# Orion Group
# Financial Statement Release 2018

ORION
Building well-being

ORION CORPORATION FINANCIAL STATEMENT RELEASE 2018 6 FEBRUARY 2019 at 12.00 EET

# Orion Group Financial Statement Release for 2018

Orion's net sales for continuing operations in 2018 totalled EUR 977 million (EUR 1,034 million in 2017).

- Operating profit for continuing operations was EUR 253 (284) million.
- Profit for continuing operations before taxes was EUR 248 (278) million.
- Equity ratio was 69% (65%).
- ROCE before taxes was 44% (36%).
- ROE after taxes was 45% (34%).
- Basic earnings per share for continuing operations were EUR 1.40 (1.56) and basic earnings per share including also discontinued operations were EUR 2.35 (1.61).
- Cash flow per share before financial items was EUR 2.32 (1.09).
- The sale of the Orion Diagnostica business division was closed on 30 April 2018. Following the transaction, the Group has only one reporting segment, Pharmaceuticals business. In the Financial Statement Release, Orion Diagnostica business is reported as a discontinued operation, and as a rule, the statement only covers continuing operations.
- Financial objectives remain unchanged.
- The Board of Directors proposes payment of a dividend of EUR 1.50 per share (2017: EUR 1.45 per share).
- Orion estimates that in 2019 net sales will be slightly higher than in 2018. The estimated net sales include the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide. Operating profit is estimated to be at the same level as in 2018. The estimated operating profit includes the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide as well as significant investments in actions to generate growth. The complete outlook estimate and the basis for it can be found in this report under 'Outlook for 2019' and 'Basis for outlook'."

## ORION'S KEY FIGURES FOR THE REVIEW PERIOD

| Continuing operations | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Net sales, EUR million | **262.4** | 265.9 | -1.4% | **977.5** | 1,033.6 | -5.4% |
| Operating profit, EUR million | **68.6** | 70.5 | -2.6% | **252.8** | 284.1 | -11.0% |
| % of net sales | **26.1%** | 26.5% | | **25.9%** | 27.5% | |
| Profit before taxes, EUR million | **67.5** | 69.0 | -2.1% | **248.4** | 277.7 | -10.6% |
| % of net sales | **25.7%** | 25.9% | | **25.4%** | 26.9% | |
| Income tax expense, EUR million | **13.7** | 14.6 | -6.0% | **51.0** | 58.6 | -13.0% |
| R&D expenses, EUR million | **27.8** | 26.5 | +4.6% | **104.0** | 99.1 | +4.9% |
| % of net sales | **10.6%** | 10.0% | | **10.6%** | 9.6% | |
| Capital expenditure, EUR million | **35.4** | 14.8 | +138.7% | **64.8** | 75.0 | -13.5% |
| % of net sales | **13.5%** | 5.6% | | **6.6%** | 7.2% | |
| Basic earnings per share, EUR | **0.38** | 0.38 | -0.6% | **1.40** | 1.56 | -10.3% |
| Diluted earnings per share, EUR | **0.38** | 0.38 | -0.6% | **1.40** | 1.56 | -10.3% |
| Personnel at the end of the period | | | | **3,154** | 3,161 | -0.2% |
| Average personnel during the period | | | | **3,179** | 3,205 | -0.8% |

| Continuing and discontinued operations | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Assets total, EUR million | | | | **1,146.7** | 1,055.5 | +8.6% |
| Equity ratio, % | | | | **68.8%** | 64.6% | |
| Gearing, % | | | | **-17.1%** | -1.9% | |
| Interest-bearing liabilities, EUR million | | | | **151.5** | 151.3 | +0.1% |
| Non-interest-bearing liabilities, EUR million | | | | **222.1** | 224.5 | -1.1% |
| Cash and cash equivalents and money market investments, EUR million | | | | **283.7** | 164.1 | +72.9% |
| ROCE (before taxes), % | | | | **44.3%** | 36.2% | |
| ROE (after taxes), % | | | | **45.5%** | 34.2% | |
| Basic earnings per share, EUR | **0.38** | 0.39 | -3.8% | **2.35** | 1.61 | +46.0% |
| Diluted earnings per share, EUR | **0.38** | 0.39 | -3.8% | **2.35** | 1.61 | +46.0% |
| Cash flow per share before financial items, EUR | **0.22** | 0.22 | -0.3% | **2.32** | 1.09 | +112.4% |
| Equity per share, EUR | | | | **5.50** | 4.83 | +13.7% |
| Personnel expenses, EUR million | | | | **202.8** | 218.1 | -7.0% |

| Discontinued operations | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Profit for the period as stated in the consolidated statement of comprehensive income, EUR million | | 0.7 | -100.0% | **132.9** | 6.9 | |
| Capital gain, EUR million | | | | **128.4** | | |
| Sales-related expenses, EUR million | | | | **-0.8** | | |
| Item related to transfer of benefit pension plans, EUR million | | | | **4.5** | | |
| Basic earnings per share, EUR | | 0.01 | -100.0% | **0.95** | 0.05 | |
| Diluted earnings per share, EUR | | 0.01 | -100.0% | **0.95** | 0.05 | |

**President and CEO Timo Lappalainen:**

## Important year for future growth

"Our key objective in the upcoming years is to systematically strive for growing more rapidly than the growth in the market and to increase our net sales to EUR 1.5 billion by 2025. The capital gain from the sale of the Orion Diagnostica business division in 2018 allows additional investments in our own pharmaceutical research as well as in boosting our sales and marketing efforts, among other things. It also allows us to maintain the good level of dividends. The growth projects will burden the profit in 2019, but at the same time the investments lay an important basis for our growth targets.

Our single most important growth project during the next few years is the development of the prostate cancer drug darolutamide, in which crucial progress was made in the year under review. The Phase III trial of darolutamide in patients with non-metastatic castration-resistant prostate cancer, which was carried out in cooperation with Bayer, met the primary endpoint in October: the oral androgen receptor antagonist darolutamide significantly extended metastasis-free survival compared to placebo. More detailed data from the trial will be presented in mid-February at the ASCO GU (Genitourinary Cancers Symposium). Bayer has started the discussions with health authorities regarding the submission for a marketing authorisation application, but the timing is still open. Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). If the process proceeds as planned, in the best-case scenario, the product could be launched in the United States already at the end of this year. We are eligible to receive significant milestone payments upon first commercial sales, which amount to EUR 45 million in the United States. We also continue our ongoing trial with Bayer which evaluates darolutamide in patients with metastatic prostate cancer. Darolutamide's potential will attain a significant increase upon completion of this second Phase III clinical trial (ARASENS) approximately in 2022.

The agreement in early December to reacquire the sales and distribution rights for the Parkinson's disease drug Stalevo from Novartis reinforces Orion's growth targets in Europe. The repatriation of the sales rights will initially increase sales by about EUR 20 million on annual level. The fact that we, as the developer and manufacturer of the drug, are also responsible for the sale and distribution of the product in its entire domestic market area in Europe further highlights Orion's role as a major pharmaceutical company focusing on central nervous system disorders. It will also enable us to more actively promote Stalevo's sales and extend the life cycle of the product.

In the year under review, we also made the decision to start on our own a Phase III clinical trial (REFALS) evaluating orally administered levosimendan (ODM-109) for the treatment of symptoms of amyotrophic lateral sclerosis (ALS). We will invest approximately EUR 60 million over the next three years in this project.

We also continue to seek in-licensing opportunities of research projects in the late stage of development and new products.

Our profitability in 2018 was good: our operating profit margin for continuing operations was 26%, and above our financial target. Our cash flow was stronger than in the comparative period. Net sales and operating profit for our continuing operations were lower than in the comparative period, which was due to unfavourable exchange rate changes, milestone payments and royalties being lower than in the previous year and research and development expenses being higher than in the comparative period. Other than that, the profitability of the business was on the same level as in the comparative period despite many challenges, including price decreases in Finland and lower sales of biosimilars.

Net sales of Proprietary Products slightly increased from the previous year. Its most promising source of growth in the near term is the Easyhaler product family for the treatment of asthma and COPD, the sales growth of which remained strong especially due to the budesonide-formoterol product. In the period under review, we invested in the sales and marketing of the product family particularly in Germany. The sales of the sixth product of the Easyhaler product family, salmeterol-fluticasone, started in the last quarter of the year in the first European countries. There are also plans to further expand the product

family with new products in future. Development of the seventh product, tiotropium, is progressing according to plan.

The sales of branded Parkinson's drugs were lower than in the previous year, as anticipated. However, the decline in sales was significantly slower than our long-term average has been. We expect sales of Parkinson's drugs to continue to decrease in the coming years, as the products have generic competition in practically all markets. Due to additional sales following the reacquisition of Stalevo's sales and distribution rights, Orion's branded Parkinson's drugs sales are expected in 2019 to remain at the same level as in the previous year despite continuously expanding generic competition.

Sales of Dexdor intensive care sedative remained at a good level and grew in most of the countries despite generic competition having expanded to several European countries. Sales of Simdax, a drug for treatment of acute decompensated heart failure, increased slightly.

Net sales of Specialty Products decreased in Finland and Scandinavia. Tougher price competition in Finland following decisions made in 2016 regarding the pricing of substitutable generic drugs has led to an overall decrease in the reference priced prescription drugs market. The impact on Orion has been significant due to our broad product range and market share. Price competition reduced our sales in Finland by approximately EUR 15 million a year both in 2017 and 2018. The impact has sustained longer than previously anticipated. We expect prices to continue decreasing in 2019, but we anticipate the impact on sales to be slightly lower than in 2018.

The sales of Remsima biosimilar (infliximab), a driver of Specialty Products sales growth in 2017, were significantly lower than in the comparative period due to intensified competition. In order to succeed in this competitive market, we need a broad product portfolio. In 2018, we expanded it with Amgevita (adalimumab), our first biosimilar for outpatient use, by signing an agreement for its sale and marketing in Finland with Amgen. Amgevita's sales started in the last quarter of the year.

The Animal Health business developed favourably and net sales grew faster than the market.

The ongoing projects supporting growth are expected to burden Orion's profit in 2019 by an estimated EUR 30 million. This comprises clearly increased depreciation as well as investments in sales and marketing and research. At the same time, operating profit is burdened by intense price competition in the market and gradually expanding generic competition for Orion's old proprietary drugs.

Orion estimates that in 2019 net sales will be slightly higher than in 2018. The estimated net sales include the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide. Operating profit is estimated to be at the same level as in 2018. The estimated operating profit includes the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide as well as significant investments in measures to boost growth. The complete outlook estimate and the basis for it can be found in this report under 'Outlook for 2019' and 'Basis for outlook'."

## Events during the period

On 4 January 2018, Orion announced that it will improve the competitiveness of its laboratory operations by renewing their operating model in Finland. The completion of co-operation negotiations was announced on 28 February 2018.

On 1 March 2018, Orion transferred altogether 112,961 Orion Corporation B shares held by the Company as a share reward for earning periods 2015–2017 and 2017 to the key persons employed by the Orion Group and belonging to the Share-Based Incentive Plans of the Orion Group.

On 19 March 2018, Orion announced having received positive conclusions for the salmeterol-fluticasone Easyhaler® combination under the EU's decentralised procedures (DCP). The deliveries to the first countries started in October.

On 20 March 2018, Orion Corporation's Annual General Meeting was held in Helsinki.

On 21 April 2018, Orion signed an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business division) to an investment fund managed by Axcel Management A/S. The sale was closed on 30 April 2018. Following the transaction, Orion has only one reporting segment, Pharmaceuticals business. A capital gain of EUR 128 million was booked for the transaction in 2018.

On 14 June 2018, the new manufacturing facility at Fermion's Hanko plant was commissioned. Orion invested more than EUR 30 million in the project.

On 6 July 2018, Orion announced that the first patients had been recruited in the Phase III clinical trial (REFALS), in which orally administered levosimendan (ODM-109) is being evaluated for the treatment of symptoms of amyotrophic lateral sclerosis (ALS).

On 19 September 2018 Orion announced changes in responsibility areas of its Group Executive Management Board members and the establishment of a new Growth Projects function. Mr. Markku Huhta-Koivisto, Senior Vice President, Proprietary Products business division, took the responsibility for projects aiming at Orion Group's growth, as Senior Vice President, Growth Projects. Ms. Satu Ahomäki, Senior Vice President, Global Sales took responsibility for the Proprietary Products business division in addition to her Global Sales (sales of human pharmaceuticals) line function. The responsibility area of Ms. Ahomäki is called Commercial Operations. Dr. Liisa Hurme, Senior Vice President, Specialty Products and Fermion took the responsibility for the Supply Chain line function. In addition, Fermion business division will still belong to Hurme's responsibility area. Ms. Virve Laitinen, Senior Vice President, Supply Chain took the responsibility for the Specialty Products business division. The changes took effect on 1 October 2018 and 1 January 2019.

On 24 October 2018, Orion announced that it had signed an agreement with Amgen on the marketing and sales of the adalimumab biosimilar Amgevita® in Finland. Amgevita is Orion's first biosimilar for outpatient use. The product's sales started in the last quarter of the year.

On 24 October 2018 Orion and Bayer announced that they had completed the Phase III clinical trial (ARAMIS) of darolutamide, the novel oral androgen receptor antagonist for the treatment of patients with non-metastatic castration-resistant prostate cancer. The primary endpoint of the trial was met: Darolutamide significantly extended metastasis-free survival compared to placebo. The safety profile and the tolerability of darolutamide were consistent with previously published data. An abstract of the study will be published on 11 February 2019, and the full data will be presented at the ASCO GU (Genitourinary Cancers Symposium) on 14 February 2019. Bayer is discussing the data from the trial with health authorities regarding the submission for marketing authorisation application. Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment in men with non-metastatic castration-resistant prostate cancer.

Bayer has covered the majority of the darolutamide development costs. Bayer has the right to commercialize darolutamide globally while Orion has the option of co-promoting the product in Europe. In addition, Orion will manufacture the product for global markets.

Based on the terms of the agreement between Orion and Bayer, Orion is eligible to receive milestone payments from Bayer upon first commercial sale of darolutamide as follows:

- EUR 45 million upon first commercial sale in the United States
- EUR 20 million upon first commercial sale in the EU
- EUR 8 million upon first commercial sale in Japan

Besides milestone payments, Orion will also receive tiered royalties on the product sales, which will be approximately 20 percent, including production revenue. With sales increase, royalties may increase slightly. Orion also has the possibility to receive one-off payments from Bayer if certain sales targets are met.

