.

The corresponding liability to the lessor is included in the financial statements as financial liabilities. Leases where the lessor retains substantially all the risks and rewards of ownership of the assets are classified as operating leases. Operating lease expenditures are expensed on a straight-line basis over the lease terms.

## 4 Accounting policies continued

### D. Goodwill

Goodwill arising on the acquisition of subsidiaries is measured at cost less accumulated impairment losses. Goodwill is recorded as the surplus of the consideration transferred over the Group's interest in the fair value of the acquired net assets. Any goodwill and fair value adjustments are recorded as assets and liabilities of the acquired business in the functional currency of that business. Goodwill is not amortised but is assessed for possible impairment at each reporting date and is additionally tested annually for impairment. Goodwill may also arise upon investments in associates, being the surplus of the cost of investment over the Group's share of the fair value of the net identifiable assets. Such goodwill is recorded within investments in associates.

### E. Other intangible assets

Other intangible assets are recognised 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 Group are stated at cost less accumulated amortisation (see below) and impairment losses, if any.

Subsequent expenditures on capitalised intangible assets are capitalised 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 amortised from the date they are available for use on a straight-line basis over their useful lives, being the estimated period over which the Group will use the assets.

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

| Timeframe | |
|---|---|
| Development costs | from date available for use until date of patent expiry |
| Patents and rights | from start date until date of expiry |
| Trademarks | 10 years |
| Licenses | Duration of License agreement |

Patents and rights are amortised over their useful life to their date of expiry.

Trademarks and licenses: trademarks are amortised over 10 years, licenses are amortised over the duration of the agreement to which they relate.

Expenditures on research activities, undertaken with the prospect of gaining new technical knowledge and understanding, are recognised in the income statements as an expense as incurred. Development costs are capitalised 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 amortisation and accumulated impairment losses. The intangible asset is amortised 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.

The recoverable amount is the higher between the fair value net of disposal costs and the value in use, as defined in the following paragraph.

## 4 Accounting policies continued

### F. Financial instruments

Financial assets primarily include trade and other receivables, cash and cash equivalents, investments in other companies, investments in funds and debt instruments that represent temporary investments of available funds and do not satisfy the requirements for being classified as cash equivalents.

Financial liabilities primarily consist of debt, trade payables and other liabilities.

#### i Recognition and initial measurement

Trade receivables and debt securities issued are initially recognised when they are originated. All other financial assets and financial liabilities are initially recognised when the Group becomes a party to the contractual provisions of the instrument.

A financial asset (unless it is a trade receivable without a significant financing component) or financial liability is initially measured at fair value plus, for an item not at FVTPL, transaction costs that are directly attributable to its acquisition or issue. A trade receivable without a significant financing component is initially measured at the transaction price.

#### ii Classification and subsequent measurement

Financial assets – Policy applicable from 1 January 2018

On initial recognition, a financial asset is classified as measured at: amortised cost; FVOCI – debt investment; FVOCI – equity investment; or FVTPL. The classification of financial assets under IFRS 9 is generally based on the business model in which a financial asset is managed and its contractual cash flow characteristics. The group considers whether the contractual cash flows represent solely payments of principal and interest that are consistent with a basic lending arrangement. Where the contractual terms introduce exposure to risk or volatility that are inconsistent with a basic lending arrangement, the related financial assets are classified and measured at fair value through profit or loss (FVPL).

On initial recognition of an equity investment that is not held for trading, the Group may irrevocably elect to present subsequent changes in the investment's fair value in OCI. This election is made on an investment-by-investment basis.

The following accounting policies apply to the subsequent measurement of financial assets.

| | |
|---|---|
| Financial assets at FVTPL | These assets are subsequently measured at fair value. Net gains and losses, including any interest or dividend income, are recognised in profit or loss. |
| Financial assets at amortised cost | These assets are subsequently measured at amortised cost using the effective interest method. The amortised cost is reduced by impairment losses. Interest income, foreign exchange gains and losses and impairment are recognised in profit or loss. Any gain or loss on derecognition is recognised in profit or loss. |
| Debt investments at FVOCI | These assets are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognised in profit or loss. Other net gains and losses are recognised in OCI. On derecognition, gains and losses accumulated in OCI are reclassified to profit or loss. |
| Equity investments at FVOCI | These assets are subsequently measured at fair value. Dividends are recognised as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses are recognised in OCI and are never reclassified to profit or loss. |

Factors considered by the Group in determining the business model for a group of financial assets include:

- past experience on how the cash flows for these assets were collected;
- the frequency, volume and timing of sales of financial assets in prior periods, the reasons for such sales and future sales activity expectations;
- how the asset's performance is evaluated and reported to key management personnel;
- how risks are assessed and managed and how management is compensated.

Financial assets are not reclassified subsequent to their initial recognition unless the Group changes its business model for managing financial assets, in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

Financial assets – Policy applicable before 1 January 2018

The Group classified its financial assets into one of the following categories:

- loans and receivables;
- held to maturity;
- available for sale; and
- at FVTPL.

**4 Accounting policies** continued
**F. Financial instruments** continued
**ii Classification and subsequent measurement** continued
The following accounting policies applied to the subsequent measurement of financial assets.

| | |
|---|---|
| Financial assets at FVTPL | Measured at fair value and changes therein, including any interest or dividend income, were recognised in profit or loss. |
| Held-to-maturity financial assets | Measured at amortised cost using the effective interest method. |
| Loans and receivables | Measured at amortised cost using the effective interest method. |
| Available-for-sale financial assets | Measured at fair value and changes therein, other than impairment losses, interest income and foreign currency differences on debt instruments, were recognised in OCI and accumulated in the fair value reserve. When these assets were derecognised, the gain or loss accumulated in equity was reclassified to profit or loss. |

### Financial Liabilities – Policy applicable from 1 January 2018
Financial liabilities are classified as measured at amortised cost or FVTPL. A financial liability is classified as at FVTPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognised in profit or loss. Other financial liabilities are subsequently measured at amortised cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognised in profit or loss. Any gain or loss on derecognition is also recognised in profit or loss.

### Financial liabilities– Policy applicable before 1 January 2018
Financial liabilities are classified as measured at amortised cost or FVTPL. A financial liability is classified as at FVTPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognised in profit or loss. Other financial liabilities are subsequently measured at amortised cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognised in profit or loss. Any gain or loss on derecognition is also recognised in profit or loss.

**iii Derecognition**
### Financial assets
The Group derecognises a financial asset when the contractual rights to the cash flows from the financial asset expire, or it transfers the rights to receive the contractual cash flows in a transaction in which substantially all of the risks and rewards of ownership of the financial asset are transferred or in which the Group neither transfers nor retains substantially all of the risks and rewards of ownership and it does not retain control of the financial asset.

### Financial liabilities
The Group derecognises a financial liability when its contractual obligations are discharged or cancelled, or expire. The Group also derecognises a financial liability when its terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognised at fair value. On derecognition of a financial liability, the difference between the carrying amount extinguished and the consideration paid (including any non-cash assets transferred or liabilities assumed) is recognised in profit or loss.

**iv Offsetting**
Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group currently has a legally enforceable right to set off the amounts and it intends either to settle them on a net basis or to realise the asset and settle the liability simultaneously.

**v Compound financial instruments**
Compound financial instruments issued by the Group comprise convertible notes denominated in euro that can be converted to ordinary shares at the option of the holder, when the number of shares to be issued is fixed.

The liability component of compound financial instruments is initially recognised at the fair value of a similar liability that does not have an equity conversion option. The equity component is initially recognised at the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts.

Subsequent to initial recognition, the liability component of a compound financial instrument is measured at amortised cost using the effective interest method. The equity component of a compound financial instrument is not remeasured.

Interest related to the financial liability is recognised in profit or loss. On conversion at maturity, the financial liability is reclassified to equity and no gain or loss is recognised.

**4 Accounting policies** continued

## G. Impairment

### i Financial assets

Policy applicable from 1 January 2018

The IFRS 9 impairment requirements are based on a forward-looking expected credit loss ("ECL") model. ECL is a probability-weighted estimate of the present value of cash shortfalls.

The calculation of the amount of ECL is based on the risk of default by the counterparty, which is determined by taking into account the information available at the end of each reporting period as to the counterparty's solvency, the fair value of any guarantees and the Group's historical experience. The Group considers a financial asset to be in default when: (i) the borrower is unlikely to pay its obligations in full and without consideration of compensating guarantees or collateral (if any exist); or (ii) the financial asset is more than 90 days past due.

The Group applies two impairment models for financial assets as set out in IFRS 9: the simplified approach and the general approach. The table below indicates the impairment model used for each of our financial asset categories. Impairment losses on financial assets are recognised in the Consolidated Income Statement within the corresponding line items, based on the classification of the counterparty.

| Financial Asset | IFRS 9 impairment model |
|---|---|
| Trade and other receivables | Simplified approach |
| Cash and cash equivalents | General approach |
| Debt securities carried at FVOCI | General approach |

In order to test for impairment, individually significant receivables and receivables for which collectability is at risk are assessed individually, while all other receivables are grouped into homogeneous risk categories based on shared risk characteristics such as instrument type, industry or geographical location of the counterparty.

The simplified approach for determining the lifetime ECL allowance is performed in two steps:

- All trade receivables that are in default, as defined above, are individually assessed for impairment; and
- A general reserve is recognised for all other trade receivables (including those not past due) based on historical loss rates and adjusted to current and forward looking information.

The Group applies the general approach as determined by IFRS 9 by assessing at each reporting date whether there has been a significant increase in credit risk on the financial instrument since initial recognition. The Group considers receivables to have experienced a significant increase in credit risk when certain quantitative or qualitative indicators have been met or the borrower is more than 30 days past due on its contractual payments.

The 'three-stages' for determining and measuring the impairment based on changes in credit quality since initial recognition are summarised below:

| Stage | Description | Time period for measurement of ECL |
|---|---|---|
| Stage 1 | A financial instrument that is not credit-impaired on initial recognition or that have low credit risk at the reporting date. For these assets, 12-month ECLs are recognised and interest revenue is calculated on the gross carrying amount of the asset. | 12-month ECL |
| Stage 2 | A financial instrument with a significant increase in credit risk since initial recognition but are not credit-impaired. For these assets, lifetime ECL are recognised, and interest revenue is still calculated on the gross carrying amount of the asset. | Lifetime ECL |
| Stage 3 | A financial instrument that is credit-impaired or has defaulted, (that is, where one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred). For these assets, lifetime ECL are also recognised, but interest revenue is calculated on the net carrying amount (that is, net of the ECL allowance). | Lifetime ECL |

Considering forward-looking economic information, ECL is determined by projecting the probability of default, exposure at default and loss given default for each future contractual period and for each individual exposure or collective portfolio. The discount rate used in the ECL calculation is the stated effective interest rate or an approximation thereof. Each reporting period, the assumptions underlying the ECL calculation are reviewed and updated as necessary. Since adoption, there have been no significant changes in estimation techniques or significant assumptions that led to material changes in the ECL allowance.

**4 Accounting policies** continued

**G. Impairment** continued

**i Financial assets** continued

### Credit-impaired financial assets

At each reporting date, the Group assesses whether financial assets carried at amortised cost and debt securities at FVOCI are credit-impaired. A financial asset is 'credit-impaired' when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred. Evidence that a financial asset is credit-impaired includes the following observable data:

- significant financial difficulty of the borrower or issuer;
- a breach of contract such as a default or being more than 90 days past due;
- the restructuring of a loan or advance by the Group on terms that the Group would not consider otherwise;
- it is probable that the borrower will enter bankruptcy or other financial reorganisation; or
- the disappearance of an active market for a security because of financial difficulties.

### Presentation of allowance for ECL in the statement of financial position

Loss allowances for financial assets measured at amortised cost are deducted from the gross carrying amount of the assets. For debt securities at FVOCI, the loss allowance is charged to profit or loss and is recognised in OCI.

### Write-off

The gross carrying amount of a financial asset is written-off to the extent that there is no realistic prospect of recovery. This is generally the case when the Group determines that a debtor does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off. However, financial assets that are written off could still be subject to enforcement activities.

### Policy applicable before 1 January 2018

Financial assets not classified as at FVTPL were assessed at each reporting date to determine whether there was objective evidence of impairment.

Objective evidence that financial assets were impaired included:

- default or delinquency by a debtor;
- restructuring of an amount due to the Group on terms that the Group would not consider otherwise;
- indications that a debtor or issuer would enter bankruptcy;
- adverse changes in the payment status of borrowers or issuers;
- the disappearance of an active market for a security because of financial difficulties; or
- observable data indicating that there was a measurable decrease in the expected cash flows from a group of financial assets.

For an investment in an equity instrument, objective evidence of impairment included a significant or prolonged decline in its fair value below its cost. The Group considered a decline of 20% to be significant and a period of nine months to be prolonged.

Financial assets measured at amortised cost: an impairment loss was calculated as the difference between an asset's carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses were recognised in profit or loss and reflected in an allowance account. When the Group considered that there were no realistic prospects of recovery of the asset, the relevant amounts were written off. If the amount of impairment loss subsequently decreased and the decrease was related objectively to an event occurring after the impairment was recognised, then the previously recognised impairment loss was reversed through profit or loss.

Available-for-sale financial asset: an amount comprising the difference between its cost (net of any principal payment and amortisation) and its current fair value, less any impairment loss previously recognised in other comprehensive income, is transferred from other comprehensive income to profit or loss. If the fair value of an impaired available-for-sale debt security subsequently increased and the increase was related objectively to an event occurring after the impairment loss was recognised, then the impairment loss was reversed through profit or loss. Impairment losses recognised in profit or loss for an investment in an equity instrument classified as available-for-sale were not reversed through profit or loss.

**ii Impairment of property, plant and equipment and intangible assets**

The carrying amounts of the Group's tangible and intangible assets are reviewed at each balance sheet date to determine whether there is any indication of impairment. If any such indication exists, the asset's recoverable amount is estimated.

For goodwill assets that have an indefinite useful life and intangible assets that are not yet available for use, the recoverable amount is estimated at each balance sheet date.

An impairment loss is recognised whenever the carrying amount of an asset or its cash-generating unit exceeds its recoverable amount. Impairment losses are recognised in the income statements.

The recoverable amount is the higher of an asset's fair value less costs of disposal, if there is an active market, and its value in use. If there is no binding sales agreement, the fair value is estimated at the amount expressed by an active market, by recent transactions or on the basis of the best available information indicating the amount that the Company would obtain from the asset's sale.

**4 Accounting policies** continued

**G. Impairment** continued

**ii Impairment of property, plant and equipment and intangible assets** continued

Value in use is the present value of the estimated future cash flows expected to arise from the continuing use of an asset or cash-generating unit and from its disposal at the end of its useful life. The cash flows are determined on the basis of reasonable and documented assumptions representing the best estimate of the future economic conditions that will take place over the residual useful life of the asset, giving greatest weight to external indicators. The discounting rate (pre-tax) takes into account the risk implicit in the business sector and the financial component based on the timing. With the exception of losses on goodwill, impairments in value are reversed when there is an indication that the impairment loss may no longer exist and there has been a change in the estimates used to determine the recoverable amount. An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortisation, if no impairment loss had been recognised.

**H. Inventories**

Inventories are stated at the lower of acquisition or production cost and net realisable value. Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and selling expenses.

The cost of inventories is determined in accordance with the first-in first-out (FIFO) principle and includes expenditure incurred in acquiring the inventories and bringing them to their existing location and condition. In the case of manufactured inventories and work in progress, the cost includes an appropriate share of overhead costs that may reasonably be attributable to the performance of manufacturing activities in normal operating conditions.

A provision for inventories is calculated to take into account obsolete and slow-moving items, considering their possible future use and realisable value. Estimated realisable value represents the estimated sales price in normal business, net of estimated costs to sell.

**I. Cash and cash equivalents**

Cash and cash equivalents comprises cash balances and call deposits. Bank overdrafts that are repayable on demand and form an integral part of the Group's cash management are included as a component of cash and cash equivalents for the purpose of the statement of cash flows.

**J. Employee benefits**

**i Defined contribution pension plans**

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

**ii Employee termination benefits**

The employee termination benefit (Trattamento di fine rapporto, TFR) only refers to the Italian companies of the Group, is considered as a defined benefit plan under IAS 19. The benefits guaranteed to employees, in the form of the employee termination benefit paid out upon leaving the Company, are recognised in the period in which the right matures. The relating liability is calculated on the basis of actuarial assumptions and the benefit vested and not yet paid out at the balance sheet date, applying the criteria required by the Italian law.

The discounting process is based on demographic and financial assumptions, using the Projected Unit Credit Method (vested benefit method) applied by professional actuaries. This method involves calculating the average present value of the vested pension benefit on the basis of the employee's service rendered to the measurement date, based on a projection of the employee's remuneration.
The amount of employee benefits that vested during the year is recognised in the income statement as Labour costs. The theoretical finance charge that the Company would incur if it were to borrow in the marketplace an amount equal to the provision for employee severance indemnities is posted to Net financial income (expense). Actuarial gains and losses that arise from changes in the actuarial assumptions used are recognised in the comprehensive income statement, taking into account the average working lives of the employees.

Specifically, in accordance with Budget Law No. 296 of 27 December 2006, only the liability for vested employee severance benefits that remained at the Company was valued for IAS 19 purposes, since the portion applicable to future vesting benefits is being paid to separate entities (supplemental pension funds or INPS funds). As a result of these payments, the Company has no further obligations with regard to the work that employees will perform in the future (so-called defined-contribution plan).

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

The Group 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 Group revises its estimate of the number of options that are expected to become exercisable.

**4 Accounting policies** continued

**J. Employee benefits** continued

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

It recognises 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.

### K. Provisions

Provisions are recorded when:

- the Group has an obligation, legal or constructive, to third parties,
- it is probable that resources will be expensed in order to meet the obligation,
- a reliable estimate of the amounts of the obligation can be made.

An implied obligation is defined as an obligation arising when the Group has made other parties aware, by way of routine procedure, public company policy or a sufficiently specific announcement, that it accepts the obligation in a way that, as a consequence, it leads the third party to believe that the Group will honour its obligation. Provisions for risks and charges are recognised at an amount which represents the best estimate of the amount the Group will have to pay in order to settle the obligation, or otherwise transfer it to third parties at the end of the year. When the effect of the time value of money is material and the payment dates for the obligations may be estimated reliably, the provision is calculated by discounting the estimated future financial cash flows using a pre-tax discount rate in order to reflect the current market assessments of the current value of money and the specific risks connected to the liabilities. Following discounting, the increase in the provision is recognised in the income statement caption financial expenses.

The provisions are updated regularly to reflect changes in cost estimates, settlement times and the discount rate. Reviews of the estimate of the provisions are recognised under the same income statement caption where the provision was previously recognised.

### L. Revenue

The Group has initially applied IFRS 15 from 1 January 2018. Information about the Group's accounting policies relating to contracts with customers along with the effect of initially applying IFRS 15 is provided in note 3(A).

### M. Net operating expenses

Research government grants are recognised at their fair value at the moment in which the issuing body has confirmed its approval and the proceeds are definite; they are recognised in the income statement over the period necessary to match them with the costs that they are intended to compensate. Interest income is accounted for based on the effective rate of return on an accrual basis.

Payments made under operating leases are recognised in income statements on a straight-line basis over the term of the lease. Minimum lease payments made under finance leases are apportioned between the finance expense and the reduction of the outstanding liability.

Expenditures on research activities, undertaken with the prospect of gaining new technical know-ledge and understanding, as well as development costs not capitalised, are recognised in the income statement as an expense as incurred.

### N. Income tax

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

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 recognised to the extent that it is probable that future taxable profit will be available against which they can be utilised.

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.

### O. Treasury shares

Treasury shares are presented as a deduction from equity. The purchase cost of treasury shares and the sales proceeds of any subsequent sale are presented as movements in equity.

### P. Dividend distribution

Dividend distribution to the company's shareholders is recognised in the Group's financial statements in the period in which the dividends are approved by the Company's shareholders.

## 4 Accounting policies continued

### Q. 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 (loss) 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.

### R. Segment reporting

Management has identified only one business segment which is the pharmaceutical segment. Management did not identify other operating segments to which specific and different risks and benefits can be related to and the Management's reports to support the decision process are regularly and consistently prepared. Moreover, the Management did not believe that costs of investments could be reasonably allocated unless through an arbitrary allocation, which would not provide a better disclosure than that provided by the pharmaceutical sector, considered as a whole. In particular, under the Group's current organisational structure most of the investments made and costs incurred by the Group while performing its production activities cannot be allocated to a specific geographical area or that, to date, segment reporting by either geographical area or products or customers would not improve the understanding of the Group's results or the presentation of risks and profitability.

### S. Critical accounting estimates, assumptions and judgments

The preparation of the consolidated financial statements and the related notes requires the use of estimates and assumptions that affect the application of accounting policies and the reported amount of assets, liabilities, income and expenses. 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. However, as they are estimates, actual future results could differ from those included in the consolidated financial statements. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised 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 consolidated financial statements, are reported below.

#### i. Impairment of non-financial assets

Management have reviewed the carrying amount of property, plant and equipment, goodwill, other intangible assets and financial assets at balance sheet date to determine whether there was any indication of impairment. See accounting policy in note 4(G)(ii) for further information.

#### ii Impairment of financial assets

At each reporting date, the Group assesses whether financial assets carried at amortised cost and debt securities at FVOCI are credit-impaired. See accounting policy in note 4(G)(i) for further information.

#### iii Deferred tax assets

The Group has a considerable amount of tax losses carried forward and temporary differences between carrying amount of assets and liabilities for financial reporting purposes and for taxation purposes that allow for the recognition of deferred tax assets. Deferred tax assets are recognised only to the extent that it is probable that future taxable profits will be available against which the asset can be utilised, determined on the basis of future results forecasts.

#### iv Development costs

Development costs are capitalised in accordance with the accounting policy detailed in Other intangible assets. Development costs associated with Methylene Blue MMX (CB-17-01), Aemcolo™ (CB-01-11), Eleview® (CB-17-04) and Remimazolam (CB-07-01) were capitalised from the start of 2016 as management believe that capitalisation criteria was met from that date. The development projects are progressing in line with technical and economical plans and having been reviewed, Management confirm the recoverability of the relevant capitalised costs based on probable future economic benefits. Refer to note 14 Other intangible assets for further information.

#### v Business model assessment

Classification and measurement of financial assets depends on the results of the SPPI and the business model test. The Group determines the business model at a level that reflects how groups of financial assets are managed together to achieve a particular business objective. This assessment includes judgement reflecting all relevant evidence including how the performance of the assets is evaluated and their performance measured, the risks that affect the performance of the assets and how these are managed and how the managers of the assets are compensated. See accounting policy in note 4(F)(ii) for further information.

**4 Accounting policies** continued

**S. Critical accounting estimates, assumptions and judgments** continued

**vi Significant increase in credit risk**

ECL are measured as an allowance equal to 12-month ECL for stage 1 assets, or lifetime ECL for stage 2 or stage 3 assets. An asset moves to stage 2 when its credit risk has increased significantly since initial recognition. IFRS 9 does not define what constitutes a significant increase in credit risk. In assessing whether the credit risk of an asset has significantly increased the Group takes into account qualitative and quantitative reasonable and supportable forward-looking information. See accounting policy in note 4(G)(ii) for further information.

**vii Calculation of loss allowance**

When measuring ECL the Group uses reasonable and supportable forward-looking information, which is based on assumptions for the future movement of different economic drivers and how these drivers will affect each other. Probability of default is an estimate of the likelihood of default over a given time horizon. Loss given default is an estimate of the loss arising on default. See accounting policy in note 4(G)(ii) for further information.

**vii Discount rate used to determine the carrying amount of the Group's defined benefit obligation**

The determination of the Group's defined benefit obligation depends on certain assumptions, which include selection of the discount rate which is performed by a professional actuary. See note 31 Share-based payment for detail of assumptions used.

**ix Revenue recognition: estimation of expected returns**

The amount of revenue recognised is adjusted for expected returns, which are estimated based on historical data. See accounting policy in note 3(A) for further information.

**x Fair value measurement**

**Share-based compensation expenses**

The Group 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 recognised could be different. Additional information is reported in accounting policy note 4(J)(iii).

**Acquisition of subsidiary**

Fair value of the consideration transferred (including contingent consideration) and fair value of the assets acquired and liabilities assumed, measured on a provisional basis. Refer to note 13 Acquisition of subsidiary for further information.

## 5 Restatement of Consolidated income statement and Consolidated cash flow statement

The 2017 Consolidated Income Statement comparative, published in 'Annual Report 2017', has been restated as follows:

'Share of result of associate' is now presented below 'Net financial income/(expenses)'.

| | Year ended 31 December 2017 | | |
|---|---|---|---|
| EUR 1,000 | Previously reported | Adjustment Reclassification | Restated amount |
| **Revenue** | **67,242** | – | **67,242** |
| **Net operating expenses** | **(76,846)** | – | **(76,846)** |
| Share of result of associate | (5,892) | 5,892 | **–** |
| **Operating loss** | **(15,496)** | – | **(9,604)** |
| **Net financial income/(expense)** | **(16,936)** | – | **(16,936)** |
| Share of result of associate | – | (5,892) | **(5,892)** |
| **Loss before taxes** | **(32,432)** | – | **(32,432)** |

The Group's share in the loss of Cassiopea was presented in prior years as part of the operating result. There is no obligation in relation to the presentation of the income statement under IAS 1. However, the standard states that components can only be presented as part of the results of operating activities or similar line item, when these are representative of activities that would normally be regarded as 'operating'. Given that Cosmo do not exercise control over Cassiopea, Management consider it more appropriate to present the 'Share of result in associate' below the operating result.

## 5 Restatement of Consolidated income statement and Consolidated cash flow statement continued

The 2017 Consolidated cash flow statement comparative, published in 'Annual Report 2017', has been restated as follows:

| | Year ended 31 December 2017 | | |
|---|---|---|---|
| EUR 1,000 | Previously reported | Adjustment Reclassification | Restated amount |
| Accrual to employee benefits | 393 | (393) | – |
| Movement in employee benefits/pension provision | – | (72) | (72) |
| Impairment loss on financial assets available for sale | 24 | (24) | – |
| Loss on financial investments | – | 1,445 | 1,445 |
| **Operating cash inflow before changes in working capital** | **(12)** | **956** | **944** |
| | | | |
| Change in trade payables | 6,095 | (840) | 5,255 |
| Payment of employee benefits | (465) | 465 | – |
| **Net cash from operating activities** | **(10,009)** | **581** | **(9,428)** |
| | | | |
| Disposal of financial assets | 64,160 | (1,421) | 62,739 |
| **Cash flows from investing activities** | **(22,308)** | **(1,421)** | **(23,729)** |
| | | | |
| **Net increase/(decrease) in cash and cash equivalents** | **40,353** | **(840)** | **39,513** |
| **Cash and cash equivalents at the beginning of the year** | **117,649** | **–** | **117,649** |
| Net foreign exchange differences | (13,058) | 840 | (12,218) |
| **Cash and cash equivalents at the end of the year** | **144,944** | **–** | **144,944** |

The above restatement relates to reclassifications between line items. The restated presentation is viewed as providing more relevant and understandable information to the users of these Consolidated Financial Statements.

## 6 Revenue

### A. Disaggregation of revenue from contracts with customers

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Manufacturing on behalf of third parties: | | |
| Manufacturing of generic products and specialty drugs | 7,775 | 8,261 |
| Manufacturing of MMX® products | 27,515 | 36,315 |
| Related services | 2,280 | 722 |
| Other revenues from sales | 945 | 805 |
| Marketed products – Eleview® | 6,759 | 1,568 |
| Licence fees, up-front fees and milestones | 5,705 | 1,500 |
| Royalties | 14,638 | 18,071 |
| **Total revenue** | **65,617** | **67,242** |

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Own products | 54,617 | 57,454 |
| Third-party products | 11,000 | 9,788 |
| **Total revenue** | **65,617** | **67,242** |

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Uceris® | 17,530 | 25,722 |
| Cortiment® | 3,868 | 4,412 |
| Mezavant® / Mesavancol® / Lialda® | 20,707 | 25,218 |
| Eleview® | 6,760 | 1,568 |
| Generic | 7,775 | 8,261 |
| Other | 8,977 | 2,061 |
| **Total revenue** | **65,617** | **67,242** |

During 2018 Cosmo's largest customer accounted for 26.7% (2017: 38.3%) of revenues and the second largest accounted for 26.5% (2017: 31.6%).

## 6 Revenue continued

### B. Contract balances

| EUR 1,000 | 31 December 2018 | 01 January 2018 |
|---|---|---|
| Receivables, included in 'trade receivables' | 12,762 | 13,190 |
| Contract liabilities, included in 'other current liabilities' | (60) | – |
| Refund liabilities, included in 'other current liabilities' | (27) | (266) |

The contract liabilities primarily relate to the advance consideration received from customers for services for which revenue is recognised at point in time. This will be recognised as revenue when the services are rendered in subsequent months. Refer to note 3(A) for explanation of 'refund liabilities'.

