Orion Group Interim Report January-September 2016 n







ORION CORPORATION / INTERIM REPORT / JANUARY-SEPTEMBER 2016 / 25 October 2016 at 12:00 noon EEST

## Orion Group Interim Report January–September 2016

Orion's net sales in January–September 2016 totalled EUR 794 million (EUR 754 million in January–September 2015).

- Operating profit was EUR 256 (216) million.
- Operating profit includes about EUR 22 million of capital gains received in the third quarter.
- Profit before taxes was EUR 253 (213) million.
- Equity ratio was 60% (53%).
- ROCE before taxes was 45% (40%).
- ROE after taxes was 45% (44%).
- Basic earnings per share were EUR 1.43 (1.20).
- Cash flow per share before financial items was EUR 1.23 (1.11).
- The outlook estimate for 2016 remains unchanged. Orion estimates that in 2016 net sales will be slightly higher than in 2015. Operating profit excluding possible capital gains is estimated to exceed EUR 270 million.

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

	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Net sales, EUR million	258.6	239.1	+8.2%	793.6	754.0	+5.3%	1,015.6
Operating profit, EUR million	92.0	58.6	+57.1%	255.9	215.6	+18.7%	266.6
% of net sales	35.6%	24.5%		32.2%	28.6%		26.2%
Profit before taxes, EUR million	91.0	57.0	+59.5%	253.2	212.6	+19.1%	262.3
% of net sales	35.2%	23.9%		31.9%	28.2%		25.8%
Income tax expense, EUR million	18.5	11.7	+58.1%	51.8	43.8	+18.1%	54.2
R&D expenses, EUR million	26.9	23.3	+15.6%	80.3	76.5	+5.0%	108.1
% of net sales	10.4%	9.7%		10.1%	10.1%		10.6%
Capital expenditure, EUR million	11.8	11.0	+7.1%	34.0	30.3	+12.4%	44.5
% of net sales	4.5%	4.6%		4.3%	4.0%		4.4%
Assets total, EUR million				998.6	974.0	+2.5%	1,047.4
Equity ratio, %				59.5%	52.5%		57.4%
Gearing, %				-4.2%	-0.1%		-9.6%
Interest-bearing liabilities, EUR million				173.3	219.7	-21.1%	187.8
Non-interest-bearing liabilities, EUR million				236.4	249.3	-5.2%	264.6
Cash and cash equivalents and money market investments, EUR million				198.2	220.2	-10.0%	245.2
ROCE (before taxes), %				45.2%	40.1%		35.7%
ROE (after taxes), %				45.4%	44.1%		37.5%
Basic earnings per share, EUR	0.52	0.32	+60.3%	1.43	1.20	+19.4%	1.48
Diluted earnings per share, EUR	0.52	0.32	+60.3%	1.43	1.20	+19.4%	1.48
Cash flow per share before financial items, EUR	0.67	0.44	+51.6%	1.23	1.11	+10.7%	1.51
Equity per share, EUR				4.19	3.59	+16.9%	4.22
Personnel at the end of the period				3,445	3,392	+1.6%	3,401
Average personnel during the period				3,442	3,442		3,431
Personnel expenses, EUR million				162.3	163.3	-0.6%	220.6



### President and CEO Timo Lappalainen:

# "Business developed well – capital gains enhanced strong operating profit growth"

"In January–September 2016 our net sales and operating profit were higher than in January–September 2015. The clear growth in operating profit is explained by the growth in net sales and about EUR 22 million of total capital gains received in the third quarter.

"As regards our key proprietary products, the Dexdor sedative used in intensive care and Easyhaler product family for treatment of asthma and chronic obstructive pulmonary disease maintained their strong growth. Sales of Simdax for treatment of acute decompensated heart failure also continued to grow well. After the review period, through the decentralised procedure the budesonide-formoterol Easyhaler combined formulation received marketing authorisation for Germany, where the national approval process has commenced. Sales of Orion's branded Parkinson's drugs Stalevo, Comtess and Comtan continued to decline, but more slowly than expected.

"Net sales of the Specialty Products business division rose in all the key market areas: Finland, Scandinavia and Eastern Europe. As regards the business division's products, sales of the biosimilar Remsima remained strong relative to the comparative period, but the growth rate has clearly slowed since the start of the year due to the timings of tendering competitions and periods covered by delivery agreements.

"There have been changes in our clinical pharmaceutical development portfolio since the summer. We are commencing a new Phase I clinical trial with a BET protein inhibitor (ODM-207) which inhibit transcription of key oncogenes in many cancers. We have decided to discontinue trials with a CYP17 enzyme and androgen receptor inhibitor (ODM-204) for treatment of castration-resistant prostate cancer based on the pharmacokinetic findings of the Phase I clinical trial. Other ongoing clinical pharmaceutical development projects in various phases have progressed as planned.

"Our outlook estimate for 2016 remains unchanged. We estimate that in 2016 net sales will be slightly higher than in 2015. We estimate that operating profit excluding possible capital gains will exceed EUR 270 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 18 July Orion sold its shares in Pharmaservice Oy to Oriola-KD Corporation.

On 2 September Orion and Menarini commenced collaboration in marketing the budesonide-formoterol Easyhaler<sup>®</sup> combined formulation.

On 5 September Orion sold its shares in Ekokem Corporation to Fortum Corporation.

## Events after the period

On 12 October the budesonide-formoterol Easyhaler<sup>®</sup> combined formulation received marketing authorisation for Germany through the decentralised procedure (DCP).