In addition to the completed ARAMIS trial, Orion and Bayer have an ongoing Phase III clinical trial (ARASENS) which evaluates the safety and efficacy of darolutamide in patients with metastatic hormone-sensitive prostate cancer. Expected to be completed in 2022, there are no separate milestone payments related to the ARASENS trial.

On 3 December 2018, the sales and distribution rights in certain European countries for the Parkinson's disease drug Stalevo®, developed by Orion, transferred back to Orion from Novartis. Orion paid USD 24.5 million for the transfer of the sales rights and estimates that as a result of the return of the rights, Orion's Stalevo sales may increase initially by about EUR 20 million on annual level.

## Events after the period

On 9 January 2019, the Nomination Committee of Orion Corporation gave its recommendation to the Board of Directors for the proposal to the Annual General Meeting 2019 concerning the composition of the Board of Directors to be elected.

## News conference and teleconference

A news conference and teleconference on the published results will be held on Wednesday 6 February 2019 at 13.30 EET at Orion's head office (address: Orionintie 1A, Espoo). President and CEO Timo Lappalainen will give a brief presentation in English on the financial review.

The event can be followed as a live webcast accessible on Orion's website at http://www.orion.fi/en/investors. After the presentation, questions can be asked also via teleconference in Finnish and English.

The conference call ID is 685819 and the telephone numbers to participate in the teleconference are:

Finland: +358 (0)9 7479 0360
Sweden: +46 (0)8 5033 6573
United Kingdom: +44 (0)330 336 9104
United States: +1 323-794-2095

### News conference recordings

A recording of the webcast of the event in English and a recording of the presentation by the President and CEO in Finnish will be published on Orion's website during Wednesday 6 February 2019.

## Financial report material

Financial reports and related presentation material will be available at http://www.orion.fi/en/investors promptly after publication. The website also has a form for subscribing to Orion's releases.

## Dates in Orion calendar 2019

| | |
|---|---|
| Annual General Meeting 2019 | Planned to be held on Tuesday 26 March 2019 |
| Interim Report January–March 2019 | Thursday 25 April 2019 |
| Half-Year Financial Report January–June 2019 | Wednesday 17 July 2019 |
| Interim Report January–September 2019 | Wednesday 23 October 2019 |

The Financial Statements and Report by the Board of Directors for 2018 will be published on the Company's website at the latest in week 10/2019.

## Capital Markets Day 2019

Orion will host a Capital Markets Day for analysts, institutional investors and media in Helsinki on Wednesday, 22 May 2019. The invitation and further information will be published closer to the event.

## For additional information about the report:


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http://www.orion.fi/en/investors

# Financial review for 1 January–31 December 2018

On 21 April 2018, Orion signed an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business division) to an investment fund managed by Axcel Management A/S. The transaction was closed on 30 April 2018.

Following the transaction, in the Financial review and the tables of the Financial Statement Release, Orion Diagnostica business is reported as a discontinued operation and as a rule, the report only covers continuing operations. Comments and figures related to discontinued operations are listed separately.

The Group currently only has one segment, the Pharmaceuticals business.

## Net sales

Orion Group's net sales in 2018 totalled EUR 977 (1,034) million, a decrease of 5%. Of the total net sales decrease of EUR 56 million, exchange rate changes accounted for EUR 16 million and lower royalties and milestone payments than in the comparative period for EUR 19 million.

Net sales from product sales also decreased due to lower sales of biosimilars, tightened price competition especially in Finland and generic competition.

## Operating profit

The Orion Group's operating profit was down by 11% at EUR 253 (284) million.

Gross profit from product sales was EUR 4 million lower than in the comparison period. The negative effect of net sales calculated in local currencies on gross profit was EUR 10 million. On the other hand, higher margin level and favourable product mix increased the gross profit by EUR 19 million. Exchange rate changes had a EUR 13 million negative effect on the gross profit.

Milestone payments, royalties and service sales had a negative effect of EUR 22 million.

## Profit impact of the sale of Orion Diagnostica

Items related to the sale of Orion Diagnostica and the profit generated by Orion Diagnostica for the period from 1 January to 30 April 2018 are entered as a discontinued operation. A capital gain of EUR 128 million was booked for the transaction. The departure of Orion Diagnostica from the Orion pension fund caused one-off income of EUR 5 million and the transaction process incurred expenses of approximately EUR one million.

## Operating expenses

The Group's sales and marketing expenses totalled EUR 195 (189) million.

R&D expenses were up by 5% at EUR 104 (99) million and accounted for 11% (10%) of the Group's net sales. Research projects are reported in more detail under 'Business Review'.

Administrative expenses were EUR 43 (49) million, down by 12%.

Other operating income and expenses were EUR 5 (5) million.

## The Group's profit including both continuing and discontinued operations

The profit of the Group's continuing operations was EUR 197 (219) million and the profit of discontinued operations was EUR 133 (7) million.

Basic earnings per share for continuing operations were EUR 1.40 (1.56) and basic earnings per share including continuing and discontinued operations were EUR 2.35 (1.61). Equity per share was EUR 5.50 (4.83).

The return on capital employed before taxes (ROCE) was 44% (36%) and the return on equity after taxes (ROE) 45% (34%).

### Financial position including both continuing and discontinued operations

The Group's gearing was -17% (-2%) and the equity ratio 69% (65%).

The Group's total liabilities at 31 December 2018 were EUR 374 (376) million. At the end of the period, interest-bearing liabilities amounted to EUR 152 (151) million, including EUR 1 (150) million of long-term loans.

The Group had EUR 284 (164) million of cash and cash equivalents and money market investments at the end of the period. The cash and cash equivalents are invested in short-term money market instruments issued by financially solid financial institutions and corporations.

After the period under review, Orion signed a EUR 100 million loan agreement with the European Investment Bank in January 2019. The loan is to be raised in 2019.

### Cash flow including both continuing and discontinued operations

Cash flow from operating activities was EUR 231 (228) million.

The cash flow from investing activities was EUR 95 (-75) million positive following the sale of Orion Diagnostica. Excluding the sale of Orion Diagnostica, cash flow from investing activities was EUR -66 (-75) million, i.e. cash flow before cash flow from financing activities was better than in the comparative period even without proceeds from the sale of Orion Diagnostica.

The cash flow from financing activities was EUR -205 (-220) million.

### Capital expenditure

The Group's capital expenditure in continuing operations totalled EUR 65 (75) million, down by 13%. This comprised EUR 36 (67) million on property, plant and equipment and EUR 29 (9) million on intangible assets. Fermion's significant expansion investment at its Hanko manufacturing plant was completed in June 2018.

## Key business targets for 2019

- Preparing for the launch and commercialisation of the prostate cancer drug darolutamide in collaboration with Bayer, assuming that the marketing authorisation process progresses as planned. Continued research and development collaboration in the ARASENS trial (metastatic prostate cancer) to expand the indication.
- Development of orally administered levosimendan (ODM-109) for ALS in phase III clinical trial and preparation of its possible commercialisation. In research and development, the potential of different projects are reviewed with consideration of the total research portfolio.
- Strengthening Orion's position as the most significant provider of generic drugs in Finland and competitive pricing.
- Development of a competitive product portfolio in Specialty Products and strengthening of product launches.
- Accelerating the growth of the Easyhaler product family and strengthening its market position. The launch of the salmeterol-fluticasone Easyhaler progressing in Europe.
- Evaluation of new in-licensing opportunities in Europe, particularly in the area of hospital care.

Orion regularly monitors the progress of these goals in its financial reports.

## Outlook for 2019

Orion estimates that in 2019 net sales will be slightly higher than in 2018 (net sales in 2018 were EUR 977 million). The estimated net sales include the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide.

Operating profit is estimated to be at the same level as in 2018 (operating profit in 2018 was EUR 253 million). The estimated operating profit includes the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide as well as significant investments in actions to generate growth.

## Basis for outlook in more detail

Orion continues persistent actions to generate growth more rapidly than the growth in the market in the long term. The ongoing projects supporting growth are expected to burden Orion's profit in 2019 by an estimated EUR 30 million. This comprises clearly increased depreciation as well as investments in sales and marketing and research. At the same time, operating profit is burdened by intense price competition in the market and gradually expanding generic competition for Orion's old proprietary drugs.

### Net sales

The sales of the Easyhaler® product family will continue to grow also in 2019 due to combined formulations (budesonide-formoterol and salmeterol-fluticasone) launched in the past few years.

In December 2018, Orion reacquired the European sales and distribution rights for the Parkinson's drug Stalevo® from Novartis. Due to the anticipated additional sales of around EUR 20 million following the transaction, the sales of Orion's branded Parkinson's drugs (Comtess®, Comtan® and Stalevo) are estimated to remain at the same level as in the previous year despite continuously expanding generic competition.

In several European countries, marketing authorisation has been granted for a generic version of Dexdor®. Generic competition commenced in Germany in 2017 and expanded to a few other European countries during 2018. In 2019, generic competition is estimated to further expand in the EU, and the sales of the product to turn to decline. Orion has also been informed that a marketing authorisation application has been filed for a generic version of Simdax® in Europe. It is, however, difficult to estimate the impact of generic competition on the sales of Dexdor and Simdax. The patent for the Simdax molecule expired in September 2015 but this is still not expected to have a material impact on sales of the product in 2019. Orion is continuing actions to defend its rights.

Sales of generic products account for a significant proportion of Orion's total sales. Competition in Finland, the most important generic market for Orion, remains intense in 2019. However, product launches continue to support Orion's position as market leader in Finland. At the beginning of 2017, changes were made to the pricing system for substitutable prescription drugs in Finland by narrowing the so-called price band. The change caused an estimated EUR 15 million yearly sales decline both in 2017 and 2018. Thus the cumulative two-year negative impact was around EUR 30 million. The 2019 outlook assumes that the impact of the system change and its effect in lowering prices will still be significant, but slightly smaller than in the two previous years. The sales of reference priced drugs declined by 7% in the Finnish pharmaceuticals market in 2018 and the sales of Orion's reference priced drugs declined by 9% (Source: IQVIA).

In 2017, the EUR 57 million sales of the biosimilar Remsima® generated a significant portion of the growth in net sales of the Specialty Products business division, but in 2018 Remsima sales were materially lower due to intensified competition and declined price level. Besides Remsima, Orion has launched other biosimilars, such as Ritemvia® (rituximab) and Amgevita® (adalimumab). As a whole, the sales of biosimilars are expected to be at the same level in 2019 as in the previous year.

Collaboration agreements with other pharmaceutical companies are an important component of Orion's business model. Agreements often include payments recorded in net sales that vary greatly from year to year. Forecasting the timing and amount of these payments is difficult. In some cases they are conditional

on, for instance, the progress or findings of research projects, which are not known until studies have been completed. On the other hand, neither the outcome nor the schedule of contract negotiations is generally not known before the final signing of the agreement. The possible EUR 45 million milestone payment associated with the commercialisation of the prostate cancer drug darolutamide in the United States is included in the outlook for 2019. However, there is still significant uncertainty regarding its timing.

### Expenditure

The start of production at Fermion's new manufacturing plant in Hanko increases production costs by around EUR 3 million following depreciation. The investment is an important part of Orion's preparation for the future. In the short term, however, increased depreciation has a negative impact on profit since the new plant replaces the one built in the 1970s.

Marketing expenditure will be higher than in the previous year due to additional promotion of sales of the Easyhaler product portfolio in countries where these products have been launched in recent years. In 2019, expenditure will also be increased by a EUR 11 million depreciation related to the acquisition of European sales and distribution rights for the Parkinson's drug Stalevo. Orion paid USD 24.5 million for the transfer of the sales rights in December 2018, and the investment will be depreciated over two years.

Because the registrations and launches of new products are projects that generally take more than a year, the increases in resources and other inputs required in 2019 were mainly planned during the previous year.

Research and development costs are estimated to be higher than in 2018, in particular due to the Phase III REFALS clinical trial evaluating levosimendan (ODM-109) for the treatment of symptoms of ALS. Of the EUR 60 million total investment in the roughly three-year trial, it is estimated that more than EUR 25 million will be spent in 2019. Research and development costs are partly the Company's internal fixed cost items, such as salaries and maintenance of the operating infrastructure, and partly external variable costs. External costs arise from, among other things, long-term clinical trials, which are typically performed in clinics located in several countries. The most important clinical trials scheduled for 2019 are either continuing from the previous year or at an advanced stage of planning, therefore their cost level can be estimated rather accurately. However, the accrued costs are materially affected by collaboration arrangements and how the costs arising are allocated between Orion and its collaboration partners. For instance, Bayer is paying the majority of the darolutamide research costs.

### Investments

The Group's total capital expenditure in 2019 is expected to be lower than in 2018, when capital expenditure was EUR 65 million.

## Near-term risks and uncertainties

The reacquisition of European sales and distribution rights for Stalevo will generate additional sales for Orion's branded Parkinson's drugs in 2019. On the other hand, sales will decline due to continued generic competition. These effects have been taken into account in the outlook estimate for the current year. However, they still entail uncertainty that may materially affect the accuracy of the estimate made at this stage.

The basic Dexdor and Simdax patents have expired. However, the products have other product protection that is still valid. In several European countries, marketing authorisation has been granted for a generic version of Dexdor. Generic competition commenced in Germany in 2017 and expanded to a few other European countries during 2018. In 2019 generic competition is estimated to further expand in the EU, and the sales of the product to turn to decline. Orion has also been informed that a marketing authorisation application has been filed for a generic version of Simdax in Europe. It is, however, difficult to estimate the impact of generic competition on the sales of Dexdor and Simdax. As regards Simdax, the possible generic competition is still not estimated to materially impact its sales in 2019. Orion is continuing actions to defend its rights.

Sales of individual products and also Orion's sales in individual markets may vary, for example depending on the extent to which the ever-tougher price and other competition prevailing in pharmaceuticals markets in recent years will specifically focus on Orion's products. Deliveries of Parkinson's drugs to Novartis, the most important collaboration partner, are based on timetables that are jointly agreed in advance. Nevertheless, they can change, for example as a consequence of decisions by Novartis concerning adjustments of stock levels. In addition, changes in market prices and exchange rates affect the value of deliveries to Novartis.