The amount of revenue recognised in the period ended 31 December 2018 from performance obligations satisfied (or partially satisfied) in previous periods is €15,829 thousand and relates to the following:

- License fees and royalties amounting to €15,638 thousand recognised in the current year in relation to licenses transferred in prior years.
- The constraint on variable revenue in relation to the Olympus distribution contract amounting to €191 thousand where there was not sufficient historical experience to estimate sell-through or to estimate returns as at 31 December 2017.

No information is provided about remaining performance obligations as at 31 December 2018 that have an original expected duration of one year or less, as allowed by IFRS 15.

## 7 Net operating expenses

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

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Other income | 886 | 470 |
| Changes in inventories of finished goods and work in progress | 84 | 919 |
| Raw materials and consumables used | (6,304) | (8,163) |
| Personnel expenses | (38,565) | (35,990) |
| Outsourced preclinical and clinical trial costs | (2,545) | (740) |
| Other operating expenses | (31,310) | (29,802) |
| Depreciation and amortisation | (4,484) | (3,540) |
| **Total net operating expenses** | **(82,238)** | **(76,846)** |

### A. Personnel expenses

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Salaries and wages | 23,982 | 21,993 |
| Social security contributions | 4,918 | 4,448 |
| Employee benefits | 414 | 393 |
| Stock options | 9,084 | 8,937 |
| Other costs | 167 | 219 |
| **Total personnel expenses** | **38,565** | **35,990** |

In 2018 personnel expenses increased to €38,565 thousand (2017: €35,990 thousand). The increase primarily relates primarily to the U.S. organisation where 81 people were employed at 31 December 2018 compared to 91 people at the same time last year but were not employed for the whole period.

In the year expense related to the value of employees and directors services exchanged for stock options was €9,084 thousand (2017: €8,937 thousand). The cost associated with the Cosmo Pharmaceuticals N.V. plan was €6,264 thousand (2017: €5,855 thousand) and cost associated with the stock option plan of Aries Pharmaceuticals Ltd was €2,820 thousand (2017: €3,082 thousand), see note 31 Share-based payment.

The average number of staff for the year ended 31 December 2018 was as follows:

| | Year ended 31 December | |
|---|---|---|
| No. of people | 2018 | 2017 |
| Managers | 18.5 | 18.0 |
| Junior managers | 63.0 | 51.5 |
| Employees | 130.5 | 114.5 |
| Workers | 90.0 | 91.5 |
| **Total average number** | **302.0** | **275.5** |

## 7 Net operating expenses continued

### A. Personnel expenses continued

The number of staff by category as at 31 December 2018 was as follows:

| | Year ended 31 December | |
|---|---|---|
| No. of people | 2018 | 2017 |
| Managers | 19 | 18 |
| Junior managers | 61 | 59 |
| Employees | 139 | 130 |
| Workers | 87 | 94 |
| **Total number** | **306** | **301** |

The number of staff employed outside the Netherlands was 306 (2017: 301).

### B. Other operating expenses

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Service costs | 28,333 | 26,948 |
| Operating lease expenses | 1,942 | 1,682 |
| Other operating costs | 1,035 | 1,172 |
| **Total other operating expenses** | **31,310** | **29,802** |

#### i Service costs

Service costs largely consist of the following;

- Advertising and marketing costs increased to €9,901 thousand from €9,477 thousand and includes costs associated with Eleview® and pre-commercialisation activities undertaken to prepare for the launch of Aemcolo™.
- External consultancy services of €7,636 thousand (2017: €5,531 thousand) primarily consist of legal fees €3,205 thousand (2017: €1,552 thousand), administrative consultancies €2,926 thousand (2017: €2,647 thousand) and scientific, regulatory and medical affairs related consultancies fees €1,505 thousand (2017: €1,332 thousand).
- Maintenance and utilities costs of €3,252 thousand (2017: €3,313 thousand) largely related to the production facilities.
- Travel expenses amounted to €2,250 thousand (2017: €2,940 thousand)
- Patent costs of €927 thousand (2017: €1,730 thousand) relate to patent registration costs and related activity during the financial year.
- Stock option plan (SOP) €505 thousand (2017: €509 thousand) for options granted to non-executive directors.
- Auditing costs for the year include €318 thousand (2017: €233 thousand) for audit fees relating to the financial statements (company, consolidated, and controlled companies).

| | BDO Audit & Assurance BV | | Other BDO network | | Total BDO | |
|---|---|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 | 2018 | 2017 |
| Audit of the financial statements | 182 | 133 | 136 | 100 | 318 | 233 |
| Other audit engagements | | – | | – | | – |
| Tax-related advisory services | | – | | – | | – |
| Other non-audit services | | – | | – | | – |
| | **182** | **133** | **136** | **100** | **318** | **233** |

- Other costs include technical assistance €881 thousand, sub-contracting and other services in relation to the manufacturing €527 thousand, insurance €386 thousand and investor relations €306 thousand.

#### ii Operating lease expenses

Operating lease expenses includes rent associated with the lease of the office and laboratory in San Diego and the lease of offices in Dublin. Other rentals include the rent of the telephone exchange system, photocopy machines and cars. The increase compared to last year relates to the rental of production facilities in Slovakia.

#### iii Other operating costs

Other operating costs include representation expenses, donations, stationary and other miscellaneous expenses. A patent write-off of €41 thousand related to certain research and development projects were discontinued and as a consequence the associated intellectual property costs which had previously been capitalised were written off.

## 8 Financial income/expenses

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| **Financial income:** | | |
| Interest income on listed bonds and securities at FVOCI | 1,449 | 2,333 |
| Interest income on cash and cash equivalents | 748 | 642 |
| Gain on sale of listed bonds and securities at FVOCI | 145 | 437 |
| Gain on investments in funds mandatorily at FVTPL | 414 | – |
| Foreign exchange gains | 5,350 | 331 |
| Movement in loss allowance on financial investments at FVOCI | 21 | – |
| Other | – | 41 |
| **Total financial income** | **8,127** | **3,784** |
| | | |
| **Financial expenses:** | | |
| Interest on bank overdraft/advance on invoices at amortised cost | (8) | (9) |
| Interest on medium and long term bank loan at amortised cost | (25) | (29) |
| Interest on financial lease payables at amortised cost | (32) | (41) |
| Interest on convertible bond at amortised cost | (582) | – |
| Impairment loss on financial assets available for sale | – | (24) |
| Loss on sale of listed bonds and securities at FVOCI | (1,806) | (1,858) |
| Loss on investments in funds mandatorily at FVTPL | (353) | – |
| Foreign exchange losses | (308) | (18,724) |
| Other | (398) | (35) |
| **Total financial expenses** | **(3,512)** | **(20,720)** |
| | | |
| **Net financial income/(expenses)** | **4,615** | **(16,936)** |

The movement in net financial income/(expenses) largely relates to net foreign exchange gains of €5,042 thousand due to the strengthening of the US$ against the Euro during the period compared to net foreign exchange losses in the prior year of €18,393 thousand.

The above financial income and expenses include the following in respect of assets/(liabilities) not at fair value through profit or loss:

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Total interest income on financial assets | 2,197 | 2,975 |
| Total interest expense on financial liabilities | (65) | (79) |
| **Total interest income/(expense) in respect of assets/(liabilities) not at FVTPL** | **2,132** | **2,896** |

## 9 Income tax expenses

### Income tax recognised in profit or loss

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Current year | (2,933) | (5,696) |
| Changes in estimates related to prior years | 1 | – |
| **Current income tax** | **(2,932)** | **(5,696)** |
| | | |
| Change in deferred tax assets | 2,905 | 6,077 |
| Change in deferred tax liabilities | (571) | (396) |
| **Deferred tax** | **2,334** | **5,681** |
| | | |
| **Total income tax expenses** | **(598)** | **(15)** |

In December 2017, numerous changes to the tax law were enacted in the US, including a decrease in the corporate tax rate from 35% to 21%. This change resulted in a loss of €764 thousand related to the remeasurement of deferred tax assets and liabilities of the Group's US entity, Aries Pharmaceuticals Inc., being recognised during the year ended 31 December 2017.

For details on deferred tax see notes 17 and 27.

## 9 Income tax expenses continued

### Income Tax recognised in other comprehensive income

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| **Items that will not be reclassified to profit or loss** | | |
| Remeasurement of defined benefit liability | 1 | (4) |
| Fair value on remeasurement of equity instruments at FVOCI | 265 | – |
| | **266** | **(4)** |
| **Items that may be reclassified subsequently to profit or loss** | | |
| Fair value on remeasurement of debt securities at FVOCI | 388 | – |
| Disposal of debt securities measured at FVOCI reclassified to profit or loss | (302) | – |
| Fair value remeasurement of available for sale financial assets | – | 694 |
| Disposal of available for sale financial assets reclassified through profit or loss | – | (401) |
| | **86** | **293** |
| **Total income tax recognised in other comprehensive income** | **352** | **289** |

### Income Tax recognised directly in equity

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Share-based payments | (2,061) | 2,061 |
| Convertible bond | 2,658 | – |
| **Total income tax recognised directly in equity** | **597** | **2061** |

### Reconciliation of effective tax rate

The applicable tax rate used to determine the theoretical income taxes in 2018 is the statutory rate applicable in Ireland of 12.5% (2017: 12.5%), the tax jurisdiction in which Cosmo Pharmaceuticals N.V. is resident. The reconciliation between the theoretical income taxes calculated on the basis of the theoretical tax rate and income taxes recognised was as follows:

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| **Result before taxes** | **(17,459)** | **(32,432)** |
| *Irish 2018 nominal corporate tax rate* | *12.50%* | *12.50%* |
| **Total theoretical income taxes** | **2,182** | **4,054** |
| Different taxation applicable for interest and gain/loss on bonds and other investments in Irish subsidiary | (609) | 2,084 |
| Permanent differences relating to ACE tax for Italian subsidiary | 84 | 61 |
| Tax effect of other permanent differences | (1,022) | (1,367) |
| Permanent difference relating other consolidation adjustments | (1,669) | (2,188) |
| Effect of different corporate tax rate in the Italian subsidiaries and Swiss Branch (a), (b) | (400) | (1,283) |
| Effect of different corporate tax rate in the US subsidiaries (c) | 587 | (1,431) |
| Under/Over provision adjustments | 103 | (23) |
| Super depreciation as for Italian law | 146 | 78 |
| **Current and deferred income tax recognised in the consolidated financial statements** | **(598)** | **(15)** |

Notes:

(a) Applicable tax rate in Italy for IRES of 24% and IRAP of 3.9%

(b) Applicable tax rate for Swiss Branch of 24.7%

(c) Applicable tax rate in US of 21% (2017: 34%)

## 10 Basic and diluted earnings per share

### Basic earnings per share

Basic earnings per share is calculated by dividing the net profit/(loss) for the year attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year. Basic earnings per share is as follows:

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Net loss attributable to shareholders | (18,007) | (32,447) |
| Weighted average number of outstanding ordinary shares | 15,005,414 | 14,809,753 |
| **Basic earnings loss per share (in EUR)** | **(1.200)** | **(2.191)** |

### Diluted earnings per share

Diluted earnings per share are calculated by dividing the net profit/(loss) for the year attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the year, after adjustments for the effects of all dilutive potential ordinary shares.

In relation to the stock option plans and the convertible bond, the potential number of ordinary shares is represented by the shares that would be issued as a consequence of the conversion of all options into ordinary shares. Potential ordinary shares only have a dilutive effect if the new ordinary shares from the exercise of stock options or the conversion right of the bondholders leads to a lower result per share.

In 2017 and 2018, potential new ordinary shares do not have a dilutive effect.

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Net loss attributable to shareholders | (18,007) | (32,447) |
| Weighted average number of outstanding ordinary shares | 15,005,414 | 14,809,753 |
| Incremental shares from assumed options exercise | n\a | n\a |
| Adjusted weighted average number of outstanding ordinary shares | 15,005,414 | 14,809,753 |
| **Diluted loss per share (in EUR)** | **(1.200)** | **(2.191)** |

## 11 Property, plant and equipment

| EUR 1,000 | Land and buildings | Plant and machinery | Industrial and commercial equipment | Other fixed assets | Assets under construction and payments on account | Total |
|---|---|---|---|---|---|---|
| ***Cost*** | | | | | | |
| **Balance at 1 January 2017** | **17,799** | **20,748** | **2,668** | **2,601** | **553** | **44,369** |
| Additions | 1,800 | 7,412 | 370 | 1,820 | 887 | 12,289 |
| Construction completed | – | 502 | – | 51 | (553) | – |
| Disposals | – | (132) | – | (27) | – | (159) |
| **Balance at 31 December 2017** | **19,599** | **28,530** | **3,038** | **4,445** | **887** | **56,499** |
| ***Accumulated depreciation*** | | | | | | |
| **Balance at 1 January 2017** | **4,008** | **15,494** | **2,345** | **1,850** | **–** | **23,697** |
| Depreciation charge for the year | 401 | 1,824 | 270 | 278 | – | 2,773 |
| Disposals | – | (110) | – | (13) | – | (123) |
| **Balance at 31 December 2017** | **4,409** | **17,208** | **2,615** | **2,115** | **–** | **26,347** |
| **Net book value** | **15,190** | **11,322** | **423** | **2,330** | **887** | **30,152** |
| ***Cost*** | | | | | | |
| **Balance at 1 January 2018** | **19,599** | **28,530** | **3,038** | **4,445** | **887** | **56,499** |
| Additions | 31 | 725 | 141 | 655 | 346 | 1,898 |
| Acquisition of Linkverse | – | 3 | 7 | 227 | – | 237 |
| Construction completed | – | 647 | – | 236 | (883) | – |
| Disposals | – | – | – | (61) | – | (61) |
| **Balance at 31 December 2018** | **19,630** | **29,905** | **3,186** | **5,502** | **350** | **58,573** |
| ***Accumulated depreciation*** | | | | | | |
| **Balance at 1 January 2018** | **4,409** | **17,208** | **2,615** | **2,115** | **–** | **26,347** |
| Depreciation charge for the year | 687 | 2,226 | 213 | 517 | – | 3,643 |
| Disposals | – | – | – | (33) | – | (33) |
| **Balance at 31 December 2018** | **5,096** | **19,434** | **2,828** | **2,599** | **–** | **29,957** |
| **Net book value** | **14,534** | **10,471** | **358** | **2,903** | **350** | **28,616** |

## 11 Property, plant and equipment continued

Property, plant and equipment primarily consists of the whole real estate property in Lainate (industrial plant, laboratories and offices), inclusive of surrounding land and of the equipment in the plant which is used for the manufacturing of MMX® tablets.

The additions in the period mainly relate to the new investment in property plant and equipment to expand the Lainate plant adding additional manufacturing capacity.

The acquisition of the entire real estate property was made through two finance leasing arrangements.

## 12 Goodwill

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Opening carrying amount | 109 | 109 |
| Additions for the period | 1,330 | – |
| Impairment for the period | – | – |
| **Closing carrying amount** | **1,439** | **109** |

Goodwill relates to the acquisition in 1997 from Parke Davis of the manufacturing business of pharmaceutical products and to the acquisition of Linkverse in 2018 (see note 13 Acquisition of subsidiary).

The goodwill has been tested for impairment. The recoverable amount is determined based on value-in-use calculations. These calculations use cash flow projections based on financial plans approved by the Management covering a 3-year period. Cash flows beyond the 3-year period are extrapolated using the estimated growth rates stated below.

Key assumptions for the goodwill positions include:

| | |
|---|---|
| Terminal growth rate[1] | 1.5% |
| Weighted average cost of capital (WACC)[2] | 10.11% |

1 Used for calculating the terminal value
2 Pretax discount rate applied to the cash flow projections

In making cash flow projections, the Management determined gross margins based on past performance and its expectations of market developments.

The growth rates used are consistent with the forecasts, and the levered WACC used is pretax. Based on the impairment test conducted, no impairments were recognised in 2017 and 2018.

## 13 Acquisition of subsidiary

On 31 July 2018, the Group acquired 30% of the shares and voting interests in Linkverse S.r.l. ("Linkverse"). As a result, the Group's equity interest in Linkverse increased from 30% to 60%, obtaining control of Linkverse.

Linkverse is an Italian company which provides products and services in the clinical research field and which has a strong knowledge in the Artificial Intelligence and Machine Learning technologies.

For the five months ended 31 December 2018, Linkverse contributed revenue of €635 thousand and a loss of €124 thousand to the Group's results. If the acquisition had occurred on 1 January 2018, management estimates that consolidated revenue would have been €66,379 thousand, and consolidated loss for the year would have been €18,123 thousand. In determining these amounts, management has assumed that the fair value adjustments, determined provisionally, that arose on the date of acquisition would have been the same if the acquisition had occurred on 1 January 2018.

### A. Consideration transferred

The following table summarises the acquisition date fair value of each major class of consideration transferred.

| EUR 1,000 | Notes | |
|---|---|---|
| Cash | | 2,183 |
| Contingent consideration | | 615 |
| **Total consideration transferred** | | **2,798** |

The contingent consideration is dependent on FDA approval for a specific product. The Group has included €615 thousand as contingent consideration related to the additional consideration, which represents its fair value at the date of acquisition. At 31 December 2018, the contingent consideration remains at €615 thousand, see note 36 Fair value measurement for further information.

## 13 Acquisition of subsidiary continued

### B. Identifiable assets acquired and liabilities assumed

The following table summarises the recognised amounts of assets acquired and liabilities assumed at the date of acquisition.

| EUR 1,000 | Notes | |
|---|---|---|
| Property, plant and equipment | 11 | 237 |
| Other intangible assets | 14 | 107 |
| Financial assets | | 52 |
| Deferred tax assets | | 48 |
| Trade receivables | | 200 |
| Current tax assets | | 258 |
| Other receivables and other assets | | 95 |
| Current financial assets | | 156 |
| Cash and cash equivalents | | 2,104 |
| Employee benefits | | (52) |
| Trade payables | | (153) |
| Current tax liabilities | | (5) |
| Other current liabilities | | (187) |
| **Total identifiable net assets acquired** | | **2,860** |

### C. Goodwill

Goodwill arising from the acquisition has been recognised as follows.

| EUR 1,000 | Notes | |
|---|---|---|
| Consideration transferred | (A) | 2,798 |
| NCI, based on their proportionate interest in the recognised amounts of the assets and liabilities of Linkverse | | 1,144 |
| Fair value of pre-existing interest in Linkverse | | 248 |
| Fair value of identifiable net assets | (B) | (2,860) |
| **Goodwill** | | **1,330** |

The remeasurement to fair value of the Group's pre-existing 30% interest in Linkverse resulted in a loss of €52 thousand (€248 thousand fair value less €300 thousand carrying amount of the equity investment at the date of acquisition). This amount has been included in the Consolidated statement of other comprehensive income.

The goodwill is attributable mainly to the skills and technical talent of Linkverse's work force and the synergies expected to be achieved from integrating the company into the Group's existing business. None of the goodwill recognised is expected to be deductible for tax purposes.

## 14 Other intangible assets

| EUR 1,000 | Patents and rights | Trademarks and licences | Development costs | Assets under construction | Total |
|---|---|---|---|---|---|
| *Cost* | | | | | |
| **Balance at 1 January 2017** | **8,835** | **10,019** | **5,762** | **–** | **24,616** |
| Additions | 756 | – | 8,990 | – | 9,746 |
| **Balance at 31 December 2017** | **9,591** | **10,019** | **14,752** | **–** | **34,362** |
| *Accumulated amortisation* | | | | | |
| **Balance at 1 January 2017** | **5,051** | **19** | **–** | **–** | **5,070** |
| Amortisation charge for the year | 720 | – | 47 | – | 767 |
| **Balance at 31 December 2017** | **5,771** | **19** | **47** | **–** | **5,837** |
| **Net book value as at 31 December 2017** | **3,820** | **10,000** | **14,705** | **–** | **28,525** |

| EUR 1,000 | Patents and rights | Trademarks and licences | Development costs | Assets under construction | Total |
|---|---|---|---|---|---|
| *Cost* | | | | | |
| **Balance at 1 January 2018** | **9,591** | **10,019** | **14,752** | **–** | **34,362** |
| Additions | 808 | – | 6,953 | 13 | 7,774 |
| Linkverse acquisition | 25 | – | – | 82 | 107 |
| Write-off | (47) | – | – | – | (47) |
| **Balance at 31 December 2018** | **10,377** | **10,019** | **21,705** | **95** | **42,196** |
| *Accumulated amortisation* | | | | | |
| **Balance at 1 January 2018** | **5,771** | **19** | **47** | **–** | **5,837** |
| Amortisation charge for the year | 746 | – | 95 | – | 841 |
| Write-off | (6) | – | – | – | (6) |
| **Balance at 31 December 2018** | **6,511** | **19** | **142** | **–** | **6,672** |
| **Net book value as at 31 December 2018** | **3,866** | **10,000** | **21,563** | **95** | **35,524** |

As at 31 December 2018, other intangible assets largely include:

### A. Patents and rights

Patents and rights of €3,866 thousand (2017: €3,820 thousand) relating to the cost of filing and extension of patents owned by the Group. Patents and rights are amortised over their useful life based on their expiry date.

### B. Trademarks and licenses

In 2016 Cosmo in-licensed Remimazolam, an ultra-short-acting sedative/ anaesthetic, from PAION AG. Under the terms of the license agreement for Remimazolam with PAION AG a €10 million upfront payment was made to PAION AG in 2016. In addition, PAION AG is entitled to receive additional payments from Cosmo of up to €42.5 million contingent upon certain milestones related to the U.S. regulatory approval process as follows: €7.5 million payable on filing of NDA (Procedural Sedation), €15 million payable upon FDA approval for Procedural sedation, €10 million payable upon FDA approval of 2nd indication and €10 million payable upon FDA approval of 3rd indication.

Following regulatory approval, tiered royalties on net sales in the U.S. ranging from 20% to 25%, which may be adjusted under certain conditions but not to below 15% of net sales. Under the terms of the license agreement, Cosmo has the right to further develop and commercialise Remimazolam (CB-07-01) in the U.S., while bearing all future associated costs for market authorisation and distribution. PAION AG is responsible for and bears all of the cost associated with the completion of U.S. trials in procedural sedation. Amortisation of the capitalised license costs of Remimazolam will start from the date of commercial use of the product on a straight-line basis over the period of its expected benefit. In addition to entering into the license agreement with PAION AG for Remimazolam and at the same time, Cosmo entered into an investment agreement with PAION AG pursuant to which Cosmo purchased 5,064,194 ordinary shares of PAION AG for €9,643 thousand. During 2017 Cosmo purchased a further 174,031 ordinary shares of PAION AG. (see note 16 Financial assets).

### C. Development costs

Development costs associated with Methylene Blue MMX (CB-17-01), Aemcolo™ (CB-01-11), Eleview® (CB-17-04) and Remimazolam (CB-07-01) development costs for which Cosmo is responsible for were capitalised from the start of 2016 as Management believe that capitalisation criteria was met from that date.

Capitalised development costs €21,563 thousand (2017: €14,705 thousand) at 31 December 2018 consist of:

(i) Methylene Blue MMX (CB-17-01), €9,835 thousand (2017: €9,464 thousand);
(ii) Aemcolo™ (CB-01-11), €7,540 thousand (2017: €3,197 thousand);
(iii) Eleview® (CB-17-04), €1,512 thousand (2017: €1,607 thousand) and;
(iv) Remimazolam (CB-07-01), €2,676 thousand (2017: €437 thousand).

**14 Other intangible assets** continued

**C. Development costs** continued

**i Methylene Blue MMX**

At the beginning of 2016 the Methylene Blue MMX phase III clinical trial was almost completed with 1,200 (or approximately 98%) of patients treated. In November 2016 Cosmo announced positive phase III results for Methylene Blue MMX with primary clinical endpoints attained. In July 2017 Cosmo announced that it had submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) seeking marketing approval for Methylene Blue MMX. In February 2018 Cosmo announced that it had entered into a license and supply agreement with Pharmascience for Methylene Blue MMX in Canada.

On 23 May 2018 Cosmo announced that it had received a Complete Response Letter ("CRL") from the FDA which stated that the FDA had determined that it could not approve the NDA in form and while the outcome of the phase III trial had translated in a statistically significant outcome, the outcome was not sufficiently "robust" and recommended that Cosmo provides confirmation of effectiveness with a second phase III trial. On 25 July 2018 the Type A meeting took place with the FDA Medical Imaging Division. The outcome of the meeting was that while some issues had been resolved some disagreement remained with the review division. On 13 September 2018 Cosmo announced that it would pursue the Formal Dispute Resolution process and file an appeal above the Medical Imaging Division level to the Office of Drug Evaluation IV (ODE IV) in the Center for Drug Evaluation and Research (CDER). On 1 November 2018 Cosmo announced that the appeal to the ODE IV had been denied with the FDA continuing to recommend a second phase III trial. On 21 December 2018 Cosmo announced that it was in the process of filing a new appeal to the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). A meeting took place with the FDA on the 18 January 2019 and on the 12 March 2019 Cosmo announced that the FDA had denied Cosmo's last appeal. Cosmo has decided not pursue further appeals and intends to present a new clinical plan with different endpoints. Upon agreement with the FDA on a new trial design Cosmo intends to immediately start a confirmatory phase III trial for the product.

With regard to European approval, Cosmo announced on 12 February 2019 that it had filed a Marketing Authorisation Application for Methylene Blue MMX 200mg tablets with the European Medicines Agency. The review procedure is expected to be concluded within 12 months. If approval is granted such approval will be automatically effective in all EU member states.

**ii Aemcolo™**

In June 2016 Cosmo announced that all primary and secondary clinical endpoints were attained in the phase III pivotal trial of Aemcolo™ for Infectious Colitis run by its licensee Dr. Falk Pharma. This was the second pivotal trial and completed the data set necessary for the filing of a New Drug Application in the US and a Marketing Application in the EU. In February 2018 Cosmo announced that it had entered into a license and supply agreement with Pharmascience for Aemcolo™ in Canada. On 19 November 2018 Cosmo announced that the FDA had approved Aemcolo™ (Rifamycin SV MMX) for the treatment of Travelers' Diarrhoea caused by non-invasive strains of Escherichia coli in adults and that marketing exclusivity would run to 2028 with the QIDP and the NCE designations. On 28 November 2018 Cosmo announced that its licensee Dr. Falk Pharma had received approval in the European Decentralized Procedure (DCP) for Relafalk (Aemcolo™) for the treatment of Travelers' Diarrhoea.

**iii Eleview®**

Eleview® is a medical device, it was approved in the US at the end of 2015 and in the EU in June 2016. Eleview® was launched in the US in May 2017 for use in gastrointestinal endoscopic procedures. In October 2017 Cosmo announced that it had entered into an exclusive co-promotion agreement for Eleview® in the US with Olympus America Inc. and an exclusive distribution agreement for Eleview® in Europe and South Africa with Fujifilm Europe B.V. In February 2018 Cosmo announced that it had entered into a license and supply agreement with Pharmascience for Eleview® in Canada. The amortisation of capitalised development costs of Eleview® over it's useful life commenced in 2017.

**iv Remimazolam**

In June 2017 PAION AG announced that Remimazolam had met the primary endpoint and successfully concluded its US phase III clinical trial in procedural sedation in patients undergoing bronchoscopy, this follows the announcement in June 2016 by PAION AG of positive Remimazolam headline data of a phase III study in procedural sedation for colonoscopy.

The development projects are progressing in line with technical and economical plans and having been reviewed, Management confirm the recoverability of the relevant capitalised costs based on probable future economic benefits. Capitalised costs include outsourced clinical trial costs, material (API, excipient) used in the preparation of clinical batches and directly related personnel expenses.

Assets are amortised from the date that they are available for use on a straight-line basis over the period of their expected benefit.

## 15 Investments in associates

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Share of result of associates | (5,453) | (5,892) |
| **Share of result of associates** | **(5,453)** | **(5,892)** |

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Cassiopea Spa | 130,402 | 135,742 |
| **Investments in associates** | **130,402** | **135,742** |

The Group's interests in associated companies at 31 December 2018 amounting to €130,402 thousand (2017: €135,742 thousand) relates to the Group interest of 45.09% in Cassiopea S.p.A. (ISIN number IT0005108359), an Italian company listed on SIX Swiss Stock Exchange. The address of the registered office is Via Cristoforo Colombo 1, Lainate (MI), Italy.

Through a secondary public offering of shares in June 2015 Cosmo sold its majority interest in Cassiopea, reducing its ownership interests from 97% to 49%. In parallel with the sale of its majority-owned interest in Cassiopea, the strategy, the structure and the corporate governance of Cassiopea, its current relevant activities and how those activities are governed, have changed. Furthermore, in July 2015 after the exercise of the over-allotment the Group's interest in Cassiopea was reduced to 45.09%. Since June 2015, considering the absence of agreements with other shareholders, the Group no longer has the ability to ensure the control of more than half of the voting rights at the shareholders' meeting and therefore cannot unilaterally govern the relevant activities of Cassiopea. Furthermore, no potential voting rights are currently attributable to the Group.

The Group has no contractual rights to appoint or remove the majority of the members of the Board of Directors and to shape the managerial and financial policies of Cassiopea. The majority of the Board Members, in fact, must be independent according to Italian company law.

