

Orion Group Interim Report January-March 2016





ORION CORPORATION / INTERIM REPORT / JANUARY-MARCH 2016 / 27 April 2016 at 12:00 noon EEST

# Orion Group Interim Report January–March 2016

Orion's net sales in January–March 2016 totalled EUR 262 million (EUR 260 million in January–March 2015).

- Operating profit was EUR 80 (83) million.
- Profit before taxes was EUR 80 (83) million.
- Equity ratio was 44% (38%).
- ROCE before taxes was 46% (50%).
- ROE after taxes was 47% (57%).
- Basic earnings per share were EUR 0.45 (0.47).
- Cash flow per share before financial items was EUR 0.29 (0.38).
- The outlook estimate for 2016 remains unchanged. Orion estimates that in 2016 net sales will be at similar level to 2015. The operating profit is estimated to exceed EUR 240 million.

### ORION'S KEY FIGURES FOR THE REVIEW PERIOD

	Q1/16	Q1/15	Change %	2015
Net sales, EUR million	262.0	259.9	+0.8%	1,015.6
Operating profit, EUR million	80.3	83.1	-3.3%	266.6
% of net sales	30.7%	32.0%		26.2%
Profit before taxes, EUR million	79.7	82.7	-3.7%	262.3
% of net sales	30.4%	31.8%		25.8%
Income tax expense, EUR million	16.4	17.0	-3.7%	54.2
R&D expenses, EUR million	24.9	25.2	-1.1%	108.1
% of net sales	9.5%	9.7%		10.6%
Capital expenditure, EUR million	9.0	8.0	+12.8%	44.5
% of net sales	3.5%	3.1%		4.4%
Assets total, EUR million	1,087.9	1,070.3	+1.6%	1,047.4
Equity ratio, %	44.1%	38.1%		57.4%
Gearing, %	-20.3%	-20.3%		-9.6%
Interest-bearing liabilities, EUR million	185.9	230.7	-19.4%	187.8
Non-interest-bearing liabilities, EUR million	426.9	437.8	-2.5%	264.6
Cash and cash equivalents and money market investments, EUR million	282.5	312.2	-9.5%	245.2
ROCE (before taxes), %	46.1%	50.4%		35.7%
ROE (after taxes), %	47.3%	57.4%		37.5%
Basic earnings per share, EUR	0.45	0.47	-3.8%	1.48
Diluted earnings per share, EUR	0.45	0.47	-3.8%	1.48
Cash flow per share before financial items, EUR	0.29	0.38	-23.2%	1.51
Equity per share, EUR	3.37	2.85	+18.2%	4.22
Personnel at the end of the period	3,409	3,418	-0.3%	3,401
Average personnel during the period	3,401	3,418	-0.5%	3,431
Personnel expenses, EUR million	53.3	54.3	-1.8%	220.6



## President and CEO Timo Lappalainen:

## "Year started well as a whole"

"In the first quarter of 2016 our net sales were at similar level to January–March 2015 and our operating profit was slightly lower.

"As regards Proprietary Products, the Easyhaler product family for treatment of asthma and chronic obstructive pulmonary disease maintained its strong growth, led by the Bufomix Easyhaler combined formulation. The Dexdor sedative used in intensive care also grew strongly, and sales of Simdax, which has been in the markets for a long time, increased too. Growth in sales of these products in the first quarter of the year was able to compensate almost fully for the decline in sales of Orion's branded Parkinson's drugs Stalevo, Comtess and Comtan due to generic competition. Generic competition to Stalevo is extending in Europe, and this is reducing sales of the product. In addition, in Japan the first marketing authorisations for generic Comtan products were granted, but generic competition has not yet commenced.

"Net sales of the Specialty Products business division grew in all key market areas, but especially well in Scandinavia and Finland, where we were again able to grow clearly faster than the market and strengthen our position as market leader. As regards the business division's products, there was strong growth in the biosimilar Remsima compared with the comparative period, but sales of other products in the portfolio also developed well.

"Net sales of the other business divisions declined in the first quarter of the year. In Animal Health, net sales in the comparative period were increased by a payment related to the sale of product rights. The decrease in sales in Fermion was mainly due to the timing of deliveries and in Orion Diagnostica due to the ending of sales of certain products that had been represented and the slowing of market growth in China.

"Further progress is being made in our clinical pharmaceutical development pipeline as we commence a Phase II clinical trial with a drug candidate for treatment of symptoms of Parkinson's disease in which the COMT inhibitor (ODM-104) developed by Orion is combined with the pharmaceutical ingredients carbidopa and long-acting levodopa used to treat Parkinson's disease. We also completed Phase I clinical safety trials with a new targeted FGFR+VEGFR inhibitor (ODM-203) for treatment of cancers. The project has continued to a Phase II clinical trial to investigate the efficacy of the drug candidate in slowing the growth of solid cancerous tumours in patients in which FGFR changes in cancerous tumours have been detected. Our other ongoing clinical development projects in different phases have also progressed as planned.

"Significant investment and production reorganisation projects undertaken in recent years to develop and ensure future growth, delivery reliability and quality standards will be continued through our investment in a new production unit at Fermion's Hanko manufacturing plant. In addition, we have commenced expansion of Easyhaler production at the Espoo pharmaceuticals production plant.

"Our outlook estimate for 2016 remains unchanged. We estimate that in 2016 net sales will be at similar level to 2015. We estimate that operating profit will exceed EUR 240 million. Our outlook estimate and the basis for it can be found in this report under 'Outlook for 2016' and 'Basis for outlook'."



# Events during the period

On 1 March Orion transferred altogether 144,350 Orion Corporation B shares held by the Company as share bonuses for the earning periods 2013–2015 and 2015 to the persons belonging to the Share-based Incentive Plan for key persons of the Group.

On 22 March Orion Corporation's Annual General Meeting was held in Helsinki.

# Events after the period

There were no significant events after the period.



## News conference and teleconference

A news conference and teleconference on the published results will be held today, Wednesday 27 April 2016, at 13:30 EEST in Hotel Kämp, address: Pohjoisesplanadi 29, Helsinki. President and CEO Timo Lappalainen will give a brief presentation in English on the financial review.

The event can be followed live as a webcast accessible at Orion's website at <a href="www.orion.fi/en/investors">www.orion.fi/en/investors</a>. After the presentation, questions can be asked by telephone in Finnish and English.

The teleconference code is 3465844 and the telephone numbers to participate in the teleconference are:

Finland: +358 (0)9 6937 9590 Sweden: +46 (0)8 5033 6538 United Kingdom: +44 (0)20 3427 1909 United States: +1 646 254 3366

## **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 the Orion website during Wednesday 27 April 2016.

## Financial report material

Financial reports and related presentation material are available at <a href="www.orion.fi/en/investors">www.orion.fi/en/investors</a> promptly after publication. The website also has a form for subscribing to Orion's releases.