### News conference and teleconference

A news conference and teleconference on the published results will be held today, Tuesday 25 October 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 <u>http://www.orion.fi/en/investors</u>. After the presentation, questions can be asked by telephone in Finnish and English.

The teleconference code is 3897800 and the telephone numbers to participate in the teleconference are:

Finland:	+358 (0)9 7479 0404
Sweden:	+46 (0)8 5065 3942
United Kingdom:	+44 (0)20 7026 5967
United States:	+1 719 325 2202

### 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 Tuesday 25 October 2016.

### Financial report material

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

## Dates in Orion Calendar 2017

Financial Statement Release for 2016	Wednesday 8 February 2017
Annual General Meeting 2017	Planned to be held on Wednesday 22 March 2017
Interim Report January–March 2017	Wednesday 26 April 2017
Half-Year Financial Report January–June 2017	Wednesday 19 July 2017
Interim Report January-September 2017	Thursday 26 October 2017

The Financial Statements and Report by the Board of Directors for 2016 will be published on the Company's website at the latest in week 9/2017.

### For additional information about the financial review:

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



## Financial review January–September 2016

### Net sales

*The Orion Group's net sales* in January–September 2016 were up by 5% at EUR 794 million (EUR 754 million in January–September 2015). The net effect of currency exchange rates was minus EUR 9 million.

*The Pharmaceuticals business's* net sales were up by 6% at EUR 754 (714) 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 7% at EUR 626 (584) 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 9% at EUR 102 (112) million, which was 14% (16%) of the Pharmaceuticals business's net sales.

The Diagnostics business's net sales were down by 3% at EUR 41 (43) million.

### **Operating profit**

*The Orion Group's* operating profit was up by 19% at EUR 256 (216) million. Milestone payments accounted for EUR 11 (5) million of the operating profit. Operating profit growth was enhanced by about EUR 22 million of capital gains.

*The Pharmaceuticals business's* operating profit was up by 18% at EUR 257 (217) million. Milestone payments accounted for EUR 11 (5) million of the operating profit.

The Diagnostics business's operating profit was down by 2% at EUR 6.6 (6.8) million.

#### **Operating expenses**

The Group's sales and marketing expenses were EUR 137 (138) million.

**R&D expenses** were EUR 80 (77) million and accounted for 10% (10%) of the Group's net sales. Pharmaceutical R&D expenses amounted to EUR 75 (71) million. Research projects are reported in more detail under Pharmaceuticals in the Business Reviews.

Administrative expenses were EUR 34 (34) million.

*Other operating income and expenses* were EUR 22 (1) million. They comprise mainly about EUR 22 million of capital gains.

### Group's profit

The Group's profit before taxes was up by 19% at EUR 253 (213) million. Basic earnings per share were EUR 1.43 (1.20) and diluted earnings per share were EUR 1.43 (1.20). Equity per share was EUR 4.19 (3.59). The return on capital employed before taxes (ROCE) was 45% (40%) and the return on equity after taxes (ROE) 45% (44%).

### **Financial position**

The Group's gearing was -4% (0%) and the equity ratio 60% (53%).

The Group's *total liabilities* at 30 September 2016 were EUR 410 (469) million. At the end of the period, interest-bearing liabilities amounted to EUR 173 (220) million, including EUR 150 (200) million of long-term loans.

The Group had EUR 198 (220) 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 181 (188) million. The decrease in cash flow was primarily due to the increase in working capital, which in turn is mostly explained by the clear decrease in non-interest-bearing liabilities compared with the end of the 2015.

*Cash flow from investing activities* was EUR -8 (-31) million, the change relative to the comparative period being explained mostly by the sales of shares.

**Cash flow from financing activities** was EUR -216 (-199) million. The change is mainly due to purchasing of the Company's shares in June (EUR -17 million). The purchase of own shares was based on the decision by the Board of Directors which was announced in a stock exchange release on 27 April 2016.

### **Capital expenditure**

The Group's capital expenditure totalled EUR 34 (30) million. This comprised EUR 29 (26) million on property, plant and equipment and EUR 4 (3) million on intangible assets.

### Outlook for 2016 (updated on 15 June 2016)

*Net sales* are estimated to be slightly higher than in 2015 (net sales were EUR 1,016 million in 2015).

*Operating profit* excluding possible capital gains is estimated to exceed EUR 270 million (operating profit was EUR 267 million in 2015).

### Basis for outlook

The outlook estimate does not include capital gains, such as capital gains on the sales of shares in Ekokem Corporation and Pharmaservice Oy. No other significant capital gains are expected during the remainder of 2016.

A financial objective of Orion is to increase net sales. In 2016 steadily growing products such as Dexdor<sup>®</sup> and the Easyhaler<sup>®</sup> product family are expected to be able to compensate for 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 significant proportion of Orion's total sales, and price competition has continued 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. In the first half of 2016 sales of Remsima<sup>®</sup> generated a significant portion of the growth in the net sales of the Speciality Products business division. In the second half of the year the growth is expected to slow due to the timing of tendering competitions for Remsima.



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 in the current and coming years. 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 similar to 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 and British pound. Possible Brexit is estimated not to have material impact on Orion in the near term. 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 30 September 2016 Orion had a total of 141,257,828 (141,257,828) shares, of which 38,581,154 (39,191,154) were A shares and 102,676,674 (102,066,674) B shares. The Group's share capital was EUR 92,238,541.46 (92,238,541.46). At the end of September 2016 Orion held 783,366 (427,716) B shares as treasury shares. On 30 September 2016 the aggregate number of votes conferred by the A and B shares was 873,516,388 (885,462,038) excluding treasury shares.