The structural exchange rate risk due to the US dollar has decreased in recent years because the share of Orion's net sales invoiced in dollars has fallen to below ten per cent and at the same time the value of purchases in dollars has increased. The greatest exchange rate risk at present relates to European currencies such as the Swedish crown and British pound. However, the overall effect of the risk due to currencies of European countries will be abated by the fact that Orion has organisations of its own in most of these countries, which means that in addition to sales income, there are also costs in these currencies. Changes in the Japanese yen exchange rate have become more important as sales of Parkinson's drugs in Japan have increased. The exchange rate effect related to the Russian rouble has increased due to the strong volatility of the currency. However, Russian sales are not a significant portion of Orion's entire net sales.

Orion's broad product range may cause risks to the delivery reliability and make it challenging to maintain the high quality standard required in production. Authorities and key customers in different countries undertake regular and detailed inspections of development and manufacturing of drugs at Orion's production sites. Any remedial actions that may be required may at least temporarily have effects that decrease delivery reliability and increase costs. Orion's product range also includes products manufactured by other pharmaceutical companies. Possible problems related to the delivery reliability or quality of the products of those manufacturers may cause a risk to Orion's delivery reliability. The single-channel system used for pharmaceuticals distribution in Finland, in which Orion's products have been delivered to customers through only one wholesaler, may also cause risks to delivery reliability. To ensure deliveries, in addition to Oriola Finland Oy, there are also other distributors temporarily distributing certain Orion products.

Research projects always entail uncertainty factors that may either increase or decrease estimated costs. The projects may progress more slowly or faster than assumed, or they may be discontinued. Nonetheless, changes that may occur in ongoing clinical studies are reflected in costs relatively slowly, and they are not expected to have a material impact on earnings in the current year. Owing to the nature of the research process, the timetables and costs of new studies that are being started are known well in advance. They therefore typically do not lead to unexpected changes in the estimated cost structure. Orion often undertakes the last, in other words Phase III, clinical trials in collaboration with other pharmaceutical companies. Commencement of these collaboration relationships and their structure also materially affect the schedule and cost level of research projects.

Collaboration arrangements are an important component of Orion's business model. Possible collaboration and licensing agreements related to these arrangements also often include payments to be recorded in net sales that may materially affect Orion's financial results. In 2014–2018 the annual payments varied from EUR 5 million to EUR 39 million. The payments may be subject to certain conditions relating to the development of research projects or sales, and whether these conditions are triggered and the timing of triggering always entail uncertainties. The possible EUR 45 million milestone payment associated with the commercialisation of the prostate cancer drug darolutamide in the United States is included in the outlook for 2019. However, there is still significant uncertainty regarding its timing.

## Orion's dividend distribution policy

Orion's dividend distribution takes into account the distributable funds and the capital expenditure and other financial requirements in the medium and long term to achieve the financial objectives.

## Proposal by the Board of Directors: dividend EUR 1.50 per share

The parent company's distributable funds are EUR 473,099,971.28, or EUR 3.36 per share. This includes EUR 338,453,364.28, or EUR 2.41 per share, of profit for the financial year. These per share amounts are calculated excluding treasury shares held by the Company.

The Board of Directors proposes payment of a dividend of EUR 1.50 per share from the parent company's distributable funds.

No dividend shall be paid on treasury shares held by the Company on the dividend distribution record date. On the day when the profit distribution was proposed, the number of shares conferring entitlement to receive dividend totalled 140,695,388, on which the total dividend payment would be EUR 211,043,082.00. The Group's payout ratio for the financial year 2018 would be 63.8% (90.1%). The dividend payment date would be 4 April 2019, and shareholders registered in the Company's shareholder register on 28 March 2019 would be entitled to the dividend payment.

The Board of Directors further proposes that EUR 250,000 (250,000) be donated to medical research and other purposes of public interest in accordance with a separate decision by the Board and that EUR 261,806,889.28 remain in equity.

## Strategy

Orion's Board of Directors has confirmed the Company's strategy for 2019–2023.

### Operating environment

Orion's strategy implementation is supported by global healthcare megatrends that have material impact on the consumption and price level of drugs as well as on pharmaceutical research. These megatrends include:

- ageing of population
- advances in science: personalised medicine, increased genetic and epigenetic data and developments in drug dosing and diagnostics
- the increasing cost burden of healthcare, need for cost-effective treatments and drugs
- increased personal responsibility for own health
- digitalisation and value-adding solutions in medication

### Mission

Orion's mission is to build well-being. Orion builds well-being by bringing to markets drugs that give patients help and an effective treatment for their illnesses. An effective drug also creates added value for the patient by improving the quality of life.

### Focus areas

The crucial focus areas for implementing the strategy are:

- **Quality and safety.** High quality, product safety and complying with requirements of authorities are indispensable in the pharmaceutical industry.
- **Competitive product portfolio** requires continuous renewal of the portfolio. Orion invests in product development, manufacturing, acquisition and effective launching of products and management of their life cycle.

- **Strong corporate culture of working together,** the basis of which is valuable and important work for the customer. Orion wants to be an excellent workplace and a responsible and attractive employer that continuously develops the well-being of its personnel at work and their expertise.
- **Partnerships.** Orion's operations are based on utilising worldwide networks. Well-managed partnerships and collaborations are a competitive advantage for the Company.
- **Productivity and flexibility.** Price pressure on drugs requires cost awareness and seamless co-operation between different parts of the Company to achieve the targeted profitability level. Flexibility to react rapidly to changes in the operating environment is also needed. Due to its size, Orion can be more agile than large companies and gain a competitive advantage from this.

### Strategic targets

The following strategic targets and their achievement are monitored in the Company with clearly defined indicators:

- **Growing faster than the markets.** The key objective in the coming years is to persistently strive for growing faster than the markets. The objective is to increase net sales to EUR 1.5 billion by 2025. Growth enables the Company to develop and take manageable risks. The target of growing faster than the markets should be achieved by the Company as a whole and in the geographic and product areas in which Orion operates.

  The sale of the Orion Diagnostica division in 2018 and the resulting capital gain will allow Orion to futher focus on growth and achieving its financial goals. Orion is currently working on numerous projects that target growth. The Company continues to invest in its own research and development activities, for example by investing in new clinical trials, and actively evaluates in-licensing opportunities of products in the late stage of development. At the same time, the capital gain strengthens Orion's equity position and ability to continue achieving its dividend distribution objective.

  The single most important growth project in the next few years is the development of the prostate cancer drug darolutamide and launching the product in cooperation with Bayer. Other than this, growth in the near future will be sought especially from the Easyhaler product family for the treatment of asthma and COPD. Growth will also be supported through various digital projects and tools that ease the daily medical care.

- **Providing new innovative and cost-effective drugs and treatments for patients**. The product development pipeline has balanced numbers of proprietary products and generic projects in different phases. In its research the Company aims for the best input/output ratio in the field.

- **Working together to benefit the customer.** Orion's personnel are committed and understand the needs of customers. The working atmosphere, customer satisfaction and Company image are outstanding.

- **Continuous improvement of performance in sustainability.** Patient safety is the most vital aspect of Orion's corporate responsibility, and managing the environmental responsibilities is an important part of the Company's sustainability. In addition, Orion aims to continuously develop the personnel's occupational safety and ability to cope with their work.

- **Strong development of profitability**

## Financial objectives

Through the financial objectives Orion aims to develop the Group's shareholder value and ensure financial stability and profitable growth. Orion's financial objectives are:

- Growing net sales more rapidly than growth of the pharmaceuticals market. Achievement of this objective requires continuous investment in development of the product portfolio.
- Maintaining profitability at a good level. The aim is operating profit that exceeds 25% of net sales.
- Keeping the equity ratio at least 50%.
- Distributing an annual dividend that in the next few years will be at least EUR 1.30 per share, and increasing the dividend in the long term.

In the short term what actually happens may deviate from the objectives.

R&D projects that have made promising progress will probably somewhat increase the Company's research expenses in the next few years. However, agreements already made relating to research projects and their good progress, and possible new agreements with partners relating to other projects are expected to generate material milestone payments in coming years. Successful projects will have a positive effect on Orion's net sales and especially operating profit even before possible approval of new proprietary drugs and before the actual commencement of product sales.

## Corporate responsibility: Material themes and indicators

Orion is committed to continuously improving its performance in sustainability. In 2018, the company conducted a materiality assessment, on the basis of which it has identified material themes and indicators for its corporate responsibility. They are prioritised in the development of operations, and the Company also regularly reports on the indicators. The key themes of Orion's corporate responsibility are related to patient safety, ensuring reliable supply of medications and manufacturing them in an environmentally sustainable way, ensuring efficient use of materials, energy efficiency and appropriate wastewater management. A more extensive report of corporate responsibility is published as part of the Report by the Board of Directors in the Financial Statements 2018, under ' Non-financial reporting '. A separate Sustainability Report for 2018 will be published in May.

| | 2018 | 2017 |
|---|---|---|
| **Total energy consumption and energy savings** | | |
| Total absolute energy consumption (MWh) | 155,198 | 160,818 |
| Energy savings achieved by saving measures and efficiency improvements, MWh | 1,074 | 3,725 |
| Energy Efficiency Programme targets achieved | 40% | 31% |
| **Occupational well-being of personnel: Workplace injuries and sick leave of the personnel** | | |
| Lost time incident frequency, LTIF 1 | 5.5 | 6.3 |
| Absence due to illness (hours of absence due to illness as percentage of total theoretical working hours) | 3.1% | 3.0% |
| **Respect for human rights and prevention of corruption and bribery** | | |
| Human rights violations in own operations reported through the whistleblowing channel | 0 | 0 |
| Anti-corruption and anti-bribery training, number of participants | n/a | 2,808 |
| **Product quality and safety** | | |
| Number of audits of Orion's operations, total | 61 | 81 |
| Audits by authorities | 13 | 19 |
| Audits by collaboration partners | 48 | 62 |
| Critical observations | 0 | 0 |
| Number of audits undertaken by Orion | 238 | 314 |
| Critical observations | 10 | 26 |
| Rejections | 1 | 5 |
| Number of customer complaints about the Pharmaceuticals business (ppm) | 56 | 64 |

LTIF 1: Indicates the workplace injury rate as injuries causing an absence of at least one day per million total actual working hours.

Key figures for audits of Orion's operations and audits conducted by the Company include GxP audits and sustainability (i.e. environmental, occupational health and safety, labour and ethics) audits.

The number of customer complaints about the Pharmaceuticals business's operations is reported as the number per million packages (ppm).

Energy Efficiency Programme: Orion is committed to the extension period of the joint Energy Efficiency Programme for the members of the Confederation of Finnish Industries (EK).

# Shares and shareholders

On 31 December 2018, Orion had a total of 141,257,828 (141,257,828) shares, of which 37,120,346 (37,120,346) were A shares and 104,137,482 (104,137,482) B shares. The Group's share capital is EUR 92,238,541.46 (92,238,541.46). At the end of 2018 Orion held 562,440 (675,401) B shares as treasury shares. On 31 December 2018, the aggregate number of votes conferred by the A and B shares was 845,981,962 (845,869,001) excluding treasury shares.

At the end of 2018, Orion had 72,802 (57,339) registered shareholders.

## Voting rights conferred by shares

Each A share entitles its holder to twenty (20) votes at General Meetings of Shareholders and each B share one (1) vote. However, a shareholder cannot vote more than 1/20 of the aggregate number of votes from the different share classes represented at a General Meeting of Shareholders. The Company itself and Orion Pension Fund do not have the right to vote at an Orion Corporation General Meeting of Shareholders.

Both share classes, A and B, confer equal rights to the Company's assets and dividends.

## Conversion of shares

The Articles of Association entitle shareholders to demand the conversion of their A shares to B shares within the limitation on the maximum number of shares of a class. No shares were converted in January–December 2018.

## Trading in Orion's shares

Orion's A shares and B shares are quoted on Nasdaq Helsinki in the Large Cap group under the Healthcare sector heading under the trading codes ORNAV and ORNBV. Trading in both of the Company's share classes commenced on 3 July 2006, and information on trading in the Company's shares has been available since that date.

On 31 December 2018, the market capitalisation of the Company's shares, excluding treasury shares, was EUR 4,261 million.

In 2018 a total of 2,131,981 A shares and 121,458,874 B shares were traded on Nasdaq Helsinki. The total value of the shares traded was EUR 3,452 million. During the year, 5.7% of the A shares and 116.6% of the B shares were traded. The average turnover in Orion's shares was 87.5%.

The price of Orion's A shares decreased by 6% and the price of its B shares by 3% in 2018. On 31 December 2018 the closing quotation was EUR 30.30 for the A shares and EUR 30.28 for the B shares. The highest quotation for Orion's A shares was EUR 35.70 and the lowest quotation was EUR 24.75. The highest quotation for the B shares in 2018 was EUR 33.50 and the lowest quotation was EUR 22.57.

Orion shares are also traded on various alternative trading platforms in addition to Nasdaq Helsinki. In 2018 Nasdaq Helsinki accounted for about 94% of the entire trading volume in Orion A shares. Nasdaq Helsinki accounted for about 63% of the entire trading volume in Orion B shares (source: Fidessa Fragmentation Index).

## Authorisations of the Board of Directors

Orion's Board of Directors was authorised by the Annual General Meeting on 22 March 2016 to decide on acquisition of shares in the Company and on a share issue in which shares held by the Company can be conveyed. The authorisation to acquire shares was utilised during 2016.

The Board of Directors is authorised to decide on conveyance of no more than 600,000 Orion Corporation B shares held by the Company. The authorisation to issue shares is valid for five years from the decision taken by the Annual General Meeting. The terms and conditions of the authorisation were reported in more detail in a stock exchange release on 22 March 2016.

The Board of Directors is not authorised to increase the share capital or to issue bonds with warrants or convertible bonds or stock options.

### Share-based incentive plans

The Group has one currently operating share-based incentive plan for key persons of the Group: Orion Group's Long-Term Incentive Plan 2016. The plan was announced in a stock exchange release published on 2 February 2016.

On 1 March 2018, Orion transferred altogether 112,961 Orion Corporation B shares held by the Company as a share reward for earning periods 2015–2017 and 2017 to the key persons employed by the Orion Group and belonging to the share-based incentive plans of the Orion Group.