## Dates in Orion Calendar 2016

Half-Yearly Report January–June 2016 Tuesday 19 July 2016

Interim Report January–September 2016 Tuesday 25 October 2016

## For additional information about the financial review:

Jari Karlson, CFO tel. +358 10 426 2883

Tuukka Hirvonen, Communications Manager tel. +358 10 426 2721 / mobile +358 50 966 2721

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



# Financial review January-March 2016

### **Net sales**

**The Orion Group's net sales** in January–March 2016 were EUR 262 million (EUR 260 million in January–March 2015). The net effect of currency exchange rates was minus EUR 5 million.

*The Pharmaceuticals business's* net sales were up by 2% at EUR 249 (245) million. The Pharmaceuticals business's net sales of products in the portfolio other than Stalevo<sup>®</sup>, Comtess<sup>®</sup>/Comtan<sup>®</sup> and Precedex<sup>®</sup>, and excluding milestone payments, were up by 9% at EUR 209 (192) million. Net sales of Orion's Stalevo<sup>®</sup> (carbidopa, levodopa and entacapone) and Comtess<sup>®</sup>/Comtan<sup>®</sup> (entacapone) Parkinson's drugs were down by 23% at EUR 33 (42) million, which was 13% (17%) of the Pharmaceuticals business's net sales.

The Diagnostics business's net sales were down by 17% at EUR 14 (16) million.

## **Operating profit**

**The Orion Group's** operating profit was down by 3% at EUR 80 (83) million. Milestone payments accounted for EUR 4 (5) million of the operating profit.

**The Pharmaceuticals business's** operating profit was down by 2% at EUR 80 (81) million. Milestone payments accounted for EUR 4 (5) million of the operating profit.

**The Diagnostics business's** operating profit was down by 34% at EUR 2.6 (4.0) million mainly due to the decrease in net sales and products with lower margins accounting for a higher proportion of sales.

## **Operating expenses**

The Group's sales and marketing expenses were EUR 44 (47) million.

**R&D expenses** were EUR 25 (25) million and accounted for 10% (10%) of the Group's net sales. Pharmaceutical R&D expenses amounted to EUR 23 (23) million. Research projects are reported in more detail under Pharmaceuticals in the Business Reviews.

Administrative expenses were EUR 11 (11) million.

Other operating income and expenses were EUR -0 (-2) million.

### Group's profit

The Group's profit before taxes was down by 4% at EUR 80 (83) million. Basic earnings per share were EUR 0.45 (0.47) and diluted earnings per share were EUR 0.45 (0.47). Equity per share was EUR 3.37 (2.85). The return on capital employed before taxes (ROCE) was 46% (50%) and the return on equity after taxes (ROE) 47% (57%).

### **Financial position**

The Group's *gearing* was -20% (-20%) and the *equity ratio* 44% (38%).

The Group's *total liabilities* at 31 March 2016 were EUR 613 (669) million. At the end of the period, interest-bearing liabilities amounted to EUR 186 (231) million, including EUR 176 (206) million of long-term loans. The non-interest-bearing liabilities in 2015 and 2016 include the dividends (EUR 183 million) transferred from equity in March but not paid until the beginning of April.

The Group had EUR 283 (312) 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 interest-bearing instruments issued by financially solid financial institutions and corporations.



### Cash flow

**Cash flow from operating activities** was EUR 52 (63) million. The decrease in cash flow was due the cash tied up in working capital increasing by EUR 10 million more than in the comparative period.

Cash flow from investing activities was EUR -12 (-10) million.

Cash flow from financing activities was EUR -2 (-4) million.

### Capital expenditure

The Group's capital expenditure totalled EUR 9 (8) million. This comprised EUR 7 (7) million on property, plant and equipment and EUR 2 (1) million on intangible assets.

## Outlook for 2016

Net sales are estimated to be at similar level to 2015 (net sales were EUR 1,016 million in 2015).

Operating profit is estimated to exceed EUR 240 million.

## Basis for outlook

A financial objective of Orion is to increase net sales. During the current year steadily growing products such as Dexdor<sup>®</sup> and the Easyhaler<sup>®</sup> product family are expected to be able to compensate for part of the decrease in net sales due to extension of generic competition to Stalevo<sup>®</sup>.

Orion's Parkinson's drugs are Comtess<sup>®</sup>, Comtan<sup>®</sup> and Stalevo<sup>®</sup>. Generic competition to them commenced in the United States in 2012 and in Europe in 2013. In the United States competition has decreased Orion's sales of these products to low levels, but in Europe the impact has so far been less. During 2016 the competition is expected to extend in Europe. In 2015 Europe accounted for about EUR 80 million of the net sales of Orion's Parkinson's drugs.

Sales of Dexdor and the Easyhaler product family, which are also key proprietary drugs, are forecast to continue to grow. The patent for the Simdax<sup>®</sup> molecule expired in September 2015 but this is not expected to have a material impact on sales of the product in the current year.

Sales of generic products have been accounting for a greater proportion of Orion's total sales, and price competition has remained intense in many markets. Competition in Finland, the most important generic market for Orion, remains intense in 2016. In addition, at the beginning of the current year there was in Finland a change to a system in which a pharmacy is always obliged to recommend to the customer the cheapest substitutable generic prescription drug. The potential negative impact of this change on Orion's sales has been taken into account in the outlook estimate. However, product launches continue to support Orion's position as market leader.

Collaboration agreements with other pharmaceutical companies are an important component of Orion's business model. Often payments related to these agreements are recorded in net sales, and they totalled EUR 8 million in 2015 and EUR 39 million in 2014. Forecasting the timing and amount of payments is difficult. Possible future payments relating to agreements already made have in some cases been conditional on, for instance, the progress of research projects or results received, which are not known until studies have been completed. On the other hand, making new agreements is generally a process for which neither the schedule nor the outcome is known before the final signing of the agreement.

Investments commenced in 2012 to develop and ensure future growth, delivery reliability and quality standards, and the related reorganisations of production were mostly completed during 2015. They are no longer expected materially to decrease production capacity and increase production costs. Projects launched as part of the reorganisations to increase production efficiency are expected gradually to improve productivity from the beginning of 2015. However, at the same time depreciation on property, plant and



equipment (EUR 30 million in 2015) has grown to about EUR 5 million higher than in 2012. In 2016 the Group's total capital expenditure is expected to be higher than in 2015, when it was EUR 43 million.

Marketing expenditure will be slightly higher than in the previous year. Because the registrations and launches of new products are projects that take more than a year, the increases in resources and other inputs required in 2016 were planned mainly during the previous year.

Research and development costs will be slightly higher than in 2015. They 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 2016 are either ongoing from the previous year or at an advanced stage of planning, therefore their cost level can be estimated rather accurately. 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 ODM-201 research costs.

## Near-term risks and uncertainties

Sales of Orion's Parkinson's drugs will decrease in 2016 due to generic competition. The effects of the competition have been taken into account in the outlook estimate for the current year. However, the timing of the extension and intensity of generic competition to Stalevo in Europe still entails uncertainty that may materially affect the accuracy of the estimate made at this stage. Competition is expected to extend in Europe during 2016, decreasing Stalevo sales. The basic Simdax and Dexdor patents have expired. However, the products have other still valid product protection. Nevertheless, for these products there is a possibility that generic competition might commence before expiry of the respective product protection. Orion has become aware that a marketing authorisation application for a generic version of Dexdor has been submitted in some European countries. Orion has commenced 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 pharmaceutical markets in recent years will specifically affect 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 among others adjustments of stock levels. In addition, changes in market prices and exchange rates affect the value of deliveries to Novartis.

