

ORION CORPORATION / INTERIM REPORT / JANUARY-SEPTEMBER 2013 22 October 2013 at 12:00 noon EEST

### Orion Group Interim Report January–September 2013

Orion's net sales in January–September 2013 totalled EUR 734 million (EUR 726 million in January–September 2012).

- Operating profit was EUR 202 (220) million.
- Profit before taxes was EUR 200 (219) million.
- Equity ratio was 52% (59%).
- ROCE before taxes was 39% (50%).
- ROE after taxes was 41% (46%).
- Basic earnings per share were EUR 1.07 (1.17).
- Cash flow per share before financial items was EUR 0.56 (0.92).
- The outlook estimate for 2013 remains unchanged. Orion estimates that in 2013 net sales will be at similar level to 2012 and that operating profit will be slightly lower than in 2012.
- Promising results from Phase II clinical trials of ODM-201.
- Orion and Endo have terminated their collaboration agreement concerning oncology drug research, development and commercialisation. Among others, all the rights of ODM-201 revert to Orion.
- Orion and Hospira have extended their licensing agreement concerning the sedative agent Precedex® in the markets outside the Europe.

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

	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Net sales, EUR million	236.9	245.8	-3.6%	734.3	726.0	+1.1%	980.4
International operations, EUR million	169.3	182.5	-7.3%	531.2	536.0	-0.9%	723.1
% of net sales	71.5%	74.3%		72.3%	73.8%		73.8%
Operating profit, EUR million	66.6	75.6	-11.9%	201.8	219.5	-8.1%	278.3
% of net sales	28.1%	30.8%		27.5%	30.2%		28.4%
Profit before taxes, EUR million	65.3	75.3	-13.4%	199.6	218.5	-8.7%	276.6
% of net sales	27.6%	30.6%		27.2%	30.1%		28.2%
Income tax expense, EUR million	16.2	18.7	-13.4%	49.1	54.0	-9.2%	69.7
R&D expenses, EUR million	21.2	26.3	-19.5%	72.2	73.9	-2.3%	105.8
% of net sales	9.0%	10.7%		9.8%	10.2%		10.8%
Capital expenditure, EUR million	21.1	12.7	+66.1%	57.8	36.0	+60.3%	46.8
% of net sales	8.9%	5.2%		7.9%	5.0%		4.8%
Assets total, EUR million				926.8	782.7	+18.4%	835.7
Equity ratio, %				51.5%	58.9%		61.0%
Gearing, %				20.5%	7.7%		-1.7%
Interest-bearing liabilities, EUR million				270.8	149.9	+80.7%	136.7
Non-interest-bearing liabilities, EUR million				178.5	171.7	+3.9%	189.5
Cash and cash equivalents and money market investments, EUR million				172.8	114.3	+51.2%	145.2
ROCE (before taxes), %				39.4%	49.9%		45.9%
ROE (after taxes), %				40.7%	45.6%		41.0%
Basic earnings per share, EUR	0.35	0.40	-13.4%	1.07	1.17	-8.6%	1.47
Diluted earnings per share, EUR	0.35	0.40	-13.4%	1.07	1.17	-8.6%	1.47
Cash flow per share before financial items, EUR	0.29	0.42	-30.4%	0.56	0.92	-38.9%	1.23
Equity per share, EUR				3.38	3.27	+3.4%	3.62
Personnel at the end of the period				3,530	3,489	+1.2%	3,486
Average personnel during the period				3,550	3,500	+1.4%	3,495
Personnel expenses, EUR million				156.8	154.8	+1.3%	214.8



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### President and CEO Timo Lappalainen's review

#### "Year progressed as anticipated"

"Our net sales were at similar level to the previous year and as expected our operating profit was slightly lower than in 2012.

"Deliveries of our Parkinson's drugs to Novartis were clearly lower than in the previous year. The decrease in the past quarter was strengthened by about EUR 10 million of non-recurring compensatory payments related to pricing received in the comparative period of 2012. Total sales generated by Stalevo<sup>®</sup> and Comtess<sup>®</sup> products in Orion's own sales organisation were slightly down on the comparative period.

"The entacapone molecule patent will expire in October 2013 in the United States, where generic competition commenced in April 2012. Orion has delivered generic entacapone products to its partners in the United States and will continue these deliveries after the expiry of the patent. In Europe data protection of Stalevo will expire in October 2013, after which generic competitors can refer to results from Orion's clinical trials in their applications for marketing authorisation. Despite intensifying generic competition, Parkinson's drugs will continue to be an important product group for Orion.