Shares received based on the one-year earning periods under the share-based incentive plan cannot be transferred during the restricted period defined for the plan. For the three-year earning periods, there is no restricted period.

### Share ownership

Orion's shares are in the book-entry system maintained by Euroclear Finland, and Euroclear Finland maintains Orion's official shareholder register.

At the end of 2018, Orion had a total of 72,802 (57,339) registered shareholders, of whom 95% (95%) were private individuals. They held 42% (40%) of the entire share stock and had 62% (62%) of the total votes. There were 45 (56) million nominee-registered and foreign-owned shares, which was 32% (40%) of all shares, and they conferred entitlement to 7% (9%) of the total votes.

At the end of 2018, Orion held 562,440 (675,401) B shares as treasury shares, which is 0.4% (0.5%) of the Company's total share stock and 0.07% (0.08%) of the total votes.

### Notification threshold

There were no threshold notifications during 2018.

### Management's shareholdings

At the end of 2018, the members of the Board of Directors owned a total of 620,574 of the Company's shares, of which 564,228 were A shares and 56,346 B shares. At the end of 2018, the President CEO owned 105,976 of the Company's shares, which were all B shares. The members of the Group's Executive Management Board (excluding the President and CEO) owned a total of 186,161 of the Company's shares, which were all B shares. Thus, the Company's executive management held 0.65% of all of the Company's shares and 1.37% of the total votes.

The Company does not have stock option programmes.

## Personnel

The average number of employees in the Orion Group in 2018 was 3,179 (3,205). At the end of December 2018, the Group had a total of 3,154 (3,161) employees, of whom 2,485 (2,526) worked in Finland and 669 (635) outside Finland.

Salaries and other personnel expenses in 2018 totalled EUR 201 (204) million.

## Significant legal proceedings

Companies belonging to the Orion Group are parties to various legal disputes, which are not, however, considered to be significant legal proceedings for the Group.

# Business review

Orion signed an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business division) on 21 April 2018. The transaction was closed on 30 April 2018. Following the transaction, Orion Diagnostica business is reported as a discontinued operation. As a result, the Group only has one reporting segment, the Pharmaceuticals business. In the Financial Statement Release, Orion Diagnostica business is reported as a discontinued operation, and as a rule, the report only covers continuing operations.

## Review of human pharmaceuticals market

Finland is the most important individual market for Orion, generating about one-third of the Group's net sales. According to IQVIA statistics, a significant share of Orion's prescription drug sales in the Finnish pharmacy channel, approximately 69%, were reference priced drugs in 2018. The sales of Orion's reference priced prescription drugs decreased slightly more than the market. The decline was mostly due to the change made in the pricing system for substitutable prescription drugs at the beginning 2017, which has been followed by toughened price competition. The average price of reference priced drugs in the market decreased during 2018 approximately 10% from the comparative period. The impact of price competition on Orion has been significant due to the Company's broad product range and significant market share in Finland. The total sales of Orion's human pharmaceuticals, including both medicinal and non-medicinal products, was clearly behind market trend in 2018. The growth in the Finnish pharmaceuticals market has mostly been generated by proprietary products, while they only account for a small share of Orion's net sales in Finland.

Sales of human pharmaceuticals in Finland (medicinal and non-medicinal products):

| EUR million | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|
| **Reference priced prescription drugs (pharmacy channel)** | | | |
| Market | 490 | 528 | -7% |
| Orion | 126 | 139 | -9% |
| **Self-care products (pharmacy channel)** | | | |
| Market | 384 | 372 | +3% |
| Orion | 96 | 96 | 0% |
| **Total sales of human pharmaceuticals (hospital and pharmacy channel)** | | | |
| Market | 2,746 | 2,545 | +8% |
| Orion | 314 | 341 | -8% |

Source: IQVIA pharmaceutical sales statistics 1-12/2018

Despite the challenging operating environment, Orion has maintained its position as leader in marketing pharmaceuticals in Finland. There was no major change in its market share compared to the previous year. Orion has a particularly strong position in reference priced prescription drugs and in self-care product sales, with its market share being a quarter of the market in each.

Orion's market share in the sales of human pharmaceuticals in Finland (medicinal and non-medicinal products):

| Orion's market share, % | 1-12/18 | 1-12/17 |
|---|---|---|
| Reference priced prescription drugs (pharmacy channel) | 26% | 26% |
| Self-care products (pharmacy channel) | 25% | 26% |
| Human pharmaceuticals in total (hospital and pharmacy channel) | 11% | 13% |

Source: IQVIA pharmaceutical sales statistics 1-12/2018

Orion is a significant player also in the Scandinavian generics market.

The most important individual therapy area for Orion is still the treatment of Parkinson's disease. In 2018, Orion's branded Parkinson's drugs containing entacapone (Stalevo®, Comtess® and Comtan®) accounted for 10% of the Group's net sales.

Total sales of Orion's branded Parkinson's drugs:

| EUR or USD million | | MAT9/2018 | MAT9/2017 | Change % |
|---|---|---|---|---|
| United States | USD | **5** | 7 | -28% |
| Europe TOP 5 | EUR | **42** | 56 | -25% |
| Japan | EUR | **67** | 75 | -11% |

Source: IQVIA pharmaceutical sales statistics MAT9/2018 (10/2017-9/2018)
Europe TOP 5: Germany, United Kingdom, France, Spain and Italy

According to IQVIA pharmaceutical sales statistics, in Europe total sales of the most common intravenous anaesthetics and intensive care sedatives (propofol, midazolam, remifentanil and dexmedetomidine) in the 12-month period ending in September 2018 were up by 3% at EUR 558 (540) million. According to IQVIA pharmaceutical sales statistics, sales of Orion's Dexdor® intensive care sedative (dexmedetomidine) were up by 5% at EUR 64 (61) million in Europe.

### Net sales and operating profit of the Pharmaceuticals business

Net sales of the Pharmaceuticals business in 2018 were down by 5% at EUR 977 (1,034) million. The Pharmaceuticals business's operating profit was down by 10% at EUR 265 (296) million. Milestone payments accounted for EUR 5 (12) million and royalties for EUR 17 (30) million of net sales and operating profit.

The operating profit of the Pharmaceuticals business was 27% (29%) of the segment's net sales.

Net sales of Orion's top ten pharmaceuticals in 2018 were EUR 457 (475) million. They accounted for 47% (46%) of the total net sales of the Pharmaceuticals business.

### Proprietary Products

The product portfolio of Proprietary Products consists of patented prescription products in three therapy areas: central nervous system diseases, oncology and critical care, and Easyhaler® pulmonary drugs.

Net sales of the Proprietary Products business division in 2018 were up by 2% at EUR 357 (351) million.

Orion's drugs for treatment of Parkinson's disease are Stalevo® (active pharmaceutical ingredients carbidopa, levodopa and entacapone) and Comtess®/Comtan® (entacapone). Their total net sales in 2018 were down by 3% at EUR 100 (104) million. Strong fluctuations between quarters have been a typical feature in product sales due to the timing of deliveries to key partners. However, the decrease in annual sales was significantly slower than long-term average. In the longer term, Orion expects sales of Parkinson's drugs to continue to decrease, as the products have generic competition in practically all markets. In the United States, Orion's Parkinson's drugs have several generic competitors, and competition is increasing in Europe and also in other markets. In Japan Comtan has generic competitors, but generic competition to Stalevo has not yet commenced.

Breakdown of sales of Parkinson's drugs:

| EUR million | 2018 | 2017 | Change % |
|---|---|---|---|
| Deliveries to key partners | **78** | 76 | 2% |
| Orion's own sales | **22** | 28 | -19% |

The European sales and distribution rights for the Parkinson's drug Stalevo were transferred back from Novartis to Orion in early December. The reacquisition rights reinforces Orion's growth targets in Europe. Orion estimates that the return of the sales rights will initially increase its Stalevo sales by about EUR 20 million on annual level. Due to additional sales, Orion's branded Parkinson's drugs sales are estimated in 2019 to remain at the same level as in the previous year despite continuously expanding generic competition. In conjunction with the signing of the agreement Orion paid USD 24.5 million for the transfer of the sales rights, and the investment will be depreciated over two years. Stalevo has been on the market since 2003, and Orion has been responsible for selling and marketing the product in the Nordic and Baltic countries, Germany, Poland, the United Kingdom and Ireland. The sales and marketing rights for Stalevo will transfer back to Orion in another 18 EU countries and also some European countries outside of the EU.

Total net sales of the Easyhaler product family for treatment of asthma and chronic obstructive pulmonary disease were up by 18% in 2018 at EUR 90 (77) million. Orion's Easyhaler is a dry-powder inhaler developed in-house, for which Orion has developed Easyhaler-adapted dry powder formulations of several well-known generic active substances (salbutamol, beclometasone, budesonide, formoterol, salmeterol and fluticasone). The growth of the Easyhaler product family in 2018 was mainly due to the strong sales of the budesonide-formoterol combined formulation, which was up by 29% at EUR 52 (40) million. Launched in 2014, the product is on sale in all key European markets. Besides Orion's sales, co-marketing partner Menarini sells the budesodine-formoterol combined formulation in France and in a few Southern European countries. The first marketing authorisation applications have also been submitted outside Europe. Menarini is the distributor of the budesonide-formoterol combined formulation in the Asia and Pacific region, and Hikma Pharmaceuticals PLC in the Middle East and North Africa.

Orion's market position in budesonide-formoterol product varies considerably by country. For example in Sweden, Orion had a strong position with 40% share of the market volume in November 2018, while in Germany, where Orion's share of the market of this product was 7%, Orion believes it can achieve growth. During the year under review, Orion increased its resources in the sales and marketing of the Easyhaler product family particularly in Germany.

In March 2018, Orion received positive conclusions for the salmeterol-fluticasone Easyhaler under the decentralised EU marketing authorisation procedure, and the national approval procedures of the marketing authorisation applications started in 23 EU countries. Sales started in the first European countries in the last quarter of the year. The salmeterol-fluticasone combined formulation is the sixth product of the Easyhaler product family. In this formulation fluticasone acts as an anti-inflammatory agent and salmeterol acts as a long-acting bronchodilator.

Orion is also currently engaged in developing a seventh Easyhaler product, with tiotropium as the active pharmaceutical ingredient, for the European market. The expansion of Easyhaler production facility at the Espoo pharmaceuticals production plant was completed in the first half of the year, which will allow production volumes to increase as the product family expands.

Net sales of Orion's Dexdor® intensive care sedative (dexmedetomidine) decreased by 2% to EUR 63 (64) million in 2018. Sales continued to grow in almost all European markets, which compensated the decline in the countries where the product has generic competition. In 2018, there was significant generic competition only in Germany. However, marketing authorisation has been granted for generic versions of Dexdor in several European countries, and it is to be assumed that after the patent protection expires in the first quarter of 2019, generic competition will continue to gradually expand in the EU. However, there are country-specific differences in the expansion, which depend on the timing of tendering competitions, among other things. Sales of the Precedex® intensive care sedative were up by 3% at EUR 26 (25) million. The sales comprise both royalties and sales of the pharmaceutical ingredient.

Simdax®, a drug for treatment of acute decompensated heart failure is sold in some 60 countries worldwide. Net sales of the product in 2018 were up by 4% at EUR 59 (57) million. Orion was informed in the first quarter of 2018 that a marketing authorisation application has been filed for a generic version of Simdax in Europe. The patent for the product's molecule expired in 2015, but possible generic competition is still not expected to have a material impact on sales of the product in 2019.

Orion has launched digital development projects in several therapy areas to improve patient well-being and treatment adherence. Project Daisy involves developing a digital service to improve Parkinson's disease patients' overall well-being. The service facilitates the medical practitioner's work and eases the patient's daily life. The aim is, among other things, to optimise the patient's quality ON-time (the period when medication is effective, and symptoms are under control) and medication by gathering data on the patient's condition via a mobile device, for example.

Orion and Fifth Corner Inc., a Finnish company developing digital coaching solutions, have signed an agreement to seek for new solutions to improve the quality of life of prostate cancer patients. The goal of the collaborative research project is to help prostate cancer patients manage the stress caused by the disease.

### Specialty Products

Net sales of the Specialty Products business division's off-patent, i.e. generic prescription drugs, self-care products and biosimilars in 2018 were down by 9% at EUR 473 (519) million.

Finland, Scandinavia and Eastern Europe and Russia are the most important markets for Specialty Products. The business division's sales in Finland in 2018 were EUR 273 (292) million, down by 7%. Sales declined in particular due to continued intensive price competition in generic drugs, mostly resulting from the changing operating environment, in other words the change made to the pricing system for substitutable prescription drugs in Finland at the beginning of 2017. Price competition reduced Orion's sales in Finland by approximately EUR 15 million annually both in 2017 and 2018. Orion estimates that the impact of the system change and its effect in lowering prices will still be significant in 2019, but slightly smaller than in 2018.

In Scandinavia, sales of Specialty Products totalled EUR 69 (94) million, down by 26%. The decline in sales was in particular due to the decreased sales of the biosimilar Remsima®. In Eastern Europe and Russia, Specialty Products sales were up by 2% at EUR 66 (65) million.

In Specialty Products, 71 (67)% of the net sales came from generic drugs, 24 (22)% from self-care products and 5 (11)% from biosimilars.

The biosimilars net sales totalled EUR 25 (57) million, down by 56%. Net sales of Remsima (infliximab), a biosimilar for the treatment of rheumatoid arthritis among other things, were EUR 17 (57) million. Remsima sales declined by 70% due to intensified competition and the subsequently significantly declined price level. Due to the situation of tendering competitions, Orion had no deliveries to Denmark or Norway in the second half of the year. In late 2018, however, Orion won the Norwegian national tender for Remsima, and deliveries are expected to start in the first quarter of 2019. In Denmark, Orion did not win the tendering competition that took place at the end of 2018. In the first quarter of 2018, Orion launched its second biosimilar, Ritemvia® (rituximab), for treatment of lymphoma, among other things. The the launch of the product in countries is proceeding according to the opening of tendering competitions. The timing of the launch of the third biosimilar, trastuzumab, is still open. In October 2018, Orion signed an agreement with Amgen on the marketing and sales of Orion's first biosimilar for outpatient use in Finland, Amgevita® (adalimumab). The sales of Amgevita, which is used to treat chronic inflammatory diseases and psoriasis, among others, started at the end of the year.