The 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. The greatest exchange rate risk at present relates to European currencies such the Swedish crown. 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.

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 generally 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 a total of EUR 39 million of such payments were received, which was clearly higher than average for the payments received by Orion in previous years. The payments received in 2015 totalled EUR 8 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.

## 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.

## Shares and shareholders

On 31 March 2016 Orion had a total of 141,257,828 (141,257,828) shares, of which 38,906,154 (40,412,981) were A shares and 102,351,674 (100,844,847) B shares. The Group's share capital was EUR 92,238,541.46 (92,238,541.46). At the end of March 2016 Orion held 283,366 (427,716) B shares as treasury shares. On 31 March 2016 the aggregate number of votes conferred by the A and B shares was 880,191,388 (908,676,751) excluding treasury shares.

At the end of March 2016, Orion had 49,370 (51,872) 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–March 2016.

## **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 this date.

On 31 March 2016 the market capitalisation of the Company's shares, excluding treasury shares, was EUR 4,089 million.

Orion shares are also traded on various alternative trading platforms in addition to Nasdaq Helsinki.



### **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 Board of Directors is authorised to decide on acquisition of no more than 500,000 Orion Corporation B shares. The authorisation to acquire shares is valid for 18 months from the decision taken by the Annual General Meeting. 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 authorisations 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**

Orion Group's Long-Term Incentive Plan 2013

Orion has a currently operating share-based incentive plan for key persons of the Group, which was announced in a stock exchange release published on 5 February 2013.

On 1 March 2016 Orion transferred altogether 144,350 Orion Corporation B shares held by the Company as share bonuses for the earning periods 2013–2015 and 2015 to the key persons belonging to the incentive plans of the Orion Group.

Orion Group's Long-Term Incentive Plan 2016

In February 2016 the Board of Directors of Orion Corporation decided on a new share-based incentive plan for key persons of the Group. The Plan includes earning periods and the Board of Directors will annually decide on the beginning and duration of the earning periods in 2016, 2017 and 2018. The Board of Directors will decide on the earnings criteria and on targets to be established for them at the beginning of each earning period. The target group of the Plan consists of a maximum of 50 people. The total maximum amount of rewards to be paid on the basis of the Plan is 500,000 Orion Corporation B shares and a cash payment corresponding to the value of the shares. The incentive plan is reported in more detail in a stock exchange release on 2 February 2016.

### 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 March 2016 Orion had a total of 49,370 (51,872) registered shareholders, of whom 96% (95%) were private individuals holding 41% (42%) of the entire share stock and 62% (62%) of the total votes. There were altogether 58 (55) million nominee-registered shares, which was 41% (39%) of all shares, and they conferred entitlement to 9% (8%) of the total votes.

At the end of March 2016 Orion held 283,366 (427,716) B shares as treasury shares, which is 0.2% (0.3%) of the Company's total share stock and 0.03% (0.05%) of the total votes.



## Decisions by the Annual General Meeting

The Annual General Meeting of the Shareholders of Orion Corporation was held on 22 March 2016 in Messukeskus Helsinki, Expo and Convention Centre. The following matters among others were handled at the meeting.

### Adoption of the financial statements for financial year 1 January to 31 December 2015

The Annual General Meeting adopted the financial statements of the Company and Group as per 31 December 2015.

### Dividend EUR 1.30 per share

A dividend of EUR 1.30 per share was approved in accordance with the Board's proposal. The record date for dividend distribution was 24 March 2016 and the payment date was 4 April 2016.

### Discharge from liability

The members of the Board of Directors and the President and CEO were discharged from liability for the financial year 1 January to 31 December 2015.

#### Remuneration of the members of the Board of Directors

The remuneration of the members of the Board of Directors shall remain unchanged. As the annual fees for the term of office of the Board of Directors, the Chairman shall receive EUR 76,000, the Vice Chairman shall receive EUR 51,000 and the other Board members shall receive EUR 38,000 each. Furthermore, as a fee for each meeting attended, the Chairman shall receive EUR 1,200, the Vice Chairman shall receive EUR 900 and the other Board members shall receive EUR 600 each. The travel expenses of Board members shall be paid in accordance with previous practice. The aforementioned meeting fees shall also be paid to the Chairmen and to the members of the committees established by the Board.

Of the aforementioned annual fees, 60% was to be paid in cash and 40% in the Company's shares, so Orion Corporation B shares were to be acquired in the period 29 March to 1 April 2016 from the stock exchange in amounts corresponding to EUR 30,400 for the Chairman, EUR 20,400 for the Vice Chairman and EUR 15,200 for each of the other Board members. The part of the annual fee paid in cash, which corresponds to the approximate sum necessary for the payment of the income taxes on the fees, was to be paid no later than 29 April 2016. The annual fees encompass the full term of office of the Board of Directors.

It was also decided that the Company shall pay the transfer tax related to the portion of the annual fees of the members of the Board of Directors to be paid in shares.

### Members and Chairman of the Board of Directors

The number of members in the Board of Directors was confirmed to be seven. Sirpa Jalkanen, Timo Maasilta, Mikael Silvennoinen, Hannu Syrjänen, Heikki Westerlund and Jukka Ylppö were re-elected as members of the Board of Directors for the following term of office, and Eija Ronkainen was elected as a new member. Hannu Syrjänen was re-elected as the Chairman of the Board of Directors.

### Auditor and auditor's fee

PricewaterhouseCoopers Oy, authorised public accountants, were elected as the auditor for the following term of office. The auditor's fee shall be paid against an invoice approved by the Company.



## Constitution of the Board of Directors

At its constitutive meeting following the Annual General Meeting, the Board of Directors elected Timo Maasilta as its Vice Chairman.

## Personnel

The average number of employees in the Orion Group in January–March 2016 was 3,401 (3,418). At the end of March 2016 the Group had a total of 3,409 (3,418) employees, of whom 2,731 (2,745) worked in Finland and 678 (673) outside Finland.

Salaries and other personnel expenses in January–March 2016 totalled EUR 53 (54) 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 Reviews**

## **Pharmaceuticals**

### Review of human pharmaceuticals market

Finland is the most important individual market for Orion, generating about one-third of the total net sales. According to IMS Health statistics, **Finnish wholesale of human pharmaceuticals** in January–March 2016 was up by 2% on the previous year at EUR 534 (521) million. Orion was able to increase its sales faster than market growth, and strengthened its position as leader in marketing pharmaceuticals in Finland. According to statistics collected by IMS Health, **Orion's wholesale of human pharmaceuticals in Finland** in January–March 2016 amounted to EUR 69 (63) million, up by 11% compared with the previous year. Orion's market share of Finnish pharmaceuticals markets was 13% (12%).

The most important individual therapy area for Orion is still the treatment of Parkinson's disease. Orion's branded Parkinson's drugs containing entacapone (Stalevo<sup>®</sup>, Comtess<sup>®</sup> and Comtan<sup>®</sup>) account for under 15% of the Group's net sales.