At the end of September 2016, Orion had 48,824 (49,219) 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. In January–September 2016 325,000 shares were converted.



### 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 30 September 2016 the market capitalisation of the Company's shares, excluding treasury shares, was EUR 4,918 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.

On 27 April 2016 Orion's Board of Directors decided to acquire shares in the Company as authorised by the Annual General Meeting. In the period 3–15 June 2016 the Company acquired 500,000 B shares in the Company in accordance with the decision. The shares were acquired for use as part of the Orion Group's incentive plans. Following the acquisitions, the Board of Directors does not have any outstanding authorisation to decide to acquire shares in the Company.

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 Plan**

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 September 2016, Orion had a total of 48,824 (49,219) registered shareholders, of whom 96% (96%) were private individuals holding 40% (41%) of the entire share stock and 61% (62%) of the total votes. There were altogether 59 (59) million nominee-registered shares, which was 42% (42%) of all shares, and they conferred entitlement to 9% (9%) of the total votes.

At the end of September 2016 Orion held 783,366 (427,716) B shares as treasury shares, which is 0.55% (0.3%) of the Company's total share stock and 0.09% (0.05%) of the total votes.



### Personnel

The average number of employees in the Orion Group in January–September 2016 was 3,442 (3,442). At the end of September 2016 the Group had a total of 3,445 (3,392) employees, of whom 2,784 (2,722) worked in Finland and 661 (670) outside Finland.

Salaries and other personnel expenses in January–September 2016 totalled EUR 162 (163) 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–September 2016 was up by 4% on the previous year at EUR 1,680 (1,620) 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–September 2016 amounted to EUR 217 (195) million, up by 12% 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		MAT6/2016	MAT6/2015	Change %
United States	USD	876	850	+3%
Europe TOP 5	EUR	919	956	-4%
Japan	EUR	608	543	+12%

Source: IMS Health pharmaceutical sales statistics MAT6/2016 (7/2015-6/2016)

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		MAT6/2016	MAT6/2015	Change %
United States	USD	71	96	-26%
Europe TOP 5	EUR	118	135	-12%
Japan	EUR	72	60	+21%

Source: IMS Health pharmaceutical sales statistics MAT6/2016 (7/2015-6/2016)

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

EUR or USD million		MAT6/2016	MAT6/2015	Change %
United States *	USD	9	14	-34%
Europe TOP 5	EUR	80	108	-25%
Japan	EUR	72	60	+21%

Source: IMS Health pharmaceutical sales statistics MAT6/2016 (7/2015–6/2016)

\*) Sales of generic entacapone products by Sandoz, which is part of the Novartis Group, were previously included in US sales but are no longer included.

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 1% in the United States, on average 9% 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 June 2016 were up by 4% at EUR 530 (511) million. According to IMS Health pharmaceutical sales statistics, sales of Orion's Dexdor<sup>®</sup> intensive care sedative (dexmedetomidine) were up by 26% at EUR 41 (32) million in Europe.



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

In January–September 2016 the Pharmaceuticals business's net sales were EUR 754 (714) million and its operating profit was EUR 257 (217) million. Milestone payments accounted for EUR 11 (5) million of the net sales and operating profit, and comprised mainly a milestone payment of EUR 5 million from Bayer related to ODM-201 project technology transfer and milestone payments related to marketing rights to the Easyhaler product family. The operating profit of the Pharmaceuticals business was 34% (30%) of the segment's net sales.

Net sales of Orion's top ten pharmaceuticals in January–September 2016 were up by 9% at EUR 337 (310) million. They accounted for 45% (43%) 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 7% at EUR 626 (584) 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<sup>®</sup> pulmonary drugs.

Net sales of Proprietary Products in January–September 2016 were up by 10% at EUR 269 (244) million. Growth was enhanced by higher milestone payments than in the previous year, but product sales were also higher than in the comparative period. Sales of Parkinson's drugs continued to decline, but this decline was 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–September 2016 were down by 9% at EUR 102 (112) 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 is extending. 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	9M 2016	9M 2015	Change %
Stalevo deliveries to Novartis	54	51	+5%
Comtan deliveries to Novartis	22	25	-12%
Orion's Stalevo sales	23	31	-25%
Orion's Comtess sales	3	5	-36%

Net sales of Simdax<sup>®</sup>, a drug for treatment of acute decompensated heart failure, in January–September 2016 were up by 9% at EUR 41 (37) million. Simdax is sold in altogether over fifty countries worldwide.

Total net sales of the Easyhaler<sup>®</sup> product family for treatment of asthma and chronic obstructive pulmonary disease were up by 28% in January–September 2016 at EUR 47 (37) million. The increase was mainly due to sales of the Bufomix Easyhaler<sup>®</sup> combined formulation (budesonide-formoterol). Sales of Bufomix Easyhaler were up by 78% at EUR 20 (11) million in January–September 2016. After the review period, through the decentralised procedure the budesonide-formoterol Easyhaler combined formulation received marketing authorisation for Germany, where the national approval process has commenced. Processing of marketing authorisation applications for the combined formulation is ongoing in the United Kingdom and France. Orion is expanding Easyhaler production at the Espoo pharmaceuticals production plant. Orion has entered into a collaboration agreement with Menarini for the co-marketing of the budesonide-formoterol Easyhaler<sup>®</sup> combined formulation in Germany, Italy, Spain and Portugal. In addition, the parties have agreed an exclusive licence and distribution arrangement for Menarini in France and Turkey.