No other conditions allow the Group to exercise 'de facto' control over Cassiopea, and it does not have the power to unilaterally determine its relevant activities.

Consequently, Cassiopea has been de-consolidated from the date on which control ceased on 30 June 2015.

The following table shows the financial data of Cassiopea S.p.A. reconciled to the relative carrying amount in the Group consolidated statement of financial position, considering the fair value adjustment due to the loss of control in Cassiopea S.p.A. in 2015:

| EUR 1,000 | Cassiopea financial data as at 31/12/2018 | Cassiopea financial data as at 31/12/2017 |
|---|---|---|
| **Financial statement** | | |
| Total non-current assets | 9,760 | 9,104 |
| Total current assets | 6,780 | 19,365 |
| **Total assets** | **16,540** | **28,469** |
| Total current liabilities | 2,028 | 2,115 |
| **Total liabilities** | **2,028** | **2,115** |
| **Total Equity as at 31 December 2018** | **14,512** | **26,354** |
| | | |
| **Income statement for the year ended 31 December 2018** | | |
| Operating result | (13,214) | (10,725) |
| Loss before taxes | (12,656) | (13,656) |
| Loss after tax | (12,656) | (13,656) |

| EUR 1,000 | Total shareholders' Equity | Group's Pro quota Equity | Adjustment for Fair value remeasurement | Consolidated investment carrying amount |
|---|---|---|---|---|
| **Cassiopea SpA** | **14,512** | **6,543** | **123,859** | **130,402** |

The fair value of ownership interest in Cassiopea S.p.A. based on the quoted market price of the shares listed on SIX Swiss Exchange as at 31 December 2018 is equal to €146,447 thousand (4,508,987 shares at CHF 36.60 FX 1.1269) (2017: €134,155 thousand (4,508,987 share at CHF 34.8 FX 1.1696). As at 27 March 2019 the fair value based on the market price is equal to €184,451 thousand (4,508,987 shares at CHF 45.80 per share, F/X 1.1196).

## 16 Financial assets

The effect of initially applying IFRS 9 in the Group's financial instruments is described in note 3. Due to the transition method chosen in applying IFRS 9, comparative information has not been restated to reflect the new requirements.

### Non-current

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Debt securities measured at FVOCI | 26,330 | – |
| Other financial assets available for sale – investment securities | – | 74,459 |
| Equity instruments measured at FVOCI – Paion shares | 11,472 | – |
| Financial assets available for sale – PAION AG shares | – | 14,195 |
| Equity instruments measured at FVOCI – AIMM and RSouth shares | 2,594 | – |
| Financial assets available for sale – AIMM shares | – | 2,594 |
| Equity instruments measured at FVOCI – Volitionrx shares | 1,459 | – |
| Financial assets available for sale – VolitionRx shares | – | 2,263 |
| Financial assets available for sale – Linkverse shares | – | 300 |
| **Non-current financial assets** | **41,855** | **93,811** |

### Current

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Debt securities measured at FVOCI | 12,055 | – |
| Other financial assets available for sale – current investment securities | – | 27,759 |
| Investments in funds measured at FVTPL | 126,692 | – |
| **Current financial assets** | **138,747** | **27,759** |

Debt securities consist of listed bonds. Gains and losses arising from the adjustment to the fair value, were recognised in other comprehensive income. Investments in funds include investments in "Money market", "Supply chain finance", "Corporate short duration" and "Floating rate credit" funds. Gains and losses arising from the adjustment to the fair value were recognised in profit or loss.

### Equity instruments designated as at FVOCI

At 1 January 2018, the Group designated the investments shown below as equity securities at FVOCI because these equity securities represent investments that the Group intends to hold for the long-term for strategic purposes. In 2017, these investments were classified as available-for-sale.

Paion shares relate to 8.2% of the capital of PAION AG, a company listed on the Frankfurt Stock Exchange Prime Standard (PA8), acquired in 2016 when the Company also entered into a license agreement for Remimazolam (see note 14 Other Intangible assets). In addition to the stake acquired in 2016 the Company subscribed to a capital increase in Paion in February 2017 and as at 31 December 2018 Cosmo owns 5,238,225 PAION AG shares. As at 31 December 2018 the fair value of the Group's interest in PAION AG was €11,472 thousand (2017: €14,195 thousand) or €2.19 per share (Market Price Frankfurt Stock Exchange). The loss of €2,723 thousand (2017: gain of €1,432 thousand) in the period was recognised in other comprehensive income net of the tax effect.

In the prior year, AIMM shares referred to 6.48% of the capital of AIMM Therapeutics B.V. (Amsterdam – The Netherlands) "AIMM", a company focused on antibody discovery, acquired in June 2013 for €2,594 thousand. During 2018 the company demerged. On 20 June 2018, RSouth Antibodies B.V. (Amsterdam – The Netherlands ) "RSouth" was incorporated and received two respiratory syncytial virus "RSV" related assets. The remaining assets in AIMM relate to its cancer portfolio. As at 31 December 2018, Cosmo holds 6.44% of the capital of Rsouth and 3.31% of the capital of AIMM. As at 31 December 2018 the investments in AIMM and RSouth, which are not publicly traded, have been fair valued using a value in use approach (DCF) which did not indicate any material change in the carrying amount of the investments.

VolitionRx shares refer to 2.61% of the capital of VolitionRx Limited, a U.S. clinical stage life sciences company listed on the NYSE MKT (VNRX) and focused on developing blood-based diagnostic tests for detecting and diagnosing cancer and other diseases acquired in March 2016. As at 31 December 2018 the fair value was US$1,671 thousand (2017: US$ 2,714 thousand) (€1,459 thousand (2017: €2,263 thousand)) or US$1.81 per share (NYSE MKT). The loss of €804 thousand (2017: loss of €1,739 thousand) in the period was recognised in other comprehensive income net of the tax effect.

On 31 July 2018, the Group acquired an additional 30% of the shares and voting interests in Linkverse S.r.l. ("Linkverse"). As a result, the Group's equity interest in Linkverse increased from 30% to 60%, obtaining control of Linkverse. Refer to note 13 Acquisition of subsidiary for further information.

## 17 Deferred tax assets

The movement in deferred tax assets was as follows:

| EUR 1,000 | As at 1 January 2017 | Changes during the year | | | | | As at 31 December 2017 | Changes during the year | | | | | | | As at 31 December 2018 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Increase | Decrease | OCI | Equity | FX | | Business combination | Reclass | Increase | Decrease | OCI | Equity | FX | |
| Maintenance and leasing expenses | 44 | 75 | (8) | – | – | – | 111 | – | – | 64 | (47) | – | – | – | 128 |
| Goodwill depreciation | 132 | 44 | – | – | – | – | 176 | – | – | 44 | – | – | – | – | 220 |
| Entertaining expenses and others | 1 | – | (1) | – | – | – | – | – | – | – | – | – | – | – | – |
| Director's fee not paid | – | 3 | – | – | – | – | 3 | – | – | – | (3) | – | – | – | – |
| Losses carried forward | 527 | 1,470 | – | – | – | – | 1,997 | 47 | – | 1,736 | – | – | – | – | 3,780 |
| Patents | 117 | – | (29) | – | – | – | 88 | – | – | – | (29) | – | – | – | 59 |
| Gain on assignment of enterprise | 122 | – | (61) | – | – | – | 61 | – | – | – | (61) | – | – | – | – |
| Development costs | 17 | 34 | – | – | – | – | 51 | – | – | 29 | – | – | – | – | 80 |
| Fair value financial investments | 315 | – | – | (157) | – | – | 158 | – | – | 368 | – | 335 | – | – | 861 |
| Losses on sale of financial investments | 854 | 650 | – | – | – | – | 1,504 | – | – | 756 | (9) | – | – | – | 2,251 |
| Unrealised F/X losses on financial investments | – | 997 | – | – | – | – | 997 | – | – | – | (997) | – | – | – | – |
| Intercompany transactions elimination | 164 | 1,816 | (86) | – | – | – | 1,894 | – | – | 2,083 | (79) | – | – | – | 3,898 |
| ESOP & other differences | 285 | 1,173 | – | – | 2,061 | (103) | 3,416 | – | – | – | (948) | – | (2,061) | 34 | 441 |
| Employee benefits | – | – | – | – | – | – | – | 1 | 5 | – | (1) | 1 | – | – | 6 |
| **Total deferred tax assets** | **2,578** | **6,262** | **(185)** | **(157)** | **2,061** | **(103)** | **10,456** | **48** | **5** | **5,080** | **(2,174)** | **336** | **(2,061)** | **34** | **11,724** |

The deferred tax assets included in the consolidated financial statements as at 31 December 2018 are deemed recoverable on the basis of future economic forecasts. In the analysis of the recoverability of this item, based on the normal estimation process that the Management carries out in the preparation of the Consolidated financial statements, along with and consistent with the impairment testing of goodwill as well as the assumptions regarding growth that form the basis of future results forecasts did not highlight any critical areas that would require adjustments to the deferred tax asset values.

## 17 Deferred tax assets continued

The following table sets out the nature of temporary differences relating to Deferred tax assets.

| EUR 1,000 | Temporary differences as at 31 December 2017 | % | Tax effect as at 31 December 2017 | Temporary differences as at 31 December 2018 | % | Tax effect as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Maintenance and leasing expenses | 460 | 24.00 | 111 | 533 | 24.00 | 128 |
| Goodwill depreciation | 630 | 27.90 | 176 | 787 | 27.90 | 220 |
| Director's fee not paid | 13 | 24.00 | 3 | – | – | – |
| Losses carried forward | 15,972 | 12.50 | 1,997 | 29,192 | 12.95 | 3,780 |
| Patents | 709 | 12.50 | 88 | 472 | 12.50 | 59 |
| Gain on assignment of enterprise | 218 | 27.90 | 61 | – | 0.00 | – |
| Development costs | 408 | 12.50 | 51 | 643 | 12.50 | 80 |
| Fair value financial investments | 478 | 33.00 | 158 | 2,607 | 33.00 | 861 |
| Losses on sale of financial investment | 4,561 | 32.96 | 1,504 | 6,817 | 33.00 | 2,251 |
| Unrealised F/X losses on investment | 3,022 | 33.00 | 997 | – | – | – |
| Intercompany transactions elimination | 8,327 | 22.76 | 1,894 | 17,268 | 22.58 | 3,898 |
| ESOP & other differences | 15,128 | 22.58 | 3,416 | 1,950 | 22.58 | 441 |
| Employee benefits | – | – | – | 26 | 24.00 | 6 |
| **Total deferred tax assets** | **49,926** | | **10,456** | **60,295** | | **11,724** |

## 18 Inventories

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Raw materials, auxiliary materials and consumables | 2,777 | 2,166 |
| Work in progress | 862 | 657 |
| Finished goods | 518 | 638 |
| Allowance for inventory obsolescence | (220) | (220) |
| **Total inventories** | **3,937** | **3,241** |

The item 'Raw materials, auxiliary materials and consumables' covers the raw materials and packaging materials used by the Group in its manufacturing activity.

The value of raw materials in 2018 and 2017 includes an allowance for inventory obsolescence, amounting to €220 thousand, which specifically refers to a slow-moving item.

On adaption of IFRS 15, an asset for a right to recover returned goods is recognised in relation to Elview product sold with a right of return amounting to nil (2017; €266 thousand). This is included in 'Finished goods'.

## 19 Trade receivables

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Customers receivables | 9,510 | 4,391 |
| Invoices to be issued | 3,295 | 8,831 |
| Loss allowance | (43) | (32) |
| **Total trade receivables** | **12,762** | **13,190** |

Trade receivables includes receivables from customers in relation to revenue from commercial products, manufacturing of pharmaceutical products and supply of related services and from the royalties with respect to the license agreements for MMX® products, net of the loss allowance.

Information about the Group's exposure to credit and market risks, and impairment losses for trade receivables is included in note 35 Financial risk management objectives and policies.

## 20 Current tax and other tax assets

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Advance payments of income taxes | 3,033 | 2,737 |
| Withholding taxes | 2,198 | 235 |
| **Total current tax and other tax assets** | **5,231** | **2,972** |

Current tax assets mainly include advance payments for income taxes exceeding the amount due for the year and withholding taxes to tax withheld at source from royalties and interest.

## 21 Other receivables and other assets

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Receivables from associates companies | 164 | 56 |
| VAT receivables | 710 | 3,617 |
| Prepaid expenses | 434 | 440 |
| Other prepaid | 1,493 | 1,087 |
| **Total other receivables and other assets** | **2,801** | **5,200** |

Other prepaid expenses mainly include advance payments to suppliers of goods and services.

## 22 Cash and cash equivalents

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Cash at hand | 15 | 14 |
| Bank accounts | 210,674 | 144,930 |
| **Total cash and cash equivalents** | **210,689** | **144,944** |

Bank accounts include availability on current bank accounts and short-term deposits.

## 23 Total shareholders' equity

Total shareholders' equity comprises the following:

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Share capital | 3,910 | 3,910 |
| Share premium | 84,448 | 84,448 |
| Other reserves | 47,845 | 47,845 |
| Treasury shares | (18,353) | – |
| Stock option plan reserve | 19,299 | 9,597 |
| Fair value reserve | (56) | 3,894 |
| Equity component of convertible bond | 7,011 | – |
| Employee benefits actuarial gains/losses reserve | (163) | (155) |
| Currency translation reserve | (197) | 958 |
| Retained earnings | 318,023 | 352,067 |
| Loss for the period | (18,007) | (32,447) |
| **Equity attributable to owners of the company** | **443,760** | **470,117** |
| Non-controlling interests | 1,094 | – |
| **TOTAL EQUITY** | **444,854** | **470,117** |

### Share capital

| EUR 1,000 | Ordinary shares 2018 | 2017 | Preference shares 2018 | 2017 |
|---|---|---|---|---|
| In issue at 1 January | 15,037,483 | 14,418,983 | – | – |
| Exercise of share options | – | 618,500 | – | – |
| **In issue at 31 December – fully paid** | **15,037,483** | **15,037,483** | **–** | **–** |
| **Authorised at 31 December – par value EUR 0.26** | **36,047,457** | **36,047,457** | **36,047,457** | **36,047,457** |

As at 31 December 2018 the authorised share capital amounts to €18,744,677.64 and is divided into 36,047,457 ordinary shares, each with a nominal value of €0.26 and 36,047,457 preferred shares, each with a nominal value of €0.26.

## 23 Total shareholders' equity continued

### Share premium

As at 31 December 2018 the share premium of €84,448 thousand relates to the proceeds from the issue of the 618,500 shares on 31 March 2017 as a result of the exercise of vested stock options and from the sale of treasury shares in 2017.

### Other reserves

Include reserves available for distribution.

### Treasury shares

As at 31 December 2018, the number of treasury shares amounted to 201,770 which were purchased during the period at an average purchase price of CHF 103.35 per share.

### Shares in issue and outstanding

| | Ordinary shares | | |
|---|---|---|---|
| EUR 1,000 | 2018 | 2017 | 2016 |
| In issue at 1 January | 15,037,483 | 14,418,983 | 14,418,983 |
| Treasury shares | – | 315,447 | 315,447 |
| **Outstanding at 1 January** | **15,037,483** | **14,103,536** | **14,103,536** |
| Issue of new shares | – | 618,500 | – |
| Treasury shares sold | – | 315,447 | – |
| Treasury shares purchased | (201,770) | – | – |
| **Outstanding at 31 December – fully paid** | **14,835,713** | **15,037,483** | **14,103,536** |

### Stock option plan reserve

The stock option plan reserve relates to the stock option plan of Cosmo Pharmaceuticals N.V. allocated in 2014, 2016, 2017 and 2018 and to the stock option plan of its subsidiary Aries Pharmaceuticals Ltd. allocated in 2016, 2017 and 2018.

### Fair value reserve

The fair value reserve comprises:

- the cumulative net change in the fair value of equity investments designated at FVOCI (2017: financial assets available-for-sale); and
- the cumulative net change in fair value of debt securities at FVOCI (2017: financial assets available-for-sale) until the assets are derecognised or reclassified. This amount is reduced by the amount of loss allowance.

### Equity component of convertible bond

The reserve for convertible bond comprises the amount allocated to the equity component for the convertible bond issued by the Group in November 2018. The equity component was valued at €9,669 thousand on initial recognition, see note 25(B) Interest-bearing loans and borrowings (non-current and current). A deferred tax liability was also recognised on initial recognition with a corresponding entry to equity amounting to €2,658 thousand.

### Employee benefits actuarial gains/losses reserve

Employee benefits actuarial gains/ losses reserve includes the cumulated actuarial gains/losses on the employee benefits, recorded following the application of the amendment to IAS 19.

### Currency Translation reserve

Currency translation differences arise from the consolidation of foreign entities with a functional currency other than the euro.

### Non-controlling interests

On 31 July 2018, the Group's equity interest in Linkverse increased from 30% to 60% and Linkverse became a subsidiary from that date. The non-controlling interest refers to the 40% portion of equity ownership in Linkverse not attributable to Cosmo (see note 24 Non-controlling interests).

### Dividend

No dividend was paid during 2018. During 2017, a dividend of €1.50 per share or €22,556 thousand was paid out of retained earnings.

## 24 Non-controlling interests

The following table summarises the information relating the Group's subsidiary Linkverse that has a material NCI, before any intra-group eliminations.

| EUR 1,000 | Year ended 31 December 2018 |
|---|---|
| **NCI percentage** | **40%** |
| Non-current assets | 610 |
| Current assets | 2,570 |
| Non-current liabilities | (74) |
| Current liabilities | (374) |
| **Net assets** | **2,732** |
| Net assets attributable to NCI | 1,094 |
| Revenue | 635 |
| Loss for the period | (124) |
| Loss allocated to NCI | (50) |
| Cash flows from operating activities | (486) |
| Cash flows from investment activities | (104) |
| Cash flows from financing activities | – |
| **Net decrease in cash and cash equivalents** | **(590)** |

On 31 July 2018, the Group's equity interest in Linkverse increased from 30 to 60% and Linkverse became a subsidiary from that date (see Note 14 Acquisition of subsidiary). Accordingly, the information relating to Linkverse is only for the period from 1 August to 31 December 2018.

## 25 Interest-bearing loans and borrowings (non-current and current)

### a) Non-current

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Bank loans | 1,084 | 1,211 |
| Convertible bond – liability component | 154,322 | – |
| Financial lease liabilities | 2,217 | 2,616 |
| **Total interest-bearing loans and borrowings (non-current)** | **157,623** | **3,827** |

Non-current bank loan detail:

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| UBI Banca | 1,084 | 1,211 |
| **Bank loans (non-current)** | **1,084** | **1,211** |

### b) Current

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Bank loans | 127 | 243 |
| Financial lease liabilities | 400 | 406 |
| **Total interest-bearing loans and borrowings (current)** | **527** | **649** |

Current bank loan detail:

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| UBI Banca | 127 | 124 |
| Centrobanca | – | 119 |
| **Bank loans (current)** | **127** | **243** |

## 25 Interest-bearing loans and borrowings (non-current and current) continued

### A. Bank loans

As at 31 December 2018 non-current bank loans were €1,084 thousand and current bank loans €127 thousand (2017: €1,211 thousand and €124 thousand respectively) consisting of:

– As at 31 December 2018 loan balances owed to UBI Banca of €1,211 thousand (2017: €1,335 thousand). This balance outstanding to UBI Banca represents the amounts outstanding at 31 December 2018 in relation to a subsidised loan of €1,412 thousand drawn as follows:
  i. €1,271 thousand drawn on 3 October 2014
  ii. €141 thousand drawn on 1 July 2016

This subsidised loan from UBI Banca has an interest rate of 0.5% and is pursuant to a grant filed in 2002 with the Italian Ministry of Economic Development for the research project on LMW Heparin. This loan must be repaid in full by 13 November 2027. The repayment of the loan is in accordance with the amortisation schedule agreed with the lender and commenced on 13 November 2018.

### B. Convertible bond – liability component

| EUR 1,000 | Notes | |
|---|---|---|
| Issue size (1,750 notes at €100 thousand par value) | | 175,000 |
| Issue price (95% of principal amount) | | (8,750) |
| **Proceeds from issue of convertible bond** | | **166,250** |
| Transaction costs | | (2,841) |
| **Net proceeds** | | **163,409** |
| Amount classified as equity (net of transaction costs of €168 thousand) | 23 | (9,669) |
| Accrued interest | | 582 |
| **Carrying amount of liability at 31 December 2018** | | **154,322** |

On the 29th of November, Cosmo announces that it has successfully placed €175 million senior unsecured convertible bonds due 2023. The net proceeds from the Offering will be used for general corporate purposes, potential acquisitions and in-licensing transactions. The Bonds have a maturity of 5 years and will be convertible into ordinary shares of Cosmo Pharmaceuticals N.V., sourced from existing authorised share capital, on or after 15 January 2019.

The Bonds has a coupon of 2.50%, payable semi-annually in arrear, and a conversion price of €122.68, corresponding to a conversion premium of 20% above the reference price of the Shares. The Bonds, which will be issued in denominations of €100 thousand, are issued at 95% of their principal amount and, unless previously converted or repurchased and cancelled, redeemed at 100% of their principal amount. Cosmo Pharmaceuticals N.V. is entitled to redeem the Bonds at their principal amount (plus accrued interest) in accordance with the terms and conditions of the Bonds at any time (i) on or after the date falling 3 years and 21 days after their issue date, if the price of a Share is equal to or exceeds 130% of the then prevailing conversion price over a certain period or (ii) if less than 15% of the aggregate principal amount of the Bonds remains outstanding. At maturity, Cosmo Pharmaceuticals N.V. will be entitled to redeem the Bonds at their principal amount (plus accrued interest) by delivering a number of Shares equal to a maximum specified percentage plus an additional cash amount, if applicable, in accordance with the terms and conditions of the Bonds. Holders of the Bonds who convert their Bonds will receive Shares with a par value of €0.26 per Share.

### C. Finance lease liability

Financial lease liabilities refers to various financial leasing contracts and relates to the real estate complex of Lainate and to plant and machinery. Refer to note 35(C) for detail on the lease arrangements and note 35(B) for future minimum lease payments.

### D. Reconciliation of movements of financial liabilities to cashflows arising from financing activities

| EUR 1,000 | 2017 | Cashflows | Non-cash changes – equity component | Non-cash changes – accrued interest | Non-cash changes – amortised cost | 2018 |
|---|---|---|---|---|---|---|
| Proceeds from issue of convertible bond (net of transaction costs) | – | 163,409 | (9,669) | 582 | – | 154,322 |
| Repayment of bank loans | 1,454 | (260) | – | – | 17 | 1,211 |
| Repayment of financial lease liabilities | 3,022 | (405) | – | – | – | 2,617 |
| | **4,476** | **162,744** | **(9,669)** | **582** | **17** | **158,150** |

## 25 Interest-bearing loans and borrowings (non-current and current) continued

| EUR 1,000 | 2016 | Cashflows | Non-cash changes – equity component | Non-cash changes – accrued interest | Non-cash changes – amortised cost | 2017 |
|---|---|---|---|---|---|---|
| Repayment of bank loans | 1,555 | (122) | – | – | 21 | 1,454 |
| Repayment of financial lease liabilities | 3,754 | (732) | – | – | – | 3,022 |
| | **5,309** | **(854)** | **–** | **–** | **21** | **4,476** |

## 26 Employee benefits

The item Employee benefits (trattamento di fine rapporto, TFR) only refers to the Italian companies of the Group and has been determined on an actuarial calculation method, in compliance with the revised IAS 19.

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| **Employee benefits** | **365** | **318** |

The movements in the period are as follows:

| | | Changes during the year | | | | | |
|---|---|---|---|---|---|---|---|
| EUR 1,000 | As at 1 January 2017 | Accrued | Interest cost | Actuarial (Gain)/losses | Business combination | Utilised | As at 31 December 2017 |
| Employee benefits | 409 | 393 | (1) | (18) | – | (465) | 318 |
| **Total Employee benefits** | **409** | **393** | **(1)** | **(18)** | **–** | **(465)** | **318** |

| | | Changes during the year | | | | | |
|---|---|---|---|---|---|---|---|
| EUR 1,000 | As at 1 January 2018 | Accrued | Interest cost | Actuarial (Gain)/losses | Business combination | Utilised | As at 31 December 2018 |
| Employee benefits | 318 | 414 | (1) | 7 | 52 | (425) | 365 |
| **Total Employee benefits** | **318** | **414** | **(1)** | **7** | **52** | **(425)** | **365** |

The principal assumptions for the purpose of the actuarial valuation were as follows:

| | Year ended 31 December | |
|---|---|---|
| % | 2018 | 2017 |
| Discount rate (EUR Composite A yield curve) | 0.94%-2.03% | 0.87% |
| Inflation rate | 1.50% | 1.50% |
| Future salary increase (inflation rate included) | 0%-2% | n/a |
| Future pension increase | n/a | n/a |
| Mortality rate | SI2017 | RGS 48 |
| Average annual departure rate | 6.28%-7.56% | 6.05% |

Amounts recognised in the income statements are as follows:

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Current services cost* | 414 | 393 |
| Interest expenses on obligation** | (1) | (1) |

* of which 397 and 379 respectively for 2018 and 2017, amount transferred to external fund

** interest expenses calculated on the present value of the liabilities for defined benefits plan

Amounts recognised in the Other comprehensive income are as follows:

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Actuarial (gains)/losses | 7 | (18) |

## 27 Deferred tax liabilities

The movement in deferred tax liabilities during 2018 and 2017 was as follows:

| EUR 1,000 | As at 31 January 2017 | Changes during the year | | | As at 31 December 2017 | Changes during the year | | | | | As at 31 December 2018 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Increase | Decrease | OCI | | Reclass | Increase | Decrease | OCI | Equity | |
| Development costs | (737) | (1,152) | – | – | (1,889) | – | (888) | – | – | – | (2,777) |
| Amortisation of patents and software | (84) | – | 22 | – | (62) | – | – | 20 | – | – | (42) |
| Intangible assets recognised in business combinations | (331) | – | 55 | – | (276) | – | – | 55 | – | – | (221) |
| Goodwill | (30) | – | – | – | (30) | – | – | – | – | – | (30) |
| Financial lease on property, plant & equipment | (1,714) | (125) | 34 | – | (1,805) | – | (77) | 126 | – | – | (1,756) |
| Interests and F/X on financial investments | (450) | – | 255 | – | (195) | – | (8) | 124 | 7 | – | (72) |
| Unrealised F/X gain on financial investments | (506) | – | 506 | – | – | – | – | – | – | – | – |
| Fair value of loans | (24) | – | 5 | – | (19) | – | – | 4 | – | – | (15) |
| Convertible bond | – | – | – | – | – | – | – | 73 | – | (2,658) | (2,585) |
| Fair value financial investments | (459) | – | – | 450 | (9) | – | – | – | 9 | – | – |
| Employee benefits | 5 | 4 | – | (4) | 5 | (5) | – | – | – | – | – |
| **Total deferred tax liabilities** | **(4,330)** | **(1,273)** | **877** | **446** | **(4,280)** | **(5)** | **(973)** | **402** | **16** | **(2,658)** | **(7,499)** |

## 27 Deferred tax liabilities continued

The following table sets out the nature of temporary differences relating to Deferred tax liabilities:

| EUR 1,000 | Temporary differences as at 31 December 2017 | % | Tax effect as at 31 December 2017 | Temporary differences as at 31 December 2018 | % | Tax effect as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Development costs | (15,112) | 12.50 | (1,889) | (22,215) | 12.50 | (2,777) |
| Amortisation of patents and software | (502) | 12.50 | (62) | (335) | 12.50 | (42) |
| Intangible assets recognised in business combinations | (990) | 27.90 | (276) | (792) | 27.90 | (221) |
| Goodwill | (108) | 27.90 | (30) | (108) | 27.90 | (30) |
| Financial lease on property, plant & equipment | (6,469) | 27.90 | (1,805) | (6,294) | 27.90 | (1,756) |
| Interests and F/X on investment securities | (779) | 25.00 | (195) | (290) | 25.00 | (72) |
| Fair value of loans | (80) | 24.00 | (19) | (63) | 24.00 | (15) |
| Convertible bond | – | – | – | (20,678) | 12.50 | (2,585) |
| Fair value of financial investments | (28) | 33.00 | (9) | – | – | – |
| Employee benefits | 23 | 24.00 | 5 | – | – | – |
| **Total deferred tax liabilities** | **(24,045)** | | **(4,280)** | **(50,775)** | | **(7,499)** |

## 28 Trade payables

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Trade payables | 5,270 | 7,640 |
| Accruals | 3,536 | 3,688 |
| **Total trade payables** | **8,806** | **11,328** |

## 29 Current tax and other tax liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Tax payables | 44 | 1,191 |
| **Total current tax liabilities** | **44** | **1,191** |
| Withholding tax for employees | 374 | 342 |
| Withholding tax for consultants | 6 | 5 |
| **Total other tax liabilities** | **380** | **347** |
| **Total current tax and other tax liabilities** | **424** | **1,538** |

## 30 Other current liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Social security payables | 451 | 496 |
| VAT payable | 5 | 8 |
| Contingent consideration | 615 | – |
| Other liabilities | 4,131 | 4,805 |
| Contract liabilities | 60 | – |
| Refund Liabilities | 27 | 266 |
| Accrued expenses | 299 | 342 |
| **Total other current liabilities** | **5,588** | **5,917** |

Social security payables comprises both the contributions withheld from salaries and the contributions due in accordance with current laws and regulations. Other liabilities mainly includes payables to employees related to accruals of deferred pay elements, calculated on the basis of the collective labour agreement currently in force and accrued employee bonuses. Contingent consideration refers to the Linkverse acquisition and is mandatorily measured at FVTPL.