"Although sales of Parkinson's drugs clearly declined, net sales of the Proprietary Products business division decreased only slightly because *dexdor*<sup>®</sup> and Precedex<sup>®</sup> maintained strong growth. In addition, after the review period, we extended the licensing agreement with Hospira concerning the sedative agent Precedex<sup>®</sup> in the markets outside the Europe. We are also pleased that all the other business divisions increased net sales during the year. Fermion, which manufactures active pharmaceutical ingredients, increased sales especially strongly.

"At the end of September we reported positive Phase II clinical trial results for an androgen receptor antagonist (ODM-201) for the treatment of advanced prostate cancer. The collaboration agreement with Endo Pharmaceuticals concerning development of ODM-201 has been terminated and subject to an ongoing royalty obligation due Endo, all rights to ODM-201 revert to Orion. Ending the collaboration with Endo will not affect progress of the project. We have started preparations for a Phase III clinical trial and also continue negotiations to find a suitable partner for collaboration on the next phase of worldwide development and commercialisation of the product. A broader collaboration agreement between the companies concerning oncology drug research, development and commercialisation has also been terminated. All the drug candidates covered by the agreement and all their rights will return to respective originators.

"In addition, we have continued negotiations with possible partners for the further development of an alpha-2c adrenoceptor antagonist (ORM-12741) being developed for the treatment of Alzheimer's disease.

"The significant ongoing investment and production reorganisation projects have progressed as planned during the year. Through the measures being undertaken, we will develop and ensure future growth, delivery reliability and quality standards. However, the projects have been temporarily increasing production costs and decreasing production capacity, and that has reduced our margin this year.

"Our outlook estimate, which can be found with the basis for it on pages 6–7 of this report, remains unchanged. We estimate that our net sales will be at similar level to the previous year and our operating profit will be slightly lower than in 2012."



### Events during the period

On 25 July Orion announced that it had reached agreement with Mylan Pharmaceuticals Inc. in the patent dispute concerning the proprietary drug Stalevo<sup>®</sup>.

### Events after the period

On 21 October Orion Corporation and Hospira, Inc. announced that they have extended the licensing agreement concerning the sedative agent Precedex® in the markets outside the Europe.

On 22 October Orion Corporation and Phyxius Pharma, Inc. announced that they have entered into a licensing agreement for levosimendan injection in the USA and Canada.



### News conference and teleconference

A news conference and teleconference on the published results will be held today, Tuesday 22 October 2013, 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 <u>www.orion.fi/en/investors</u>. After the presentation, questions can be asked by telephone in Finnish and English. The teleconference code is **937158** and to participate in the teleconference, please call:

from Finland: +358 (0)9 2313 9201 from United Kingdom: +44 (0)20 7162 0077 from Sweden: +46 (0)8 5052 0110 from United States: +1 334 323 6201

A more comprehensive list of country-specific telephone numbers can be found at www.orion.fi/en/investors.

#### 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 available on the Orion website later today.

### Financial report material

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

### Dates in Orion Calendar 2013–2014

Capital Markets Day in Helsinki	Wednesday 20 November 2013
Financial Statement Release for 2013	Tuesday 4 February 2014
Annual General Meeting 2014	Tuesday 25 March 2014
Interim Report January–March 2014	Tuesday 29 April 2014
Interim Report January–June 2014	Tuesday 29 July 2014
Interim Report January–September 2014	Tuesday 21 October 2014

The Financial Statements and Report by the Board of Directors for 2013 will be published on the Company's website at the latest in week 10/2014.

### 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

www.orion.fi/en www.orion.fi/en/investors



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### Financial review Q1–Q3/2013

#### Net sales

*The Orion Group's net sales* in January–September 2013 were EUR 734 million (EUR 726 million in January–September 2012). The net effect of currency exchange rates was EUR -9 million.

*The Pharmaceuticals business's* net sales were EUR 693 (687) 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 19% at EUR 156 (192) million, which was 22% (28%) of the Pharmaceuticals business's net sales. The net sales of other products in the portfolio were up by 9% at EUR 538 (495) million.

The Diagnostics business's net sales were up by 6% at EUR 43 (41) million.

#### **Operating profit**

The Orion Group's operating profit was down by 8% at EUR 202 (220) million.