### Total sales of all Parkinson's drugs:

EUR or USD million		2015	2014	Change %
United States	USD	846	812	+4%
Europe TOP 5	EUR	929	992	-6%
Japan	EUR	573	507	+13%

Source: IMS Health pharmaceutical sales statistics MAT12/2015 (1/2015-12/2015)

The five largest European markets for Parkinson's disease drugs were Germany, the United Kingdom, France, Spain and Italy.

Total sales of all Parkinson's drugs containing entacapone:

EUR or USD million		2015	2014	Change %
United States	USD	83	108	-23%
Europe TOP 5	EUR	126	144	-13%
Japan	EUR	66	54	+23%

Source: IMS Health pharmaceutical sales statistics MAT12/2015 (1/2015–12/2015)

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

EUR or USD million		2015	2014	Change %
United States	USD	17	17	+2%
Europe TOP 5	EUR	95	123	-23%
Japan	EUR	66	54	+23%

Source: IMS Health pharmaceutical sales statistics MAT12/2015 (1/2015–12/2015)

Sales of Orion's branded Parkinson's drugs decreased in Europe due to commencement of generic competition. Sales increased in Japan mainly because Stalevo was launched in that market during 2015. The market share of Orion's branded Parkinson's drugs was 2% in the United States, on average 10% in the five largest European markets and 12% in Japan.

According to IMS Health 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 December 2015 were up by 5% at EUR 525 (501) million. According to IMS Health pharmaceutical sales statistics, sales of Orion's **Dexdor**<sup>®</sup> **intensive care sedative** (dexmedetomidine) were up by 30% at EUR 36 (28) million in Europe.



# Interim Report Q1/2016

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

In January–March 2016 the Pharmaceuticals business's net sales were EUR 249 (245) million and its operating profit was EUR 80 (81) million. Milestone payments accounted for EUR 4 (5) million of the net sales and operating profit. During the review period Orion received a milestone payment of EUR 4 million related to marketing rights to the Easyhaler product family. The operating profit of the Pharmaceuticals business was 32% (33%) of the segment's net sales.

Net sales of Orion's top ten pharmaceuticals in January–March 2016 were up by 5% at EUR 113 (107) million. They accounted for 45% (44%) of the total net sales of the Pharmaceuticals business.

Net sales of the Pharmaceuticals business other than Stalevo<sup>®</sup>, Comtess<sup>®</sup>/Comtan<sup>®</sup> and Precedex<sup>®</sup> and excluding milestone payments were up by 9% at EUR 209 (192) million.

### **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 Proprietary Products in January–March 2016 were EUR 88 (89) million. Sales of Parkinson's drugs continued to decline, but this decline was almost fully compensated by the good growth in sales of other products.

Orion's drugs for treatment of Parkinson's disease are Stalevo<sup>®</sup> (active ingredients carbidopa, levodopa and entacapone) and Comtess<sup>®</sup>/Comtan<sup>®</sup> (entacapone). Their total net sales in January–March 2016 were down by 23% at EUR 33 (42) million. In the United States Orion's Parkinson's drugs have several generic competitors. In Europe Comtess and Comtan have several generic competitors, and generic competition to Stalevo extended. In addition, in certain countries compulsory price reductions related to the opening of the market to generic competition are reducing Orion's sales. In Japan the first marketing authorisations for generic Comtan products were granted, but generic competition has not yet commenced.

### Breakdown of sales of Parkinson's drugs:

EUR million	Q1/2016	Q1/2015	Change %_
Stalevo deliveries to Novartis	19	20	-2%
Comtan deliveries to Novartis	4	10	-56%
Orion's Stalevo sales	8	11	-33%
Orion's Comtess sales	1	2	-20%

Net sales of Simdax<sup>®</sup>, a drug for treatment of acute decompensated heart failure, in January–March 2016 were up by 8% at EUR 14 (13) million. Simdax is sold in altogether over fifty countries worldwide.

Total net sales of the Easyhaler® product family for treatment of asthma and chronic obstructive pulmonary disease were up by 25% in January–March 2016 at EUR 16 (12) million. The increase was mainly due to sales of the Bufomix Easyhaler® combined formulation (budesonide-formoterol). Sales of Bufomix Easyhaler were up by 78% at EUR 6 (3) million in January–March 2016. During the review period the budesonide-formoterol combined formulation received national marketing authorisation in Italy (product name Fobuler®) and the Netherlands (product name Bufoler Easyhaler®). In addition, Orion has submitted marketing authorisation applications for the combined formulation in Germany, the United Kingdom and France. Orion has commenced expansion of Easyhaler production at the Espoo pharmaceuticals production plant.

Net sales of Orion's Dexdor® intensive care sedative (dexmedetomidine) in January–March 2016 were up by 28% at EUR 14 (11) million.



### **Specialty Products**

Net sales of the Specialty Products business division's off-patent, i.e. generic prescription drugs, self-care products and biosimilars in January–March 2016 were up by 13% at EUR 123 (109) million. Sales of generic entacapone products were down by 47% at EUR 3 (6) million. Sales of products from the rest of the portfolio were up by 17%. Over half of this growth came from the biosimilar Remsima<sup>®</sup>.

Finland, Scandinavia, and Eastern Europe and Russia are the most important markets for Specialty Products. The business division's sales in Finland in January–March 2016 were up by 8% at EUR 70 (65) million. Orion managed to increase its sales, especially in prescription drugs. Sales were up by 44% at EUR 21 (15) million in Scandinavia and sales were up by 6% at EUR 12 (12) million in Eastern Europe and Russia.

Net sales of Remsima<sup>®</sup> for treatment of rheumatoid arthritis among other things were EUR 12 (3) million in January–March 2016. The main explanation for the strong growth is that Orion won many tendering competitions in 2015, but they were not yet apparent in sales for the comparative period. Some of the net sales in the first quarter of 2016 still came from Norway, where Orion did not win the national tendering competition for the twelve-month period beginning in March 2016. A significant portion of the net sales came from Denmark, where Orion won the national tendering competition in summer 2015. Remsima is a biosimilar infliximab developed and manufactured by Orion's collaboration partner, for which Orion has marketing rights in the Nordic countries and Estonia.

#### **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 January–March 2016 were down by 16% at EUR 18 (22) million. Product sales developed well in the review period, but net sales in the comparative period included a non-recurring milestone payment recorded on the sale of product rights, which explains the decrease in total net sales. Sales of the animal sedative product family at EUR 7 (7) million accounted for 37% (32%) of the division's net sales. The 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.

### **Fermion**

Fermion manufactures active pharmaceutical ingredients for Orion and other pharmaceutical companies. Its product range comprises nearly 30 pharmaceutical ingredients. 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 January–March 2016 excluding pharmaceutical ingredients supplied for Orion's own use were down by 28% at EUR 11 (15) million and accounted for nearly two-thirds of Fermion's entire net sales. The decrease was mainly due to the timing of product deliveries. During the review period Fermion announced its investment of over EUR 30 million in a new production unit at Hanko in the period 2016–2018.