Net sales of Orion's Dexdor<sup>®</sup> intensive care sedative (dexmedetomidine) in January–September 2016 were up by 26% at EUR 41 (32) 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–September 2016 were up by 10% at EUR 372 (339) million. Sales of generic entacapone products were down by 44% at EUR 10 (17) million. Sales of products from the rest of the portfolio were up by 13%. About one-third 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–September 2016 were up by 8% at EUR 218 (201) million. Orion managed to increase its sales, especially in prescription drugs. Sales were up by 19% at EUR 60 (51) million in Scandinavia and up by 10% at EUR 41 (38) million in Eastern Europe and Russia.

Net sales of Remsima<sup>®</sup> for treatment of rheumatoid arthritis among other things were EUR 31 (17) million in January–September 2016. In the first half of 2016 the product grew especially strongly because Orion won many tendering competitions in 2015, such as the national tendering competition in Denmark, which were not yet apparent in sales in the first half of 2015. The reason for the clear slowdown in growth apparent in the third quarter is that Orion did not win the national tendering competition in Norway for the twelve-month period beginning in March 2016, and a significant portion of net sales came from Denmark, which was already contributing to sales in the comparative period. 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–September 2016 were down by 10% at EUR 54 (59) million. A large part of the decrease in net sales is explained by the milestone payment recorded on the sale of product rights included net sales in the comparative period. Sales of the animal sedative product family at EUR 16 (21) million accounted for 29% (35%) of the division's net sales. The product family comprises Orion's animal sedatives Dexdomitor<sup>®</sup> (dexmedetomidine), Domitor<sup>®</sup> (medetomidine) and Domosedan<sup>®</sup> (detomidine), and antagonist Antisedan<sup>®</sup> (atipamezole), which reverses the effects of the sedatives.

Sales of Sileo<sup>®</sup> launched in 2015 and indicated for alleviation of fear associated with noise in dogs have started well, especially thanks to the deliveries made to the partner in the United States. Net sales of Sileo in January–September 2016 were EUR 4 million.

#### 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–September 2016 excluding pharmaceutical ingredients supplied for Orion's own use were down by 24% at EUR 33 (43) million and accounted for over one-half of Fermion's entire net sales.

#### **Research and development projects**

The Group's **R&D expenses** in January–September 2016 were EUR 80 (77) million, of which the Pharmaceuticals business accounted for EUR 75 (71) 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 antagonist* (ODM-201). The companies have an ongoing joint Phase III



clinical trial (ARAMIS) for evaluation of the efficacy and safety of ODM-201 in patients with non-metastatic castration-resistant prostate cancer (nmCRPC).

Orion and Bayer have agreed to expand the ODM-201 development programme and during 2016 commence a new Phase III trial (ARASENS) that will evaluate the efficacy and safety of the drug candidate in combination with standard androgen deprivation therapy (ADT) and the chemotherapy drug docetaxel in patients having newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) who are starting hormone therapy.

Orion has an ongoing project to broaden the range of the **Easyhaler**<sup>®</sup> **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. Processing of the marketing authorisation applications submitted is ongoing in France and the United Kingdom based on the results received. 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 has commenced 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 an ongoing Phase II clinical trial with a new *targeted FGFR+VEGFR inhibitor* (ODM-203) for treatment of cancers. The trial will 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 decided to discontinue trials with a **CYP17** enzyme and androgen receptor inhibitor (ODM-204) for treatment of castration-resistant prostate cancer (CRPC) based on the pharmacokinetic findings of the Phase I clinical trial.

Orion is commencing a Phase I clinical trial with the *BET protein inhibitor* (ODM-207) which inhibit 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 the tolerability of ODM-207 and provisionally will assess antitumour activity in cancer patients.

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, Tenax was investigating the possibility of gaining an additional indication of septic shock for levosimendan, but the clinical trial results reported in October did not support further development for this indication.

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–September 2016 were down by 3% at EUR 41 (43) million.

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.

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 2% at EUR 6.6 (6.8) million. The operating profit accounted for 16% (16%) of the segment's net sales.

Espoo, 25 October 2016

Board of Directors of Orion Corporation

**Orion Corporation** 

Timo Lappalainen *President and CEO*  Jari Karlson CFO



## <u>Tables</u>

### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

EUR million	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Net sales	258.6	239.1	+8.2%	793.6	754.0	+5.3%	1,015.6
Cost of goods sold	-106.8	-105.3	+1.4%	-308.5	-291.2	+5.9%	-405.8
Gross profit	151.7	133.7	+13.4%	485.1	462.8	+4.8%	609.8
Other operating income and expenses	22.4	1.1		22.3	0.8		1.5
Sales and marketing expenses	-44.6	-42.8	+4.3%	-137.4	-137.6	-0.2%	-190.4
R&D expenses	-26.9	-23.3	+15.6%	-80.3	-76.5	+5.0%	-108.1
Administrative expenses	-10.5	-10.2	+3.8%	-33.9	-33.8	+0.5%	-46.2
Operating profit	92.0	58.6	+57.1%	255.9	215.6	+18.7%	266.6
Finance income	0.2	0.0	+707.0%	0.6	0.6	-1.7%	0.8
Finance expenses	-1.2	-1.6	-21.2%	-3.7	-4.1	-10.3%	-5.5
Share of associated companies' results				0.4	0.4	-5.2%	0.4
Profit before taxes	91.0	57.0	+59.5%	253.2	212.6	+19.1%	262.3
Income tax expense	-18.5	-11.7	+58.1%	-51.8	-43.8	+18.1%	-54.2
Profit for the period	72.5	45.3	+59.9%	201.5	168.8	+19.4%	208.2