**The Pharmaceuticals business's** operating profit was down by 9% at EUR 205 (224) million. The gross profit percentage was lower than in the comparative period due to products with lower margins accounting for an increasing proportion of sales, lower prices and higher production costs. Costs were increased by the ongoing extensive investment and production facility modification projects, which have temporarily decreased production capacity and at the same time increased costs. Operating expenses were slightly down. Net sales and operating profit in the comparative period were enhanced by a total of EUR 10 million of long-term compensatory payments related to the pricing of partner deliveries.

*The Diagnostics business's* operating profit was up by 33% at EUR 3.9 (2.9) million due to good growth in sales. The profit includes EUR 1.6 million of expenses recorded in June related to contraction of the product portfolio, closure of the Turku manufacturing plant and personnel reductions.

#### **Operating expenses**

The Group's sales and marketing expenses were down by 2% at EUR 145 (148) million.

**R&D expenses** were down by 2% at EUR 72 (74) million and accounted for 10% (10%) of the Group's net sales. Pharmaceutical R&D expenses amounted to EUR 66 (68) million. Research projects are reported in more detail under Pharmaceuticals in the Business Reviews.

Administrative expenses were EUR 32 (33) million.

Other operating income and expenses increased profit by EUR 3 (2) million.

#### Group's profit

The Group's profit before taxes totalled EUR 200 (219) million. Basic earnings per share were EUR 1.07 (1.17) and diluted earnings per share were EUR 1.07 (1.17). Equity per share was EUR 3.38 (3.27). The return on capital employed before taxes (ROCE) was 39% (50%) and the return on equity after taxes (ROE) 41% (46%).

#### **Financial position**

The Group's gearing was 21% (8%) and the equity ratio 52% (59%).

The Group's *total liabilities* at 30 September 2013 were EUR 449 (322) million. At the end of the period, interest-bearing liabilities amounted to EUR 271 (150) million, including EUR 241 (120) million of long-term loans.

The Group had EUR 173 (114) million of *cash and cash equivalents and money market investments* at the end of the period, which are invested in short-term interest-bearing instruments issued by financially solid financial institutions and corporations.



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#### Cash flow

**Cash flow from operating activities** was lower than in the comparative period at EUR 131 (168) million. The cash flow was lower because the operating profit decreased and the amount tied up into working capital increased by more than in the comparative period. The clear EUR 20 million year-on-year increase in inventories was mainly due to ensuring the reliability of deliveries as the product portfolio and supply chain were expanded. The slightly higher amount tied up into working capital than in the comparative period was also due to receivables and especially other receivables such as advance payments related to licensing agreements. In addition, income taxes paid were up by EUR 7 million on the comparative period.

Cash flow from investing activities was EUR -52 (-38) million.

*Cash flow from financing activities* was EUR -51 (-139) million. The difference was mainly due to the EUR 150 million bond issued in June 2013.

#### **Capital expenditure**

The Group's capital expenditure totalled EUR 58 (36) million. This comprised EUR 52 (30) million on property, plant and equipment and EUR 6 (6) million on intangible assets.

### Outlook for 2013

Net sales will be at similar level to 2012 (net sales in 2012 were EUR 980 million).

Operating profit will be slightly lower than in 2012 (operating profit in 2012 was EUR 278 million).

*The Group's capital expenditure* will be about EUR 80 million excluding substantial corporate or product acquisitions (the Group's capital expenditure in 2012 was EUR 47 million).

### Basis for outlook

Competition in the Finnish market will remain intense in 2013. However, product launches will continue to support Orion's position as market leader.

The generic competition that commenced in April 2012 in the United States has decreased sales of Orion's Parkinson's drugs. The decrease will continue in 2013 because generic products will be in the markets during the whole year and, in addition, the number of competitors will be greater than in 2012. US markets accounted for about EUR 60 million of the net sales of Orion's Parkinson's drugs in 2011 and about EUR 33 million in 2012. In addition, sales of generic entacapone products to the United States amounted to about EUR 17 million in 2012.

The entacapone molecule patent expired in November 2012 in the main European countries for Orion, and as a result there will be generic competitors to Comtan and Comtess in these markets in 2013. Data protection of Stalevo will end in the European Union in October 2013 and generic competition is not expected to commence in Europe during the current year, even though the first generic marketing authorisation application in Europe has already been submitted. The total sales of Orion's Parkinson's drugs in Europe are expected to be slightly lower than in 2012. Elsewhere in the world generic competition is not expected to have a material impact on sales volumes of these products in the current year, but declining prices and depreciation in the exchange rate of the Japanese yen relative to the euro will decrease sales.