## 31 Share-based payment

### Stock option plan of Cosmo Pharmaceuticals N.V.

**Option Series 3 and 4**

On 26 March 2014, the Board of Directors granted a total of 638,000 options with a vesting period of three years, expiring on 26 March 2020 and an exercise price of CHF 100.36 for 150,000 options (Option series 3) and an exercise price of CHF 79.64 for 488,000 options (Option series 4). The options granted are recognised as costs over the vesting period.

**31 Share-based payment** continued

**Stock option plan of Cosmo Pharmaceuticals N.V.** continued

**Option Series 3 and 4** continued

With regard to Option Series 3 and Option Series 4, following the exercise of 618,500 options on 31 March 2017, 2,000 options are outstanding relating to Option Series 3 and 16,000 options are outstanding relating to Option Series 4.

**Option Series 5**

On 28 July 2016, the Board of Directors granted a total of 43,000 options with a vesting period of three years, expiring on 28 July 2022 at an exercise price of CHF 159.00 (Option series 5).

**Option Series 6**

On 11 April 2017, the Board of Directors granted a total of 832,300 options with a vesting period of three years, expiring on 11 April 2023 and an exercise price of CHF 154.90 (Option series 6). In 2018 2,000 options were forfeited relating to this option series.

**Option Series 7**

On 31 May 2017, the Board of Directors granted a total of 16,000 options with a vesting period of three years, expiring on 31 May 2023 and an exercise price of CHF 163.00 (Option series 7).

**Option Series 8**

On 3 December 2018, the Board of Directors granted a total of 24,000 options with a vesting period of three years, expiring on 3 December 2024 and an exercise price of CHF 120.20 (Option series 8).

The key terms and conditions related to the grants under these programmes are as follows; all options are to be settled by the physical delivery of shares.

| Option series | Number | Grant date | Vesting date | Expiry date | Exercise price CHF | Fair value of the option at the grant date CHF |
|---|---|---|---|---|---|---|
| Option series 3 – issued 26 March 2014 | 2,000 | 26/03/2014 | 26/03/2017 | 26/03/2020 | 100.36 | 24.20 |
| Option series 4 – issued 26 March 2014 | 16,000 | 26/03/2014 | 26/03/2017 | 26/03/2020 | 79.64 | 35.01 |
| Option series 5 – issued 28 July 2016 | 43,000 | 28/07/2016 | 28/07/2019 | 28/07/2022 | 159.00 | 27.37 |
| Option series 6 – issued 11 April 2017 | 830,300 | 11/04/2017 | 11/04/2020 | 11/04/2023 | 154.90 | 25.05 |
| Option series 7 – issued 31 May 2017 | 16,000 | 31/05/2017 | 31/05/2020 | 31/05/2023 | 163.00 | 26.62 |
| Option series 8 – issued 3 December 2018 | 24,000 | 03/12/2018 | 03/12/2021 | 03/12/2024 | 120.20 | 13.18 |
| **Outstanding as at 31 December 2018** | **931,300** | | | | | |

The inputs used in the measurement of the fair values at grant date of the Cosmo Pharmaceuticals N.V. stock option plan for options granted during 2018 were as follows:

| Option Series | 8 |
|---|---|
| Issue Date | 03/12/18 |
| Previous monthly average at grant date share price (in CHF) | 120.20 |
| Share price at grant date (in CHF) | 106.30 |
| Exercise price (in CHF) | 120.20 |
| Expected volatility | 25% |
| Employee Exit Rate | 0% |
| Option life | 1,096 days |
| Risk-free interest rate | 0.48% |
| Dividend yield | 0.50% |

The fair value of the options granted has been determined on the basis of the binomial tree generated by the Fincad program, a technique similar to the Black-Scholes valuation model.

The expected volatility of the underlying instrument measures the expected fluctuations in price/value for a given period. The indicator that measures volatility in the model used to evaluate the options is the annualised standard deviation of the compound returns of a share.

In 2018, the expense for the value of employees' and directors' services exchanged for stock options in relation to the Stock option plan of Cosmo Pharmaceuticals N.V. amounted to €6,769 thousand (2017: €6,364 thousand) of which €6,264 thousand (2017: €5,855 thousand) for management and personnel and €505 thousand (2017: €509 thousand) for non-executive Directors.

The number and weighted-average exercise prices of share options under the share option programmes is as follows:

| | 2018 | | 2017 | |
|---|---|---|---|---|
| | Number | Weighted average exercise price CHF | Number | Weighted average exercise price CHF |
| **Outstanding as at 1 January** | **909,300** | **153.79** | **679,500** | **89.19** |
| Granted during the period | 24,000 | 120.20 | 848,300 | 155.05 |
| Forfeited during the period | (2,000) | 154.90 | – | – |
| Exercised during the period | – | – | (618,500) | 84.55 |
| **Outstanding as at 31 December** | **931,300** | **152.92** | **909,300** | **153.79** |
| Exercisable as at 31 December | 18,000 | 81.94 | 18,000 | 81.94 |

**31 Share-based payment** continued

**Stock option plan of Cosmo Pharmaceuticals N.V.** continued

The share options outstanding at the end of 2018 had a weighted average exercise price of CHF 152.92 and a weighted average remaining contractual life of 4.2 years.

**Stock option plan of Aries Pharmaceuticals Ltd.**

On 22 July 2016 the board of Aries Pharmaceuticals Ltd. established a share option program that entitles certain employees of Aries Pharmaceuticals Ltd. and its subsidiary Aries Pharmaceuticals Inc. to purchase share in Aries Pharmaceuticals Ltd. During 2018 the Board of Directors of Aries Pharmaceuticals Ltd. granted a total of 708,620 options.

The key terms and conditions related to the grants under these programmes are as follows; all options are to be settled by the physical delivery of shares.

| Option series | Number | Grant date | Vesting date | Expiry date | Exercise price EUR | Fair value of the option at the grant date EUR |
|---|---|---|---|---|---|---|
| 1a) Issued 28 July 2016 | 1,550,000 | 28/07/2016 | 28/07/2018 | 27/07/2023 | 5.00 | 1.117 |
| 1b) Issued 28 July 2016 | 775,000 | 28/07/2016 | 28/07/2019 | 27/07/2023 | 5.00 | 1.252 |
| 1c) Issued 28 July 2016 | 775,000 | 28/07/2016 | 28/07/2020 | 27/07/2023 | 5.00 | 1.365 |
| 2a) Issued 31 October 2016 | 540,250 | 31/10/2016 | 31/10/2018 | 30/10/2023 | 5.00 | 1.124 |
| 2b) Issued 31 October 2016 | 270,125 | 31/10/2016 | 31/10/2019 | 30/10/2023 | 5.00 | 1.263 |
| 2c) Issued 31 October 2016 | 270,125 | 31/10/2016 | 31/10/2020 | 30/10/2023 | 5.00 | 1.378 |
| 3a) Issued 1 January 2017 | 123,200 | 01/01/2017 | 01/01/2019 | 31/12/2023 | 9.00 | 2.029 |
| 3b) Issued 1 January 2017 | 61,600 | 01/01/2017 | 01/01/2020 | 31/12/2023 | 9.00 | 2.282 |
| 3c) Issued 1 January 2017 | 61,600 | 01/01/2017 | 01/01/2021 | 31/12/2023 | 9.00 | 2.491 |
| 4a) Issued 31 March 2017 | 384,750 | 31/03/2017 | 31/03/2019 | 30/03/2024 | 9.00 | 2.038 |
| 4b) Issued 31 March 2017 | 192,375 | 31/03/2017 | 31/03/2020 | 30/03/2024 | 9.00 | 2.294 |
| 4c) Issued 31 March 2017 | 192,375 | 31/03/2017 | 31/03/2021 | 30/03/2024 | 9.00 | 2.506 |
| 5a) Issued 30 May 2017 | 74,500 | 30/05/2017 | 30/05/2019 | 29/05/2024 | 9.00 | 1.755 |
| 5b) Issued 30 May 2017 | 37,250 | 30/05/2017 | 30/05/2020 | 29/05/2024 | 9.00 | 1.948 |
| 5c) Issued 30 May 2017 | 37,250 | 30/05/2017 | 30/05/2021 | 29/05/2024 | 9.00 | 2.116 |
| 7a) Issued 25 October 2017 | 18,750 | 25/10/2017 | 25/10/2019 | 24/10/2024 | 9.00 | 1.753 |
| 7b) Issued 25 October 2017 | 9,375 | 25/10/2017 | 25/10/2020 | 24/10/2024 | 9.00 | 1.950 |
| 7c) Issued 25 October 2017 | 9,375 | 25/10/2017 | 25/10/2021 | 24/10/2024 | 9.00 | 2.121 |

**31 Share-based payment** continued

**Stock option plan of Aries Pharmaceuticals Ltd.** continued

| Option series | Number | Grant date | Vesting date | Expiry date | Exercise price EUR | Fair value of the option at the grant date EUR |
|---|---|---|---|---|---|---|
| 9a) Issued 2 January 2018 | 28,207 | 02/01/2018 | 02/01/2020 | 01/01/2025 | 10.24 | 1.986 |
| 9b) Issued 2 January 2018 | 14,113 | 02/01/2018 | 02/01/2021 | 01/01/2025 | 10.24 | 2.206 |
| 9c) Issued 2 January 2018 | 14,094 | 02/01/2018 | 02/01/2022 | 01/01/2025 | 10.24 | 2.400 |
| 10) Issued 2 January 2018 | 146,125 | 02/01/2018 | 02/01/2019 | 01/01/2025 | 10.24 | 1.639 |
| 11a) Issued 22 March 2018 | 76,801 | 22/03/2018 | 22/03/2020 | 21/03/2025 | 10.04 | 1.947 |
| 11b) Issued 22 March 2018 | 38,401 | 22/03/2018 | 22/03/2021 | 21/03/2025 | 10.04 | 2.163 |
| 11c) Issued 22 March 2018 | 38,400 | 22/03/2018 | 22/03/2022 | 21/03/2025 | 10.04 | 2.353 |
| 12) Issued 22 March 2018 | 145,625 | 22/03/2018 | 22/03/2019 | 21/03/2025 | 10.04 | 1.698 |
| 13a) Issued 4 July 2018 | 25,600 | 04/07/2018 | 04/07/2020 | 03/07/2025 | 5.00 | 0.981 |
| 13b) Issued 4 July 2018 | 12,800 | 04/07/2018 | 04/07/2021 | 03/07/2025 | 5.00 | 1.093 |
| 13c) Issued 4 July 2018 | 12,800 | 04/07/2018 | 04/07/2022 | 03/07/2025 | 5.00 | 1.190 |
| 14) Issued 4 July 2018 | 22,250 | 04/07/2018 | 04/07/2019 | 03/07/2025 | 5.00 | 0.826 |
| 15a) Issued 19 September 2018 | 1,200 | 19/09/2018 | 19/09/2020 | 18/09/2025 | 5.00 | 0.985 |
| 15b) Issued 19 September 2018 | 600 | 19/09/2018 | 19/09/2021 | 18/09/2025 | 5.00 | 1.100 |
| 15c) Issued 19 September 2018 | 600 | 19/09/2018 | 19/09/2022 | 18/09/2025 | 5.00 | 1.198 |
| 16a) Issued 12 November 2018 | 19,350 | 12/11/2018 | 12/11/2020 | 11/11/2025 | 5.00 | 0.985 |
| 16a) Issued 12 November 2018 | 9,675 | 12/11/2018 | 12/11/2021 | 11/11/2025 | 5.00 | 1.098 |
| 16a) Issued 12 November 2018 | 9,675 | 12/11/2018 | 12/11/2022 | 11/11/2025 | 5.00 | 1.197 |
| 17) Issued 12 November 2018 | 7,500 | 12/11/2018 | 12/11/2019 | 11/11/2025 | 5.00 | 0.849 |
| **Outstanding as at 31 December 2018** | **6,006,716** | | | | | |

**31 Share-based payment** continued

**Stock option plan of Aries Pharmaceuticals Ltd.** continued

The inputs used in the measurement of the fair values at grant date of the Aries Pharmaceuticals Ltd. stock option plan for options granted during 2018 were as follows:

| Option Series | 9a) | 9b) | 9c) | 10) | 11a) | 11b) | 11c) | 12) |
|---|---|---|---|---|---|---|---|---|
| Issue Date | 02/01/18 | 02/01/18 | 02/01/18 | 02/01/18 | 22/03/18 | 22/03/18 | 22/03/18 | 22/03/18 |
| Exercise price (in EUR) | 10.24 | 10.24 | 10.24 | 10.24 | 10.04 | 10.04 | 10.04 | 10.04 |
| Expected option life (days) | 1,826 | 1,460 | 1,095 | 2,191 | 1,825 | 1,460 | 1,095 | 2,191 |
| Expected volatility | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| Employee Exit Rate | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Risk-free interest rate | 0.24% | 0.31% | 0.35% | 0.16% | 0.34% | 0.44% | 0.52% | 0.25% |
| Dividend yield | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Exercise Multiple | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |

| Option Series | 13a) | 13b) | 13c) | 14) | 15a) | 15b) | 15c) | 16a) |
|---|---|---|---|---|---|---|---|---|
| Issue Date | 04/07/18 | 04/07/18 | 04/07/18 | 04/07/18 | 19/09/18 | 19/09/18 | 19/09/18 | 12/11/18 |
| Exercise price (in EUR) | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 | 5.00 |
| Expected option life (days) | 1,825 | 1,460 | 1,095 | 2,191 | 1,825 | 1,460 | 1,095 | 1,825 |
| Expected volatility | 25% | 25% | 25% | 25% | 25% | 25% | 25% | 25% |
| Employee Exit Rate | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Risk-free interest rate | 0.32% | 0.41% | 0.49% | 0.14% | 0.41% | 0.51% | 0.59% | 0.40% |
| Dividend yield | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% | 0.00% |
| Exercise Multiple | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |

| Option Series | 16b) | 16c) | 17 |
|---|---|---|---|
| Issue Date | 12/11/18 | 12/11/18 | 12/11/18 |
| Exercise price (in EUR) | 5.00 | 5.00 | 5.00 |
| Expected option life (days) | 1,460 | 1,095 | 2,191 |
| Expected volatility | 25% | 25% | 25% |
| Employee Exit Rate | 0.00% | 0.00% | 0.00% |
| Risk-free interest rate | 0.49% | 0.57% | 0.31% |
| Dividend yield | 0.00% | 0.00% | 0.00% |
| Exercise Multiple | 1.2 | 1.2 | 1.2 |

The fair value of the options granted has been determined on the basis of the binomial tree generated by the Fincad program, a technique similar to the Black-Scholes valuation model.

The expected volatility of the underlying instrument measures the expected fluctuations in price/value for a given period. The indicator that measures volatility in the model used to evaluate the options is the annualised standard deviation of the compound returns of a share. Aries Pharmaceuticals Ltd. is not listed; therefore, it was considered appropriated to assume the volatility equal to peer companies.

In 2018, the expense for the value of employees' and directors' services exchanged for stock options in relation to the Stock option plan of Aries Pharmaceuticals Ltd. amounted to €2,820 thousand (2017: €3,082 thousand) for management and personnel.

The number and weighted-average exercise prices of share options under the share option programmes.

## 31 Share-based payment continued

### Stock option plan of Aries Pharmaceuticals Ltd. continued

| | 2018 | | 2017 | |
|---|---|---|---|---|
| | Number | Weighted average exercise price EUR | Number | Weighted average exercise price EUR |
| **Outstanding as at 1 January** | **5,951,700** | **6.20** | **4,180,500** | **5.00** |
| Granted during the period | 708,620 | 9.20 | 1,771,200 | 9.02 |
| Forfeited during the period | (653,604) | 9.15 | – | – |
| Outstanding as at 31 December | 6,006,716 | 6.23 | 5,951,700 | 6.20 |
| **Exercisable as at 31 December** | **2,090,250** | **5.00** | **–** | **–** |

The share options outstanding at the end of 2018 had a weighted average exercise price of €6.23 and a weighted average remaining contractual life of 4.9 years.

## 32 Banks loans, contractual obligation, contingencies and commitments

The following table sets forth the contractual commitments and principal payments the Group was obliged to make as of 31 December 2018 and 2017 under debt instruments, financial leases and other agreements.

| EUR 1,000 | Total | Less than 1 year | 1-5 years | More than 5 years |
|---|---|---|---|---|
| Bank loans | 1,454 | 243 | 518 | 693 |
| Financial lease liabilities | 3,022 | 406 | 2,616 | – |
| Employee benefits | 318 | – | – | 318 |
| Operating lease expenses[1] | 5,437 | 1,257 | 3,488 | 692 |
| **Total contractual obligations 31 December 2017** | **10,231** | **1,906** | **6,622** | **1,703** |
| | | | | |
| Bank loans | 1,211 | 127 | 525 | 559 |
| Financial lease liabilities | 2,617 | 400 | 2,217 | – |
| Employee benefits | 365 | – | – | 365 |
| Convertible bond | 175,000 | – | 175,000 | – |
| Operating lease expenses[1] | 4,478 | 1,302 | 2,729 | 447 |
| **Total contractual obligations 31 December 2018** | **183,671** | **1,829** | **180,471** | **1,371** |

1 Not a balance sheet item

Bank loans, financial lease liabilities and convertible bond represent the remaining principle outstanding. Employee benefits as at 31 December 2018 includes €365 thousand (2017: €318 thousand) related to required indemnities for termination of employees (Indennità di fine rapporto, TFR) of the Italian Group companies. These obligations are payable to employees upon the termination of employment and, although in practice a part of this liability may come due within 12 months, this portion is not quantifiable and is conventionally treated as long-term.

Operating lease expenses refers to the leases for the offices and laboratory, for computer and office equipment and for company car. Office and laboratory leases typically run for between 5 to 10 years, the shorter period leases with an option to renew the lease after that date. Lease rentals are renegotiated periodically to reflect market rents.

### Contingent liabilities

In 2016 Cosmo in-licensed Remimazolam, an ultra-short-acting sedative/anaesthetic, from PAION AG. Under the terms of the license agreement for Remimazolam with PAION AG a €10 million upfront payment was made to PAION AG in 2016. In addition, PAION AG is entitled to receive additional payments from the Group of up to €42.5 million contingent upon certain milestones related to the U.S. regulatory approval process as follows: €7.5 million payable on filing of NDA (Procedural sedation), €15 million payable upon FDA approval for Procedural sedation, €10 million payable upon FDA approval of 2nd indication and €10 million payable upon FDA approval of 3rd indication. Cosmo plan to file the NDA (Procedural sedation) with the FDA in the first half of 2019. The other indications will depend on subsequent successful clinical trials.

## 33 Legal Proceedings

### Uceris® Arbitration

On 12 May 2017 the Company, in relation to its license agreement for Uceris®, announced that it had filed for arbitration against Santarus Inc. ('Santarus') and its affiliate Valeant Pharmaceuticals Ireland Ltd ('Valeant Ireland', collectively 'Valeant') under the Rules of Arbitration of the International Chamber of Commerce (No. 22453/GR, Cosmo Technologies Ltd. et al. v. Santarus, Inc. et al.). A hearing was conducted from October 5 to 8, 2017.

On 12 April 2018 Cosmo announced that the ICC Arbitral Tribunal had ruled that Valeant was not in breach of the Uceris® license agreement and that Cosmo will reimburse Valeant's legal costs. Legal fees of €2,716 thousand were expensed during 2018 in relation to the case.

## 34 Related party transactions

The Company's major shareholder is Cosmo Holding S.a.r.l., which as at 31 December 2018 owns 5,571,209 of the Company shares amounting to 37.05% of the issued shares.

Any member of the board who has an interest in a related party transaction which is under discussion by the board must abstain from this discussion and abstain from any vote on the approval of the related party transaction under discussion.

### Cassiopea S.p.A.

In the year 2018 the Group charged its associate company Cassiopea S.p.A. under a service agreement €532 thousand (2017: €517 thousand) for research and development services, regulatory services and related activities and €144 thousand (2017: €138 thousand) for secretarial and accounting services. As at 31 December 2018 the amount owed by Cassiopea S.p.A. to the Group was €164 thousand (2017: €56 thousand).

On 12 December 2018, Cosmo agreed an unsecured term loan facility expiring on 31 December 2021 of €10 million. Cosmo may, at its sole discretion, extend the loan facility by a further €10 million under the same terms and conditions. To date, no drawdowns of the loan facility have been made.

Since May 2015 under an agreement with Cassiopea S.p.A., Cosmo Pharmaceuticals has provided Cassiopea S.p.A. with Chief Financial Officer and Chief Scientific Officer services by Hans Christoph Tanner and Luigi Moro. The Group has provided these services to Cassiopea S.p.A. at no charge. The services provided under this agreement shall not exceed 30% of the respective available working time of the individuals providing those services. During 2017 the board of Cassiopea S.p.A. granted 20,000, 20,000 and 10,000 options to subscribe to Cassiopea S.p.A. shares to Luigi Moro (CSO), Hans Christoph Tanner (Head of Transaction Office) and Marco Lecchi (Head of Internal Audit) respectively. In 2017 Cosmo Pharmaceutical N.V., under a stock option plan, granted 18,000 options to certain employees of Cassiopea S.p.A.

### Director and Key Management compensation

Compensation to the Board of Directors and Executive Management personnel recognised in the income statement in 2018 was as follows:

EUR

| Board of Directors | Function | Base compensation | Additional compensation | Stock options | Total compensation |
|---|---|---|---|---|---|
| Mauro Ajani | Chairman | 30,000 | 370,000 | 1,092,022 | 1,492,022 |
| Alessandro della Chà | member, executive CEO | 30,000 | 570,000 | 1,092,022 | 1,692,022 |
| Dieter Enkelmann | member, non-executive | 30,000 | – | 124,803 | 154,803 |
| Hans Christoph Tanner | member, executive Head of TO | 30,000 | 162,000 | 624,013 | 816,013 |
| Maria Grazia Roncarolo | member, non-executive | 30,000 | – | 124,803 | 154,803 |
| Kevin Donovan | member, non-executive | 30,000 | – | 124,803 | 154,803 |
| Eimear Cowhey | member, non-executive | 30,000 | – | 130,156 | 160,156 |
| **Total** | | **210,000** | **1,102,000** | **3,312,620** | **4,624,620** |

The Cash bonus payments relate to payments under the Group incentive arrangements.

EUR

| Executive Management | No. of members | Base compensation | Cash bonus | Fringe benefits | Stock options | Total compensation |
|---|---|---|---|---|---|---|
| Executive Management* | 16 members | 2,859,692 | 170,512 | 111,579 | 4,268,851 | 7,410,634 |
| highest paid of 16 members | | 380,874 | 93,314 | 23,134 | 1,080,969 | 1,578,291 |

* excluding Chairman, CEO and Head of Transactions Office

The base compensation of Executive Management is inclusive of the amount contributed by Cosmo Group to State and employer-defined contribution pension funds. The Cash bonus payments relate to payments under the Group incentive arrangements.

## 34 Related party transactions continued

### Director and Key Management compensation continued

As at 31 December 2018 in relation to the Stock option plan of Cosmo Pharmaceuticals N.V. the situation was as follows:

| Non-executive Members of the Board | Outstanding as at 1 January 2018 | Granted | Forfeited | Exercised 2018 | Expired | Outstanding as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Dieter Enkelmann | 32,000 | – | – | – | – | 32,000 |
| Maria Grazia Roncarolo | 16,000 | – | – | – | – | 16,000 |
| Kevin Donovan | 16,000 | – | – | – | – | 16,000 |
| Eimear Cowhey | 16,000 | – | – | – | – | 16,000 |
| **Total** | **80,000** | **–** | **–** | **–** | **–** | **80,000** |
| Of which exercisable | 16,000 | – | – | – | – | 16,000 |

| Executive Members of the Board and Members of Management detailed if allocation exceeds 50,000 options | Outstanding as at 1 January 2018 | Granted | Forfeited | Exercised in 2018 | Expired | Outstanding as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Mauro S. Ajani | 140,000 | – | – | – | – | 140,000 |
| Alessandro Della Chà | 140,000 | – | – | – | – | 140,000 |
| Hans Christoph Tanner | 80,000 | – | – | – | – | 80,000 |
| Giuseppe Cipriano | 80,000 | – | – | – | – | 80,000 |
| Luigi Moro | 80,000 | – | – | – | – | 80,000 |
| Other management | 204,300 | 24,000 | – | – | – | 228,300 |
| **Total** | **724,300** | **24,000** | **–** | **–** | **–** | **748,300** |
| Of which exercisable | – | – | – | – | – | – |

In relation to the Cosmo Pharmaceuticals N.V. Stock option plan, as it relates to Board of Directors and Executive Management, as at 31 December 2018 16,000 of the outstanding options were vested. The compensation programs promote long-term value creation and the sustainability of the company.

As at 31 December 2018 the stock option plan of Aries Pharmaceuticals Ltd. in relation to Executive Management was as follows:

| Executive Members of the Board and Members of Management detailed if allocation exceeds 200,000 options | Outstanding as at 1 January 2018 | Granted | Forfeited | Exercised in 2018 | Expired | Outstanding as at 2018 31 December |
|---|---|---|---|---|---|---|
| Tom Joyce | 3,100,000 | – | – | – | – | 3,100,000 |
| John Hee | 720,000 | 45,000 | – | – | – | 765,000 |
| Blake Boland | 286,000 | 30,750 | – | – | – | 316,750 |
| | **4,106,000** | **75,750** | **–** | **–** | **–** | **4,181,750** |
| Of which exercisable | – | – | – | – | – | 2,053,000 |

As at 31 December 2018, 2,053,000 of the outstanding options of the Aries Pharmaceuticals Ltd. stock option plan, as it relates to Executive Management, were vested and exercisable.

## 35 Financial risk management objectives and policies

### Financial risk management

The Group's financial assets, such as cash and cash equivalents, trade receivables and other receivables, investments in other companies, investments in funds and debt securities are managed by the Group's Investment Committee.

The Group's principal financial liabilities, which comprise bank loans, financial leases, convertible bond and trade payables, are mainly related to finance raise for its operations.

The Group is exposed to various financial risk in the normal course of business. The principle financial risks to which it is exposed include credit risks related to the creditworthiness of its customers and counterparties of investment portfolio, with which it invests surplus cash funds, liquidity risks associated with the availability of sufficient capital resources, foreign currency risks, including both translation and transaction risk, and interest rate risk.

The Group measures and manages financial risks in accordance with Group Policy. The board of directors has overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identity and analyse the risks faced by the Group, to set appropriate risk limits and controls and to monitor risks and adherence to limits. The Audit Committee of the board periodically reviews the policies and adequacy of the risk management framework in relation to risk faced by the Group and reports regularly to the board of directors on its activities.

To illustrate the correlation between the financial instruments and the related risk exposure, a description of the policies and the measures adopted by the Group to manage its financial risk exposure is provided below. The Group aims to maintain a disciplined and constructive control environment in which all employees understand their roles and obligations.

The Group has exposure to the following risks arising from financial instruments:

- credit risk;
- liquidity risk;
- Market risk.
- foreign currency risk; and
- other market price risk.

### A. Credit risk

Credit risk is the risk of financial loss to the Group if a customer or a counterparty to a financial instrument fails to meet its contractual obligations. It arises mainly from the Group's trade receivables, from cash and cash equivalents and from investments in debt securities.

Impairment losses on financial assets and contract assets recognised in profit or loss in 2018 amounted to €21 thousand (2017: nil) and related to debt securities at FVOCI.

### Trade and other receivables

The Group's has a credit risk exposure in respect of the creditworthiness of its customers. The Group has series of long-standing customers and has established on-going monitoring for risk of credit deterioration. Credit risk for new customers is managed by ensuring strict credit procedures. In the event where a new customer credit rating is not available, the customer is required to provide bank references and any failure to obtain sufficient comfort over the creditworthiness, the Group will transact based on prepayment basis. In addition to this, in order to reduce general credit risk concentration, the Group sets limits for credit days of its customers.

The Group has experienced no instances of trade receivables written-off / bad debts to date. The Group assesses that there are no factors specific to our customers or general economic conditions, in both the current as well as the forecast direction, of conditions at the reporting date that are indicative of potential material credit losses.