### OTHER COMPREHENSIVE INCOME INCLUDING TAX EFFECTS

Change in value of cash flow hedges		0.0			0.1		0.1
Change in value of available-for-sale financial assets	-5.7	-0.2		-5.2	0.8		1.1
Translation differences	-1.4	-1.6		-5.2	1.6		1.8
Items that may be reclassified subsequently to profit and loss	-7.1	-1.7		-10.3	2.5		3.0
Items due to remeasurement of defined benefit plans	-0.0	0.0		-0.0	-0.3		49.1
Items that will not be reclassified to profit and loss	-0.0	0.0		-0.0	-0.3		49.1
Other comprehensive income net of tax	-7.1	-1.7		-10.4	2.2		52.1
Comprehensive income for the period including tax effects	65.4	43.7	+49.8%	191.1	171.0	+11.8%	260.2
PROFIT ATTRIBUTABLE TO: Owners of the parent company	72.5	45.3	+59.9%	201.5	168.8	+19.4%	208.2
Non-controlling interests	0.0	0.0		0.0	0.0		0.0
COMPREHENSIVE INCOME ATTRIBUTABLE TO	:						
Owners of the parent company	65.4	43.7	+49.8%	191.1	171.0	+11.8%	260.2
Non-controlling interests	0.0	0.0		0.0	0.0		0.0
Basic earnings per share, EUR <sup>1)</sup>	0.52	0.32	+60.3%	1.43	1.20	+19.4%	1.48
Diluted earnings per share, EUR <sup>1)</sup>	0.52	0.32	+60.3%	1.43	1.20	+19.4%	1.48
Depreciation, amortisation and impairment	10.2	9.9	+2.7%	30.4	31.0	-2.1%	41.8

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



### CONSOLIDATED STATEMENT OF FINANCIAL POSITION

### ASSETS

EUR million	9/16	9/15	Change %	12/15
Property, plant and equipment	282.0	272.3	+3.6%	276.4
Goodwill	13.5	13.5		13.5
Intangible rights	38.5	42.9	-10.2%	41.7
Other intangible assets	2.5	2.5	-0.9%	2.5
Investments in associates	0.1	2.6	-97.3%	2.6
Available-for-sale financial assets	0.4	6.6	-94.7%	6.9
Pension asset	18.6			24.4
Deferred tax assets	1.1	8.3	-86.5%	1.1
Other non-current assets	3.9	2.9	+32.2%	4.1
Non-current assets total	360.5	351.5	+2.6%	373.3
Inventories	218.4	189.5	+15.3%	205.7
Trade receivables	185.5	170.5	+8.8%	192.1
Other receivables	35.9	42.3	-15.2%	31.1
Money market investments	20.0			
Cash and cash equivalents	178.2	220.2	-19.1%	245.2
Current assets total	638.0	622.5	+2.5%	674.1
Assets total	998.6	974.0	+2.5%	1,047.4

### EQUITY AND LIABILITIES

EUR million	9/16	9/15	Change %	12/15
Share capital	92.2	92.2		92.2
Expendable fund	0.5	0.5		0.5
Other reserves	2.1	6.7	-69.0%	6.9
Retained earnings	494.1	405.7	+21.8%	495.3
Equity attributable to owners of the parent company	588.9	505.1	+16.6%	594.9
Non-controlling interests	0.0	0.0	+7.0%	0.0
Equity total	588.9	505.1	+16.6%	594.9
Deferred tax liabilities	34.4	31.8	+8.2%	37.8
Pension liability	3.0	38.6	-92.1%	3.1
Provisions	0.3	0.3	-12.6%	0.3
Interest-bearing non-current liabilities	150.1	200.2	-25.0%	177.9
Other non-current liabilities	0.0	0.1	-55.9%	0.0
Non-current liabilities total	187.8	271.0	-30.7%	219.2
Trade payables	83.3	63.9	+30.3%	99.1
Current tax liabilities	15.4	5.7	+169.1%	1.2
Other current liabilities	99.9	108.7	-8.0%	122.8
Provisions	0.0	0.2	-87.9%	0.3
Interest-bearing current liabilities	23.2	19.5	+19.2%	9.9
Current liabilities total	221.9	198.0	+12.1%	233.3
Liabilities total	409.7	468.9	-12.6%	452.5
Equity and liabilities total	998.6	974.0	+2.5%	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

	Equity attributable to support of the parent company							
	Equity attributable to owners of the parent company							
EUR million	a.	b.	С.	d.	е.	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						168.8		168.8
Other comprehensive income:								
Change in value of cash flow hedges			0.1					0.1
Change in value of available-for-sale financial assets			0.8					0.8
Translation differences					1.6			1.6
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						2.6		2.6
Other adjustments			-0.1			-0.3	0.0	-0.3
Equity at 30 September 2015	92.2	0.5	6.7	-51.0	-1.8	458.5	0.0	505.1
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						201.5		201.5
Other comprehensive income:								
Change in value of available-for-sale financial assets			-5.2					-5.2
Translation differences					-5.2			-5.2
Items due to remeasurement of defined benefit plans				-0.0				-0.0
Transactions with owners								
Dividend and capital repayment						-183.3		-183.3
Treasury shares						-16.8		-16.8
Share-based incentive plan						3.0		3.0
Other adjustments			0.3			-0.4	0.0	-0.0
Equity at 30 September 2016	92.2	0.5	2.1	-1.7	-6.7	502.5	0.0	588.9