### Research and development projects

The Group's **R&D** expenses in January–March 2016 were EUR 25 (25) million, of which the Pharmaceuticals business accounted for EUR 23 (23) million. The Group's R&D expenses accounted for 10% (10%) of the Group's net sales. R&D expenses also include expenses related to development of the current portfolio.

In 2014 Orion commenced global collaboration with Bayer in the development and commercialisation of a novel oral *androgen receptor inhibitor* (ODM-201). The companies have an ongoing joint Phase III clinical trial for further evaluation of the efficacy and safety of ODM-201 in patients with non-metastatic castration-resistant prostate cancer (nm-CRPC).



# Interim Report Q1/2016

Orion has an ongoing project to broaden the range of the *Easyhaler® product family*. Orion is developing a *fluticasone-salmeterol combined formulation* for European markets. In this formulation fluticasone acts as an anti-inflammatory agent and salmeterol acts as a long-acting bronchodilator.

In autumn 2015 Orion completed the additional trials with the *budesonide-formoterol combined formulation* in the Easyhaler<sup>®</sup> product family. Based on the results received, Orion has submitted a marketing authorisation application in Germany, France and the United Kingdom. In this formulation budesonide acts as an anti-inflammatory agent and formoterol acts as a long-acting bronchodilator.

Orion is continuing development of an *alpha-2c adrenoceptor antagonist* (ORM-12741) for treatment of symptoms of Alzheimer's disease in collaboration with Janssen Pharmaceuticals Inc. Orion has an ongoing Phase IIa clinical trial with a new drug formulation. In the initial Phase IIa clinical trial conducted by Orion, the efficacy and safety of the drug candidate in treatment of cognitive and behavioural symptoms related to Alzheimer's disease were investigated with positive results.

Orion has an ongoing Phase II clinical trial with *orally administered levosimendan* (ODM-109) for treatment of patients with amyotrophic lateral sclerosis (ALS). Levosimendan is a troponin C selective calcium sensitiser enhancing cardiac and skeletal muscle function. Available studies indicate that levosimendan has the potential to support diaphragm and thus respiratory function as well as strength and endurance of other skeletal muscles in patients with ALS.

Orion is commencing a Phase II clinical trial with a drug candidate for treatment of symptoms of Parkinson's disease in which the *COMT inhibitor* (ODM-104) developed by Orion is combined with the pharmaceutical ingredients carbidopa and long-acting levodopa used to treat Parkinson's disease. In the trial the efficacy of the drug candidate in treating symptoms of Parkinson's disease will be investigated and the product will be compared with a Stalevo product already in the markets in which the active ingredients are the COMT inhibitor entacapone, carbidopa and levodopa.

Orion has completed Phase I clinical safety trials with a new *targeted FGFR+VEGFR inhibitor* (ODM-203) for treatment of cancers. The project has progressed to a Phase II clinical trial to investigate the efficacy of the drug candidate in slowing the growth of solid cancerous tumours in patients in which FGFR changes in cancerous tumours have been detected.

Orion has ongoing Phase I clinical safety trials with *CYP17 enzyme and androgen receptor inhibitor* (ODM-204). The pre-clinical study results indicated that ODM-204 blocks the growth of castration-resistant prostate cancer (CRPC).

Orion has ongoing Phase I clinical safety trials with a *novel*, *highly potent*, *selective and reversible negative allosteric modulator of Transient Receptor Potential A1 (TRPA1) ion channel* (ODM-108) for treatment of neuropathic pain. ODM-108 did not demonstrate sedation when tested at pre-clinically effective doses.

Orion's partner Tenax Therapeutics, Inc. will develop and commercialise *levosimendan* in US and Canadian markets for a new cardiovascular indication, prevention of low cardiac output syndrome (LCOS) in cardiac surgery patients. The company has an ongoing Phase III clinical trial for this indication. In addition, the company is investigating the possibility of gaining an additional indication of septic shock for levosimendan.

Orion's collaboration partner Recro Pharma, Inc. is developing an intranasal formulation of **dexmedetomidine** for treatment of pain. Recro has decided to change the target indication from post-operational pain to peri-procedural pain. The company has announced that it is planning to commence a new clinical Phase II trial concerning the new indication.

In addition, Orion has several projects in the early research phase investigating central nervous system diseases, cancer and neuropathic pain, among others.



# **Diagnostics**

Orion Diagnostica manufactures convenient and quick in vitro diagnostic tests and testing systems suitable for point-of-care testing. Net sales of the Diagnostics business in January–March 2016 were down by 17% at EUR 14 (16) million. The decrease was mainly due to the ending of distribution of certain products that had been represented and slowing market growth in China compared with the comparative period.

QuikRead<sup>®</sup> infection tests remained the main product, with sales continuing to increase. With the help of CRP tests from the QuikRead go<sup>®</sup> product family in infectious disease diagnostics, antibiotic treatment can be targeted at patients that need it and unnecessary use of antibiotics avoided in situations in which a patient would not benefit from them. Avoiding unnecessary antibiotic treatments helps in tackling the growing problem of antibiotic resistance. During the review period the QuikRead go<sup>®</sup> CRP test received clearance from the US Food and Drug Administration (FDA) for marketing of the product for laboratory use in the United States, and preparation to launch the product in US markets has commenced.

Launching of the first Orion GenRead<sup>®</sup> test system products – an instrument and a C. difficile test for detecting C. difficile bacteria causing intestinal infection related to antibiotic treatment – continued as planned. The test gives the first positive C. difficile results already within 20 minutes, which is a significant advantage in treating a patient. Orion GenRead<sup>®</sup> is based on an isothermal nucleic acid amplification technique, SIBA<sup>®</sup> technology.

The operating profit of the Diagnostics business was down by 34% at EUR 2.6 (4.0) million. The decrease was mainly due to the decrease in net sales and products with lower margins accounting for a higher proportion of sales. The Diagnostics business's operating profit accounted for 19% (24%) of the segment's net sales.