At 31 December 2018, the ageing of trade and other receivables that were not impaired was as follows: Comparative amounts for 2017 represent the allowance account for impairment losses under IAS 39.

| EUR 1,000 | As at 31 December | |
|---|---|---|
| **Ageing of trade receivables** | **2018** | **2017** |
| Current | 11,922 | 13,008 |
| Past due 1 – 30 days | 876 | 156 |
| Past due 30 – 60 days | – | – |
| Past due 60 – 90 days | – | – |
| Past due 90 – 120 days | – | – |
| Past due 120 + days | 7 | 58 |
| Loss allowance | (43) | (32) |
| **Total trade receivables** | **12,762** | **13,190** |

## 35 Financial risk management objectives and policies continued

### A. Credit risk continued

### Trade and other receivables continued

The changes in the allowance for impairment in respect of trade and other receivables during the year was as follows:

| EUR 1,000<br>Movement in allowance for impairment | As at 31 December<br>2018 | <br>2017 |
|---|---|---|
| **Balance at beginning of the year** | **32** | **32** |
| Acquisition of Linkverse | 11 | – |
| Amounts written-off as uncollectible | – | – |
| Amounts recovered during the year | – | – |
| Net measurement of loss allowance | – | – |
| **Balance at end of the year** | **43** | **32** |

At present, there are no pending litigations with reference to Group's trade receivables, nor has there been any record of litigations in the past. Nevertheless, receivables are constantly monitored by the Management within the context of a risk management system, approved by the board of directors.

### Debt securities

The Group limits its exposure to credit risk by investing only in liquid debt securities and only with counterparties that have a good credit quality. The Group monitors changes in credit risk by tracking published external credit ratings.

12-month and lifetime probabilities of default are based on historical data supplied by Moodys for each credit rating. Loss given default (LGD) parameters generally reflect an assumed recovery rate of 50% except when a security is credit-impaired, in which case the estimate of loss is based on the instrument's current market price and original effective interest rate.

The following table presents an analysis of the credit quality of debt securities:

| EUR 1,000<br>Credit rating | As at 31 December<br>2018<br>FVOCI<br>12 month ECLs | <br>2017<br>Available-for -sale |
|---|---|---|
| BBB- to AAA | 38,385 | 84,655 |
| BB- to BB+ | – | 2,192 |
| **Gross carrying amounts** | **38,385** | **86,847** |

The Group did not have any debt securities that were past due at 31 December 2018.

The movement in the allowance for impairment in respect of debt securities at FVOCI during the year was as follows:

| EUR 1,000 | |
|---|---|
| **Loss allowance at 31 December 2017 under IAS 39** | – |
| Adjustment on application of IFRS 9 | 54 |
| **Balance at 1 January 2018 under IFRS 9** | **54** |
| Net remeasurement of loss allowance | * |
| Financial assets derecognised | (21) |
| **Loss allowance at 31 December 2018** | **33** |

* Less than €1 thousand

The investments held at 31 December 2017 were previously classified as available-for-sale and no impairment loss had been recognised at that date or during 2017.

### Cash and cash equivalents

Credit risk exposure also exists in relation to the investment by the Group in the cash which the Group places on deposit with financial institutions. The Group's actively manages these risks by placing deposits with financial institutions in accordance with strict credit risk management policies and controls as specified by the Group's board of directors.

The Group's cash and cash equivalents as at 31 December 2018 was held on deposit with banks whose FITCH credit rating ranged from BB- to AA+, 97.3% of deposits were held with banks with a FITCH credit rating of BBB- (Good Credit Quality) or higher.

Impairment on cash and cash equivalents has been measured on a 12-month expected loss basis and reflects the short maturities of the exposures. The Group considers that its cash and cash equivalents have low credit risk based on the external credit ratings of the counterparties. The identified impairment loss was considered immaterial.

### Other financial assets at amortised cost

Other financial assets at amortised cost include loans to collaboration partners, related party receivables and other receivables. The identified impairment loss was considered immaterial.

**35 Financial risk management objectives and policies** continued

**A. Credit risk** continued

**Financial assets at fair value through profit or loss**

The entity is also exposed to credit risk in relation to investments in funds that are measured at fair value through profit or loss. The maximum exposure at the end of the reporting period is the carrying amount of these investments €126,692 thousand.

**B. Liquidity risk**

Liquidity risk is the risk that an entity will encounter difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset.

The Group's primary objectives in managing liquidity is to ensure:

i adequate resources to fund its continued operations,

ii availability of sufficient resources to sustain future development and growth of the business,

iii maintain sufficient resources to mitigate risks and unforeseen events which may arise.

The Group manages risks associated with liquidity by investing its cash in short-term deposits and short-term financial investment which can be readily realised into cash. Where the Group has entered into a long-term financial investment obligation, the maturity dates are spread out evenly in order to attain the most effective rate of liquidity. The Group prioritises management of liquidity risk efficiently over optimisation of its investment income.

Liquidity risk is managed by considering the maturity of the Group's financial assets (e.g., cash and cash equivalents, accounts receivables and other financial assets) as well as projected cash flows from operations to ensure, as far as possible, that it will have sufficient liquidity to meet its liabilities when they are due. The Group maintains flexibility in funding, and monitors rolling forecasts of the Group's liquidity reserve (which comprises cash and cash equivalents on the basis of expected cash flows).

The following are the remaining contractual maturities of financial liabilities at the reporting date. The amounts are gross and undiscounted and include contractual interest payments. Total Financial lease liabilities at 31 December 2018 of €2,689 thousand (2017: €3,136 thousand) represent future minimum lease payments.

| EUR 1,000 | Carrying amount | Total | Less than 1 year | 1-2 years | 2-5 years | More than 5 years |
|---|---|---|---|---|---|---|
| Convertible bond | 154,322 | 196,875 | 4,375 | 4,375 | 188,125 | – |
| Bank loans | 1,211 | 1,305 | 145 | 145 | 435 | 580 |
| Financial lease liabilities | 2,616 | 2,689 | 430 | 445 | 1,814 | – |
| Trade payables | 8,806 | 8,806 | 8,806 | – | – | – |
| Contingent consideration | 615 | 615 | 615 | – | – | – |
| **Total as at 31 December 2018** | **167,570** | **210,290** | **14,371** | **4,965** | **190,374** | **580** |
| | | | | | | |
| Bank loans | 1,454 | 1,574 | 269 | 145 | 435 | 725 |
| Financial lease liabilities | 3,022 | 3,136 | 439 | 431 | 2,266 | – |
| Trade payables | 11,328 | 11,328 | 11,328 | – | – | – |
| **Total as at 31 December 2017** | **15,804** | **16,038** | **12,036** | **576** | **2,701** | **725** |

**C. Market risk**

Market risk is the risk that changes in market prices, such as foreign exchange rates, interest rates, investment securities and equity prices, will affect the Group's income 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 optimising the return.

**Interest rate risk**

The Group is exposed to interest rate risk in respect of its cash and cash equivalents, bank loans and financial leases with variable interest rates. No material hedging activities such as interest rate swaps were utilised during the financial period under review. Except for a very small level of debt our interest rate exposure is restricted to our investments. The Group primarily invests in fixed rate instruments with maturities varying according to our liquidity needs. This process is overseen by an investment committee and implemented by an external expert investment manager.

## 35 Financial risk management objectives and policies continued

### C. Market risk continued

#### Interest rate risk continued

The Group is exposed to interest rate risk in relation to its variable rate, medium and long-term debt obligations and cash and cash equivalents, as identified in the following tables:

| | | | | | 31 December 2018 | |
|---|---|---|---|---|---|---|
| EUR/1,000 | Currency | Interest | Interest rate | Expiry | Original value | Carrying amount |
| **Fixed interest rate subsidised loans** | | | | | | |
| Centrobanca | EUR | fixed rate | 0.816% | 06/10/2018 | 1,052 | – |
| UBI Banca | EUR | fixed rate | 0.500% | 13/11/2027 | 1,412 | 1,211 |
| **Uncommited/ commited bank overdraft** | | | | | | |
| Various banks (2) | EUR | floating rate | Euribor +various% | until revocation | 40 | – |
| **Financial lease liabilities** | | | | | | |
| BNL BNP Paribas Leasing (various) | EUR | floating rate | Euribor +2.70% | from 01/07/2017 to 01/03/2018 | 2,177 | – |
| Leasint Spa Real estate (*) | EUR | floating rate | Euribor +1.45% | 27/10/2021 | 4,745 | 2,616 |
| ***Convertible bond*** | EUR | fixed rate | 2.50% | 05/12/2023 | 175,000 | 154,322 |

| | | | | | 31 December 2017 | |
|---|---|---|---|---|---|---|
| EUR/1,000 | Currency | Interest | Interest rate | Expiry | Original value | Carrying amount |
| **Fixed interest rate subsidised loans** | | | | | | |
| Centrobanca | EUR | fixed rate | 0.816% | 06/10/2018 | 1,052 | 119 |
| UBI Banca | EUR | fixed rate | 0.500% | 13/11/2027 | 1,412 | 1,335 |
| **Uncommited/ commited bank overdraft** | | | | | | |
| Various banks (2) | EUR | floating rate | Euribor +various% | until revocation | 40 | – |
| Financial lease liabilities | | | | | | |
| BNL BNP Paribas Leasing (various) | EUR | floating rate | Euribor +2.70% | from 01/07/2017 to 01/03/2018 | 2,177 | 23 |
| Leasint Spa Real estate (*) | EUR | floating rate | Euribor +1.45% | 27/10/2021 | 4,745 | 2,999 |

(*) from CCRE acquisition, value at the date of the acquisition

| | | | | | 31 December 2018 | |
|---|---|---|---|---|---|---|
| EUR/1,000 | Currency | Interest | Interest rate | Expiry | Original value | Carrying amount |
| Cash at hand | Various | N/A | N/A | N/A | N/A | 15 |
| Bank accounts various banks (9) | EUR | floating rate | Euribor ±various% | N/A | N/A | 181,535 |
| Bank accounts various banks (5) | USD | floating rate | Euribor ±various% | N/A | N/A | 20,247 |
| Bank accounts various banks (2) | CHF | floating rate | Euribor ±various% | N/A | N/A | 8,892 |

**35 Financial risk management objectives and policies** continued

**C. Market risk** continued

Interest rate risk continued

| | 31 December 2017 | | | | | |
|---|---|---|---|---|---|---|
| EUR/1,000 | Currency | Interest | Interest rate | Expiry | Original value | Carrying amount |
| Cash at hand | Various | N/A | N/A | N/A | N/A | 14 |
| Bank accounts various banks (9) | EUR | floating rate | Euribor ±various% | N/A | N/A | 43,236 |
| Bank accounts various banks (5) | USD | floating rate | Euribor ±various% | N/A | N/A | 94,164 |
| Bank accounts various banks (2) | CHF | floating rate | Euribor ±various% | N/A | N/A | 7,530 |

The table below provides an indication of the impact on the profit before tax of a parallel ± 50 basis-point shift of the rate curve estimated as of 31 December 2018 and 2017. The analysis was carried out by assuming that the other variables remained constant.

| | Profit or (loss) | |
|---|---|---|
| 31 December 2018 | 50 bp | 50 bp |
| EUR/1,000 | increase | decrease |
| Variable rate instruments | (14) | 14 |
| Cash and cash equivalents | 572 | (572) |
| **Cash flow sensitivity (net)** | **558** | **(558)** |

| | Profit or (loss) | |
|---|---|---|
| 31 December 2017 | 50 bp | 50 bp |
| EUR/1,000 | increase | decrease |
| Variable rate instruments | (18) | 18 |
| Cash and cash equivalents | 687 | (642) |
| **Cash flow sensitivity (net)** | **669** | **(624)** |

Sensitivity analysis – investment in fixed rate financial instruments

The potential loss in fair value of fixed rate financial instruments (investments securities) held as at 31 December 2018, resulting from a hypothetical +25 basis-point estimated shift of the interest rate curve as of 31 December 2018, would have been approximately €222 thousand (2017: €569 thousand). A -25 basis-point estimated shift of the interest rate curve would have had the opposite effect, for the equal amount shown above.

**D. Foreign currency risk**

The Group is subject to a number of foreign currency risks for transactions that are denominated in a currency other than its functional currency and given the global nature of its operations. Since 2016, the Group is subject to increased exposure to fluctuation in exchange rates between US dollar and Euro due to its expansion in operations into U.S. Market. The group has two subsidiaries whose functional currency is US dollar and these are not exposed to foreign currency risk on positions in US dollar.

The Group uses natural hedging to manage its foreign exchange exposures and monitors its foreign currency cash inflows and outflows.

The Group is exposed to currency risk on revenues and costs that are denominated in a currency other than the functional currency of the Group (EUR). The Group at year end have bank deposits, investment in securities (bond), investments in funds, trade receivables or payables denominated in a currency different from the functional currency (EUR). Changes in exchange rates may result in exchange gains or losses arising from these situations.

At the present time no foreign currency hedges are in place but the Group regularly reviews this position.

Sensitivity analysis – foreign currency risk

In relation to 2018 revenue and operating costs a 10% strengthening of the euro against the US dollar as at 31 December 2018 would have resulted in an increased loss of €274 thousand (2017: reduced loss of €309 thousand). A 10% weakening of the euro against the US dollar as at 31 December 2018 and 2017 would have had the opposite effect, for the equal amount shown above. Furthermore in relation to 2018 revenue a 10% strengthening of the euro against the CAD as at 31 December 2018 would have resulted in a reduced loss of €320 thousand. A 10% weakening of the euro against the CAD as at 31 December 2018 would have had the opposite effect, for the equal amount shown above.

In relation to monetary assets and liabilities held in foreign currency at year end a 5% strengthening of the euro against the US dollar as at 31 December 2018 would have resulted in a loss increase of €1,825 thousand (2017: loss increase of €6,089 thousand). A 5% weakening of the euro against the US dollar as at 31 December 2018 and 2017 would have had the opposite effect, for the equal amount shown above.

## 35 Financial risk management objectives and policies continued

### E. Other market price risk

Market price risk exists in relation to equity investments. The Group will from time to time reassess whether it is appropriate to hedge these risks. Generally, however, it will only enter into investments where it thinks that the value will appreciate and will therefore generally not hedge the market risks.

- In March 2016 the Group acquired an equity stake in VolitionRX whose shares are listed on the NYSE MKT and on June 2016 acquired an equity stake in PAION AG whose shares are listed on the Frankfurt Stock Exchange Prime Standard (see note 16, Financial assets).
- This equity ownership in the two companies reflects the Group's confidence in the long-term value of VolitionRX and PAION AG business: the investments are actively monitored and managed on a fair value basis.
- In 2018 the Group began investing in funds consisting of investments in 'Money market', 'Supply chain finance', 'Corporate short duration' and 'Floating rate credit' funds. The portfolio is managed by an investment manager, Credit Suisse, who actively buys and sells instruments within the portfolio to generate short-term profits.

### Sensitivity analysis – other market risk

Assuming that the other variables remained constant, a 10% increase in the share price as at 31 December 2018 of VolitionRX and PAION AG would have increased other comprehensive income and equity by €146 thousand and by €1,147 thousand respectively; an equal change in the opposite direction would have decreased equity by €146 thousand and by €1,147 thousand respectively.

In relation to the investment in funds measured at FVTPL, a 0.5 % increase in the price as at 31 December 2018 would have resulted in a reduced loss of €633 thousand. A 0.5% decrease in the stock price would have had the opposite effect, for the equal amount shown above.

### F. Capital management

The Group's goal is to maintain a strong capital base so as to sustain future development of the business and to maximize long-term shareholder value.

The measures and mechanisms implemented by the Group to manage its exposure to financial risks have been detailed in the note above.

### G. Share capital and share premium

As at 31 December 2018 the authorised share capital amounts to €18,744,677.64 and is divided into 36,047,457 ordinary shares, each with a nominal value of €0.26 and 36,047,457 preferred shares, each with a nominal value of €0.26.

As at 31 December 2018 15,037, 483 ordinary shares (2017: 15,037, 483 ordinary shares) were issued and fully paid.

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Total assets | 625,686 | 497,974 |
| Equity | 444,854 | 470,117 |
| **Equity ratio** | **71.1%** | **94.4%** |

## 36 Fair value measurement

### Qualitative information

The fair value is the price that would be received when selling an asset or paid when transferring a liability in an orderly transaction between market participants (i.e. not as part of the compulsory liquidation or a below-cost sale) as at the measurement date. Fair value is a market measurement criterion, not specifically referring to a single entity. Underlying the definition of fair value is the assumption that the company is carrying out normal operations, without any intention of liquidating its assets, significantly reducing the level of operations or carrying out transactions at unfavourable conditions.

An entity has to measure the fair value of an asset or liability by adopting the assumptions that would be used market participants when pricing an asset or liability, presuming that they act with a view to satisfying their own economic interest in the best way possible.

The fair value of financial instruments is determined according to a hierarchy of criteria based on the origin, type and quality of the information used (IFRS 13). In detail, this hierarchy assigns top priority to quoted prices (unadjusted) in active markets and less importance to unobservable inputs. Three different levels of input are identified:

a. level 1: input represented by quoted prices (unadjusted) in active markets for identical assets or liabilities accessible by the entity as at the measurement date,
b. level 2: input other than quoted prices included in level 1 that are directly or indirectly observable for the assets or liabilities to be measured,
c. level 3: unobservable input for the asset or liability.

A market is regarded as active if quoted prices, representing actual and regularly occurring market transactions considering a normal reference period, are readily and regularly available from an exchange, dealer, broker, industry group, pricing service or regulatory agency.

In specific cases research is carried out in order to verify the significance of official market values.
In the event of a significant reduction in the volume or level of operations compared to normal operations for the asset or liability (or for similar assets or liabilities) highlighted by a number of indicators (number of transactions, limited significance of market prices, significant increase in implicit premiums for liquidity risk, expansion or increase of the bid-ask spread, reduction or total lack of market for new issues, limited publicly-available information), analyses of the transactions or of the quoted prices are carried out: if the conclusion is reached that the market is inactive, the asset or liability is reclassified to level 2 of the fair value hierarchy.

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

This table shows the comparison of fair values versus carrying amounts of financial assets and liabilities, as required by IFRS 7.

| | | As at 31 December 2018 | | As at 31 December 2017 | |
|---|---|---|---|---|---|
| EUR 1,000 | *Classification* | Carrying amount | Fair value | Carrying amount | Fair value |
| **Non-current financial assets** | | | | | |
| Equity instruments – AIMM & other | FVOCI – equity instrument | 2,594 | 2,594 | – | – |
| Equity instruments – Paion shares | FVOCI – equity instrument (2017: FVOCI (AFS)) | 11,472 | 11,472 | 14,195 | 14,195 |
| Equity instruments – Volitionrx shares | FVOCI – equity instrument (2017: FVOCI (AFS)) | 1,459 | 1,459 | 2,263 | 2,263 |
| Debt securities | FVOCI – debt instrument (2017: FVOCI (AFS)) | 26,330 | 26,330 | 74,459 | 74,459 |
| **Current financial assets** | | | | | |
| Debt securities | FVOCI – debt instrument (2017: FVOCI (AFS)) | 12,055 | 12,055 | 12,388 | 12,388 |
| Investment in funds | Mandatorily at FVTPL (2017: FVOCI (AFS)) | 126,692 | 126,692 | 15,371 | 15,371 |
| **Total Assets** | | **180,602** | **180,602** | **118,676** | **118,676** |
| Contingent consideration | Mandatorily at FVTPL | (615) | (615) | – | – |
| **Total liabilities** | | **(615)** | **(615)** | – | – |

## 36 Fair value measurement continued

### Financial assets and liabilities that are measured at fair value on a recurring basis continued

The following table shows the fair-value hierarchy for financial assets that are measured at fair value on a recurring basis at 31 December 2018 and 2017:

| | As at 31 December 2018 | | | | As at 31 December 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| EUR 1,000 | Level 1 | Level 2 | Level 3 | Total | Level 1 | Level 2 | Level 3 | Total |
| **Non-current financial assets** | | | | | | | | |
| Equity instruments – AIMM & other | – | – | 2,594 | 2,594 | – | – | – | – |
| Equity instruments – Paion shares | 11,472 | – | – | 11,472 | 14,195 | – | – | 14,195 |
| Equity instruments – Volitionrx shares | 1,459 | – | – | 1,459 | 2,263 | – | – | 2,263 |
| Debt securities | 26,330 | – | – | 26,330 | 62,798 | 11,661 | – | 74,459 |
| **Current financial assets** | | | | | | | | |
| Debt securities | 12,056 | – | – | 12,056 | 8,783 | 3,605 | – | 12,388 |
| Investment in funds | 126,691 | – | – | 126,691 | 15,371 | – | – | 15,371 |
| **Total Assets** | **178,008** | **–** | **2,594** | **180,602** | **103,410** | **15,266** | **–** | **118,676** |
| | | | | | | | | |
| Contingent consideration | – | – | (615) | (615) | – | – | – | – |
| **Total liabilities** | **–** | **–** | **(615)** | **(615)** | **–** | **–** | **–** | **–** |

The following are considered as level 1 financial instruments:

- shares valued using official closing prices and/or fixing provided by regulated stock exchanges,
- bonds and investments in funds valued using official closing prices and/or fixing provided by local authorities (central bank, monetary authority or local stock exchange),
- bonds and investments in funds quoted on Multilateral Trading Facility (i.e. the EuroTLX or NASD TRACE circuit) or for which it is possible to continuously derive the quotation from the main price contribution international platforms.

When no quotation on an active market exists or the market is not functioning regularly, that is, when the market does not have a sufficient and continuous number of trades, and bid-ask spreads and volatilities that are not sufficiently contained, the fair value of the financial instruments is mainly determined through the use of valuation techniques whose objective is the establishment of the price at which, in an orderly transaction, the asset could be sold or the liability transferred between market participants, as at the measurement date, under current market conditions.

In the case of level 2 inputs, the valuation is based on prices taken from official listings of instruments which are similar in terms of risk profile.

In particular, the level 2 valuation measurements reproduce prices of financial instruments not quoted on active markets and do not contain discretional parameters for which values may not be inferred from quotations of financial instruments present on active markets or fixed at levels capable of reproducing quotations on active markets.
The level 2, as at 31 December 2017, primarily includes bond and investments in bond funds without official quotations expressed by an active market and for which the Net Asset Value (NAV) provided by the Fund Administrator is considered as the fund's fair value. This value may be analysed based on the financial instruments underlying the bond funds with the purpose to assign the fair value hierarchy level resulting from an individual valuation process aimed at verifying specific risks (counterparty risk, illiquidity risk).

In addition to this, the Group, with the external asset manager, periodically makes an assessment regarding the marketability of each investment security to confirm the assigned level and the fair value measurement. The assessment distinguishes three different categories:

i. Investments that can be sold within one day without an expected meaningful impact on price
ii. Investments that can be sold within one day with an expected price impact of approximately 0.25%
iii. Illiquid investments, which require more than one day to be liquidated

In case the investment is included in iii., it's fair value is reclassified to level 2 of the fair value hierarchy.
In 2018 there were no transfers between Levels 1 and 2 in the fair value hierarchy, and the changes were due disposals of debt instruments during the period.

The level 3 consist of the following:

- equity investments for which there is no quoted market price in an active market. The fair value has been fair valued using a value in use approach (DCF) model and did not indicate any material change in the carry value of the investment. This valuation model considers the present value of expected future cashflows, discounted using a risk-adjusted discount rate.
- contingent consideration in relation to the acquisition of Linkverse. The full amount of the contingent consideration has been recognised as the outcome of the contingent event (NDA approval for a specific product) is reasonably certain. The result of the NDA application will be announced in the third quarter of 2019.

The only movement in level 3 during 2018 was the contingent consideration assumed on the acquisition of Linkverse. Equity instruments – AIMM & other were not measured at fair value on a recurring basis in the prior year.

## 36 Fair value measurement

### Financial assets and liabilities not measured at fair value on recurring basis

This table shows the comparison of fair values versus carrying amounts of financial assets and liabilities, as required by IFRS 7.

| | | As at 31 December 2018 | | As at 31 December 2017 | |
|---|---|---|---|---|---|
| EUR 1,000 | *Classification* | Carrying amount | Fair value | Carrying amount | Fair value |
| Non-current financial assets | 2017: Cost (AFS) | – | – | 2,894 | 2,894 |
| Other non-current receivables (*) | Amortised cost (2017: Loans and receivables) | 173 | 173 | 173 | 173 |
| Trade receivables | Amortised cost (2017: Loans and receivables) | 12,762 | 12,762 | 13,190 | 13,190 |
| Other receivables and other assets(*) | Amortised cost (2017: Loans and receivables) | 164 | 164 | 56 | 56 |
| Cash and cash equivalents | Amortised cost (2017: Loans and receivables) | 210,689 | 210,689 | 144,944 | 144,944 |
| **Total Assets** | | **223,788** | **223,788** | **161,257** | **161,257** |
| Financial lease liabilities | Amortised cost | (2,617) | (2,617) | (3,022) | (3,022) |
| Subsidised loans | Amortised cost | (1,211) | (1,274) | (1,454) | (1,537) |
| Trade payables | Amortised cost | (8,806) | (8,806) | (11,328) | (11,328) |
| Convertible bond – liability component | Amortised cost | (154,322) | (154,322) | – | – |
| Other current liabilities(*) | Amortised cost | (359) | (359) | (266) | (266) |
| **Total Liabilities** | | **(167,315)** | **(167,378)** | **(16,070)** | **(16,153)** |
| Unrecognised (loss) gain | | | (63) | | (83) |

(*) only financial assets/liabilities

Non-current financial assets in the prior year which included shareholdings in AIMM and other investments previously maintained at initial recognised cost, considered representative of its fair value are now measured at fair value on a recurring basis.

For financial instruments represented by Trade receivables, Other receivables and other assets, Trade payables and Other current liabilities, for which the present value of future cash flows is also taking into account the credit risk of the counterparties, does not differ significantly from carrying value, we assume that the carrying value is a reasonable approximation of the fair value.

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

For Financial lease liabilities, Unsecured bank loans and Convertible bond, included at level 2, the carrying amount approximates the fair value calculated based on the present value of future principal and interest cash flows, discounted at the interest market rate at the reporting date.

Subsidised loans are included in Level 2 of the fair-value hierarchy and has been estimated with discounted cash flows models. The main inputs used are year-end market interest rates.

## 37 Subsequent events

Cosmo announced during 2018 that it was in the process of filing a new appeal to the Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER) in relation to the New Drug Application (NDA) seeking marketing approval for Methylene Blue MMX. Meetings took place with the US Food and Drug Administration (FDA) on 18 January 2019 and on 12 March 2019 following which Cosmo announced that the FDA had denied the last appeal. Cosmo has decided to not pursue further appeals and intends to present a new clinical plan with different endpoints. Upon agreement with the FDA on a new trial design, Cosmo intends to immediately start a confirmatory phase III trial for the product.

In February 2019 the Group filed a Marketing Authorization Application for Methylene Blue MMX 200mg tablets with the European Medicines Agency.

In January 2019 the Group agreed a restructuring plan to significantly reduce the cost base of its U.S. operation. This decision was taken due to the delays encountered with the approval of Methylene Blue MMX with the FDA. Restructuring costs to be incurred in 2019 are expected to be approximately €3.5 million. Management estimate a year-on-year cost saving of approximately €18.5 million following the restructure giving a net saving of €15 million in 2019 compared to 2018.

On 6 March 2019, Cosmo acquired the remaining 40% of Linkverse S.r.l. bringing the Groups total shareholding to 100%.