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### CONSOLIDATED STATEMENT OF CASH FLOWS

Money market investments at the end of the period

Cash and cash equivalents in the statement of cash flows

EUR million	9M 2016	9M 2015	2015
Operating profit	255.9	215.6	266.6
Adjustments	15.3	40.4	53.5
Change in working capital	-45.9	-31.9	-14.9
Interest paid	-9.7	-9.7	-10.9
Interest received	5.8	6.7	7.7
Dividends received	0.1	0.2	0.2
Income taxes paid	-40.7	-33.4	-47.2
Total net cash flow from operating activities	180.7	187.9	254.9
Investments in property, plant and equipment	-29.0	-28.5	-38.4
Investments in intangible assets	-4.9	-3.6	-4.8
Sales of property, plant and equipment, and available-for-sale investments, and divestments of associates	26.2	0.7	1.0
Total net cash flow from investing activities	-7.7	-31.4	-42.2
Current loans raised	1.2	1.4	1.4
Repayments of current loans	-1.1	-1.5	-2.7
Non-current loans raised		0.3	
Repayments of non-current loans	-15.9	-15.6	-46.2
Treasury shares	-16.8		
Dividends paid and other distribution of profits	-183.4	-183.2	-183.3
Total net cash flow from financing activities	-216.1	-198.6	-230.8
Net change in cash and cash equivalents	-43.0	-42.2	-18.1
Cash and cash equivalents at the beginning of the period	245.2	258.5	258.5
Foreign exchange differences	-4.0	3.8	4.8
Net change in cash and cash equivalents	-43.0	-42.2	-18.1
Cash and cash equivalents at the end of the period	198.2	220.2	245.2
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	178.2	220.2	245.2

20.0

198.2

220.2

245.2



EUR million	9/16	9/15	12/15
Carrying amount at the beginning of the period	276.4	269.1	269.1
Additions	29.3	26.5	38.7
Disposals	-0.9	-0.6	-1.1
Depreciation and impairments	-22.9	-22.6	-30.2
Carrying amount at the end of the period	282.0	272.3	276.4

### CHANGES IN INTANGIBLE ASSETS (EXCLUDING GOODWILL)

EUR million	9/16	9/15	12/15
Carrying amount at the beginning of the period	44.3	50.4	50.4
Additions	4.2	3.3	5.4
Amortisation and impairments	-7.5	-8.4	-11.5
Carrying amount at the end of the period	41.0	45.4	44.3

### COMMITMENTS AND CONTINGENCIES

EUR million	9/16	9/15	12/15
CONTINGENCIES FOR OWN LIABILITIES			
Guarantees	4.1	3.8	5.2
OTHER LIABILITIES			
Leasing liabilities (excluding finance lease contracts)	7.0	6.8	7.3
Other liabilities	0.3	0.3	0.3

### DERIVATIVES

EUR million	9/16	9/15	12/15
CURRENCY FORWARD CONTRACTS AND CURRENCY SWAPS			
Fair value, EUR million	-0.4	-0.3	-0.0
Nominal value, EUR million	35.2	48.7	49.1
CURRENCY OPTIONS			
Fair value, EUR million	-0.0	0.0	-0.0
Nominal value, EUR million	37.4	29.1	39.2
INTEREST RATE SWAPS			
Fair value, EUR million		-0.1	-0.0
Nominal value, EUR million		12.5	11.6
ELECTRICITY DERIVATIVES			
Fair value, EUR million		-0.1	
Nominal amount, GWh		6	



### FAIR VALUE MEASUREMENT AND HIERARCHY OF FINANCIAL INSTRUMENTS

EUR million	Level 1	Level 2	Level 3	Total
Derivatives				
Currency derivatives		0.1		0.1
Available-for-sale financial assets				
Shares and investments			0.4	0.4
Assets total		0.1	0.4	0.5
Derivatives				
Currency derivatives		-0.6		-0.6
Liabilities total		-0.6		-0.6

The level 1 fair value of financial instruments 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	9M 2016	9M 2015	2015
Management's employment benefits	6.3	6.1	6.6

## Operating segment performance

### NET SALES BY BUSINESS DIVISION

EUR million	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Pharmaceuticals	245.7	227.1	+8.2%	754.5	713.6	+5.7%	960.9
Proprietary Products	83.4	72.9	+14.4%	268.7	244.4	+10.0%	322.5
Specialty Products	125.9	115.2	+9.3%	371.9	338.7	+9.8%	471.2
Animal Health	15.4	15.6	-1.5%	53.6	59.3	-9.7%	77.0
Fermion	12.7	14.8	-14.1%	32.9	43.5	-24.2%	52.7
Contract manufacturing and other	8.3	8.6	-2.8%	27.3	27.7	-1.4%	37.5
Diagnostics	13.4	12.5	+7.6%	41.3	42.6	-3.1%	57.8
Group items	-0.6	-0.5	+9.7%	-2.1	-2.2	-4.6%	-3.1
Group total	258.6	239.1	+8.2%	793.6	754.0	+5.3%	1,015.6