In 2018, Orion launched 74 (79) specialty products, of which 57 (60) were prescription drugs and 17 (19) self-care products or non-medicinal products. The products were launched in Finland and Scandinavia. In Finland, Orion launched a new product in the Burana product family for pain. The new product launched, Buranagel, is the first pain gel in Finland with ibuprofen as the active pharmaceutical ingredient. The Burana product family has been in the market for more than 30 years.

### Animal Health

In the Nordic countries and some Eastern European markets Orion itself sells veterinary drugs, and in other markets the Company operates through partners. In addition, in the Nordic countries Orion markets and sells veterinary drugs manufactured by several other companies. Orion's Animal Health business division has a strong market position in the Nordic countries, its home markets.

Net sales of the Animal Health business division in 2018 increased by 6% to EUR 80 (76) million, which means that the net sales grew faster than the market. At EUR 34 (31) million, sales of animal sedative products accounted for 42% (40%) of the Animal Health business division's total net sales. The animal sedative product family comprises Orion's animal sedatives Dexdomitor® (dexmedetomidine), Domitor® (medetomidine) and Domosedan® (detomidine), and antagonist Antisedan® (atipamezole), which reverses the effects of the sedatives.

In February 2018, Orion received positive conclusions under the decentralised EU marketing authorisation procedure for Clevor®. Clevor, with ropinirole as the active ingredient, is an eye-drop formula designed to treat poisoning in dogs. Orion is currently developing an online service, ToxBuddy, to provide veterinary practitioners with information and support for treating poisoning in dogs. The service gives tools for the practitioner to assess the severity of poisoning and receive treatment instructions, among other things.

### Fermion

Fermion manufactures active pharmaceutical ingredients for Orion and other pharmaceutical companies. Its product range comprises nearly 30 pharmaceutical ingredients. Fermion's aim is to captively produce the active pharmaceutical ingredients for Orion's in-house developed proprietary drugs. For other pharmaceutical companies Fermion manufactures generic pharmaceutical ingredients and offers contract manufacturing services for development and manufacturing of new active pharmaceutical ingredients.

Fermion's net sales in 2018 excluding deliveries for Orion's own use were EUR 51 (51) million and accounted for over one-half of Fermion's total net sales. In recent years order cycles in the trade in pharmaceutical raw materials have become ever shorter, and this has led to clearly greater fluctuation in business volume than before within each year and between different years.

Fermion's significant, over EUR 30 million expansion investment at its Hanko manufacturing plant was completed in the second quarter of the year, and production has started. The investment involved preparation for compliance of tightening regulatory requirements and ensures preparedness to meet increasing demand. The objective was also to strengthen Fermion's competitiveness in the global market. Nearly 100% of the plant's production is exported. Around twenty active pharmaceutical ingredients are manufactured in Hanko, including entacapone and azathioprine, in which Fermion is the leading manufacturer globally.

## Research and development

The Group's R&D expenses totalled EUR 104 (99) million in 2018, up by 5%, and accounted for 11% (10%) of the Group's net sales. R&D expenses also include expenses related to development of the current portfolio.

In the first quarter of 2018, Orion started a research project to expand the Easyhaler product family for treatment of asthma and COPD, by developing a tiotropium formulation for European markets. The bioequivalence study with the formulation is ongoing. Tiotropium is a long-acting anticholinergic bronchodilator used in the treatment of chronic obstructive pulmonary disease.

In October 2018 Orion and Bayer completed the Phase III clinical trial (ARAMIS) of darolutamide, the novel oral androgen receptor antagonist for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC). The primary endpoint of the trial was met: Darolutamide significantly extended metastasis-free survival compared to placebo. The safety profile and the tolerability of darolutamide were consistent with previously published data. The full data from the trial will be presented at the ASCO GU (Genitourinary Cancers Symposium) in San Francisco. An abstract will be published on 11 February 2019 and the data will be presented on 14 February 2019. Bayer is discussing the data from the trial with health authorities regarding the submission for marketing authorisation application. Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment in men with non-metastatic castration-resistant prostate cancer. Commenced in 2014, the ARAMIS trial evaluated the efficacy and safety of darolutamide in patients with non-metastatic castration-resistant prostate cancer who are currently being treated with androgen deprivation therapy (ADT) as standard of care and are at risk of developing metastatic disease. In the double-blind, placebo-controlled trial, more than 1,500 patients were randomized to receive 600 mg of darolutamide or matching placebo twice a day. The primary endpoint was metastasis-free survival, defined as time between randomization and evidence of metastasis or death from any cause.

In addition to the completed ARAMIS trial, Orion and Bayer also have another ongoing Phase III clinical trial (ARASENS), which evaluates the efficacy and safety of darolutamide in the treatment of patients with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) who are starting hormone therapy. The treatment is darolutamide in combination with hormonal therapy (androgen deprivation therapy) and docetaxel, a chemotherapy drug. The trial, which commenced at the end of 2016, is on track, and patient recruitment was finalized in the second quarter of 2018. The trial is estimated to be completed in 2022.

In the second quarter of 2018, Orion recruited the first patients in the Phase III clinical trial (REFALS) in which orally administered levosimendan (ODM-109) is being evaluated for the treatment of symptoms of amyotrophic lateral sclerosis (ALS). International recruitment is ongoing. The purpose of the trial is to demonstrate that orally administered levosimendan, by enhancing respiratory muscle function, can help maintain breathing capacity and so benefit overall functioning of patients with ALS. Levosimendan does not cure ALS. The aim is to delay the need for ventilation support and thus improve the patient's quality of life. Orion is conducting the trial on its own and is investing around EUR 60 million in the study over approximately three years. If the results of the trial are positive, Orion aims to file for marketing authorisation in the United States and Europe. Orally administered levosimendan has been granted an Orphan Drug Designation in the United States and in the European Union. The trial will involve 450 patients and approximately a hundred clinical sites in the United States, Canada, the EU and Australia. The patients will be treated in the trial for around one year. Levosimendan is a molecule developed by Orion and launched already in 2000 for the treatment of acute decompensated heart failure.

In the second quarter of 2018, Orion completed the Phase II clinical trial with a drug candidate for the treatment of symptoms of Parkinson's disease in which a new levodopa/carbidopa formulation is combined with the COMT inhibitor (ODM-104) developed by Orion. In the trial, the product was compared with a Stalevo product already in the market in which the active pharmaceutical ingredients are the COMT inhibitor entacapone, carbidopa and levodopa. The primary endpoint of the trial was met. Orion is analysing the results and evaluating moving on to Phase III. Decisions will be made with consideration of the totality of Orion's R&D projects as well as alternative investment opportunities in other research projects. Orion is looking for a potential collaboration partner for the trial.

Orion has an ongoing Phase II clinical trial with a new targeted FGFR+VEGFR inhibitor (ODM-203) for the treatment of cancers. The trial will investigate the efficacy of the drug candidate in slowing the growth of solid cancerous tumours in patients with detected FGFR changes in cancerous tumours.

Orion has an ongoing Phase I clinical trial with a BET protein inhibitor (ODM-207) which inhibits transcription of key oncogenes such as Myc in many cancers. In preclinical studies, ODM-207 has shown antiproliferative effects in several solid tumour cell lines. The trial will investigate the safety and tolerability of the drug candidate and provisionally its efficacy in cancer patients.

In the first quarter of 2018, Orion commenced a Phase I clinical trial for the development of a novel selective hormone synthesis inhibitor (CYP11A1 inhibitor) for castration-resistant prostate cancer. Patient recruitment is proceeding as planned. In preclinical studies, the molecule (ODM-208) has shown antitumor activity. It has potential efficacy also for those cancers that have become resistant to the standard hormonal treatments. Orion is the first pharmaceutical company to develop a drug with this mechanism. The trial will investigate the safety and tolerability of the drug candidate in prostate cancer patients, but Orion also plans to study the potential of the molecule for breast cancer treatment.

Orion also has several projects in the early research phase investigating central nervous system diseases, cancer, neuropathic pain and rare diseases regarded as Finnish heritage diseases, among others.

In 2017, Orion launched its new R&D organisation. With the new organisation, Orion is expanding its drug development competence to include also biological drugs.

## Discontinued operations: Diagnostics

Orion signed an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business division) on 21 April 2018. The transaction was closed on 30 April 2018. Following the transaction, the Orion Diagnostica segment is reported as a discontinued operation.

Espoo, 6 February 2019

Board of Directors of Orion Corporation

**Orion Corporation**

Timo Lappalainen
*President and CEO*

Jari Karlson
*CFO*

# Tables

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

### Continuing operations

| EUR million | 10-12/18 | Adjusted 10-12/17 | Change % | 1-12/18 | Adjusted 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| **Net sales** | **262.4** | 265.9 | -1.4% | **977.5** | 1,033.6 | -5.4% |
| Cost of goods sold | **-101.2** | -105.0 | -3.6% | **-387.9** | -417.6 | -7.1% |
| **Gross profit** | **161.2** | 161.0 | +0.1% | **589.6** | 616.0 | -4.3% |
| Other operating income and expenses | **1.4** | 1.7 | -17.2% | **5.5** | 4.9 | +10.8% |
| Sales and marketing expenses | **-55.4** | -49.7 | +11.4% | **-195.3** | -188.9 | +3.4% |
| R&D expenses | **-27.8** | -26.5 | +4.6% | **-104.0** | -99.1 | +4.9% |
| Administrative expenses | **-10.9** | -16.0 | -32.0% | **-43.0** | -48.8 | -11.8% |
| **Operating profit** | **68.6** | 70.5 | -2.6% | **252.8** | 284.1 | -11.0% |
| Finance income | **0.3** | -1.8 | +118.2% | **0.3** | 0.2 | +54.7% |
| Finance expenses | **-1.4** | 0.4 | -425.7% | **-4.7** | -6.6 | -29.2% |
| **Profit before taxes** | **67.5** | 69.0 | -2.1% | **248.4** | 277.7 | -10.6% |
| Income tax expense | **-13.7** | -14.6 | -6.0% | **-51.0** | -58.6 | -13.0% |
| **Profit for the period for continuing operations** | **53.7** | 54.4 | -1.3% | **197.3** | 219.1 | -9.9% |
| | | | | | | |
| **Profit for the period for discontinued operations** | **-0.4** | 0.7 | -150.7% | **132.9** | 7.0 | |
| | | | | | | |
| **Profit for the period** | **53.1** | 55.2 | -3.7% | **330.3** | 226.0 | +46.2% |
| **OTHER COMPREHENSIVE INCOME INCLUDING TAX EFFECTS[1]** | | | | | | |
| Translation differences | **-0.4** | -0.3 | | **-1.7** | -1.4 | |
| **Items that may be reclassified subsequently to profit and loss** | **-0.4** | -0.3 | | **-1.7** | -1.4 | |
| Items due to remeasurement of defined benefit pension plans (continuing operations) | **-16.9** | 27.4 | | **-21.4** | 27.4 | -178.1% |
| Items due to remeasurement of defined benefit pension plans (discontinued operations) | | 2.5 | | **2.9** | 2.5 | +16.4% |
| **Items that will not be reclassified to profit and loss** | **-16.9** | 29.9 | | **-18.5** | 29.9 | -161.8% |
| **Other comprehensive income net of tax** | **-17.3** | 29.6 | -158.5% | **-20.1** | 28.5 | -170.7% |
| **Comprehensive income for the period including tax effects** | **35.8** | 84.7 | -57.7% | **310.1** | 254.5 | +21.9% |
| **PROFIT ATTRIBUTABLE TO[1]** | | | | | | |
| Owners of the parent company | **53.1** | 55.2 | -3.7% | **330.3** | 226.0 | +46.2% |
| Non-controlling interests | | 0.0 | | | -0.0 | |
| **COMPREHENSIVE INCOME ATTRIBUTABLE TO[1]** | | | | | | |
| Owners of the parent company | **35.8** | 84.7 | -57.7% | **310.1** | 254.5 | +21.9% |
| Non-controlling interests | | 0.0 | | | -0.0 | |
| **Continuing operations** | | | | | | |
| **Basic earnings per share, EUR[2]** | **0.38** | 0.38 | -0.6% | **1.40** | 1.56 | -10.3% |
| **Diluted earnings per share, EUR[2]** | **0.38** | 0.38 | -0.6% | **1.40** | 1.56 | -10.3% |
| | | | | | | |
| Depreciation, amortisation and impairment | **11.1** | 10.3 | +7.8% | **41.1** | 39.5 | +4.0% |
| Personnel expenses | **52.2** | 55.3 | -5.5% | **200.7** | 203.9 | -1.6% |

**Discontinued operations**

| EUR million | 10-12/18 | Adjusted 10-12/17 | Change % | 1-12/18 | Adjusted 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| **Basic earnings per share, EUR²** | | 0.01 | | **0.95** | 0.05 | |
| **Diluted earnings per share, EUR²** | | 0.01 | | **0.95** | 0.05 | |
| Depreciation, amortisation and impairment | | 0.7 | -100.0% | **0.7** | 2.8 | -75.2% |
| Personnel expenses | | 3.7 | -100.0% | **2.1** | 14.2 | -85.1% |

[1]The figures in the table include both continuing and discontinued operations.
[2] The figure has been calculated from the profit attributable to the owners of the parent company.
IFRS 15 and IFRS 9 standards have been adopted by using the cumulative effect method, and therefore figures of the comparative periods have not been adjusted.