# COMPANY FINANCIAL STATEMENTS

## Company income statement

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 |
|---|---|---|---|
| **Revenue** | 6 | **9,275** | **9,668** |
| Other income | | 18 | 19 |
| Personnel expenses | 7 | (8,326) | (8,115) |
| Other operating expenses | 8 | (3,675) | (4,367) |
| Depreciation and amortisation | | (35) | (25) |
| Dividends and other income from investments | 9 | 7,898 | 10,333 |
| **Operating profit** | | **5,155** | **7,513** |
| Financial income | | 7,627 | 2,948 |
| Financial expenses | | (3,067) | (15,863) |
| **Net financial income/(expense)** | 10 | **4,560** | **(12,915)** |
| **Profit/(loss)/before taxes** | | **9,715** | **(5,402)** |
| Income tax expenses | 11 | 207 | 1,836 |
| **Profit/(loss) for the period** | | **9,922** | **(3,566)** |

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

## Company statement of other comprehensive income

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 |
|---|---|---|---|
| **Profit/(loss) for the period (A)** | | **9,922** | **(3,566)** |
| **Other comprehensive income** | | | |
| ***Items that may be reclassified subsequently to profit or loss*** | | | |
| Losses on debt securities measured at FVOCI | | (799) | – |
| Losses on disposal of debt securities measured at FVOCI reclassified to profit or loss | | 899 | – |
| Losses on fair value of available for sale financial assets | | – | (393) |
| Losses on disposal of available for sale financial assets reclassified to profit or loss | | – | 262 |
| Exchange differences on translating foreign operations | | 113 | (80) |
| Income tax | 11 | (33) | 43 |
| **Total items that may be reclassified subsequently to profit or loss** | | **180** | **(168)** |
| **Total other comprehensive income/(loss), net of tax (B)** | | **180** | **(168)** |
| **Total comprehensive income (A)+(B)** | | **10,102** | **(3,734)** |

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

## Company statement of financial position

| EUR 1,000 | Notes | As at 31 December 2018 | 2017 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Property, plant and equipment | 12 | 188 | 182 |
| Investments | 13 | 47,676 | 46,157 |
| Financial assets | 14 | 17,372 | 62,565 |
| Deferred tax assets | 15 | 1,404 | 1,338 |
| Other non-current receivables | 16 | 83,312 | 43,290 |
| **Total non-current assets** | | **149,952** | **153,532** |
| **Current assets** | | | |
| Current tax assets | | 48 | 48 |
| Other receivables and other assets | 17 | 2,461 | 2,846 |
| Current financial assets | 14 | 113,356 | 26,734 |
| Cash and cash equivalents | 18 | 168,662 | 89,807 |
| **Total current assets** | | **284,527** | **119,435** |
| ***TOTAL ASSETS*** | | **434,479** | **272,967** |

| EUR 1,000 | Notes | As at 31 December 2018 | 2017 |
|---|---|---|---|
| **EQUITY** | | | |
| Share capital | | 3,910 | 3,910 |
| Share premium | | 84,448 | 84,448 |
| Other reserves | | 181,239 | 185,990 |
| Retained earnings | | 6,827 | (3,566) |
| **Equity attributable to owners of the company** | | **276,424** | **270,782** |
| **TOTAL EQUITY** | 19 | **276,424** | **270,782** |
| **LIABILITIES** | | | |
| **Non-current liabilities** | | | |
| Interest-bearing loans and borrowings | 20 | 154,322 | – |
| Deferred tax liabilities | 21 | 2,632 | 171 |
| **Total non-current liabilities** | | **156,954** | **171** |
| **Current liabilities** | | | |
| Trade payables | 22 | 877 | 427 |
| Current tax and other tax liabilities | 23 | 132 | 1,102 |
| Other current liabilities | 24 | 92 | 485 |
| **Total current liabilities** | | **1,101** | **2,014** |
| ***TOTAL LIABILITIES*** | | **158,055** | **2,185** |
| **TOTAL EQUITY AND LIABILITIES** | | **434,479** | **272,967** |

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

## Company cash flow statement

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 (restated note 5) |
|---|---|---|---|
| **Profit/(loss) for the period before tax** | | **9,715** | **(5,402)** |
| Adjustments for: | | | |
| Depreciation and amortisation | 12 | 35 | 25 |
| Share payment based expenses | 7, 8 | 5,363 | 5,067 |
| Interest income recognised in profit or loss | | (1,159) | (2,438) |
| Loss on financial investments | | 1,537 | 452 |
| Dividend reclassification | 9 | (7,898) | (10,333) |
| Net unrealised foreign exchange differences | | (4,753) | 14,203 |
| **Operating cash inflow before changes in working capital** | | **2,840** | **1,574** |
| | | | |
| Change in trade payables | | 450 | 178 |
| Change in other receivables and other assets | | 322 | 2,390 |
| Change in other current liabilities | | (393) | (5,967) |
| Change in other tax liabilities | | 2 | (58) |
| **Cash flows from operating activities** | | **3,221** | **(1,883)** |
| Income taxes paid/(net) | | (1,061) | (758) |
| **Net cash from operating activities** | | **2,160** | **(2,641)** |
| | | | |
| Investments in property, plant and equipment | 12 | (41) | (86) |
| Amounts advanced to subsidiaries | | (42,735) | (31,296) |
| Repayments by subsidiaries | | 5,300 | 800 |
| Investments in financial assets | | (143,417) | (55,171) |
| Disposal of financial assets | | 100,186 | 42,121 |
| Dividend received | 9 | 7,898 | 11,380 |
| Interest received | | 2,345 | 2,716 |
| **Cash flows from investing activities** | | **(70,464)** | **(29,536)** |

| EUR 1,000 | Notes | Year ended 31 December 2018 | 2017 (restated note 5) |
|---|---|---|---|
| Purchase of treasury share | | – | 47,290 |
| Sale of treasury share | 19 | (18,353) | – |
| Capital increase/Stock option exercise | | – | 48,963 |
| Dividends paid | | – | (22,556) |
| Issue of convertible bond | 20 | 166,250 | – |
| Transaction costs related to loans and borrowings | 20 | (2,841) | – |
| **Cash flows from financing activities** | | **145,056** | **73,697** |
| | | | |
| **Net increase in cash and cash equivalents** | | **76,752** | **41,520** |
| **Cash and cash equivalents at the beginning of the period** | | **89,807** | **57,820** |
| Net foreign exchange differences | | 2,103 | (9,533) |
| **Cash and cash equivalents at the end of the period** | | **168,662** | **89,807** |
| | | | |
| Cash at hand | 18 | 8 | 5 |
| Bank accounts | 18 | 168,654 | 89,802 |
| **Total cash and cash equivalents at the end of the period** | | **168,662** | **89,807** |

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

## Company statement of changes in equity

| EUR 1,000 | Number of shares (n) | Share capital | Share premium | Other reserves | Treasury shares | Stock option plan reserve | Fair value reserve | Equity component of convertible bond | Currency translation reserve | Retained earnings | Total Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Net equity as at 1 January 2017** | **14,418,983** | **3,749** | **–** | **192,097** | **(28,073)** | **15,745** | **51** | **—** | **186** | **10,577** | **194,332** |
| Total comprehensive income for the period | | | | | | | | | | | |
| Loss for the period | | | | | | | | | | (3,566) | (3,566) |
| Other comprehensive income for the period | | | | | | | (88) | | (80) | | (168) |
| **Total comprehensive income for the period** | | **–** | **–** | **–** | **–** | **–** | **(88)** | **–** | **(80)** | **(3,566)** | **(3,734)** |
| Transactions with owners of the company | | | | | | | | | | | |
| Dividends payment | | | | (11,979) | | | | | | (10,577) | (22,556) |
| Capital increase/stock option exercise | 618,500 | 161 | 65,231 | | | (16,429) | | | | | 48,963 |
| Personnel cost for stock options | | | | | | 6,487 | | | | | 6,487 |
| Sale of treasury shares | | | 19,217 | | 28,073 | | | | | | 47,290 |
| **Total transactions with owners of the Company** | | **161** | **84,448** | **(11,979)** | **28,073** | **(9,942)** | **–** | **–** | **–** | **(10,577)** | **80,184** |
| **Net equity as at 31 December 2017** | **15,037,483** | **3,910** | **84,448** | **180,118** | **–** | **5,803** | **(37)** | **–** | **106** | **(3,566)** | **270,782** |

| EUR 1,000 | Number of shares (n) | Share capital | Share premium | Other reserves | Treasury shares | Stock option plan reserve | Fair value reserve | Equity component of convertible bond | Currency translation reserve | Retained earnings | Total Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Net equity as at 31 December 2017** | **15,037,483** | **3,910** | **84,448** | **180,118** | **–** | **5,803** | **(37)** | **–** | **106** | **(3,566)** | **270,782** |
| **Impact of the adoption of IFRS 9** | | | | | | | (471) | | | 471 | **–** |
| **Net equity as at 1 January 2018** | **15,037,483** | **3,910** | **84,448** | **180,118** | **–** | **5,803** | **(508)** | **–** | **106** | **(3,095)** | **270,782** |
| Total comprehensive income for the period | | | | | | | | | | | |
| Profit for the period | | | | | | | | | | 9,922 | 9,922 |
| Other comprehensive income for the period | | | | | | | 67 | | 113 | | 180 |
| **Total comprehensive income for the period** | | **–** | **–** | **–** | **–** | **–** | **67** | **–** | **113** | **9,922** | **10,102** |
| Transactions with owners of the company | | | | | | | | | | | |
| Personnel cost for stock options | | | | | | 6,882 | | | | | 6,882 |
| Purchase of treasury shares | | | | | (18,353) | | | | | | (18,353) |
| Issue of convertible bond | | | | | | | | 7,011 | | | 7,011 |
| **Total transactions with owners of the Company** | | **–** | **–** | **–** | **(18,353)** | **6,882** | **–** | **7,011** | **–** | **–** | **(4,460)** |
| **Net equity as at 31 December 2018** | **15,037,483** | **3,910** | **84,448** | **180,118** | **(18,353)** | **12,685** | **(441)** | **7,011** | **219** | **6,827** | **276,424** |

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

## 1 General information

Cosmo Pharmaceuticals N.V. with its subsidiaries and associates, ('Cosmo' or 'Cosmo Pharmaceuticals' or 'Company' or 'Group') is a specialty pharmaceutical company registered in the Netherlands and with its seat of management at Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland, and listed on the SIX Swiss Exchange (SIX: COPN), the Company has a Swiss branch located in Lugano, Switzerland.

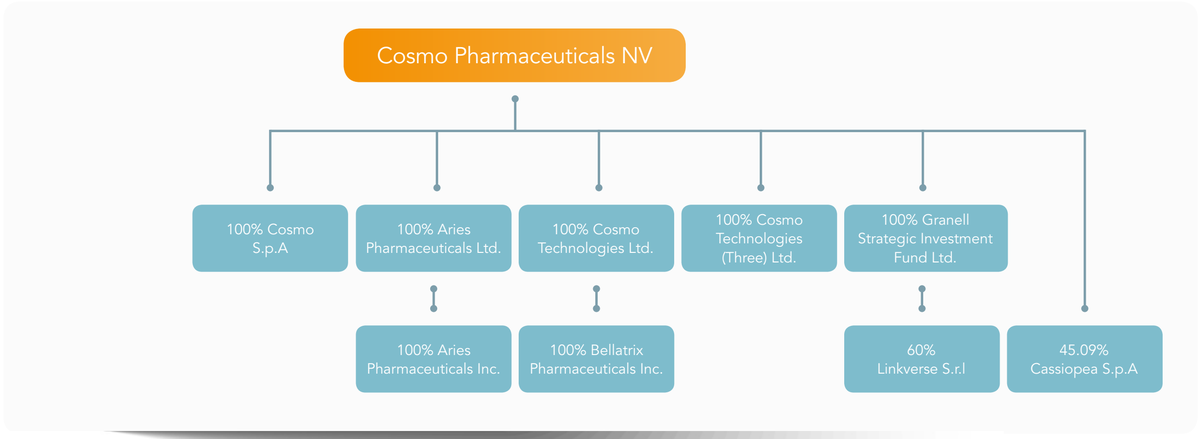
The Company is registered at the Dutch trade register under number 65617738.

Cosmo is a pharmaceutical company with a specialised focus on gastroenterology and endoscopy. We develop and manufacture products which are distributed globally. Our mission is to improve people's lives by developing innovative treatments that address unmet clinical needs and improve clinical outcomes.

Since 12 March 2007, Cosmo Pharmaceuticals' shares have been publicly listed on the Swiss Stock Exchange (SIX: COPN). The Company's stock market capitalisation as at 31 December 2018 was equal to CHF 1,321,794,756, EUR 1,172,947,694.

Cosmo Pharmaceuticals N.V. (the 'Company', 'Cosmo'), is the parent company of Cosmo Pharmaceuticals Group and it holds direct and indirect interests in the Group's principal operating companies.

### Group Structure as of 31 December 2018:




During 2018, Cristoforo Colombo Real Estate S.r.l. merged with Cosmo S.p.A. and a controlling interest in Linkverse S.r.l. was acquired. Cassiopea S.p.A. is an associate – refer to note 13 Investments.

## 2 Basis of preparation

### Authorisation of Company Financial Statements and compliance with International Financial Reporting Standards

The 2018 Statutory Financial Statements are the separate financial statements for Cosmo Pharmaceuticals N.V. The Financial Statements, together with notes thereto of Cosmo Pharmaceuticals N.V., at 31 December 2018 were authorised for issuance by the Board of Directors on 28 March 2019 and have been prepared in accordance with the International Financial Reporting Standards (IFRS) as adopted by the European Union (EU-IFRS) and part 9 of Book 2 of the Dutch Civil Code. The designation 'IFRS' also includes International Accounting Standards (IAS) as well as all interpretations of the IFRS Interpretations Committee (IFRIC).

### Basis of Preparation

As parent company for Cosmo Group, Cosmo Pharmaceuticals N.V. has also prepared consolidated financial statements for the year ended 31 December 2018. The financial statements are prepared under the historical cost convention (modified where applicable for the valuation of certain financial instruments), as well as on the going concern assumption. Cosmo Group's assessment is that no material uncertainty exists as to its ability to continue as a going concern.

Cosmo's financial statements and notes are prepared and presented in thousands of euro, except where otherwise stated, rounding the amounts to the nearest thousand.

In consideration of the activities carried out by Cosmo Pharmaceuticals N.V., presentation of the Statutory Income Statement is based on the function of revenues and expenses as it is considered more representative of the format used for internal reporting and management purposes and is in line with international practice in the pharmaceutical sector. The statement of financial position has been prepared presenting asset and liabilities as current and non-current; the statements of cash flows present cash flows from operating activities using the indirect method and the statement of changes in equity includes all the changes in equity.

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

## 3 Changes in accounting policies

### New standards, interpretations and amendments effective from 1 January 2018

The Company has initially applied IFRS 9 from 1 January 2018. A number of other new standards are also effective from 1 January 2018 but they do not have a material effect on the Company's financial statements.

**A. IFRS 9 Financial Instruments**

IFRS 9 sets out requirements for recognising and measuring financial assets, financial liabilities and some contracts to buy or sell non-financial items. This standard replaces IAS 39 Financial Instruments: Recognition and Measurement.

In particular, it amends the previous guidance in two main areas;

- The classification and measurement of financial assets, which is driven by cash flow characteristics and the business model in which an asset is held;
- The accounting for impairment of financial assets through the introduction of an 'expected credit loss' impairment model, replacing the incurred loss method under IAS 39.

In accordance with the transitional provisions in IFRS 9, the Company did not restate prior periods. Comparative figures have not been restated for the classification and measurement provisions of the standard, including impairment, and continue to be reported under the accounting standards in effect for periods prior to 1 January 2018. The impact of adoption on our Company Financial Statements was not material.

The following table summarises the impact, net of tax, of transition to IFRS 9 on the opening balance of reserves and retained earnings.

EUR 1,000

| | |
|---|---|
| **Fair value reserve** | |
| Recognition of expected credit losses under IFRS 9 for debt securities measured at FVOCI | 44 |
| Reclassification of unrealised gain on investment in funds measured at FVTPL | (746) |
| Related tax | 231 |
| **Restated at 31 December 2017** | **(471)** |
| **Retained earnings** | |
| Recognition of expected credit losses under IFRS 9 for debt securities measured at FVOCI | (44) |
| Reclassification of unrealised gain on investment in funds measured at FVTPL | 746 |
| Related tax | (231) |
| **Restated at 31 December 2017** | **471** |

### Financial assets and liabilities

Financial assets primarily include trade and other receivables, cash and cash equivalents, investments in funds and debt securities that represent temporary investments of available funds and do not satisfy the requirements for being classified as cash equivalents. Financial liabilities primarily consist of debt, trade payables and other liabilities. The classification of financial liabilities under IFRS 9 is unchanged compared with the previous accounting requirements under IAS 39.

The details of new significant accounting policies and the nature and effect of the changes to previous accounting policies are set out below.

#### i Classification and measurement of financial assets and financial liabilities

IFRS 9 largely retains the existing requirements in IAS 39 for the classification and measurement of financial liabilities. However, it eliminates the previous IAS 39 categories for financial assets of held to maturity, loans and receivables and available for sale. IFRS 9 contains three principal classification categories for financial assets: measured at amortised cost, FVOCI and FVTPL. The classification of financial assets under IFRS 9 is generally based on the business model in which a financial asset is managed and its contractual cash flow characteristics.

The adoption of IFRS 9 has not had a significant effect on the Company's accounting policies related to financial liabilities.

For an explanation of how the Group classifies and measures financial instruments and accounts for related gains and losses under IFRS 9, see Consolidated Financial Statements, Accounting policies note 3(F)(ii).

The following table and the accompanying notes below explain the original measurement categories under IAS 39 and the new measurement categories under IFRS 9 for each class of the Company's financial assets and financial liabilities as at 1 January 2018.

## 3 Changes in accounting policies continued

### New standards, interpretations and amendments effective from 1 January 2018 continued

#### A. IFRS 9 Financial Instruments continued

| Financial statement line item | Note | Original classification under IAS 39 | Original carrying amount under IAS 39 | New carrying amount under IFRS 9 | New classification under IFRS 9 | Financial statement line item |
|---|---|---|---|---|---|---|
| **Non-current financial assets** | | | | | | |
| Other financial assets available for sale – investment securities | (a) | FVOCI (AFS) | 62,565 | 62,565 | FVOCI – debt instrument | Debt securities measured at FVOCI |
| Other non-current receivables | (b) | Loans and receivables | 43,290 | 43,290 | Amortised cost | Other non-current receivables |
| **Current financial assets** | | | | | | |
| Other financial assets available for sale – investment securities | (a) | FVOCI (AFS) | 26,734 | 11,363 | FVOCI – debt instrument | Debt securities measured at FVOCI |
| | (c) | | | 15,371 | Mandatorily at FVTPL | Investment in funds measured at FVTPL |
| Other receivables and other assets | (b) | Loans and receivables | 2,504 | 2,504 | Amortised cost | Other receivables and other assets |
| Cash and cash equivalents | (d) | Loans and receivables | 89,807 | 89,807 | Amortised cost | Cash and cash equivalents |
| **Total financial assets** | | | **224,900** | **224,900** | | |

**(a)** The corporate debt securities categorized as available-for-sale under IAS 39 are held by Group treasury in a separate portfolio to provide interest income, but may be sold to meet liquidity requirements arising in the normal course of business. The Company considers that these securities are held within a business model whose objective is achieved both by collecting contractual cash flows and by selling securities. The corporate debt securities mature in one to five years and the contractual terms of these financial assets give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding. These assets have therefore been classified as financial assets at FVOCI under IFRS 9.

**(b)** Other receivables and other assets and other non-current receivables that were classified as loans and receivables under IAS 39 are now classified at amortised cost.

**(c)** Investments in funds were categorized as available-for-sale under IAS 39. The portfolio is managed by an investment manager, who actively buys and sells instruments within the portfolio to generate short-term profits. These assets have been classified as financial assets at FVTPL under IFRS 9.

**(d)** Cash and cash equivalents include cash at banks and short-term deposits that are readily convertible into cash with original maturities of six months or less at the date of purchase. Cash and cash equivalents are subject to an insignificant risk of changes in value and consist of balances across various financial institutions. Cash at banks and other cash equivalents are measured at amortised cost.

**3 Changes in accounting policies** continued

**New standards, interpretations and amendments effective from 1 January 2018** continued

**A. IFRS 9 Financial Instruments** continued

ii Impairment of financial assets

**Impact of the new impairment model**

The Company has determined that the application of IFRS 9's impairment requirements at 1 January 2018 results in an additional impairment allowance as follows:

| EUR 1,000 | |
|---|---|
| **Loss allowance at 31 December 2017 under IAS 39** | **–** |
| **Additional impairment recognised at 1 January 2018 on:** | |
| Debt securities measured at FVOCI | 44 |
| **Loss allowance at 1 January 2018 under IFRS 9** | **44** |

The debt securities at FVOCI held by the Company are considered to have low credit risk, and the loss allowance recognised during the period was therefore limited to 12 months expected losses. The credit risk on debt securities at FVOCI has not increased significantly since initial recognition. Management consider 'low credit risk' for listed bonds to be an investment grade credit rating with at least one major rating agency.

**Standards, amendments and interpretations issued but not yet effective**

A number of new standards are effective for annual periods beginning after 1 January 2019 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these Company financial statements.

Of those standards that are not yet effective, IFRS 16 is expected to have a material impact on the Company's financial statements in the period of initial application.

**B. IFRS 16 Leases**

The Company is required to adopt IFRS 16 Leases from 1 January 2019. The Company has assessed the estimated impact that initial application of IFRS 16 will have on its financial statements, as described below. The actual impacts of adopting the standard on 1 January 2019 may change because the new accounting policies are subject to change until the Company presents its first financial statements that include the date of initial application.

IFRS 16 introduces a single, on-balance sheet lease accounting model for lessees. A lessee recognises a right-of-use asset representing its right to use the underlying asset and a lease liability representing its obligation to make lease payments. There are recognition exemptions for short-term leases and leases of low-value items. Lessor accounting remains similar to the current standard, i.e. lessors continue to classify leases as finance or operating leases.

IFRS 16 replaces existing leases guidance, including IAS 17 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases – Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease.

The Company will recognise new assets and liabilities for its operating leases of office buildings and company cars. The nature of expenses related to those leases will now change because the Company will recognise a depreciation charge for right-of-use assets and interest expense on lease liabilities. Previously, the Company recognised operating lease expense on a straight-line basis over the term of the lease, and recognised assets and liabilities only to the extent that there was a timing difference between actual lease payments and the expense recognised.

Based on the information currently available, the Group estimates that it will recognise additional lease liabilities of €1,826 thousand and a right-of-use asset of the same amount as at 1 January 2019.

**C. Other standards**

The following amended standards and interpretations are not expected to have a significant impact on the Company's consolidated financial statements.

- IFRIC 23 Uncertainty over Tax Treatments.
- Prepayment Features with Negative Compensation (Amendments to IFRS 9).
- Long-term Interests in Associates and Joint Ventures (Amendments to IAS 28).
- Plan Amendment, Curtailment or Settlement (Amendments to IAS 19).
- Annual Improvements to IFRS Standards 2015–2017 Cycle – various standards.
- Amendments to References to Conceptual Framework in IFRS Standards.
- IFRS 17 Insurance Contracts.

## 4 Accounting policies

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

### A. Property, plant and equipment

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

Subsequent expenditures are capitalised only if they increase the future economic benefits embodied in the related item of property, plant and equipment. All other expenditures are expensed as incurred.

Depreciation is recognised 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.

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 tangible assets – office equipment – furniture | 8 years |

### B. Investments

Investments in subsidiaries and associates are recognised at cost and adjusted for any impairment losses. Any positive difference, arising on acquisition, between the purchase cost and fair value of net assets acquired in an investee company is included in the carrying amount of the investment.

Investments in subsidiaries and associates are reviewed for impairment indicators. If impairment indicators exist an impairment test is carried out. Where an impairment loss exists, it is recognised immediately through the income statement. If an impairment loss is subsequently reversed, the increase in carrying amount (up to a maximum of purchase cost) is recognised through the income statement.

### C. Financial instruments

The Company has initially applied IFRS 9 from 1 January 2018. Information about accounting policies relating to Financial instruments is provided in the Consolidated Financial Statements, note 4(F) Accounting policies.

### D. Foreign currency transactions

Transactions in foreign currency are translated into Euro using the exchange rate on the transaction date. Monetary assets and liabilities denominated in foreign currencies at the balance sheet date are translated into Euro at the foreign exchange rate at that date. Foreign exchange differences arising on translation are recognised 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 at the date the fair value was determined.

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

### E. Cash and cash equivalents

Cash and cash equivalents comprises cash balances and call deposits. Bank overdrafts that are repayable on demand and form an integral part of the Company's cash management are included as a component of cash and cash equivalents for the purpose of the statement of cash flows.

### F. Employee benefits

**i Defined contribution pension plans**

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

**ii 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 recognises 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.

**4 Accounting policies** continued

The compensation component from stock option plans based on Cosmo Pharmaceuticals N.V. shares relating to employees of other Group companies is recognised as a capital contribution to the subsidiaries which employ the beneficiaries of the stock option plans, in accordance with IFRS 2 and, as a result, is recorded as an increase in the carrying amount of the investment, with a balancing entry recognised directly in equity.

### G. Treasury shares

Treasury shares are presented as a deduction from equity. The purchase cost of treasury shares and the sales proceeds of any subsequent sale are presented as movements in equity.

### H. Dividends received

Dividends from investees are recognised in the income statement when the right to receive the dividend is established.

### I. Revenue

**Policy applicable from 1 January 2018**

Performance obligations are satisfied when the services are performed. Invoices are generated and revenue is recognised at that point in time. Invoices are usually payable within 30 days.

**Policy applicable before 1 January 2018**

Revenue is recognised when it is probable that economic benefits associated with a transaction will flow to the Company and the amount can be reliably measured. Revenue is presented net of any adjusting items.

### J. Income tax

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

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 recognised to the extent that it is probable that future taxable profit will be available against which they can be utilised.

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.

### K. Dividend distribution

Dividend distribution to the company's shareholders is recognised as change in equity in the period in which the dividends are approved by the Company's shareholders.

### L. Critical accounting estimates, assumptions and judgments

The statutory financial statements are prepared in accordance with IFRS, which require the use of judgments, estimates and assumptions that affect the carrying amount of assets and liabilities, the disclosure of contingent assets and liabilities and income and expense for the period.

These 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. However, as they are estimates, actual future results could differ from those included in the financial statements. Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised 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 consolidated financial statements, are listed below. Information about accounting policies relating to Critical accounting estimates, assumptions and judgments is provided in the Consolidated Financial Statements, note 4(S) Accounting policies.

i Impairment of non-financial assets
ii Impairment of financial assets
iii Deferred tax assets
iv Business model assessment
v Significant increase in credit risk
vii Calculation of loss allowance
viii Fair value measurement
- Share-based compensation expenses

## 5 Restatement of Company cash flow statement

The 2017 Company cash flow statement comparative, published in 'Annual Report 2017', has been restated as follows:

| | Year ended 31 December 2017 | | |
|---|---|---|---|
| EUR 1,000 | Previously reported | Adjustment Reclassification | Restated amount |
| Loss on financial investments | – | 452 | **452** |
| **Operating cash inflow before changes in working capital** | **1,122** | **452** | **1,574** |
| Change in trade payables | 98 | 80 | 178 |
| **Net cash from operating activities** | **(3,173)** | **532** | **(2,641)** |
| Disposal of financial assets | 42,573 | (452) | 42,121 |
| **Cash flows from investing activities** | **(29,084)** | **(452)** | **(29,536)** |
| **Net increase/(decrease) in cash and cash equivalents** | **41,440** | **80** | **41,520** |
| **Cash and cash equivalents at the beginning of the year** | **57,820** | **–** | **57,820** |
| Net foreign exchange differences | (9,453) | (80) | (9,533) |
| **Cash and cash equivalents at the end of the year** | **89,807** | **–** | **89,807** |

The above restatement relates to reclassifications between line items. The restated presentation is viewed as providing more relevant and understandable information to the users of these Company Financial Statements.

## 6 Revenue

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Revenue from services rendered to group companies | 9,275 | 9,668 |
| **Total revenue** | **9,275** | **9,668** |

Revenues relates to services rendered by Cosmo Pharmaceuticals N.V. to the principal companies in the Group.

## 7 Personnel expenses

| | Year ended 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Salaries and wages | 3,034 | 3,105 |
| Social security contributions | 414 | 403 |
| Stock options | 4,859 | 4,593 |
| Other costs | 19 | 14 |
| **Total personnel expenses** | **8,326** | **8,115** |

In 2018 the expense for the value of employees' and Directors' services exchanged for stock options amounted to €4,859 thousand (2017: €4,593 thousand) and it refers to the cost in relation to the options granted by the Board of Directors (see Consolidated Financial Statement, note 31 Share-based payment).

The average numbers of staff for the year ended 31 December 2018 was as follows:

| | Year ended 31 December | |
|---|---|---|
| No. of people | 2018 | 2017 |
| Managers | 10.0 | 9.0 |
| Junior managers | 3.0 | 3.5 |
| Employees | 10.0 | 8.5 |
| **Total average number** | **23.0** | **21.0** |

The number of staff as at 31 December 2018 by category was as follows:

| | Year ended 31 December | |
|---|---|---|
| No. of people | 2018 | 2017 |
| Managers | 10 | 10 |
| Junior managers | 3 | 3 |
| Employees | 11 | 9 |
| **Total number** | **24** | **22** |

Staff numbers increased to 24 as at 31 December 2018. The number of staff employed outside the Netherlands was 24 (2017: 22).

## 8 Other operating expenses

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Service costs | 2,966 | 3,542 |
| Operating lease expenses | 554 | 654 |
| Other operating costs | 155 | 171 |
| **Total other operating expenses** | **3,675** | **4,367** |

### i Service Costs

Service costs primarily consists of support and consulting services in the administrative, financial and legal fees, as well as IT systems, investor relations and travel costs. Service costs includes €505 thousand (2017: €474 thousand) for the Stock option plan (SOP) for options granted to non-executive directors.

### ii Operating lease expenses

Operating lease expenses includes rent associated with the lease of the office in Lugano and Dublin. Other rentals include the rent of the telephone exchange system, photocopy machines and cars.

### iii Other operating costs

Other operating costs include representation expenses, donations, stationary and other miscellaneous expenses.

## 9 Dividends and other income from investments

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Dividend from group companies | 7,898 | 10,333 |
| **Dividends and other income from investments** | **7,898** | **10,333** |

In 2018 a dividend of €7,898 thousand (2017: €9,050 thousand) was received from Cosmo Technologies (Three) Ltd. In 2017, a dividend of EUR 1,283 thousand was received from Cosmo R&D S.r.l. as a consequence of its liquidation.