### **OPERATING PROFIT BY BUSINESS AREA**

EUR million	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Pharmaceuticals	91.8	59.7	+53.8%	256.8	216.8	+18.4%	269.0
Diagnostics	2.2	1.1	+93.0%	6.6	6.8	-1.9%	8.5
Group items	-2.0	-2.3	-11.6%	-7.6	-8.0	-4.7%	-10.9
Group total	92.0	58.6	+57.1%	255.9	215.6	+18.7%	266.6

### NET SALES BY ANNUAL QUARTERS

		2016			2015			
EUR million	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Pharmaceuticals	245.7	259.5	249.3	247.3	227.1	242.0	244.5	241.5
Diagnostics	13.4	14.4	13.5	15.2	12.5	13.9	16.2	14.5
Group items	-0.6	-0.7	-0.8	-0.9	-0.5	-0.9	-0.8	-0.8
Group total	258.6	273.1	262.0	261.6	239.1	255.0	259.9	255.3

### **OPERATING PROFIT BY ANNUAL QUARTERS**

	2016				2015			
EUR million	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Pharmaceuticals	91.8	84.9	80.1	52.1	59.7	75.8	81.4	56.9
Diagnostics	2.2	1.8	2.6	1.7	1.1	1.6	4.0	1.5
Group items	-2.0	-3.2	-2.4	-2.9	-2.3	-3.5	-2.2	-3.1
Group total	92.0	83.5	80.3	50.9	58.6	74.0	83.1	55.3

#### **GEOGRAPHICAL BREAKDOWN OF NET SALES BY ANNUAL QUARTERS**

		2016			2015			
EUR million	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Finland	84.4	82.1	80.1	85.1	78.1	76.9	78.4	79.6
Scandinavia	39.6	44.3	44.7	47.0	39.1	40.9	36.9	35.6
Other Europe	78.1	85.5	83.2	81.9	70.7	77.5	86.6	89.1
North America	18.7	19.6	18.2	16.1	17.9	20.6	21.6	24.5
Other markets	37.8	41.6	35.8	31.5	33.2	39.1	36.4	26.5
Group total	258.6	273.1	262.0	261.6	239.1	255.0	259.9	255.3

# ORION

### **Business reviews**

### **KEY FIGURES FOR PHARMACEUTICALS BUSINESS**

EUR million	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Net sales	245.7	227.1	+8.2%	754.5	713.6	+5.7%	960.9
Operating profit	91.8	59.7	+53.8%	256.8	216.8	+18.4%	269.0
% of net sales	37.4%	26.3%		34.0%	30.4%		28.0%
R&D expenses	25.3	21.8	+16.5%	75.3	71.2	+5.7%	101.0
% of net sales	10.3%	9.6%		10.0%	10.0%		10.5%
Capital expenditure	11.2	10.2	+9.6%	33.0	27.5	+20.0%	40.6
% of net sales	4.5%	4.5%		4.4%	3.9%		4.2%
Sales revenue from proprietary products	88.0	80.2	+9.8%	282.4	270.9	+4.2%	354.7
Assets				738.2	684.8		740.8
Liabilities				175.9	166.0		211.0
Personnel at the end of the period				3,140	3,076		3,078

### TOP TEN BEST-SELLING PHARMACEUTICAL PRODUCTS

EUR million	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Stalevo <sup>®</sup> , Comtess <sup>®</sup> and Comtan <sup>®</sup> (Parkinson's disease)	30.7	31.8	-3.5%	102.3	112.3	-8.9%	137.5
Easyhaler <sup>®</sup> product family (asthma, COPD)	14.9	11.5	+30.0%	46.8	36.6	+27.9%	51.3
Simdax <sup>®</sup> (acute decompensated heart failure)	13.2	11.6	+13.7%	40.8	37.5	+8.9%	51.1
Dexdor <sup>®</sup> (intensive care sedative)	12.9	10.2	+26.3%	40.6	32.1	+26.5%	44.5
Remsima <sup>®</sup> (rheumatoid arthritis, inflammatory bowel diseases)	9.4	8.4	+12.0%	31.1	16.7	+86.3%	28.1
Burana <sup>®</sup> (inflammatory pain)	6.2	5.9	+5.9%	16.6	16.9	-1.9%	22.7
Dexdomitor <sup>®</sup> , Domitor <sup>®</sup> , Domosedan <sup>®</sup> and Antisedan <sup>®</sup> (animal sedatives)	3.7	4.8	-22.1%	15.8	20.8	-24.0%	27.3
Precedex <sup>®</sup> (intensive care sedative)	5.8	4.1	+39.0%	15.6	12.4	+25.7%	17.8
Marevan <sup>®</sup> (anticoagulant)	5.2	3.7	+39.5%	14.1	14.1	+0.1%	19.2
Atorvastatin Orion <sup>®</sup> (hypercholesterolaemia)	4.7	3.7	+24.3%	12.9	10.5	+23.2%	15.2
Total	106.6	95.7	+11.4%	336.5	309.8	+8.6%	414.6
Share of pharmaceutical net sales	43%	42%		45%	43%		43%