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

**ASSETS**

| EUR million | 12/18 | 12/17 | Change % |
|---|---|---|---|
| Property, plant and equipment | **316.9** | 323.1 | -1.9% |
| Goodwill | **13.5** | 13.5 | |
| Intangible rights | **47.5** | 36.7 | +29.2% |
| Other intangible assets | **2.7** | 2.6 | +3.6% |
| Investments in associates | **0.1** | 0.1 | -1.8% |
| Other investments | **0.3** | 0.3 | -0.5% |
| Pension asset | **31.5** | 55.2 | -42.9% |
| Deferred tax assets | **5.1** | 1.3 | +291.2% |
| Other non-current assets | **0.9** | 1.9 | -52.4% |
| **Non-current assets total** | **418.5** | 434.7 | -3.7% |
| | | | |
| Inventories | **222.1** | 225.4 | -1.5% |
| Trade receivables | **188.8** | 199.0 | -5.1% |
| Other receivables | **33.7** | 32.4 | +4.0% |
| Money market investments | **35.0** | | |
| Cash and cash equivalents | **248.7** | 164.1 | +51.6% |
| **Current assets total** | **728.2** | 620.8 | +17.3% |
| | | | |
| **Assets total** | **1,146.7** | 1,055.5 | +8.6% |

**EQUITY AND LIABILITIES**

| EUR million | 12/18 | 12/17 | Change % |
|---|---|---|---|
| Share capital | **92.2** | 92.2 | |
| Expendable fund | **0.5** | 0.5 | |
| Other reserves | **2.4** | 2.4 | -0.2% |
| Retained earnings | **678.0** | 584.6 | +16.0% |
| **Equity attributable to owners of the parent company** | **773.1** | 679.7 | +13.7% |
| Non-controlling interests | | -0.0 | -100.0% |
| **Equity total** | **773.1** | 679.7 | +13.7% |
| | | | |
| Deferred tax liabilities | **37.8** | 42.3 | -10.6% |
| Pension liability | **3.6** | 3.2 | +11.9% |
| Provisions | **0.3** | 0.3 | +16.9% |
| Interest-bearing non-current liabilities | **0.6** | 150.3 | -99.6% |
| Other non-current liabilities | **17.4** | 0.0 | |
| **Non-current liabilities total** | **59.8** | 196.2 | -69.5% |
| | | | |
| Trade payables | **74.9** | 83.2 | -9.9% |
| Current tax liabilities | **1.5** | 3.0 | -49.4% |
| Other current liabilities | **86.4** | 92.4 | -6.4% |
| Interest-bearing current liabilities | **150.9** | 1.1 | |
| **Current liabilities total** | **313.8** | 179.7 | +74.7% |
| | | | |
| **Liabilities total** | **373.6** | 375.8 | -0.6% |
| | | | |
| **Equity and liabilities total** | **1,146.7** | 1,055.5 | +8.6% |

The consolidated statement of financial position includes both continuing and discontinued operations.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

a. Share capital
b. Expendable fund
c. Other reserves
d. Items due to remeasurement of defined benefit pension plans
e. Translation differences
f. Retained earnings
g. Non-controlling interests
**h. Equity total**

| | Equity attributable to owners of the parent company | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| EUR million | a. | b. | c. | d. | e. | f. | g. | **h.** |
| **Equity at 1 January 2017** | 92.2 | 0.5 | 2.1 | 2.0 | -5.0 | 549.5 | 0.0 | **641.4** |
| Profit for the period | | | | | | 226.0 | | **226.0** |
| **Other comprehensive income** | | | | | | | | |
| Translation differences | | | | | -1.0 | -0.4 | | **-1.4** |
| Items due to remeasurement of defined benefit pension plans | | | | 29.9 | | | | **29.9** |
| **Transactions with owners** | | | | | | | | |
| Dividend and capital repayment | | | | | | -217.9 | | **-217.9** |
| Share-based incentive plan | | | | | | 2.4 | | **2.4** |
| Other adjustments | | | 0.3 | | | -0.9 | -0.0 | **-0.7** |
| **Equity at 31 December 2017** | 92.2 | 0.5 | 2.3 | 31.9 | -5.9 | 558.6 | -0.0 | **679.7** |
| Impact of adoption of the IFRS 15 and IFRS 9 standards | | | | | | -16.5 | | **-16.5** |
| **Adjusted equity at 31 December 2017** | 92.2 | 0.5 | 2.3 | 31.9 | -5.9 | 542.1 | -0.0 | **663.2** |
| Profit for the period | | | | | | 330.3 | | **330.3** |
| **Other comprehensive income** | | | | | | | | |
| Translation differences | | | | | -1.8 | 0.2 | | **-1.6** |
| Items due to remeasurement of defined benefit pension plans | | | | -21.4 | | 2.9 | | **-18.5** |
| **Transactions with owners** | | | | | | | | |
| Dividend and capital repayment | | | | | | -203.8 | | **-203.8** |
| Share-based incentive plan | | | | | | 3.9 | | **3.9** |
| Other adjustments | | | 0.1 | | | -0.4 | 0.0 | **-0.3** |
| **Equity at 31 December 2018** | **92.2** | **0.5** | **2.4** | **10.5** | **-7.7** | **675.3** | | **773.1** |

The consolidated statement of changes in equity includes both continuing and discontinued operations.

## CONSOLIDATED STATEMENT OF CASH FLOWS

| EUR million | 1-12/18 | 1-12/17 |
|---|---|---|
| Operating profit | **387.3** | 293.0 |
| Adjustments | **-87.8** | 49.1 |
| Change in working capital | **-10.2** | -38.9 |
| Interest paid | **-5.9** | -6.2 |
| Interest received | **1.7** | 1.4 |
| Dividends received | **0.0** | 0.0 |
| Income taxes paid | **-54.3** | -70.0 |
| **Total net cash flow from operating activities** | **230.9** | 228.4 |
| | | |
| Investments in property, plant and equipment | **-38.1** | -67.1 |
| Investments in intangible assets | **-28.7** | -9.4 |
| | | |
| Sales of property, plant and equipment and other investments | **0.9** | 1.6 |
| Sales of subsidiaries | **161.3** | |
| **Total net cash flow from investing activities** | **95.4** | -74.9 |
| | | |
| Current loans raised | **1.3** | 1.3 |
| Repayments of current loans | **-2.6** | -3.5 |
| Dividends paid and other distribution of profits | **-203.9** | -218.0 |
| **Total net cash flow from financing activities** | **-205.3** | -220.3 |
| | | |
| **Net change in cash and cash equivalents** | **121.1** | -66.8 |
| | | |
| Cash and cash equivalents at the beginning of the period | **164.1** | 231.9 |
| Foreign exchange differences | **-1.5** | -1.0 |
| Impact of discontinued operations | **-0.9** | |
| Net change in cash and cash equivalents | **121.9** | -66.8 |
| Cash and cash equivalents at the end of the period | **283.7** | 164.1 |
| | | |
| **Reconciliation of cash and cash equivalents in statement of financial position** | | |
| Cash and cash equivalents in statement of financial position at the end of the period | **248.7** | 164.1 |
| Money market investments at the end of the period | **35.0** | |
| **Cash and cash equivalents in the statement of cash flows** | **283.7** | 164.1 |

The consolidated statement of cash flows includes both continuing and discontinued operations.

## DISCONTINUED OPERATIONS

On 23 January 2018, Orion announced that it had decided to investigate the possible sale of Orion Diagnostica or other transaction that would result in transfer of Orion Diagnostica outside the Orion Group. As a result of the investigation, an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business) was signed with an investment fund managed by Axcel Management A/S (Axcel) on 21 April 2018. The transaction was closed on 30 April 2018. In the Financial Review and the tables of the Financial Statement Release, Orion Diagnostica business is reported as a discontinued operation. The profit of discontinued operations in 2018 was EUR 132.9 (7.0) million.

The selling price of Orion Diagnostica was EUR 161.7 million and Orion booked in the review period a EUR 128.4 million capital gain included in the comprehensive income statement as part of discontinued operations. In addition, Orion has the possibility to receive an additional selling price of EUR 60 million maximum. The payment of this component is based on the return on investment for Axcel at the time of their exit. Due to the uncertainty relating to the euro value and timing of the additional price, the capital gain does not include any part of the additional price component.

## PROFIT FOR THE PERIOD FOR DISCONTINUED OPERATIONS

| EUR million | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|
| Net sales | **18.7** | 53.8 | -65.3% |
| Capital gain from sale of discontinued operations | **128.4** | | |
| Expenses related to sale of discontinued operations | **-0.8** | | |
| Item related to fulfilment of an obligation under IAS 19 | **4.5** | | |
| Other operating expenses | **-16.2** | -44.9 | -63.9% |
| **Operating profit** | **134.6** | 8.9 | |
| Income tax expense | **-1.6** | -1.9 | -15.8% |
| **Profit for the period** | **132.9** | 7.0 | |

## CASH FLOW FROM DISCONTINUED OPERATIONS

| EUR million | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|
| Cash flow from operating activities | **-8.5** | 8.9 | -195.5% |
| Cash flow from investing activities | **149.0** | -1.3 | |

Orion Diagnostica employees will no longer be insured under the Orion Pension Fund. The transfer of insurance portfolio to the new insurer chosen by Orion Diagnostica involved a transfer of assets of Orion Pension Fund corresponding to the amount of pension liability of employees insured within the fund. The transfer of portfolio constituted a fulfilment of an obligation under IAS 19, as the employer companies continuing operations after the sale have no obligations with regard to the pension cover of Orion Diagnostica employees. Orion Diagnostica's share of the pension asset to the Orion Pension Fund in the consolidated balance at the closing date of the transaction on 30 April 2018 was EUR 4.5 million. This share is presented as part of the income statement of discontinued operations and it improves the operating profit of discontinued operations.

## CHANGES IN PROPERTY, PLANT AND EQUIPMENT

| EUR million | 12/18 | 12/17 |
|---|---|---|
| Carrying amount at the beginning of the period | **323.1** | 289.1 |
| - discontinued operations | **-10.0** | |
| Additions | **36.1** | 67.4 |
| Disposals | **-0.9** | -1.0 |
| Amortisation and impairments | **-31.1** | -32.1 |
| **Carrying amount at the end of the period** | **316.9** | 323.1 |

## CHANGES IN INTANGIBLE ASSETS (EXCLUDING GOODWILL)

| EUR million | 12/18 | 12/17 |
|---|---|---|
| Carrying amount at the beginning of the period | **39.4** | 40.4 |
| - discontinued operations | **-8.0** | |
| Additions | **28.7** | 9.1 |
| Disposals | **-0.0** | -0.1 |
| Amortisation and impairments | **-10.0** | -10.2 |
| **Carrying amount at the end of the period** | **50.2** | 39.4 |

## COMMITMENTS AND CONTINGENCIES

| EUR million | 12/18 | 12/17 |
|---|---|---|
| **CONTINGENCIES FOR OWN LIABILITIES** | | |
| Guarantees | **4.5** | 3.6 |
| **OTHER LIABILITIES** | | |
| Leasing liabilities (excluding finance lease contracts) | **14.5** | 13.3 |
| Other liabilities | **0.3** | 0.3 |

## DERIVATIVES

| EUR million | 12/18 | 12/17 |
|---|---|---|
| **CURRENCY FORWARD CONTRACTS AND CURRENCY SWAPS** | | |
| Fair value, EUR million | **0.2** | 0.1 |
| Nominal value, EUR million | **32.6** | 32.4 |
| **CURRENCY OPTIONS** | | |
| Fair value, EUR million | **0.0** | 0.1 |
| Nominal value, EUR million | **31.8** | 45.4 |

## FAIR VALUE MEASUREMENT AND HIERARCHY OF FINANCIAL INSTRUMENTS

| EUR million | Level 1 | Level 2 | Level 3 | Total |
|---|---|---|---|---|
| Derivatives | | | | |
| Currency derivatives | | 0.4 | | 0.4 |
| Money market investments | 35.0 | | | 35.0 |
| Other investments | | | | |
| Shares and investments | | | 0.3 | 0.3 |
| **Assets total** | 35.0 | 0.4 | 0.3 | 35.7 |
| | | | | |
| Derivatives | | | | |
| Currency derivatives | | -0.1 | | -0.1 |
| **Liabilities total** | | -0.1 | | -0.1 |

The fair value of level 1 financial instruments is based on quotations available in active markets. The fair value of level 2 derivatives is based on data feeds available in the markets. The fair value of level 3 financial instruments cannot be estimated on the basis of data available in the markets.

In the Group the principle is applied that transfers between levels of fair value hierarchy are recognised on the date on which the event triggering the transfer occurred.

No transfers between levels occurred during the reporting period.

## RELATED PARTY TRANSACTIONS

| EUR million | 12/18 | 12/17 |
|---|---|---|
| Management's employment benefits | **5.9** | 7.1 |

# Operating segment performance for continuing operations

## NET SALES BY BUSINESS DIVISION

| EUR million | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Pharmaceuticals | **262.4** | 265.9 | -1.4% | **977.5** | 1,033.6 | -5.4% |
| Proprietary Products [1)] | **96.0** | 90.3 | +6.3% | **356.9** | 351.4 | +1.6% |
| Specialty Products | **126.5** | 132.3 | -4.4% | **473.1** | 519.0 | -8.8% |
| Animal Health | **22.6** | 20.2 | +11.5% | **80.4** | 75.9 | +5.9% |
| Fermion | **13.2** | 10.6 | +25.4% | **50.7** | 51.0 | -0.5% |
| Contract manufacturing and other | **4,1** | 12.5 | -67.5% | **16.3** | 36.2 | -55.0% |
| **Group total** | **262.4** | 265.9 | -1.4% | **977.5** | 1,033.6 | -5.4% |

1) The net sales of Proprietary Products during the period 1-12/18 includes EUR 2.0 million of sales revenue for performance obligations to be transferred to customers that will be entered as income over time.