## 10 Financial income/expenses

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| **Financial income:** | | |
| Interest income on listed bonds and securities at FVOCI | 1,265 | 1,975 |
| Interest income on cash and cash equivalents | 476 | 463 |
| Gain on sale of listed bonds and securities at FVOCI | 145 | 437 |
| Gain on investments in funds mandatorily at FVTPL | 347 | – |
| Foreign exchange gains | 5,375 | 73 |
| Movement in loss allowance on financial investments at FVOCI | 19 | – |
| **Total financial income** | **7,627** | **2,948** |
| **Financial expenses:** | | |
| Interest on bank overdraft/advance on invoices at amortised cost | (8) | – |
| Interest on convertible bond at amortised cost | (582) | – |
| Loss on sale of listed bonds and securities at FVOCI | (1,766) | (889) |
| Loss on investments in funds mandatorily at FVTPL | (282) | – |
| Foreign exchange losses | (237) | (14,959) |
| Other | (192) | (15) |
| **Total financial expenses** | **(3,067)** | **(15,863)** |
| **Net financial income/(expense)** | **4,560** | **(12,915)** |

The Company holds US$ cash balances and US$ denominated investments. Net foreign exchange gains of €5,138 thousand (2017: losses of €14,886 thousand) arose during the period as a result of the movement in the Euro/US$ exchange rate over the period.

## 11 Income tax expenses

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Income tax | (86) | (86) |
| Changes in estimates related to prior years | (3) | – |
| **Current income tax** | **(89)** | **(86)** |
| Deferred tax assets | 105 | 1,320 |
| Deferred tax liabilities | 191 | 602 |
| **Deferred tax** | **296** | **1,922** |
| **Total income tax expenses** | **207** | **1,836** |

### Income Tax recognised in other comprehensive income

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| **Items that may be reclassified subsequently to profit or loss:** | | |
| Fair value on remeasurement of debt securities at FVOCI | 264 | – |
| Disposal of debt securities measured at FVOCI reclassified to profit or loss | (297) | – |
| Fair value remeasurement of available for sale financial assets | – | 129 |
| Disposal of available for sale financial assets reclassified through profit or loss | – | (86) |
| **Total income tax recognised in other comprehensive income** | **(33)** | **43** |

### Income Tax recognised directly in equity

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| Convertible bond | 2,658 | – |
| **Total income tax recognised directly in equity** | **2,658** | **–** |

### Reconciliation of effective tax rate

The applicable tax rate used to determine the theoretical income taxes in 2017 is the statutory rate applicable in Ireland of 12.5% (2017:12.5%), the tax jurisdiction in which Cosmo Pharmaceuticals N.V. is resident. The reconciliation between the theoretical income taxes calculated on the basis of the theoretical tax rate and income taxes recognised was as follows:

| EUR 1,000 | Year ended 31 December 2018 | 2017 |
|---|---|---|
| **Profit before taxes** | **9,715** | **(5,402)** |
| *Irish 2018 nominal corporate tax rate* | 12.50% | 12.50% |
| **Total theoretical income taxes** | **(1,214)** | **675** |
| Different taxation applicable for interest and gain/loss on bonds and other investments | (517) | 753 |
| Tax effect of other permanent differences | 598 | (997) |
| Effect of different corporate tax rate in the Swiss Branch (a) | 416 | 427 |
| Under/Over provision adjustments | (2) | – |
| Group relief | 926 | 978 |
| **Current and deferred income tax recognised in the consolidated financial statements** | **207** | **1,836** |

Notes:
(a) Applicable tax rate for Swiss Branch of 24.7%

## 12 Property, plant and equipment

| EUR 1,000 | Other fixed assets | Total |
|---|---|---|
| ***Cost*** | | |
| **Balance at 1 January 2017** | **150** | **150** |
| Additions | 86 | 86 |
| **Balance at 31 December 2017** | **236** | **236** |
| ***Accumulated depreciation*** | | |
| **Balance at 1 January 2017** | **29** | **29** |
| Depreciation charge for the year | 25 | 25 |
| **Balance at 31 December 2017** | **54** | **54** |
| **Net book value as at 31 December 2017** | **182** | **182** |

| EUR 1,000 | Other fixed assets | Total |
|---|---|---|
| ***Cost*** | | |
| **Balance at 1 January 2018** | **236** | **236** |
| Additions | 41 | 41 |
| **Balance at 31 December 2018** | **277** | **277** |
| ***Accumulated depreciation*** | | |
| **Balance at 1 January 2018** | **54** | **54** |
| Depreciation charge for the year | 35 | 35 |
| **Balance at 31 December 2018** | **89** | **89** |
| **Net book value as at 31 December 2018** | **188** | **188** |

## 13 Investments

| | As at 31 December | |
|---|---|---|
| EUR 1,000 | 2018 | 2017 |
| Cosmo S.p.A. | 20,325 | 6,050 |
| Cosmo Technologies Ltd. | 3,912 | 3,638 |
| Cristoforo Colombo Real Estate S.r.l. | – | 13,144 |
| Cassiopea S.p.A. | 23,073 | 22,959 |
| Granell Strategic Investment Fund Ltd. | 356 | 356 |
| Cosmo Technologies (Three) Ltd. | * | * |
| Aries Pharmaceuticals Ltd. | 10 | 10 |
| **Investments** | **47,676** | **46,157** |

## 13 Investments continued

| EUR 1,000 | % interest | 1 January 2018 | Increases | Decreases | Reclassification and other changes | Impairment (loss)/reversals | 31 December 2018 | % interest |
|---|---|---|---|---|---|---|---|---|
| **Cosmo S.p.A.** | 100.00 | **6,050** | 14,275 | | | | **20,325** | 100.00 |
| – Gross carrying amount | | 6,050 | 14,275 | | | | 20,325 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cosmo Technologies Ltd.** | 100.00 | **3,638** | 274 | | | | **3,912** | 100.00 |
| – Gross carrying amount | | 3,638 | 274 | | | | 3,912 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cristoforo Colombo Real Estate S.r.l.** | 100.00 | **13,144** | | (13,144) | | | – | – |
| – Gross carrying amount | | 13,144 | | (13,144) | | | – | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cassiopea S.p.A.** | 45.09 | **22,959** | 114 | | | | **23,073** | 45.09 |
| – Gross carrying amount | | 22,959 | 114 | | | | 23,073 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Granell Strategic Investment Fund Ltd.** | 100.00 | **356** | | | | | **356** | 100.00 |
| – Gross carrying amount | | 1,800 | | | | | 1,800 | |
| – Accumulated impairment losses | | (1,444) | | | | | (1,444) | |
| **Cosmo Technologies (Three) Ltd.** | 100.00 | * | | | | | * | 100.00 |
| – Gross carrying amount | | * | | | | | * | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Aries Pharmaceuticals Ltd.** | 100.00 | **10** | | | | | **10** | 100.00 |
| – Gross carrying amount | | 10 | | | | | 10 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Total Investments** | | **46,157** | **14,663** | **(13,144)** | **–** | **–** | **47,676** | |

## 13 Investments continued

| EUR 1,000 | % interest | 1 January 2017 | Increases | Decreases | Reclassification and other changes | Impairment (loss)/reversals | 31 December 2017 | % interest |
|---|---|---|---|---|---|---|---|---|
| **Cosmo S.p.A.** | 100.00 | **5,030** | **1,020** | | | | **6,050** | 100.00 |
| – Gross carrying amount | | 5,030 | 1,020 | | | | 6,050 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cosmo Technologies Ltd.** | 100.00 | **3,360** | **278** | | | | **3,638** | 100.00 |
| – Gross carrying amount | | 3,360 | 278 | | | | 3,638 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cosmo R&D S.r.l.** | 99.58 | **1,047** | | **(1,047)** | | | – | – |
| – Gross carrying amount | | 1,047 | | (1,047) | | | – | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cristoforo Colombo Real Estate S.r.l.** | 100.00 | **13,144** | | | | | **13,144** | 100.00 |
| – Gross carrying amount | | 13,144 | | | | | 13,144 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Cassiopea S.p.A.** | 45.09 | **22,837** | **122** | | | | **22,959** | 45.09 |
| – Gross carrying amount | | 22,837 | **122** | | | | 22,959 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Granell Strategic Investment Fund Ltd.** | 100.00 | **356** | | | | | **356** | 100.00 |
| – Gross carrying amount | | 1,800 | | | | | 1,800 | |
| – Accumulated impairment losses | | (1,444) | | | | | (1,444) | |
| **Cosmo Technologies (Three) Ltd.** | 100.00 | * | | | | | * | 100.00 |
| – Gross carrying amount | | * | | | | | * | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Aries Pharmaceuticals Ltd.** | 100.00 | **10** | | | | | **10** | 100.00 |
| – Gross carrying amount | | 10 | | | | | 10 | |
| – Accumulated impairment losses | | – | | | | | – | |
| **Total Investments** | | **45,784** | **1,420** | **(1,047)** | **–** | **–** | **46,157** | |

*Less than EUR 1 thousand

## 13 Investments continued

Significant changes to investments during the year were as follows:

- Capital contributions to Cosmo S.p.A., Cosmo Technologies Ltd. and Cassiopea S.p.A. in relation to Cosmo's ESOP relating to the employees of subsidiaries.
- Merger of Cristoforo Colombo Real Estate S.r.l. with Cosmo S.p.A.

As at 31 December 2018 investments are as follows:

| Name | Registered Office | Country | Currency | Share capital | Profit/(loss) for the period | Equity | % interest held |
|---|---|---|---|---|---|---|---|
| Cosmo S.p.A. | Lainate (MI) | Italy | Eur | 2,300,000 | 3,810,096 | 36,982,677.23 | 100.00% |
| Cosmo Technologies Ltd. | Dublin | Ireland | Eur | 250,000 | 8,088,461 | 103,414,705 | 100.00% |
| Granell Strategic Investment Fund Ltd. | Dublin | Ireland | Eur | 100,000 | (11,896) | 935,600 | 100.00% |
| Cosmo Technologies (Three) Ltd. | Dublin | Ireland | Eur | 1 | 5,336,257 | 3,550,775 | 100.00% |
| Aries Pharmaceuticals Ltd. | Dublin | Ireland | Eur | 10,000 | (26,252,008) | (47,466,242) | 100.00% |

The registered office of Linkverse S.r.l. is loacted in Rome, Italy, Aries Pharmaceuticals Inc. and Bellatrix Pharmaceuticals Inc. are located in San Diego, USA.

For more information in relation to the investment in the associate Cassiopea S.p.A., see Consolidated Financial Statement, note 15 Investments in associates.

## 14 Financial assets

### a) Non-current

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Debt securities measured at FVOCI | 17,372 | – |
| Other financial assets available for sale - investment securities | – | 62,565 |
| **Non-current financial assets** | **17,372** | **62,565** |

### b) Current

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Debt securities measured at FVOCI | 9,453 | – |
| Investments in funds measured at FVTPL | 103,903 | – |
| Other financial assets available for sale – investment securities | – | 26,734 |
| **Current financial assets** | **113,356** | **26,734** |

## 15 Deferred tax assets

| EUR 1,000 | As at 1 January 2017 | Changes during the year: Increase | Changes during the year: OCI | As at 31 December 2017 | Changes during the year: Increase | Changes during the year: Decrease | Changes during the year: OCI | As at 31 December 2018 |
|---|---|---|---|---|---|---|---|---|
| Depreciation of book value of PPE | – | 1 | – | 1 | * | – | – | 1 |
| Fair value financial investments | – | – | 18 | 18 | 346 | – | (39) | 325 |
| Unrealised FX loss on investment securities | – | 998 | – | 998 | – | (998) | – | – |
| Losses on sale of financial investments | – | 321 | – | 321 | 757 | – | – | 1,078 |
| **Total deferred tax assets** | **–** | **1,320** | **18** | **1,338** | **1,103** | **(998)** | **(39)** | **1,404** |

*Less than €1 thousand

## 15 Deferred tax assets continued

The following table sets out the nature of temporary differences determining the caption Deferred tax assets:

| EUR 1,000 | Temporary differences as at 31 December 2017 | % | Tax effect as at 31 December 2017 | Temporary differences as at 31 December 2018 | % | Tax effect as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Depreciation of book value of PPE | 8 | 12.50 | 1 | 8 | 12.50 | 1 |
| Fair value financial investments | 55 | 33.00 | 18 | 987 | 33.00 | 325 |
| Unrealised FX loss on investment securities | 3,022 | 33.00 | 998 | – | – | – |
| Losses on sale of financial assets | 974 | 33.00 | 321 | 3,266 | 33.00 | 1,078 |
| **Total deferred tax assets** | **4,059** | | **1,338** | **4,261** | | **1,404** |

## 16 Other non-current receivables

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Receivables from group companies | 83,312 | 43,290 |
| **Total other non-current receivables** | **83,312** | **43,290** |

Receivables from group companies as at 31 December 2018 include interest-free loans to subsidiaries consisting of: i) €67,362 thousand (2017: €31,940 thousand) to Aries Pharmaceuticals Ltd. ii) €14,900 thousand (2017: €10,000 thousand) to Granell Strategic Investment Fund Ltd., iii) €1,050 thousand (2017: €1,350 thousand) to Cosmo S.p.A.

## 17 Other receivables and other assets

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Other receivables from group companies | 2,272 | 2,499 |
| VAT receivables | – | 242 |
| Receivables from group companies for consolidated VAT | 44 | – |
| Prepaid expenses | 51 | 36 |
| Other prepaid | 94 | 69 |
| **Total other receivables and other assets** | **2,461** | **2,846** |

Other receivables from group companies relate to services rendered by Cosmo Pharmaceuticals N.V. to the principal companies in the Group.

## 18 Cash and cash equivalents

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Cash at hand | 8 | 5 |
| Bank accounts | 168,654 | 89,802 |
| **Total cash and cash equivalents** | **168,662** | **89,807** |

Bank accounts include current bank accounts and short-term deposits.

## 19 Total shareholders' equity

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Share capital | 3,910 | 3,910 |
| Share premium | 84,448 | 84,448 |
| Other reserves | 180,118 | 180,118 |
| Treasury shares | (18,353) | – |
| Stock option plan reserve | 12,685 | 5,803 |
| Fair value reserve | (441) | (37) |
| Equity component of convertible bond | 7,011 | – |
| Currency translation reserve | 219 | 106 |
| Retained earnings | (3,095) | – |
| Profit/(loss) for the period | 9,922 | (3,566) |
| **Equity attributable to owners of the company** | **276,424** | **270,782** |
| **Total equity** | **276,424** | **270,782** |

### Share capital

| EUR 1,000 | Ordinary shares 2018 | Ordinary shares 2017 | Preference shares 2018 | Preference shares 2017 |
|---|---|---|---|---|
| In issue at 1 January | 15,037,483 | 14,418,983 | – | – |
| Exercise of share options | – | 618,500 | – | – |
| **In issue at 31 December – fully paid** | **15,037,483** | **15,037,483** | **–** | **–** |
| **Authorised at 31 December – par value EUR 0.26** | **36,047,457** | **36,047,457** | **36,047,457** | **36,047,457** |

## 19 Total shareholders' equity continued

As at 31 December 2018 the authorised share capital amounts to €18,744,677.64 and is divided into 36,047,457 ordinary shares, each with a nominal value of €0.26 and 36,047,457 preferred shares, each with a nominal value of €0.26.

### Share premium

As at 31 December 2018 the share premium of €84,448 thousand relates to the proceeds from the issue of the 618,500 shares on 31 March 2017 as a result of the exercise of vested stock options and from the sale of treasury shares in 2017.

### Other reserves

Include reserves available for distribution.

### Treasury shares

As at 31 December 2018, the number of treasury shares amounted to 201,770 which were purchased during the period at an average purchase price of CHF 103.35 per share.

### Shares in issue and outstanding

| | Ordinary shares | | |
|---|---|---|---|
| EUR 1,000 | 2018 | 2017 | 2016 |
| In issue at 1 January | 15,037,483 | 14,418,983 | 14,418,983 |
| Treasury shares | – | 315,447 | 315,447 |
| **Outstanding at 1 January** | **15,037,483** | **14,103,536** | **14,103,536** |
| Issue of new shares | – | 618,500 | – |
| Treasury shares sold | – | 315,447 | – |
| Treasury shares purchased | (201,770) | – | – |
| **Outstanding at 31 December – fully paid** | **14,835,713** | **15,037,483** | **14,103,536** |

### Stock option plan reserve

The stock option plan reserve relates to the stock option plan of Cosmo Pharmaceuticals N.V. allocated in 2014, 2016, 2017 and 2018.

### Fair value reserve

As at 31 December 2018, fair value reserve is due to the cumulative net change in fair value of debt securities at FVOCI (2017: financial assets available-for-sale) until the assets are derecognised or reclassified. This amount is reduced by the amount of loss allowance.

### Equity component of convertible bond

The reserve for convertible bond comprises the amount allocated to the equity component for the convertible bond issued by the Group in November 2018. The equity component was valued at €9,669 thousand on initial recognition. For more information see Consolidated Financial Statement, note 25(B) Interest-bearing loans and borrowings (non-current and current). A deferred tax liability was also recognised on initial recognition with a corresponding entry to equity amounting to €2,658 thousand.

### Currency translation reserve

Currency translation differences arise from the consolidation of the accounting of the Swiss branch with a functional currency other than the Euro.

### Dividend

No dividend was paid during 2018. During 2017 a dividend of €1.50 per share or €22,556 thousand was paid out of retained earnings.

The difference between the company only equity disclosed in these Company Financial Statements and the consolidated equity disclosed in the Consolidated Financial Statements relates to the consolidation of the subsidiary companies and their inclusion in the consolidated equity. In the Company Financial Statements, subsidiary companies are included as investments at cost.

## 20 Interest-bearing loans and borrowings

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Convertible bond – liability component | 154,322 | – |
| **Total loans and borrowings (non-current)** | **154,322** | – |

On the 29th of November, Cosmo announces that it has successfully placed €175 million senior unsecured convertible bonds due 2023. The net proceeds from the Offering will be used for general corporate purposes, potential acquisitions and in-licensing transactions. For more information see Consolidated Financial Statement, note 25(B) Interest-bearing loans and borrowings (non-current and current).

## 21 Deferred tax liabilities

| EUR 1,000 | As at 1 January 2017 | Changes during the year: Increase | Decrease | OCI | As at 31 December 2017 | Changes during the year: Increase | Decrease | OCI | Equity | As at 31 December 2018 |
|---|---|---|---|---|---|---|---|---|---|---|
| Interests and F/X on investment securities | (268) | 97 | – | – | (171) | – | 124 | – | – | (47) |
| Unrealised F/X gain on investments | (506) | – | 506 | – | – | – | – | – | – | – |
| Fair value financial investments | (25) | – | – | 25 | – | – | – | – | – | – |
| Convertible bond | – | – | – | – | – | – | 73 | – | (2,658) | (2,585) |
| Other | – | – | – | – | – | (6) | – | 6 | – | – |
| **Total deferred tax liabilities** | **(799)** | **97** | **506** | **25** | **(171)** | **(6)** | **197** | **6** | **(2,658)** | **(2,632)** |

The following table sets out the nature of temporary differences determining the caption Deferred tax liabilities:

| EUR 1,000 | Temporary differences as at 31 December 2017 | % | Tax effect as at 31 December 2017 | Temporary differences as at 31 December 2018 | % | Tax effect as at 31 December 2018 |
|---|---|---|---|---|---|---|
| Interests and F/X on investment securities | (685) | 25.00 | (171) | (190) | 25.00 | (47) |
| Convertible bond | – | – | – | (20,678) | 12.50 | (2,585) |
| **Total deferred tax liabilities** | **(685)** | | **(171)** | **(20,868)** | | **(2,632)** |

## 22 Trade payables

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Trade payables | 247 | 103 |
| Accruals | 630 | 324 |
| **Total trade payables** | **877** | **427** |

Trade payables to third parties primarily relate to amounts payable for services received.

## 23 Current tax and other tax liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Withholding tax for employees | 87 | 85 |
| Tax payables | 45 | 1,017 |
| **Total current tax and other tax liabilities** | **132** | **1,102** |

## 24 Other current liabilities

| EUR 1,000 | As at 31 December 2018 | 2017 |
|---|---|---|
| Social security payables | 12 | 99 |
| VAT payable | 22 | – |
| Payables from group companies for consolidated VAT | – | 100 |
| Other liabilities | 58 | 286 |
| **Total other current liabilities** | **92** | **485** |

Other liabilities mainly includes payables to employees related to accruals of deferred pay elements, calculated on the basis of the collective labour agreement currently in force and the accrued monetary bonus calculated on the profit before taxes.

## 25 Intercompany and related party transactions

The Company's major shareholder is Cosmo Holding S.a.r.l., which as at 31 December 2018 owns 5,571,209 of the Company shares amounting to 37.05% of the issued shares.

### Cassiopea S.p.A.

Since May 2015 under an agreement with Cassiopea S.p.A., Cosmo Pharmaceuticals has provided Cassiopea S.p.A. with Chief Financial Officer and Chief Scientific Officer services by Hans Christoph Tanner and Luigi Moro. The Group has provided these services to Cassiopea S.p.A. at no charge. The services provided under this agreement shall not exceed 30% of the respective available working time of the individuals providing those services.

During 2017 the board of Cassiopea S.p.A. granted 20,000, 20,000 and 10,000 options to subscribe to Cassiopea S.p.A. shares to Luigi Moro (CSO), Hans Christoph Tanner (Head of Transaction Office) and Marco Lecchi (Head of Internal Audit) respectively. In 2017 Cosmo Pharmaceutical N.V., under a stock option plan, the Company granted 18,000 options to certain employees of Cassiopea S.p.A.

### Loans to subsidiaries

As at 31 December 2018, the Company has interest-free loans receivable of i) €67,362 thousand from Aries Pharmaceuticals Ltd ii) €14,900 thousand from its subsidiary Granell Strategic Investment Fund Ltd, and iii) €1,050 thousand from its subsidiary Cosmo S.p.A. It is Management's view that these loans are fully recoverable due to future profits.

### Services to group companies

During 2018 the Company charged group companies a total of €9,275 thousand (2017: €9,668 thousand) for management and administrative services. The Company has a receivable of €2,272 thousand (2017: €2,499 thousand) as at 31 December 2018 from its subsidiaries for these services.

### Board compensation

Board of Directors' total compensation recognised in the 2018 income statement was €4,625 thousand (2017: €4,496 thousand). For more information see Consolidated Financial Statement, note 34 Related party transactions.

## 26 Financial risk management objectives and policies

Cosmo Pharmaceuticals N.V. measures and manages financial risks in accordance with Group policy.
The Company's financial assets, such as cash and cash equivalents, investments in funds and debt securities, are managed by the Group's Investment Committee.

The major categories of risk to which the Company is exposed are credit risk, liquidity risk, interest rate risk, foreign currency risk and market price risk associated with the Company's financial assets. The Group's Audit Committee periodically reviews the policies for managing each of the above-mentioned risks.

### Credit risk

Credit risk is the risk of financial loss to the Company if a counterparty to a financial instrument fails to meet its contractual obligations.

Credit risk exposure exists in relation to the investment by the Company in financial assets, the cash which the Company places on deposit with financial institutions and loans/receivables from investments. The Company's treasury function actively manages these risks by investing in financial assets and placing deposits with financial institutions in accordance with strict credit risk management policies and controls as specified by the Board of Directors. Cosmo rates managing the credit risk as more important than optimising investment income.

#### Debt securities

The Group limits its exposure to credit risk by investing only in liquid debt securities and only with counterparties that have a good credit quality. The Group monitors changes in credit risk by tracking published external credit ratings.

**26 Financial risk management objectives and policies** continued

**Credit risk** continued

**Debt securities** continued

12-month and lifetime probabilities of default are based on historical data supplied by Moodys for each credit rating. Loss given default (LGD) parameters generally reflect an assumed recovery rate of 50% except when a security is credit-impaired, in which case the estimate of loss is based on the instrument's current market price and original effective interest rate.

All debt securities held as at 31 December 2018 had a Fitch credit rating of BBB- or higher. The Group did not have any debt securities that were past due but not impaired at 31 December 2018.

The movement in the allowance for impairment in respect of debt securities at FVOCI during the year was as follows:

| EUR 1,000 | |
|---|---|
| **Loss allowance at 31 December 2017 under IAS 39** | – |
| Adjustment on application of IFRS 9 | 44 |
| **Balance at 1 January 2018 under IFRS 9** | **44** |
| Net remeasurement of loss allowance | * |
| Financial assets derecognised | (19) |
| **Loss allowance at 31 December 2018** | **25** |

* Less than €1 thousand

The investments held at 31 December 2017 were previously classified as available-for-sale and no impairment loss had been recognised at that date or during 2017.

**Cash and cash equivalents**

The Company's cash and cash equivalents as at 31 December 2018 was held on deposit with banks whose FITCH credit rating ranged from BBB- to AA+.

**Inter-company loan receivables**

The Company has loans to subsidiaries amounting to €83,312 thousand. These loans are payable on demand, expected credit losses are based on the assumption that repayment of the loan is demanded at the reporting date. Where the counter-party has insufficient liquid assets in order to repay the loan if demanded at the reporting date, as is the case with the Aries Pharmaceuticals Ltd unsecured loan amounting to €67,362 thousand, the loan is at stage 3. The 'repay over time' recovery strategy based on cash flow forecasts indicate that the loan will be fully recoverable over a period of six years from cash generated from trading profits.

The cash flow forecasts incorporate relevant forward-looking information that is probability-weighted.

**Other financial assets at amortised cost**

Other financial assets at amortised cost include loans to related parties and other receivables. The identified impairment loss was considered immaterial.

**Financial assets at fair value through profit or loss**

The entity is also exposed to credit risk in relation to investments in funds that are measured at fair value through profit or loss. The maximum exposure at the end of the reporting period is the carrying amount of these investments €103,903 thousand (2017: €15,371 thousand).

**Liquidity risk**

Company'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 Group's reputation. Consequently, the liquidity risk to which it is exposed is strictly correlated to that which the Cosmo Pharmaceuticals Group is exposed to as a whole. To this end, the Group has invested its cash in short-term deposits or quickly realisable financial investments only. Given the very high cash and investments position the Group has been cancelling unnecessary bank facilities. The Group rates managing the liquidity risk as more important than optimising investment income.

**Interest rate risk**

The Company's exposure to the risk of changes in market interest rates relates primarily to the Company's financial investments and cash in bank deposits and equivalent investments with floating interest rates. No material-hedging activities were used during the period under review.

**Foreign currency risk**

The Company is subject to a number of foreign currency risks for transactions that are denominated in a currency other than its functional currency. Since 2016, the Company is subject to increased exposure to fluctuation in exchange rates between US dollar and Euro due to the Groups expansion in operations into U.S. Market. At the present time no foreign currency hedges are in place but the Company regularly reviews this position.

**Market price risk**

Market price risk is the risk that changes in market prices of investment securities will affect the Company's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control the market risk exposure within acceptable parameters, while optimising returns.

## 26 Financial risk management objectives and policies continued

### Capital management

Cosmo's stated objectives for capital management are to create value for shareholders, to guarantee continuity of the business and to support the development of the Group. Accordingly, the Company intends to maintain an adequate level of capital that, at the same, will enable it to achieve a satisfactory financial return for shareholders.

Neither the Company nor any of its subsidiaries are subject to capital requirements imposed by any regulatory agency or similar body.

For more information in relation to Financial risk management objectives and policies see Consolidated Financial Statement, note 35 Financial risk management objectives and policies.

## 27 Fair value measurement

The fair value is the price that would be received when selling an asset or paid when transferring a liability in an orderly transaction between market participants (i.e. not as part of the compulsory liquidation or a below-cost sale) as at the measurement date. Fair value is a market measurement criterion, not specifically referring to a single entity. Underlying the definition of fair value is the assumption that the company is carrying out normal operations, without any intention of liquidating its assets, significantly reducing the level of operations or carrying out transactions at unfavourable conditions.

An entity has to measure the fair value of an asset or liability by adopting the assumptions that would be used by market participants when pricing an asset or liability, presuming that they act with a view to satisfying their own economic interest in the best way possible.

The fair value of financial instruments is determined according to a hierarchy of criteria based on the origin, type and quality of the information used (IFRS 13). In detail, this hierarchy assigns top priority to quoted prices (unadjusted) in active markets and less importance to unobservable inputs. Three different levels of input are identified:

a. level 1: input represented by quoted prices (unadjusted) in active markets for identical assets or liabilities accessible by the entity as at the measurement date;
b. level 2: input other than quoted prices included in level 1 that are directly or indirectly observable for the assets or liabilities to be measured;
c. level 3: unobservable input for the asset or liability.

A market is regarded as active if quoted prices, representing actual and regularly occurring market transactions considering a normal reference period, are readily and regularly available from an exchange, dealer, broker, industry group, pricing service or regulatory agency.

In specific cases research is carried out in order to verify the significance of official market values. In the event of a significant reduction in the volume or level of operations compared to normal operations for the asset or liability (or for similar assets or liabilities) highlighted by a number of indicators (number of transactions, limited significance of market prices, significant increase in implicit premiums for liquidity risk, expansion or increase of the bid-ask spread, reduction or total lack of market for new issues, limited publicly-available information), analyses of the transactions or of the quoted prices are carried out: if the conclusion is reached that the market is inactive, the asset or liability is reclassified to level 2 of the fair value hierarchy.