### **KEY FIGURES FOR DIAGNOSTICS BUSINESS**

EUR million	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Net sales	13.4	12.5	+7.6%	41.3	42.6	-3.1%	57.8
Operating profit	2.2	1.1	+93.0%	6.6	6.8	-1.9%	8.5
% of net sales	16.5%	9.2%		16.1%	15.9%		14.7%
R&D expenses	1.6	1.6	+3.8%	5.2	5.4	-3.5%	7.3
% of net sales	12.1%	12.6%		12.5%	12.6%		12.6%
Capital expenditure	0.5	0.7	-25.3%	0.8	2.6	-68.6%	3.7
% of net sales	4.0%	5.7%		2.0%	6.1%		6.4%
Assets				48.0	48.3		48.3
Liabilities				8.1	12.1		16.2
Personnel at the end of the period				281	291		296



### Interim Report January–September 2016

### KEY CLINICAL PHARMACEUTICAL DEVELOPMENT PROJECTS

Project	Indication	PHASE			Registration
		I	II	ш	
Bufomix Easyhaler <sup>®</sup> (budesonide-formoterol)	Asthma, COPD	I	П	ш	Registration*
Easyhaler <sup>®</sup> salmeterol-fluticasone	Asthma, COPD	I	II	*	
ODM-201 (androgen receptor antagonist) 3)	Prostate cancer (nmCRPC)	I	II	*	
ODM-201 (androgen receptor antagonist)	Prostate cancer (mHSPC)	I	II	**	
Levosimendan	Low Cardiac Output Syndrome	I	II	*	
ORM-12741 (alpha-2c adrenoceptor antagonist) 5)	Alzheimer's disease	I	lla*		
Dexmedetomidine (intranasal)	Treatment of pain	I	llb		
ODM-109 (oral levosimendan)	ALS	I	*		
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	I	*		
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumours	I	*		
ODM-207 (BET protein inhibitor)	Cancer	<b> </b> ***			
<sup>1)</sup> Aim is to obtain marketing authorisation for product in a countries not included in decentralised marketing author	*	= Phase ongoing			
<sup>2)</sup> Bioequivalence study <sup>3)</sup> In collaboration with Bayer <sup>4)</sup> Pa	**			, Phase III will end of 2016	
<sup>5)</sup> In collaboration with Janssen Pharmaceuticals <sup>6)</sup> Partner: Recro Pharma, Inc. ODM-204 (CYP17 enzyme and androgen receptor inhibitor) project discontinued.			= New project		



## Information on Orion's shares

### **BASIC SHARE INFORMATION 30 SEPTEMBER 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	25.2	67.0	92.2
Counter book value per share, EUR	0.65	0.65	
Total number of shares	38,581,154	102,676,674	141,257,828
% of total share stock	27%	73%	100%
Number of treasury shares		783,366	783,366
Total number of shares excluding treasury shares	38,581,154	101,893,308	140,474,462
Minimum number of shares			1
Maximum number of A and B shares, and maximum number of all shares	500,000,000	500,000,000	1,000,000,000
Votes per share	20	1	
Number of votes excluding treasury shares	771,623,080	101,893,308	873,516,388
% of total votes	88%	12%	100%
Total number of shareholders	16,825	37,624	48,824

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

### **INFORMATION ON TRADING ON NASDAQ HELSINKI 1 JANUARY - 30 SEPTEMBER 2016**

	A shares	B shares	Total
Shares traded	1,412,045	39,542,003	40,954,048
% of the total number of shares	3.6%	38.6%	29.0%
Trading volume, EUR million	45.6	1,283.0	1,328.6
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	32.29	32.45	
Highest quotation, EUR (A and B 19 July 2016)	37.70	37.89	
Closing quotation on 30 September 2016, EUR	34.79	35.09	
Market capitalisation on 30 September 2016 excluding treasury shares, EUR million	1,342.2	3,575.4	4,917.7

### PERFORMANCE PER SHARE

	Q3/16	Q3/15	Change %	9M 2016	9M 2015	Change %	2015
Basic earnings per share, EUR	0.52	0.32	+60.3%	1.43	1.20	+19.4%	1.48
Diluted earnings per share, EUR	0.52	0.32	+60.3%	1.43	1.20	+19.4%	1.48
Cash flow per share before financial items, EUR	0.67	0.44	+51.6%	1.23	1.11	+10.7%	1.51
Equity per share, EUR				4.19	3.59	+16.9%	4.22
Average number of shares excluding treasury shares, 1,000 shares	140,474	140,830		140,737	140,798		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 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 report, in addition to which amendments to existing IFRS and IAS standards endorsed by the EU that have been adopted as of 1 January 2016 have been applied. 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 <u>http://www.orion.fi/en/investors</u>.

## 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	X 100
(ROCE), %	=	Total assets - Non-interest-bearing liabilities (average during the period)	<u> </u>
Return on equity (ROE), %		Profit for the period	X 10
	=	Total equity (average during the period)	10
Equity ratio, %		Equity	v 100
	=	Total assets - Advances received	_ X 100
		Interest-bearing liabilities - Cash and cash equivalents - Money market investments	
Gearing, %	=	Equity	- x 100
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		Cash flow from operating activities + Cash flow from investing activities	
financial items, EUR	=	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	x 1
	=	Earnings per share	
Effective dividend yield, %		Dividend per share	x 1
	=	Closing quotation of the period	
Price/earnings ratio (P/E)		Closing quotation of the period	
r nee/earnings ralio (F/E)	=	Earnings per share	-
Average share price, EUR		Total EUR value of shares traded	
Average Share price, EUK	=	Average number of traded shares during the period	-
Market capitalisation, EUR million	=	Number of shares at the end of the period $\times$ 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<sup>®</sup> 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.