Espoo, 27 April 2016

Board of Directors of Orion Corporation

**Orion Corporation** 

Timo Lappalainen
President and CEO

Jari Karlson CFO



Personnel expenses

# <u>Tables</u>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

EUR million	Q1/16	Q1/15	Change %	2015
Net sales	262.0	259.9	+0.8%	1,015.6
Cost of goods sold	-102.2	-91.4	+11.9%	-405.8
Gross profit	159.8	168.5	-5.2%	609.8
Other operating income and expenses	-0.2	-2.2	-92.3%	1.5
Sales and marketing expenses	-43.7	-46.6	-6.2%	-190.4
R&D expenses	-24.9	-25.2	-1.1%	-108.1
Administrative expenses	-10.6	-11.4	-6.6%	-46.2
Operating profit	80.3	83.1	-3.3%	266.6
Finance income	0.1	0.6	-78.2%	0.8
Finance expenses	-1.2	-1.4	-15.6%	-5.5
Share of associated companies' results	0.4	0.4	-5.2%	0.4
Profit before taxes	79.7	82.7	-3.7%	262.3
Income tax expense	-16.4	-17.0	-3.7%	-54.2
Profit for the period	63.3	65.7	-3.7%	208.2
Change in value of cash flow hedges		0.0		0.1
<u> </u>				
Change in value of available-for-sale investments	0.5	0.5		1.1
Translation differences	-2.1	2.5		1.8
Items that may be reclassified subsequently to profit and loss	-1.5	3.1		3.0
Items due to remeasurement of defined benefit plans	-0.0	-0.3		49.1
Items that will not be reclassified to profit and loss	-0.0	-0.3		49.1
Other comprehensive income net of tax	-1.5	2.8	0.00/	52.1
Comprehensive income for the period including tax effects	61.8	68.5	-9.8%	260.2
PROFIT ATTRIBUTABLE TO:				
Owners of the parent company	63.3	65.7	-3.7%	208.2
Non-controlling interests	0.0	0.0		0.0
COMPREHENSIVE INCOME ATTRIBUTABLE TO:				
Owners of the parent company	61.8	68.5	-9.8%	260.2
Non-controlling interests	0.0	0.0	0.070	0.0
Tron controlling interests	0.0	0.0		0.0
Basic earnings per share, EUR 1)	0.45	0.47	-3.8%	1.48
Diluted earnings per share, EUR 1)	0.45	0.47	-3.8%	1.48
Ungrana and an				
Depreciation, amortisation and impairment	9.9	9.9	+0.3%	41.8
Developed superior	<b>50.0</b>	540	4.00/	222.0

53.3

54.3

-1.8%

220.6

<sup>1)</sup> The figure has been calculated from the profit attributable to the owners of the parent company.





## **CONSOLIDATED STATEMENT OF FINANCIAL POSITION**

### **ASSETS**

EUR million	3/16	3/15	Change %	12/15
Property, plant and equipment	275.6	268.5	+2.6%	276.4
Goodwill	13.5	13.5		13.5
Intangible rights	41.0	45.9	-10.5%	41.7
Other intangible assets	2.5	2.6	-6.5%	2.5
Investments in associates	3.0	2.6	+16.5%	2.6
Available-for-sale investments	7.6	6.2	+21.4%	6.9
Pension asset	22.1			24.4
Deferred tax assets	1.0	7.6	-86.2%	1.1
Other non-current assets	4.1	1.7	+145.3%	4.1
Non-current assets total	370.5	348.5	+6.3%	373.3
Inventories	207.7	186.4	+11.4%	205.7
Trade receivables	184.9	171.5	+7.8%	192.1
Other receivables	42.3	51.7	-18.1%	31.1
Cash and cash equivalents	282.5	312.2	-9.5%	245.2
Current assets total	717.4	721.8	-0.6%	674.1
Assets total	1 087.9	1 070.3	+1.6%	1 047.4

## **EQUITY AND LIABILITIES**

EUR million	3/16	3/15	Change %	12/15
Share capital	92.2	92.2		92.2
Expendable fund	0.5	0.5		0.5
Other reserves	7.4	6.4	+15.7%	6.9
Retained earnings	374.9	302.6	+23.9%	495.3
Equity attributable to owners of the parent company	475.1	401.8	+18.2%	594.9
Non-controlling interests	0.0	0.0	-22.6%	0.0
Equity total	475.1	401.8	+18.2%	594.9
Deferred tax liabilities	36.8	30.7	+19.9%	37.8
Pension liability	3.1	34.7	-91.1%	3.1
Provisions	0.3	0.3	-11.4%	0.3
Interest-bearing non-current liabilities	175.7	206.1	-14.7%	177.9
Other non-current liabilities	0.0	0.2	-71.3%	0.0
Non-current liabilities total	215.9	271.9	-20.6%	219.2
Trade payables	80.8	65.2	+23.9%	99.1
Current tax liabilities	5.9	5.1	+14.2%	1.2
Other current liabilities	299.9	301.7	-0.6%	122.8
Provisions	0.0	0.0	+6.4%	0.3
Interest-bearing current liabilities	10.2	24.6	-58.6%	9.9
Current liabilities total	396.9	396.6		233.3
Liabilities total	612.8	668.5	-8.3%	452.5
Equity and liabilities total	1,087.9	1,070.3	+1.6%	1,047.4





## **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

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

	Equi	ity attributab	le to owners	s of the parer	t company			
EUR million	a.	b.	C.	d.	e.	f.	g.	h.
Equity at 1 January 2015	92.2	0.5	5.9	-50.8	-3.3	470.4	0.0	514.9
Profit for the period						65.7		65.7
Other comprehensive income:								
Change in value of cash flow hedges			0.0					0.0
Change in value of available-for-sale investments			0.5					0.5
Translation differences					2.6			2.6
Items due to remeasurement of defined benefit plans				-0.3				-0.3
Transactions with owners								
Dividend and capital repayment						-183.1		-183.1
Share-based incentive plan						1.6		1.6
Other adjustments			0.0			-0.3	0.0	-0.2
Equity at 31 March 2015	92.2	0.5	6.4	-51.1	-0.7	354.4	0.0	401.8
Equity at 1 January 2016	92.2	0.5	6.9	-1.6	-1.5	498.4	0.0	594.9
Profit for the period						63.3		63.3
Other comprehensive income:								
Change in value of available-for-sale investments			0.5					0.5
Translation differences					-2.0			-2.0
Items due to remeasurement of defined benefit plans				-0.0				-0.0
Transactions with owners								
Dividend and capital repayment						-183.3		-183.3
Share-based incentive plan						2.1		2.1
Other adjustments			0.0			-0.4	0.0	-0.3
Equity at 31 March 2016	92.2	0.5	7.4	-1.7	-3.6	380.2	0.0	475.1



## **CONSOLIDATED STATEMENT OF CASH FLOWS**

EUR million	Q1/16	Q1/15	2015
Operating profit	80.3	83.1	266.6
Adjustments	12.7	10.8	53.5
Change in working capital	-28.2	-18.0	-14.9
Interest paid	-2.3	-3.3	-10.9
Interest received	2.5	3.9	7.7
Dividends received			0.2
Income taxes paid	-12.6	-13.6	-47.2
Total net cash flow from operating activities	52.5	62.9	254.9
Investments in property, plant and equipment	-9.3	-9.0	-38.4
Investments in intangible assets	-2.4	-1.0	-4.8
Sales of property, plant and equipment and available-for-sale investments	0.2	0.3	1.0
Total net cash flow from investing activities	-11.5	-9.6	-42.2
Short-term loans raised	0.2	0.5	1.4
Repayments of short-term loans	-0.3	-0.7	-2.7
Long-term loans raised	0.0	0.2	
Repayments of long-term loans	-2.3	-4.1	-46.2
Dividends paid and other distribution of profits	-0.0	-0.0	-183.3
Total net cash flow from financing activities	-2.4	-4.1	-230.8
Net change in cash and cash equivalents	38.5	49.2	-18.1
Cash and cash equivalents at the beginning of the period	245.2	258.5	258.5
Foreign exchange differences	-1.3	4.4	4.8
Net change in cash and cash equivalents	38.5	49.2	-18.1
Cash and cash equivalents at the end of the period	282.5	312.2	245.2