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

This table shows the comparison of fair values versus carrying amounts of financial assets and liabilities, as required by IFRS 7.

| | | As at 31 December | | | |
|---|---|---|---|---|---|
| | | 2018 | | 2017 | |
| EUR 1,000 | *Classification* | Carrying amount | Fair value | Carrying amount | Fair value |
| **Non-current financial assets** | | | | | |
| Debt securities | FVOCI – debt instrument (2017: FVOCI (AFS)) | 17,372 | 17,372 | 62,565 | 62,565 |
| **Current financial assets** | | | | | |
| Debt securities | FVOCI – debt instrument (2017: FVOCI (AFS)) | 9,453 | 9,453 | 11,363 | 11,363 |
| Investments in funds | Mandatorily at FVTPL (2017: FVOCI (AFS)) | 103,903 | 103,903 | 15,371 | 15,371 |
| **Total** | | **130,728** | **130,728** | **89,299** | **89,299** |
| Unrecognised (loss) gain | | – | – | – | – |

## 27 Fair value measurement continued

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

The following table shows the fair value hierarchy for financial assets that are measured at fair value on a recurring basis:

| | As at 31 December 2018 | | | | As at 31 December 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| EUR 1,000 | Level 1 | Level 2 | Level 3 | Total | Level 1 | Level 2 | Level 3 | Total |
| **Non-current financial assets** | | | | | | | | |
| Debt securities | 17,372 | – | – | 17,372 | 50,904 | 11,661 | – | 62,565 |
| **Current financial assets** | | | | | | | | |
| Debt securities | 9,453 | – | – | 9,453 | 7,758 | 3,605 | – | 11,363 |
| Investments in funds | 103,903 | – | – | 103,903 | 15,371 | – | – | 15,371 |
| **Total** | **130,728** | – | – | **130,728** | **74,033** | **15,266** | **–** | **89,299** |

The following are considered as level 1 financial instruments:

a. shares valued using official closing prices and/or fixing provided by regulated stock exchanges;
b. bonds and investments in funds valued using official closing prices and/or fixing provided by local authorities (central bank, monetary authority or local stock exchange);
c. bonds and investments in funds quoted on Multilateral Trading Facility (i.e. the EuroTLX or NASD TRACE circuit) or for which it is possible to continuously derive the quotation from the main price contribution international platforms.

When no quotation on an active market exists or the market is not functioning regularly, that is, when the market does not have a sufficient and continuous number of trades, and bid-ask spreads and volatilities that are not sufficiently contained, the fair value of the financial instruments is mainly determined through the use of valuation techniques whose objective is the establishment of the price at which, in an orderly transaction, the asset could be sold or the liability transferred between market participants, as at the measurement date, under current market conditions.

In the case of level 2 inputs, the valuation is based on prices taken from official listings of instruments which are similar in terms of risk profile. In particular, the level 2 valuation measurements reproduce prices of financial instruments not quoted on active markets and do not contain discretional parameters for which values may not be inferred from quotations of financial instruments present on active markets or fixed at levels capable of reproducing quotations on active markets.

The level 2, as at 31 December 2017, primarily included bond and shares of bond funds without official quotations expressed by an active market and for which the Net Asset Value (NAV) provided by the Fund Administrator is considered as the fund's fair value. This value may be analysed based on the financial instruments underlying the funds with the purpose to assign the fair value hierarchy level resulting from an individual valuation process aimed at verifying specific risks (counterparty risk, illiquidity risk).

In addition to this, the Company, with the external asset manager, periodically makes an assessment regarding the marketability of each investment to confirm the assigned level and the fair value measurement. The assessment distinguishes three different categories:

i. Investments that can be sold within one day without an expected meaningful impact on price
ii. Investments that can be sold within one day with an expected price impact of approximately 0.25%
iii. Illiquid investments, which require more than one day to be liquidated

In case the investment is included in iii., its fair value is reclassified to level 2 of the fair value hierarchy.
In 2018 there were no significant transfers between Levels 1 and 2 in the fair value hierarchy, and the changes were due disposals of debt instruments during the period.

## 27 Fair value measurement continued

### 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, as required by IFRS 7.

| | | As at 31 December | | | |
|---|---|---|---|---|---|
| | | 2018 | | 2017 | |
| EUR 1,000 | *Classification* | Carrying amount | Fair value | Carrying amount | Fair value |
| Other non-current receivables | Amortised cost (2017: Loans and receivables) | 83,312 | 83,312 | 43,290 | 43,290 |
| Other receivables and other assets(*) | Amortised cost (2017: Loans and receivables) | 2,409 | 2,409 | 2,504 | 2,504 |
| Cash and cash equivalents | Amortised cost (2017: Loans and receivables) | 168,662 | 168,662 | 89,807 | 89,807 |
| **Total Assets** | | **254,383** | **254,383** | **135,601** | **135,601** |
| Trade payables | Amortised cost | (877) | (877) | (427) | (427) |
| Convertible bond – liability component | Amortised cost | (154,322) | (154,322) | – | – |
| Other current liabilities(*) | Amortised cost | (16) | (16) | (100) | (100) |
| **Total Liabilities** | | **(155,215)** | **(155,215)** | **(527)** | **(527)** |
| Unrecognised (loss) gain | | | – | | – |

(*) only financial assets/liabilities

For financial instruments represented by Other non-current, Other receivables and other assets, Trade payables and Other current liabilities for which the present value of future cash flows also taking into account the credit risk of the counterparties, does not differ significantly from carrying value, we assume that carrying value is a reasonable approximation of the fair value.

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

For the convertible bond the carrying amount approximates the fair value calculated based on the present value of future principal and interest cash flows, discounted at the interest market rate at the reporting date.

## 28 Subsequent events

Refer to note 37 Subsequent events of the Consolidated Financial Statements.

Dublin, Ireland, 28 March 2019
The Board of Directors

Mauro Ajani
Alessandro Della Chà
Dieter Enkelmann
Hans Christoph Tanner
Maria Grazia Roncarolo
Kevin Donovan
Eimear Cowhey

## Independent Auditor's Report

The report of the Company's independent auditor, BDO Audit & Assurance B.V., the Netherlands is set forth following this Annual Report.

## Company Offices

The Group is headquartered in Dublin, Ireland and has offices in Lugano, Switzerland; offices and a lab in San Diego, U.S.; and a manufacturing facility and offices in Lainate, Italy.

## Dividends

Dividends will be determined in accordance with the articles 26 of the Articles of Association of Cosmo Pharmaceuticals N.V. The relevant provisions of the Articles of Association read as follows:

### Article 26.

26.1 From the profits such amounts shall be reserved as the Board of Directors shall determine.

26.2 Out of the remaining profit shall, if possible, first be distributed a dividend on the preferred shares of:

(a) a percentage equal to the higher of (i) twelve (12) months LIBOR as published by ICE Benchmark Administration Limited or (ii) twelve (12) months EURIBOR as published by European Money Markets Institute, each calculated on the basis of the number of days such rate applied during the financial year to which the dividend amount relates, provided that such rate can never be below zero percent;

(b) a premium to be determined by the Board of Directors in line with market conditions on the date the preferred shares were first issued.

Dividends on preferred shares shall be calculated on the paid-up part of the nominal value of the preferred shares. Payment thereof is subject to paragraph 5 of this article. If and to the extent the profit made is not sufficient to distribute the dividend the payment will be made from the other freely distributable reserves of the Company's equity.

However, if and to the extent the issued preferred shares have been paid up from the distributable part of the equity, such in accordance with article 7 paragraph 2, no dividend shall be distributed on the preferred shares until three (3) years after the first issuance. After three (3) years a total dividend will be paid of one thousand euro (EUR 1,000.00) to be divided pro rata on all issued preferred shares.

26.3 Any profit remaining after application of the previous paragraphs shall be at the disposal of the General Meeting for distribution of dividend or reservation provided that no further distributions will be made to the holders of preferred shares.

26.4 In calculating the amount of profits to be distributed on each ordinary share, only the nominal value of the shares shall be regarded and by which the shares held by the Company in its own capital shall be disregarded.

26.5 The Company shall only be capable of making distributions to shareholders and other persons who are entitled to profits that qualify for distribution if the Company's equity is in excess of the paid and called up portion of the share capital increased by the reserves that must be set aside under the provisions of the law.

26.6 Distribution of profits shall take place after confirmation and adoption of the Annual Accounts showing that this is allowed.

26.7 The Board of Directors shall have power to pay one or more interim dividends provided that the requirement referred to in paragraph 5 concerning the Company's equity has been met.

26.8 Unless the Board of Directors decides on a different date, dividends shall be made payable immediately after they have been declared.

26.9 Dividends that have not been collected within five years after they have become payable, shall be forfeited to the Company.

26.10 Distributions can be made in cash or in kind.

26.11 The Board of Directors shall have the power to resolve upon distributions (which shall include interim distributions) from the Company's reserves, provided that the requirement referred to in paragraph 5 concerning the Company's equity has been met.

26.12 The Company may only make interim distributions if the requirement of paragraph 5 of this article has been met as evidenced by an interim statement of assets and liabilities as referred to in article 2:105 paragraph 4 of the Dutch Civil Code.

# INDEPENDENT AUDITOR'S REPORT

**To: the Shareholders and Board of Cosmo Pharmaceuticals N.V.**

## A. Report on the audit of the financial statements 2018

### Our opinion

We have audited the financial statements 2018 of Cosmo Pharmaceuticals N.V., a company incorporated under the corporate laws in Amsterdam (The Netherlands) and headquartered in Dublin (Ireland) ('the company'). The financial statements include the consolidated financial statements and the company financial statements.

| We have audited | Our opinion |
|---|---|
| The financial statements which comprise:<br>1 the consolidated and company statement of financial position as at 31 December 2018;<br>2 the following consolidated and company statements for 2018: the income statement and statement of other comprehensive income, cash flow statement and statement of changes in equity for the year then ended; and<br>3 the notes comprising a summary of the significant accounting policies and other explanatory information. | In our opinion the enclosed financial statements give a true and fair view of the financial position of Cosmo Pharmaceuticals N.V. as at 31 December 2018 and of its result and its cash flows for 2018 in accordance with International Financial Reporting Standards as adopted by the European Union and with Part 9 of Book 2 of the Dutch Civil Code. |

### Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the 'Our responsibilities for the audit of the financial statements' section of our report.

We are independent of Cosmo Pharmaceuticals N.V. in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the Wet toezicht accountantsorganisaties (Wta), the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO) and other relevant independence regulations in the Netherlands. Furthermore, we have complied with the Verordening gedrags- en beroepsregels accountants (VGBA).

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

### Materiality

Based on our professional judgment we determined the materiality for the financial statements as a whole at €1,500,000. The materiality has been calculated with reference to a benchmark of normalized profit before tax (representing 7.7% of the normalized profit before tax) which we consider to be one of the principal considerations for members of the company in assessing the financial performance of the group. We have also taken into account misstatements and/or possible misstatements that in our opinion are material for qualitative reasons for the users of the financial statements.

We agreed with the Board that misstatements in excess of €75,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

### Scope of the group audit

Cosmo Pharmaceuticals N.V. is head of a group of entities. The financial information of this group is included in the consolidated financial statements of Cosmo Pharmaceuticals N.V.

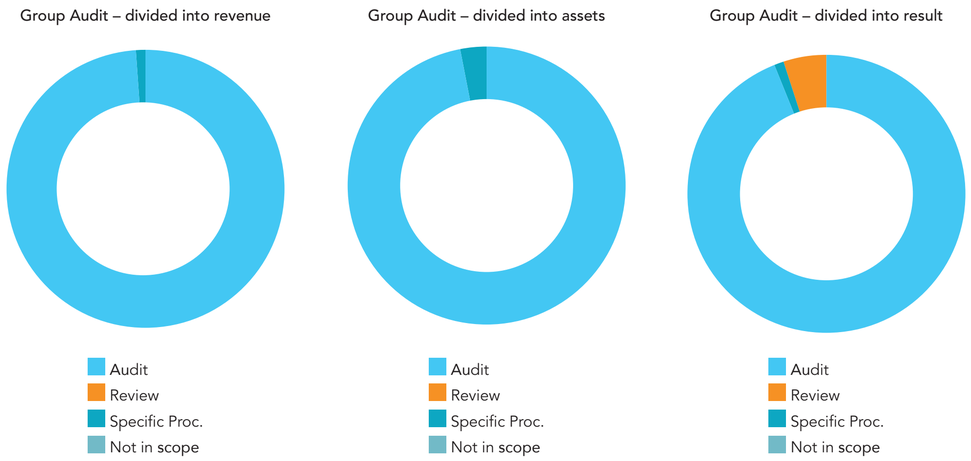
Our group audit mainly focused on significant group entities. We consider a component significant when:

- it is of individual financial significance to the group; or
- the component, due to its specific nature or circumstances, is likely to include significant risks of material misstatement, whether due to fraud or error of the group financial statements.

To this extend we:

- performed audit procedures ourselves at Cosmo Pharmaceuticals N.V.;
- used the work of other auditors when auditing entity Aries Pharmaceuticals Inc., Cosmo S.p.A., Cosmo Technologies Ltd., Cosmo Technologies (Three) Ltd. and Aries Pharmaceuticals Ltd.;
- performed review procedures or specific audit procedures at other group entities.

For clarification purposes we hereby show our scope:




By performing the procedures mentioned above at group entities, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion about the consolidated financial statements.

## Our 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. We have communicated the key audit matters to the Audit Committee. The key audit matters are not a comprehensive reflection of all matters discussed.

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.

| Capitalisation and valuation of intangible assets | Our audit approach |
|---|---|
| As at year-end, the carrying amount of the company's intangible assets is €35.5 million which includes patents and rights, trademarks and licenses, and development costs as disclosed in note 14.<br><br>A large part of the intangible assets relate to a license agreement and development cost for innovative solutions for gastrointestinal diseases and endoscopy for which market acceptance may differ from companies' expectations, making management's assessment judgmental, specifically regarding the expected future sales and profitability of developed products. Due to the estimates involved in the determination of the valuation we consider this to be a key audit matter. | For the additions during the year, we reviewed the design and implementation of the controls identified by management related to the intangible assets capitalisation and subsequent measurement and performed substantive test of details on the capitalised development costs. These procedures included, on a sample basis, testing underlying evidence including purchase invoices and reviewing the business cases which have been approved by the Board of the company. We assessed if the capitalization of the intangible assets met the requirements under IAS 38, Intangible Assets.<br><br>Additionally, we have compared management's assessment for capitalization and amortisation with other companies in the pharmaceutical industry.<br><br>For intangible assets, management is required by IAS 38 to assess whether impairment Indicators exists and if so, management is required to perform an impairment test. Our audit procedures for impairment tests included, among others, verifying the assumptions and methodologies used by the company. We compared forecasted revenue and profit margins with the approved budgets by the Board. We also verified the assumptions to which the outcome of the impairment test is most sensitive and reviewed the sensitivity analysis.<br><br>We assessed the adequacy of the disclosures in the financial statements relating to these intangible assets. |

| Revenue recognition | Our audit approach |
|---|---|
| The company recognizes revenue relating to manufacturing on behalf of third parties, license fees, up-front fees and milestones, and royalties.<br><br>During the year, the company recorded sales from manufacturing on behalf of third parties amounting to €45.3 million, royalties amounting to €14.6 million and license fees, up-front fees and milestones amounting to €5.7 million as disclosed in note 6.<br><br>Due to the different revenue streams and the complex interrelation of these streams, we have identified the completeness, existence and accuracy of revenues as a key audit matter and identified a risk that sales may be overstated as a result of management override or the focus of the company on performance and results for example in relation to the stock option plan that is in place. Furthermore, the risk of fraud in revenue recognition is a presumed fraud risk based on Dutch Standards on Auditing. | Our audit procedures included, amongst others, assessing the appropriateness of the company's revenue recognition accounting policies in accordance with IFRS 15 and testing the effectiveness of the company's controls relating to the recognition of revenue.<br><br>We performed substantive procedures for revenue including reconciliation of sales invoices to supporting records of goods dispatched or services rendered and authorised sales contracts. We have performed detailed testing, on a sample basis, of external confirmations on client level for both the outstanding receivable position per client and the total revenue per client. To gain comfort over the completeness of revenue we have tested whether production runs lead to revenue transactions.<br><br>With respect to the sales related accruals, we performed substantive procedures including cut-off procedures from invoices recorded and assessing the accuracy and completeness of provisions for credit notes.<br><br>We have also assessed the accuracy and completeness of the company's disclosures in the financial statements relating to revenue recognition. |

| Recognition of the Convertible Bond | Our audit approach |
|---|---|
| The company issued a convertible bond with a nominal value of €175 million. The bond is considered to be a compound financial instrument, accounted for as mentioned on the next page.<br><br>The debt instrument is recognised at fair value and subsequently measured at amortised cost.<br><br>The conversion option of the bondholder is directly recognised into equity and not remeasured after initial recognition.<br><br>Given the significance of this convertible bond and the estimates involved in the determination of the valuation of the convertible bond, we consider this to be a key audit matter. | Our audit procedures relating to the convertible bond included, among others, assessing the appropriateness of the company's convertible bond accounting policy and testing the design and implementation of the controls identified by management relating to the recognition of the convertible bond.<br><br>We performed substantive procedures to audit if the fixed for fixed test performed by the Company is in accordance with the requirements of IAS 32, to determine whether the conversion option of the bondholder classifies as an equity instrument;<br><br>We tested the valuation at initial recognition by testing inputs used for the fair value calculation of the financial liability and assessed its reasonability;<br><br>We verified amounts, interest calculations and maturity date to the supporting documentation;<br><br>We assessed the adequacy of the disclosures in the financial statements relating to the convertible bond in accordance with IFRS 7 and IFRS 9. |

## B. Report on other information included in the annual report

Next to the financial statements and our opinion thereon, the annual report consists of other information, including:

- the directors' report;
- the other information on page number 152;
- the overview of operating principles and activities, clinical focus and product portfolio.

Based on the procedures as mentioned below, we are of the opinion that the other information:

- is consistent with the financial statements and contains no material deficiencies;
- includes all information as required by Part 9 of Book 2 of the Dutch Civil Code.

We have read the other information and based on our knowledge and understanding obtained from the audit of the financial statements or otherwise, we have considered if the other information contains material deficiencies.

With these procedures, we have complied with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Auditing Standard 720. These procedures do not have the same scope as our audit procedures on the financial statements.

Management is responsible for the preparation of the Directors report and the other information on page number 152 in accordance with Part 9 of Book 2 of the Dutch Civil Code.

## C. Report on other legal and regulatory requirements

### Engagement

We were engaged by the General Meeting as auditor of Cosmo Pharmaceuticals N.V. of the audit for year 2016 and have operated as statutory auditor ever since that financial year.

### No prohibited non-audit services

We have not provided prohibited non-audit services as referred to in Article 5 (1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

## D. Description of responsibilities for the financial statements

### Responsibilities of management and the Board for the financial statements

The executive members of the Board are responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, the executive members of the Board are responsible for such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to errors or fraud.

As part of the preparation of the financial statements, the executive members of the Board are responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting framework mentioned, the executive members of the Board should prepare the financial statements using the going concern basis of accounting unless management either intends to liquidate the company or to cease operations or has no realistic alternative but to do so. The executive members of the Board should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Audit Committee is responsible for overseeing the company's financial reporting process.

### Our 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.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not have detected all material errors and fraud.

Misstatements can arise from errors or fraud 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. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgment and have maintained professional scepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included e.g.:

- Identifying and assessing the risks of material misstatement of the financial statements, whether due to errors or fraud, designing and performing audit procedures responsive to those risks, and obtaining 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 errors, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- Obtaining 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;
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management;
- Concluding 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 ceasing to continue as a going concern;
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures; and
- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which an audit or review had to be carried out on the complete set of financial information or specific items.

We communicate with the Board regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identify during our audit. In this respect we also submitted a report addressed to the Audit Committee in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this report addressed to the Audit Committee is consistent with our audit opinion in this auditor's report.

We 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.

Amstelveen, 28 March 2019

For and on behalf of BDO Audit & Assurance B.V.,
**drs. J.F. van Erve RA**

# INFORMATION FOR INVESTORS

## Capital structure

| EUR 1,000 | 31.12.2018 |
|---|---|
| Equity attributable to owners of the Company | 443,760 |
| Share capital | 3,910 |
| Reserves | 457,857 |
| Profit (loss) for the period | (18,007) |
| Number of issued shares | 15,037,483 |
| **Nominal value per share (in EUR)** | **0.26** |

| Major shareholders | No. of shares | % of share capital |
|---|---|---|
| Cosmo Holding S.a.r.l. | 5,571,209 | 37.05% |
| Heinrich Herz AG / Logistable SA Group | 1,252,984 | 8.33% |
| dievini Hopp BioTech Holding GmbH & Co. KG | 786,361 | 5.23% |

## Share price data

| CHF | Price | Date |
|---|---|---|
| First trading day close | 22.30 | 12.03.2007 |
| 2018 lowest | 84.05 | 27.12.2018 |
| 2018 highest | 150.70 | 03.01.2018 |
| 2018 last trading day | 87.90 | 28.12.2018 |
| Market capitalisation (in CHF million) | 1,321.79 | 31.12.2018 |

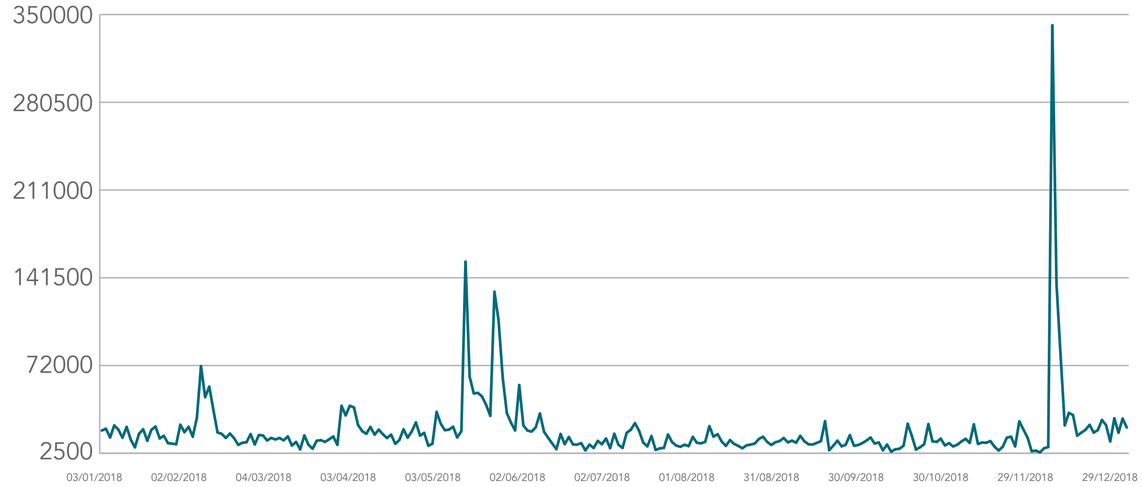
## Share earnings

| EUR | 31.12.2018 |
|---|---|
| Basic earnings per share | (1.200) |

## Stock exchange information

| Listing | SIX Swiss Exchange, Main Board |
|---|---|
| Security ID | COPN |
| ISIN | NL0011832936 |
| Swiss security number (Valor) | 2862650 |
| Number of issued shares | 15,037,483 |

## Trading volumes




## Share price

## Research coverage

| | | |
|---|---|---|
| **Jefferies International** | Peter Welford | Phone: +44 20 7029 8668 |
| **Credit Suisse** | Thomas Kaufmann | Phone: +41 44 333 05 83 |
| **Bank am Bellevue** | Laura Rossi | Phone +41 44 267 67 89 |

## Calendar

### Key reporting dates

Half-Year Report – July 2019
Annual Report – March 2020

### Upcoming conferences

Jefferies' 2019 London Healthcare Conference
London, 20-21 November 2019

Jefferies' 2019 Healthcare Conference
New York, 4-7 June 2019

# 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.

**5-aminosalicylic acid**
It is a drug derived from salicylic acid used to treat inflammation of the intestine.

**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.

**Acute**
Acute present or experienced to a severe or intense degree.

**Adenoma**
A benign tumour originating in glandular tissue.

**Adenoma Detection Rate (ADR)**
The percentage of screened patients in whom at least one adenoma is found.

**Antibiotic**
Drug that kills bacteria or prevents them from multiplying.

**AUC (area under the curve)**
Term used in pharmacokinetic studies as measure of systemic absorption.

**Autoimmune**
Relating to disease caused by antibodies or lymphocytes produced against substances naturally present in the body.

**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.

**Butyric acid**
Is a short-chain fatty acid produced in the colon by the fermentation of alimentary fibres. It is the main physiological fuel for the mucosa cells in the colon.

**Carcinoma**
A type of cancer that develops from epithelial cells.

**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 phase I assessment on a larger group of volunteers and / or patients.

**Clinical phase III**
phase III studies are randomised controlled trials on large patient groups ( ≥ 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 candidate on humans.

**Clostridium-Difficile-Associated Diarrhoea (CDAD)**
Diarrhoea due to Clostridium Difficile infection.

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

**Colon**
The colon is the part of the large intestine between the cecum and the rectum. Its primary purpose is to extract water from faeces.

**Colorectal cancer**
Cancer of the colon or rectum, also known as bowel cancer and colon cancer.

**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.

**Crohn's Disease (CD)**
It is a type of chronic Inflammatory Bowel Disease (IBD) that can affect any part of the gastrointestinal tract from mouth to anus.

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

**Diarrhoea**
It is a generally unpleasant condition in which the sufferer has frequent watery, loose bowel movements.

**Disease activity index (DAI)**
An index of severity of IBD including subjective and endoscopic evaluations.

**Diverticulitis**
Diverticulitis is a disease of the bowel, in particular the large intestine, characterised by inflammation and infection of intestinal diverticula. Diverticula are finger-shaped dilatations of the intestinal wall.

**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 Medicine Evaluation Agency.

**Endogenous**
Produced or synthesised within the organism.

**Endoscopic activity index (EAI)**
An index evaluating the severity of IBD by endoscopic examinations.

**Endoscopy**
Endoscopy means looking inside and refers to looking inside the human body for medical reasons.

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

**Epidemiologic**
Cause and development characteristics of a disease in populations.

**EPO**
European Patent Office.

**Ethical drugs**
Prescription drugs used for treatment of serious diseases.

**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.

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

**Generic drugs**
Drugs equivalent to brand drugs.

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

**Ileum**
The ileum is the final portion of the small intestine.

**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.

**Inflammatory Bowel Disease (IBD)**
A group of inflammatory conditions of the bowel, including Ulcerative Colitis and Crohn's Disease.

**Intestine**
The portion of the alimentary tract extending from the stomach to the anus, consisting of two segments, the small intestine and the large intestine (or colon).

**Inulin**
Inulins are a group of naturally occurring oligosaccharides that are fermented by intestinal bacteria leading to the production of short-chain fatty acid, including butyric acid.

**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.

**Lumen**
The lumen is the interior of a vessel within the body, such as the small central space in an artery or vein, or any of their relating vessels through which blood flows. On a larger scale, the interior of the gastrointestinal tract may also be referred to as its lumen.

**Mechanism of action**
The manner by which a drug exerts its activity.

**Methylene blue**
Methylene blue is a phenothiazine derivative that is a dye. It was discovered in 1876 and has seen use in various medical applications since 1900. One of its characteristics is that it is not absorbed by dysplastic / neoplastic cells and thus allows their detection and demarcation via endoscope.

**Monoclonal antibodies**
Identical antibodies produced by selected and restricted B lymphocytes.

**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 U.S.

**Nutraceuticals**
Refers to foods claimed to have an effect on human health. The term includes dietary supplements and special food.

**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 administrated.

**Orphan diseases**
Diseases characterised 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.

**Peptides**
Peptides (from the Greek *πεπτος*, 'digestible') are the family of short molecules formed from the linking, in a defined order, of various α-amino acids.

**Pharmaceutical manufacturing plant**
Facilities for the manufacturing of drugs, subject to Authorisation by specific health authorities.

**Pharmacokinetic**
The process by which a drug is absorbed, distributed, metabolised and eliminated by the body.

**Pharmacokinetic parameters**
Measures related to drug absorption and elimination rates that are useful to evaluate the behaviour of thedrugs after administration to a living organism (such as Cmax, Tmax, 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.

**Probiotic bacteria**
Microorganisms normally present in the intestine, producing beneficial effects.

**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.

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

**REACH**
Registration, Evaluation, Authorisation and Restriction of Chemical substances.

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

**Rectum**
The last part of the large intestine.

**Registration**
Authorisation required to market a drug.

**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.

**Ulcerative Colitis (UC)**
Ulcerative Colitis is a form of Inflammatory Bowel Disease (IBD). The disease is located only in the colon, and is characterised by presence of mucosal ulcerations. The main symptoms of active disease are usually abdominal pain and Diarrhoea mixed with blood of gradual onset.

# CONTACTS AND ADDRESSES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