## OPERATING PROFIT BY BUSINESS AREA

| EUR million | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Pharmaceuticals | **72.0** | 75.2 | -4.2% | **265.3** | 296.3 | -10.5% |
| Group items | **-3.4** | -4.7 | -27.7% | **-12.5** | -12.2 | +2.6% |
| **Group total** | **68.6** | 70.5 | -2.6% | **252.8** | 284.1 | -11.0% |

## NET SALES BY ANNUAL QUARTERS

| | 2018 | | | | 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| EUR million | **10-12** | **7-9** | **4-6** | **1-3** | **10-12** | **7-9** | **4-6** | **1-3** |
| **Group total** | 262.4 | 221.8 | 246.1 | 247.2 | 265.9 | 241.5 | 260.7 | 265.5 |

## OPERATING PROFIT BY ANNUAL QUARTERS

| | 2018 | | | | 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| EUR million | **10-12** | **7-9** | **4-6** | **1-3** | **10-12** | **7-9** | **4-6** | **1-3** |
| Pharmaceuticals | 72.0 | 47.2 | 73.6 | 72.5 | 75.2 | 57.4 | 73.5 | 90.2 |
| Group items | -3.4 | -2.6 | -3.9 | -2.7 | -4.7 | -2.5 | -3.0 | -2.0 |
| **Group total** | 68.6 | 44.6 | 69.7 | 69.8 | 70.5 | 54.9 | 70.5 | 88.2 |

## GEOGRAPHICAL BREAKDOWN OF NET SALES BY ANNUAL QUARTERS

| | 2018 | | | | 2017 | | | |
|---|---|---|---|---|---|---|---|---|
| EUR million | **10-12** | **7-9** | **4-6** | **1-3** | **10-12** | **7-9** | **4-6** | **1-3** |
| Finland | 82.7 | 74.0 | 75.4 | 80.0 | 84.6 | 80.4 | 82.4 | 81.3 |
| Scandinavia | 40.4 | 36.4 | 36.9 | 41.2 | 42.4 | 44.0 | 46.6 | 40.5 |
| Other Europe | 83.5 | 72.0 | 73.0 | 75.5 | 80.5 | 73.2 | 78.7 | 79.2 |
| North America | 15.9 | 14.9 | 13.5 | 14.0 | 27.0 | 16.8 | 15.7 | 19.3 |
| Other markets | 39.7 | 24.4 | 47.3 | 36.6 | 31.4 | 27.1 | 37.2 | 45.2 |
| **Group total** | 262.4 | 221.8 | 246.1 | 247.2 | 265.9 | 241.5 | 260.7 | 265.5 |

# Business review

## KEY FIGURES FOR PHARMACEUTICALS BUSINESS

| EUR million | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Net sales | **262.4** | 265.9 | -1.4% | **977.5** | 1,033.6 | -5.4% |
| Operating profit | **72.0** | 75.2 | -4.2% | **265.3** | 296.3 | -10.5% |
| % of net sales | **27.4%** | 28.3% | | **27.1%** | 28.7% | |
| R&D expenses | **27.8** | 26.6 | +4.7% | **104.0** | 99.1 | +5.1% |
| % of net sales | **10.6%** | 10.0% | | **10.6%** | 9.6% | |
| Capital expenditure | **35.3** | 14.8 | +137.8% | **64.6** | 74.6 | -13.5% |
| % of net sales | **13.4%** | 5.6% | | **6.6%** | 7.2% | |
| Sales revenue from proprietary products | **109.1** | 101.0 | +8.0% | **403.9** | 386.6 | +4.5% |
| Assets | | | | **840.7** | 832.1 | +1.0% |
| Liabilities | | | | **176.2** | 165.2 | +6.7% |
| Personnel at the end of the period | | | | **3,119** | 3,138 | |

## TOP TEN BEST-SELLING PHARMACEUTICAL PRODUCTS

| EUR million | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Stalevo®, Comtess® and Comtan® (Parkinson's disease) | **24.6** | 23.9 | +3.0% | **100.1** | 103.8 | -3.5% |
| Easyhaler® product family (asthma, COPD) | **26.0** | 21.5 | +21.0% | **90.4** | 76.6 | +17.9% |
| Dexdor® (intensive care sedative) | **15.1** | 17.2 | -11.9% | **63.1** | 64.1 | -1.6% |
| Simdax® (acute decompensated heart failure) | **16.1** | 14.6 | +10.0% | **59.4** | 57.2 | +3.8% |
| Dexdomitor®, Domitor®, Domosedan® and Antisedan® (animal sedatives) | **10.5** | 8.8 | +20.0% | **33.6** | 30.5 | +10.1% |
| Precedex® (intensive care sedative) | **9.9** | 6.6 | +50.1% | **25.8** | 25.0 | +3.2% |
| Biosimilars (rheumatoid arthritis, inflammatory bowel diseases, lymphoma) | **5.7** | 12.1 | -53.3% | **24.8** | 56.7 | -56.3% |
| Burana® (inflammatory pain) | **6.9** | 5.7 | +21.3% | **23.5** | 23.4 | +0.3% |
| Divina series (menopausal symptoms) | **5.0** | 5.3 | -5.6% | **18.8** | 18.6 | +1.3% |
| Marevan® (anticoagulant) | **5.5** | 5.3 | +3.7% | **17.8** | 19.2 | -6.8% |
| **Total** | **125.3** | 121.0 | +3.6% | **457.3** | 475.1 | -3.7% |
| Share of pharmaceutical net sales | **48%** | 45% | | **47%** | 46% | |

## KEY CLINICAL PHARMACEUTICAL DEVELOPMENT PROJECTS

| Project | Indication | PHASE | | | Registration |
|---|---|---|---|---|---|
| | | I | II | III | |
| Easyhaler® tiotropium | COPD | Bioequivalence study* | | | |
| Darolutamide [1)] | Prostate cancer (nmCRPC) | I | II | III | |
| Darolutamide [1)] | Prostate cancer (mHSPC) | I | II | III* | |
| ODM-109 (oral levosimendan) | ALS | I | II | III* | |
| ODM-104 (more effective COMT inhibitor) | Parkinson's disease | I | II | | |
| ODM-203 (targeted FGFR+VEGFR inhibitor) | Solid tumours | I | II* | | |
| ODM-207 (BET protein inhibitor) | Cancer | I* | | | |
| ODM-208 (CYP11A1 inhibitor) | Prostate cancer (CRPC) | I* | | | |
| [1)] In collaboration with Bayer | | * | = Phase ongoing | | |
| | | III | = Status changed vs. previous quarter | | |

# Information on Orion's shares

## BASIC SHARE INFORMATION, 31 DECEMBER 2018

| | A share | B share | Total |
|---|---|---|---|
| Trading code on Nasdaq Helsinki | ORNAV | ORNBV | |
| Listing day | 1.7.2006 | 1.7.2006 | |
| ISIN code | FI0009014369 | FI0009014377 | |
| ICB code | 4500 | 4500 | |
| Reuters code | ORNAV.HE | ORNBV.HE | |
| Bloomberg code | ORNAV.FH | ORNBV.FH | |
| Share capital, EUR million | 24.2 | 68.0 | 92.2 |
| Counter book value per share, EUR | 0.65 | 0.65 | |
| Total number of shares | 37,120,346 | 104,137,482 | 141,257,828 |
| % of total share stock | 26% | 74% | 100% |
| Number of treasury shares | | 562,440 | 562,440 |
| Total number of shares excluding treasury shares | 37,120,346 | 103,575,042 | 140,695,388 |
| Minimum number of shares | | | 1 |
| Maximum number of A and B shares, and maximum number of all shares | 500,000,000 | 1,000,000,000 | 1,000,000,000 |
| Votes per share | 20 | 1 | |
| Number of votes excluding treasury shares | 742,406,920 | 103,575,042 | 845,981,962 |
| % of total votes | 88% | 12% | 100% |
| Total number of shareholders | 20,368 | 58,903 | 72,802 |

Both share classes, A and B, confer equal rights to the Company's assets and dividends.

## INFORMATION ON TRADING ON NASDAQ HELSINKI, 1 JANUARY – 31 DECEMBER 2018

| | A share | B share | Total |
|---|---|---|---|
| Shares traded | 2,131,981 | 121,458,874 | 123,590,855 |
| % of the total number of shares | 5.7% | 116.6% | 87.5% |
| Trading volume, EUR million | 63.2 | 3,389.3 | 3,452.5 |
| Closing quotation on 31 December 2017, EUR | 32.07 | 31.08 | |
| Lowest quotation, EUR (A: 4 July 2018; B: 3 July 2018) | 24.75 | 22.57 | |
| Average quotation, EUR | 29.63 | 27.90 | |
| Highest quotation, EUR (A 23 January 2018; B 19 January 2018) | 35.70 | 33.50 | |
| Closing quotation on 31 December 2018, EUR | 30.30 | 30.28 | |
| Market capitalisation on 31 December 2018, EUR million | 1,124.7 | 3,136.3 | 4,261.0 |

## PERFORMANCE PER SHARE

| Continuing operations | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Basic earnings per share, EUR | **0.38** | 0.38 | -0.6% | **1.40** | 1.56 | -10.3% |
| Diluted earnings per share, EUR | **0.38** | 0.38 | -0.6% | **1.40** | 1.56 | -10.3% |

| Continuing and discontinued operations | 10-12/18 | 10-12/17 | Change % | 1-12/18 | 1-12/17 | Change % |
|---|---|---|---|---|---|---|
| Basic earnings per share, EUR | **0.38** | 0.39 | -3.8% | **2.35** | 1.61 | +46.0% |
| Diluted earnings per share, EUR | **0.38** | 0.39 | -3.8% | **2.35** | 1.61 | +46.0% |
| Cash flow per share before financial items, EUR | **0.22** | 0.22 | -0.3% | **2.32** | 1.09 | +112.4% |
| Equity per share, EUR | | | | **5.50** | 4.83 | +13.7% |
| Proposed dividend per share, EUR | | | | **1.50** | 1.45 | +3.4% |
| Proposed payout ratio, % | | | | **63.8%** | 90.1% | |
| Total proposed dividend, EUR million | | | | **211.0** | 203.8 | +3.5% |
| Effective dividend yield according to proposal, % | | | | | | |
| A share | | | | **5.0%** | 4.5% | |
| B share | | | | **5.0%** | 4.7% | |
| Price/earnings ratio (P/E) | | | | | | |
| A share | | | | **12.89** | 19.92 | -35.3% |
| B share | | | | **12.89** | 19.30 | -33.2% |
| Average number of shares excluding treasury shares, 1,000 shares | **140,695** | 140,582 | | **140,677** | 140,565 | |

# Appendices

## Reporting

Orion Corporation is the parent company of the Orion Group. The Group consists of one business area or operating segment and four business divisions. Orion reports on its operations segmentally.

- Pharmaceuticals business
  - Proprietary Products (patented prescription products for three therapy areas)
  - Specialty Products (off-patent generic prescription products, self-care products and biosimilars)
  - Animal Health (veterinary products for pets and production animals)
  - Fermion (active pharmaceutical ingredients for Orion and other companies)

Contract manufacturing and other, i.e. manufacturing for other companies, is included in the Pharmaceuticals business segment, but it is not a separate business division.

## Accounting policies

The Consolidated Financial Statements of the Orion Group have been prepared in accordance with International Financial Reporting Standards (IFRS) applying the IAS and IFRS standards as well as SIC and IFRIC interpretations effective at 31 December 2018.

The following new standards, interpretations and amendments to existing standards endorsed by the EU have been adopted as of 1 January 2018:

- IFRS 15 (new), *Revenue from Contracts with Customers*
- IFRS 9 (new), *Financial Instruments*
- IFRS 2 (amendment), *Share-Based Payment*
- IFRIC 22 (new), *Foreign Currency Transactions and Advance Consideration*

Relating to given research and development projects the Group is recognising revenue, which involve management judgement. Revenue recognition is based on the estimated progress of research and development projects and fulfilment of different contractual terms relating to projects.

**Adoption of IFRS 15 (Revenue from Contracts with Customers)**

IFRS 15 (Revenue from Contracts with Customers) replaced the previous IAS 18 (Revenue) and IAS 11 (Construction Contracts), which governed revenue recognition. The Group has adopted the new standard for the financial year commencing on 1 January 2018.

Adoption of IFRS 15 affects the timing of recognising revenue from sales of the sales rights to products in the markets and from collaboration with collaboration partners in clinical phases, so that net sales of these revenue flows arising from some performance obligations are recognised at a time that is different from when they have been recognised under IAS 18. Depending on the contents of the agreement, research and development projects may consist of performance obligations that are considered separately, or performance obligations may form larger entities that are considered as units. Agreements typically contain both fixed milestone payments and milestone payments that are processed as variable considerations conditional on reaching specific phases or research results.

The Group has applied the cumulative effect method in the transition and recognised the impact of IFRS 15 on 1 January 2018 in equity as an adjustment to retained earnings. An item of corresponding amount has been recognised as a counterpart entry in other liabilities in the statement of financial position. Adjustments of the opening balance have been made only in respect of contracts that had not been fully fulfilled on 1 January 2018.

The total net sales from the above-mentioned revenue flows on average account for less than five per cent of the Group's annual net sales. For the financial period 2018 net sales recorded from the revenue flows mentioned were EUR 5.2 million (2017: EUR 12.1 million), in other words 0.5 per cent (1.1 per cent) of the total consolidated net sales. In the Group's view, the effect of IFRS 15 in recognising these revenue flows as revenue is not material in proportion to the total consolidated net sales.

The Group determined that, as regards the timing of recognising net sales, IFRS 15 affects agreements that were not fully fulfilled on 1 January 2018. At the end of the financial period 2017, the Group had four agreements for which IFRS 15 had a material effect as regards the timing of recognition of the Group's revenue. Milestone payments under these agreements in previous financial periods were recognised as revenue at a single point of time. Following adoption of IFRS 15, such milestone payments will be regarded as performance obligations satisfied over time and they will be recognised as revenue over the term of the contract. The revenue will be recognised later than when the old IAS 18 was in effect.

Consequently, net sales under these agreements previously recognised in the income statement have been adjusted as of 1 January 2018 by reducing retained earnings in equity in the statement of financial position. The Group has recorded a total reduction of EUR 16.6 million of retained earnings on 1 January 2018. An increase of EUR 18.7 million in the long-term other liabilities and an increase of EUR 1.9 million in the short-term other liabilities have been recorded in the statement of financial position. An increase of EUR 4.1 million has been recorded as deferred tax assets.

The above-mentioned adjustments made to items in the statement of financial position are recognised as revenue over time as the performance obligations are satisfied. The average remaining time for satisfying the performance obligations subject to adjustments on 1 January 2018 was 11 years.

Following adoption of IFRS 15, comparative information reported by the Group have not been adjusted. Information on the impact of the adoption of IFRS 15 on the comparative period figures is provided in the summary below.