17



Nominal amount, GWh

## **CHANGES IN PROPERTY, PLANT AND EQUIPMENT**

EUR million	3/16	3/15	12/15
Carrying amount at the beginning of the period	276.4	269.1	269.1
Additions	6.9	6.9	38.7
Disposals	-0.2	-0.3	-1.1
Depreciation and impairments	-7.5	-7.3	-30.2
Carrying amount at the end of the period	275.6	268.5	276.4
CHANGES IN INTANGIBLE ASSETS (EXCLUDING GO	ODWILL)		
EUR million	3/16	3/15	12/15
Carrying amount at the beginning of the period	44.3	50.4	50.4
Additions	1.7	0.7	5.4
Disposals	-0.0		
Amortisation and impairments	-2.4	-2.6	-11.5
Carrying amount at the end of the period	43.5	48.5	44.3
COMMITMENTS AND CONTINGENCIES			
EUR million	3/16	3/15	12/15
CONTINGENCIES FOR OWN LIABILITIES			
Mortgages on land and buildings		32.0	
Guarantees	5.2	3.5	5.2
Cuaramooo		0.0	0.2
OTHER LIABILITIES			
Leasing liabilities (excluding finance lease contracts)	6.5	7.0	7.3
Other liabilities	0.3	0.3	0.3
DERIVATIVES			
EUR million	3/16	3/15	12/15
CURRENCY FORWARD CONTRACTS AND CURRENCY SWAPS			
Fair value, EUR million	-1.0	0.2	-0.0
Nominal value, EUR million	52.4	58.1	49.1
CURRENCY OPTIONS			
CURRENCY OPTIONS Fair value, EUR million	-0.1	-0.0	-0.0
Nominal value, EUR million	46.5	35.4	39.2
Normal value, LON million	40.5	00.4	33.2
INTEREST RATE SWAPS			
Fair value, EUR million		-0.1	-0.0
Nominal value, EUR million		14.3	11.6
ELECTRICITY DERIVATIVES			
Fair value, EUR million		-0.3	



## FAIR VALUE MEASUREMENT AND HIERARCHY OF FINANCIAL INSTRUMENTS

EUR million	Level 1	Level 2	Level 3	Total
Derivatives				
Currency derivatives		0.3		0.3
Available-for-sale financial assets				
Shares and investments	5.9		0.3	6.2
Assets total	5.9	0.3	0.3	6.5
Derivatives				
Currency derivatives		-1.2		-1.2
Liabilities total		-1.2		-1.2

The level 1 financial instrument fair value is based on quotations available in active markets. The level 2 financial instrument fair value is based on data feeds available in the markets. The fair value of level 3 derivatives 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	Q1/16	Q1/15	2015
Management's employment benefits	4.8	4.7	6.6



# Operating segment performance

## **NET SALES BY BUSINESS DIVISION**

EUR million	Q1/16	Q1/15	Change %	2015
Pharmaceuticals	249.3	244.5	+2.0%	960.9
Proprietary Products	88.0	89.3	-1.4%	322.5
Specialty Products	122.8	108.6	+13.1%	471.2
Animal Health	18.2	21.6	-15.6%	77.0
Fermion	10.6	14.7	-28.4%	52.7
Contract manufacturing and other	9.7	10.3	-6.1%	37.5
Diagnostics	13.5	16.2	-16.7%	57.8
Group items	-0.8	-0.8	-2.6%	-3.1
Group total	262.0	259.9	+0.8%	1,015.6

## **OPERATING PROFIT BY BUSINESS AREA**

EUR million	Q1/16	Q1/15	Change %	2015
Pharmaceuticals	80.1	81.4	-1.6%	269.0
Diagnostics	2.6	4.0	-34.2%	8.5
Group items	-2.4	-2.2	+6.5%	-10.9
Group total	80.3	83.1	-3.3%	266.6

## **NET SALES BY ANNUAL QUARTERS**

	2016		201	5			2014	
EUR million	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
Pharmaceuticals	249.3	247.3	227.1	242.0	244.5	241.5	226.2	264.8
Diagnostics	13.5	15.2	12.5	13.9	16.2	14.5	12.8	12.7
Group items	-0.8	-0.9	-0.5	-0.9	-0.8	-0.8	-0.6	-0.9
Group total	262.0	261.6	239.1	255.0	259.9	255.3	238.3	276.7

## **OPERATING PROFIT BY ANNUAL QUARTERS**

	2016		2015				2014	
EUR million	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
Pharmaceuticals	80.1	52.1	59.7	75.8	81.4	56.9	63.8	88.3
Diagnostics	2.6	1.7	1.1	1.6	4.0	1.5	1.7	0.6
Group items	-2.4	-2.9	-2.3	-3.5	-2.2	-3.1	-1.8	-2.9
Group total	80.3	50.9	58.6	74.0	83.1	55.3	63.8	86.0

## GEOGRAPHICAL BREAKDOWN OF NET SALES BY ANNUAL QUARTERS

	2016		201	5			2014	
EUR million	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
Finland	80.1	85.1	78.1	76.9	78.4	79.6	73.5	72.0
Scandinavia	44.7	47.0	39.1	40.9	36.9	35.6	31.7	34.6
Other Europe	83.2	81.9	70.7	77.5	86.6	89.1	81.3	104.9
North America	18.2	16.1	17.9	20.6	21.6	24.5	15.2	34.0
Other markets	35.8	31.5	33.2	39.1	36.4	26.5	36.6	31.2
Group total	262.0	261.6	239.1	255.0	259.9	255.3	238.3	276.7



## **Business reviews**

## **KEY FIGURES FOR PHARMACEUTICALS BUSINESS**

EUR million	Q1/16	Q1/15	Change %	2015
Net sales	249.3	244.5	+2.0%	960.9
Operating profit	80.1	81.4	-1.6%	269.0
% of net sales	32.1%	33.3%		28.0%
R&D expenses	23.4	23.4	-0.2%	101.0
% of net sales	9.4%	9.6%		10.5%
Capital expenditure	8.8	7.1	+24.2%	40.6
% of net sales	3.5%	2.9%		4.2%
Sales revenue from proprietary products	92.9	96.3	-3.5%	354.7
Assets	738.1	682.2		740.8
Liabilities	185.6	174.3		211.0
Personnel at the end of the period	3,090	3,103		3,078

## TOP TEN BEST-SELLING PHARMACEUTICAL PRODUCTS

EUR million	Q1/16	Q1/15	Change %	2015
Stalevo <sup>®</sup> , Comtess <sup>®</sup> and Comtan <sup>®</sup> (Parkinson's disease)	32.6	42.4	-23.1%	137.5
Easyhaler® product family (asthma, COPD)	15.6	12.5	+25.3%	51.3
Dexdor® (intensive care sedative)	14.2	11.1	+27.7%	44.5
Simdax® (acute decompensated heart failure)	13.7	12.7	+7.9%	51.1
Remsima® (rheumatoid arthritis, inflammatory bowel diseases)	11.7	2.8	+318.7%	28.1
Dexdomitor®, Domitor®, Domosedan® and Antisedan® (animal sedatives)	6.8	6.9	-0.9%	27.3
Marevan <sup>®</sup> (anticoagulant)	5.2	5.0	+3.2%	19.2
Burana <sup>®</sup> (inflammatory pain)	5.2	5.6	-7.3%	22.7
Trexan® (rheumatoid arthritis, cancer)	3.9	3.5	+10.5%	12.3
Precedex® (intensive care sedative)	3.8	4.6	-16.7%	17.8
Total	112.7	107.1	+5.2%	411.7
Share of pharmaceutical net sales	45%	44%		43%