## ADJUSTED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME, CONSOLIDATED STATEMENT OF FINANCIAL POSITION AND OTHER KEY FIGURES FOR THE FINANCIAL YEAR 2017

1) Earlier reported comparison information in the Interim Report and Financial Statement Release.
2) Earlier reported comparison information in the Interim Report and Financial Statement Release, if impact of IFRS 15 is taken into consideration.
3) Adjusted comparison information reported in this Financial Statement Release. Orion Diagnostica is reported as a discontinued operation.
4) Adjusted comparison information reported in this Financial Statement Release, if impact of IFRS 15 is taken into consideration. Orion Diagnostica is reported as a discontinued operation.

| | 1-12/17 | | | |
|---|---|---|---|---|
| | 1) | 2) | 3) | 4) |
| Net sales, EUR million | 1,084.6 | 1,077.2 | 1,033.6 | 1,026.2 |
| Operating profit, EUR million | 293.0 | 285.6 | 284.1 | 276.7 |
| % of net sales | 27.0% | 26.5% | 27.5% | 27.0% |
| Profit before taxes, EUR million | 286.5 | 279.1 | 277.7 | 270.3 |
| % of net sales | 26.4% | 25.9% | 26.9% | 26.3% |
| Income tax expense, EUR million | 60.5 | 59.0 | 58.6 | 57.1 |
| Profit for the period, EUR million | 226.0 | 220.1 | 219.1 | 213.1 |
| Other comprehensive income net of tax, EUR million | 28.5 | 28.5 | 26.0 | 26.0 |
| Deferred tax assets, EUR million | 1.3 | 5.4 | 1.3 | 5.4 |
| Other non-current liabilities, EUR million | 0.0 | 18.7 | 0.0 | 18.7 |
| Other current liabilities, EUR million | 92.4 | 94.3 | 92.4 | 94.3 |
| Non-interest-bearing liabilities, EUR million | 224.5 | 245.1 | 224.5 | 245.1 |
| Equity total, EUR million | 679.7 | 655.9 | 679.7 | 655.9 |
| Assets total, EUR million | 1,055.5 | 1,052.4 | 1,055.5 | 1,052.4 |
| Equity ratio, % | 64.6% | 62.5% | 64.6% | 62.5% |
| Gearing, % | -1.9% | -1.9% | -1.9% | -1.9% |
| ROCE (before taxes), % | 36.2% | 36.4% | 35.5% | 35.1% |
| ROE (after taxes), % | 34.2% | 34.4% | 33.2% | 33.3% |
| Basic earnings per share, EUR | 1.61 | 1.57 | 1.56 | 1.52 |
| Diluted earnings per share, EUR | 1.61 | 1.57 | 1.56 | 1.52 |
| Equity per share, EUR | 4.83 | 4.67 | 4.77 | 4.67 |

### Revenue recognition principles

The Group's net sales comprise three different revenue flows, for which the revenue recognition principles are described below.

Sales of goods

Consolidated net sales include revenue from sales of goods adjusted for indirect taxes and currency translation differences on sales in foreign currencies. A delivery to a customer of one batch of product constitutes one distinct performance obligation for which the revenue will be recognised in accordance with the delivery terms when the control is transferred from the Group to the customer. The selling price may include variable consideration, such as various discounts or incentives, among other things. The consideration is recognised as net sales that the Group expects to be entitled to taking into account the effects of discounts and incentives.

The Group has consignment stock arrangements in place with distributors and logistics partners operating in various countries. In these cases the Group owns the products held in the distributor's and logistics partners' consignment stock until they are delivered to the customer, at which point the Group recognises

their sale in net sales. In Finland, the arrangement between Orion and Oriola explains a significant part of the Group's total consignment stock arrangements.

Net sales consisting of product sales also comprises royalties, which the Group recognises as revenue based on agreements signed with cooperation partners. The Group has sold the sales rights of certain products to cooperation partners and is entitled to royalties determined by the sales of these products achieved by the partners. The Group recognises the royalties as revenue once the partner has sold the products and the right to royalties has been established.

Transfer of sales rights to products already in the market

The Group enters into agreements in which it transfers the sales rights to a product already in the market to an external party outside the Group and agrees to manufacture the product for that external party. For transferring sales rights and manufacturing products, depending on the agreement the Group may receive milestone payments, revenue from manufacture and sales of the products and royalty income. Typically milestone payments are fixed payments made at the time of signing of an agreement with no restitution obligation and payments related to the commercialisation of a product. The Group is deemed to satisfy the performance obligations at a single point of time.

The Group itself has generally been manufacturing the product before the sale of sales rights to the product, so the Group would have know-how related to manufacture that would otherwise not be easily attained by the customer. The transferred sales rights and product manufacture as well as royalty payments that are received later constitute separate performance obligations. Some of the considerations are variable due to conditionality of milestone payments and value adjustments related to the sales price of the products.

The Group may receive under the agreement milestone payments related to commercialisation. They are considered as distinct performance obligations if they are satisfied by a certain volume of sales achieved by the customer. The accrued sales revenue entails value for the customer, so a performance obligation subject to sales volume is considered satisfied when the target for sales has been achieved. Performance obligations related to commercialisation are treated as performance obligations satisfied at a single point of time, because estimating future sales volume entails uncertainty factors.

Clinical phase research and development work undertaken with collaboration partners

The Group has entered into agreements with collaboration partners that relate to clinical phase research and development projects. Under these agreements milestone payments shall be paid when a certain development phase has been achieved. Milestone payments normally comprise a single upfront payment for Orion's past development work received on signing the agreement and milestone payments conditional on the future achievement of phases or research results of the project. In addition, payments related to commercial rights to the finished product such as royalties may be agreed in the agreements. Depending on the content of the agreement, agreements may consist of performance obligations that are considered separately, or they may form a single service and product package that consists of performance obligations.

Fixed milestone payments on signing an agreement are considered as distinct performance obligations that are satisfied on signing of the agreement. Clinical phase trials may be conducted through many service providers, and the collaboration partner can then utilise in its own business operations the research results conveyed on signing. Research and development work performed during the agreement period is considered a separate performance obligation and milestone payments for this phase are processed as variable considerations because they are conditional on reaching specific phases or research results. Even though Orion satisfies the performance obligations over time, revenue is only recognised on confirmation of the final research results because a reliable evaluation of research results in advance would entail uncertainty factors.

The agreements may also include a decision on arranging manufacture of finished product if it can be commercialised. For each agreement, considerations related to commercialisation are evaluated on the basis of whether the milestone payments and sales of finished products together constitute a performance obligation or whether the milestone payments can be identified as performance obligations distinct from

sales of the finished product. Likewise, on the basis of each agreement, it is evaluated whether the performance obligation related to milestone payments will be satisfied at a single point of time or over a period of time. Royalty payments are recognised as revenue when the partner has sold products subject to royalties.

Agreements usually do not include a financing component, because a significant portion of the considerations is variable and their reception will be confirmed in the future.

**Adoption of IFRS 9 (Financial Instruments)**

The new IFRS 9 (Financial Instruments) has replaced IAS 39 (Financial Instruments: Recognition and Measurement) and has brought changes to the classification and measurement of financial assets and liabilities to determining impairment of them and to principles of hedge accounting. The Group has adopted the new standard for the financial year commencing on 1 January 2018.

- Following the adoption of IFRS 9 the recognition and classification of the Group's financial items has changed as presented in the table below. The changes have had no material impact on the measurement of the items.

| Reclassification of financial instruments | IAS 39 | IFRS 9 |
|---|---|---|
| Other investments | Available-for-sale financial assets | At fair value through profit or loss |
| Other non-current assets | Loans and other receivables | Amortised cost |
| Trade receivables | Loans and other receivables | Amortised cost |
| Other receivables | Loans and other receivables | Amortised cost |
| Money market investments in interest rate instruments | Available-for-sale financial assets | Amortised cost / At fair value through profit or loss |
| Cash and cash equivalents | Loans and other receivables | Amortised cost |
| Interest-bearing non-current liabilities | Amortised cost | Amortised cost |
| Other non-current liabilities | Amortised cost | Amortised cost |
| Trade payables | Amortised cost | Amortised cost |
| Other current liabilities | Amortised cost | Amortised cost |
| Interest-bearing current liabilities | Amortised cost | Amortised cost |
| Derivatives | At fair value through profit or loss | At fair value through profit or loss |

- The Group does not currently apply hedge accounting, so the changes to hedge accounting due to IFRS 9 do not affect the Company.
- Measurement of financial assets for any impairment is based on whether there is a significant credit risk related to the receivable or not. The Group evaluates the risk related to a neglected payment on a financial instrument and recognises a provision for credit loss based on the assessment. Impairment of financial instruments is based on an expected credit loss model in which earlier and greater credit losses are recognised than under IAS 39.
- A simplified approach under IFRS 9 is applied for measurement of trade receivables through which impairment of trade receivables with various due dates is entered by reducing their value by a

certain percentage allowance, which are determined based on actual credit losses taking into account economic conditions on the reporting day. The allowance percentages shall lead to impairment that corresponds to the expected credit losses of receivables over their lifetime. As regards impairment of trade receivables, the change to IFRS 9 had no material impact.

The new standard will require new more comprehensive information in the Notes; in addition, there will be some changes in presentation. They affect the nature and comprehensiveness of the information presented in the consolidated financial statements.

## Significant IFRS standards and interpretations to be adopted in the 2019 financial period

**Adoption of IFRS 16 (Leases)**

IFRS 16 will replace IAS 17, which previously regulated the accounting treatment of leases. The Group will adopt the new standard on 1 January 2019. The Group will apply IFRS 16 retrospectively by the cumulative effect method permitted by the standard.

The Group recognises as lease liability under IFRS 16 the present value of remaining lease payments, discounted using the Group's incremental borrowing rate. The right-of-use asset is measured at carrying amount as if the standard had been applied since the commencement date of the lease. The right-of-use asset is measured by discounting future lease payments using the Group's incremental borrowing rate. The difference in value of the lease liability and the right-of-use assets is recognised in equity as adjustment to retained earnings.

The Group applies the modified retrospective transition option and practical expedients permitted under IFRS 16. The Group applies a single discount rate to a portfolio of leases with reasonably similar characteristics. In the transition, leases previously classified as finance leases have been recognised at the carrying amounts of the right-of-use assets and lease liabilities measured applying IAS 17. In addition, the Group applies the exemption permitted by the standard and accounts for leases for which the term ends within 12 months or fewer of the date of initial application as short-term leases, and recognises the expense arising from them through profit or loss in the accounting period beginning on 1 January 2019. The Group will assess details such as the accuracy of lease terms after the date of initial application and revise these later if mandated by facts.

The Group has assessed the impact of IFRS 16 on the consolidated balance sheet with regard to all leases identified by the Group as well as with regard to any arrangements that may involve leases. The Group identified a total of around 400 lease agreements in different operating countries. The weighted average of the Group's incremental borrowing rate, or its discounting rate, is based on IRS market rates plus a country risk based premium.

Following the adoption of IFRS 16, the Group recognises an increase of EUR 8.7 million in right-of-use assets. EUR 8.7 million is recognised as increase in lease liabilities on the balance sheet. EUR 0.1 million is recognised as increase in retained earnings in equity. EUR 0.0 million is recognised as an increase in deferred tax assets. The difference between the leasing commitments (reported in the notes) (EUR 14.5 million) and the liabilities recognised in the opening balance on 1 January 2019 (EUR 8.7 million) is EUR 5.8 million, and it is due to short-term, minor lease contracts (EUR 3.5 million) as well as the lease of a new facility in Germany starting at the end of 2019 (EUR 2.2 million), which have not been recognised as liabilities.

**Other adjustments as of 1 January 2018**

Other new IFRS standards, interpretations and amendments to existing IFRS standards adopted from 1 January 2018 have not affected the consolidated financial statements.

The policies and calculation methods applied during the period can be found on the Orion website at http://www.orion.fi/en/investors.

## Other matters

The information published in this release is based on Orion's audited financial statement for 2018. Orion Corporation's financial statement release has been prepared in accordance with the accounting policies set out in International Accounting Standard 34 on Interim Financial Reporting. Orion has applied the same accounting principles in the preparation of the Financial Statement Release as in the Financial Statement for 2018.

The figures in parentheses are for the corresponding period of the previous year. All the figures in this report have been rounded, which is why the total sums of individual figures may differ from the total sums shown.

## CALCULATION OF THE KEY FIGURES

| | | | |
|---|---|---|---|
| Return on capital employed (ROCE), % | = | $\frac{\text{Profit before taxes + Interest and other finance expenses}}{\text{Total assets - Non-interest-bearing liabilities (average during the period)}}$ | x 100 |
| Return on equity (ROE), % | = | $\frac{\text{Profit for the period}}{\text{Total equity (average during the period)}}$ | x 100 |
| Equity ratio, % | = | $\frac{\text{Equity}}{\text{Total assets - Advances received}}$ | x 100 |
| Gearing, % | = | $\frac{\text{Interest-bearing liabilities - Cash and cash equivalents - Money market investments}}{\text{Equity}}$ | x 100 |
| Earnings per share, EUR | = | $\frac{\text{Profit available for the owners of the parent company}}{\text{Average number of shares during the period, excluding treasury shares}}$ | |
| Cash flow per share before financial items, EUR | = | $\frac{\text{Cash flow from operating activities + Cash flow from investing activities}}{\text{Average number of shares during the period, excluding treasury shares}}$ | |
| Equity per share, EUR | = | $\frac{\text{Equity attributable to owners of the parent company}}{\text{Number of shares at the end of the period, excluding treasury shares}}$ | |
| Dividend per share, EUR | = | $\frac{\text{Dividend to be distributed for the period}}{\text{Number of shares at the end of the period, excluding treasury shares}}$ | |
| Payout ratio, % | = | $\frac{\text{Dividend per share}}{\text{Earnings per share}}$ | x 100 |
| Effective dividend yield, % | = | $\frac{\text{Dividend per share}}{\text{Closing quotation of the period}}$ | x 100 |
| Price/earnings ratio (P/E) | = | $\frac{\text{Closing quotation of the period}}{\text{Earnings per share}}$ | |
| Average share price, EUR | = | $\frac{\text{Total EUR value of shares traded}}{\text{Average number of traded shares during the period}}$ | |
| Market capitalisation, EUR million | = | Number of shares at the end of the period × Closing quotation of the period | |

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Orion is a globally operating Finnish pharmaceutical company – a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals and active pharmaceutical ingredients. The company is continuously developing new drugs and treatment methods. The core therapy areas of Orion's pharmaceutical R&D are central nervous system (CNS) disorders, oncology and respiratory diseases for which Orion develops inhaled Easyhaler® pulmonary drugs. Orion's net sales in 2018 amounted to EUR 977 million and the company had about 3,200 employees at the end of the year. Orion's A and B shares are listed on Nasdaq Helsinki.