## **KEY FIGURES FOR DIAGNOSTICS BUSINESS**

EUR million	Q1/16	Q1/15	Change %	2015
Net sales	13.5	16.2	-16.7%	57.8
Operating profit	2.6	4.0	-34.2%	8.5
% of net sales	19.4%	24.5%		14.7%
R&D expenses	1.6	1.8	-11.0%	7.3
% of net sales	12.1%	11.3%		12.6%
Capital expenditure	0.2	0.9	-76.6%	3.7
% of net sales	1.5%	5.4%		6.4%
Assets	50.8	48.0		48.3
Liabilities	8.5	12.6		16.2
Personnel at the end of the period	296	290		296



## KEY CLINICAL PHARMACEUTICAL DEVELOPMENT PROJECTS

Project	Indication	PHASE			Registration
		I	II	III	
Bufomix Easyhaler® (budesonide-formoterol)	Asthma, COPD	I	II	III	Registration*
Easyhaler® salmeterol-fluticasone 2)	Asthma, COPD	I	II	III*	
ODM-201 (androgen receptor inhibitor) 3)	Prostate cancer	I	II	III*	
Levosimendan 4)	Low Cardiac Output Syndrome	I	II	III*	
ORM-12741 (alpha-2c adrenoceptor antagonist) 5)	Alzheimer's disease	I	lla*		
Dexmedetomidine (intranasal) 6)	Treatment of pain	I	IIb		
ODM-109 (oral levosimendan)	ALS	I	II*		
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	I	<u>II</u> *		
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumours	I	<u>II</u> *		
ODM-204 (CYP17 enzyme and androgen receptor inhibitor)	Prostate cancer	l*			
ODM-108 (negative allosteric modulator of TRPA1 ion channel)	Neuropathic pain	l*			
Aim is to obtain marketing authorisation for product in at least some European countries not included in decentralised marketing authorisation application process.			= Phase ongoing		ing
Bioequivalence study <sup>3)</sup> In collaboration with Bayer		<u>III</u>	= Stat	us chan	ged
Partner: Tenax Therapeutics, Inc. <sup>5</sup> In collaboration w	ith Janssen Pharmaceuticals				
Partner: Recro Pharma, Inc.					



## Information on Orion's shares

## **BASIC SHARE INFORMATION 31 MARCH 2016**

	A shares	B shares	Total
Trading code on Nasdaq Helsinki	ORNAV	ORNBV	
Listing day	1 July 2006	1 July 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	25.4	66.8	92.2
Counter book value per share, EUR	0.65	0.65	
Total number of shares	38,906,154	102,351,674	141,257,828
% of total share stock	28%	72%	100%
Number of treasury shares		283,366	283,366
Total number of shares excluding treasury shares	38,906,154	102,068,308	140,974,462
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	778,123,080	102,068,308	880,191,388
% of total votes	88%	12%	100%
Total number of shareholders	16,938	38,113	49,370

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 MARCH 2016

	A shares	B shares	Total
Shares traded	375,944	12,548,801	12,924,745
% of the total number of shares	1.0%	12.3%	9.1%
Trading volume, EUR million	11.2	373.1	384.3
Closing quotation on 31 December 2015, EUR	31.83	31.97	
Lowest quotation, EUR (A and B 9 February 2016)	27.70	27.79	
Average quotation, EUR	29.68	29.74	
Highest quotation, EUR (A 29 February and B 5 January 2016)	32.84	31.88	
Closing quotation on 31 March 2016, EUR	28.88	29.05	
Market capitalisation on 31 March 2016, EUR million	1,123.6	2,965.1	4,088.7

## PERFORMANCE PER SHARE

	Q1/16	Q1/15	Change %	2015
Basic earnings per share, EUR	0.45	0.47	-3.8%	1.48
Diluted earnings per share, EUR	0.45	0.47	-3.8%	1.48
Cash flow per share before financial items, EUR	0.29	0.38	-23.2%	1.51
Equity per share, EUR	3.37	2.85		4.22
Average number of shares excluding treasury shares, 1,000 shares	140,878	140,734		140,806



## **Appendices**

## Reporting

Orion Corporation is the parent company of the Orion Group. The Group consists of two business areas, or operating segments, and five 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 and self-care products)
  - Animal Health (veterinary products for pets and production animals)
  - Fermion (active pharmaceutical ingredients for Orion and other companies)
- Diagnostics business
  - Orion Diagnostica (diagnostic test systems for point-of-care in healthcare and hygiene tests for industry).

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, it is part of the Group's Supply Chain organisation.

## Accounting policies

This Interim Report has been prepared in accordance with the IAS 34 Interim Financial Reporting standard. The same accounting policies as for the Financial Statements for 2015 have been applied in preparing the Interim Report, except for amendments to existing IFRS and IAS standards endorsed by the EU that have been adopted as of 1 January 2016. The amendments to standards had no effect on the Consolidated Financial Statements.

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

## Other matters

The data in this financial review are not audited.

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	Profit before taxes + Interest and other finance expenses	
(ROCE), %	Total assets - Non-interest-bearing liabilities (average during the period)	
Return on equity (ROE), %	Profit for the period	
•	Total equity (average during the period)	
Equity ratio, %	Equity	
1. 9,	Total assets - Advances received	
Gearing, %	Interest-bearing liabilities - Cash and cash equivalents - Money market investments	
	Equity	
Earnings per share, EUR =	Profit available for the owners of the parent company	_
	Average number of shares during the period, excluding treasury shares	
Cash flow per share before financial items, EUR =	Cash flow from operating activities + Cash flow from investing activities	_
	Average number of shares during the period, excluding treasury shares	
Equity per share, EUR =	Equity of the owners of the parent company	
	Number of shares at the end of the period, excluding treasury share	
Dividend per share, EUR _	Dividend to be distributed for the period	
•	Number of shares at the end of the period, excluding treasury shares	
Payout ratio, % =	Dividend per share	
	Earnings per share	
Effective dividend yield, % =	Dividend per share	
	Closing quotation of the period	
Price/earnings ratio (P/E) =	Closing quotation of the period	_,
	Earnings per share	
Average share price, EUR =	Total EUR value of shares traded	
	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	

Publisher:
Orion Corporation
http://www.orion.fi/
http://www.twitter.com/OrionCorpIR

Orion is a globally operating Finnish company developing pharmaceuticals and diagnostic tests – a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals, active pharmaceutical ingredients and diagnostic tests. 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 for which Orion develops inhaled Easyhaler® pulmonary drugs.

Orion's net sales in 2015 amounted to EUR 1,016 million and the Company had about 3,400 employees. Orion's A and B shares are listed on Nasdaq Helsinki.