Net sales and operating profit in 2012 also included EUR 10 million of non-recurring long-term compensatory payments related to the pricing of partner deliveries.

A slight decrease in the gross profit as percentage of net sales is anticipated. Sales of generic products will account for a greater proportion of Orion's total sales and price competition will remain intense in many markets. In addition, significant ongoing investments to develop and ensure future growth, delivery reliability



and quality standards, and related reorganisation of production will temporarily decrease production capacity and increase production costs.

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 2013 were planned mainly during the previous year.

Research and development costs will be at similar level to 2012. 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 2013 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.

The estimated costs of the ongoing patent litigations in the United States are based on the planned timetables and work estimates. The costs due to the litigations will depend on a number of factors, which are difficult to estimate accurately.

### Near-term risks and uncertainties relating to the outlook

Sales of Orion's Parkinson's drugs will decrease in 2013 due to generic competition. The effects of the competition have been taken into account in the outlook estimate.

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 to Novartis 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.

A significant proportion of the exchange rate risk is related to the US dollar. Typically, only less than 15% of Orion's net sales comes from the United States. As regards currencies in European countries, the overall effect 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.

Orion's currently high production capacity utilisation rate and its broad product range may cause risks to the delivery reliability and make it more challenging than before to maintain the very high quality standard required. Authorities and key customers in different countries undertake regular and detailed inspections of development and manufacturing of drugs. Any remedial actions that may be required may at least temporarily reduce 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 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.



### Group's financial objectives

Orion's financial objectives are ensuring the Group's financial stability and profitable growth.

These objectives are achieved through:

- Increasing net sales. Achievement of this objective requires continuous investment in development of the product portfolio.
- Maintaining profitability at a good level, the aim being operating profit that exceeds 20% of net sales.
- Keeping the equity ratio at least 50%.

### 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 2013 Orion had a total of 141,257,828 (141,257,828) shares, of which 42,172,816 (44,293,218) were A shares and 99,085,012 (96,964,610) B shares. The Group's share capital was EUR 92,238,541.46 (92,238,541.46). At the end of September 2013 Orion held 188,991 (325,991) B shares as treasury shares. On 30 September 2013 the aggregate number of votes conferred by the A and B shares was 942,352,341 (982,502,979) excluding treasury shares.

At the end of September 2013, Orion had 56,142 (58,800) 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 the General Meetings of Shareholders. The Company itself and Orion Pension Fund do not have the right to vote at Orion Corporation's General Meetings 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 2013 a total of 1,094,402 shares were converted.

#### Trading in Orion's shares

Orion's A shares and B shares are quoted on NASDAQ OMX 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 2013 the market capitalisation of the Company's shares excluding treasury shares was EUR 2,628 million.

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



#### Authorisations of the Board of Directors

Orion's Board of Directors was authorised by the Annual General Meeting on 19 March 2013 to decide on acquisition of shares in the Company and on a share issue in which shares held by the Company can be conveyed. The authorisation to acquire shares is valid for 18 months and the authorisation to issue shares is valid for five years from the decision taken by the Annual General Meeting.

The Board of Directors is authorised to decide on acquisition of no more than 500,000 Orion Corporation B shares. Such shares shall be acquired at the market price at the time of acquisition quoted in the regulated market of NASDAQ OMX Helsinki Oy ("Stock Exchange") using funds in the Company's distributable equity. Such shares may be acquired in the regulated market of the Stock Exchange in a proportion not corresponding to the shareholders' holdings. The shares shall be acquired and paid for in accordance with the rules of the Stock Exchange and Euroclear Finland Ltd. The shares acquired can be kept, cancelled or further conveyed by the Company. The shares can be acquired for the purpose of developing the capital structure of the Company, for use in financing possible corporate acquisitions or other business arrangements of the Company, for financing capital expenditure, as part of the Company's incentive plan, or for otherwise conveying or cancelling them. The Board of Directors shall decide on other matters related to the acquisition of shares in the Company.

On 23 April 2013 Orion's Board of Directors decided to acquire shares in the Company as authorised by the Annual General Meeting. According to the decision, the Company will acquire 500,000 B shares in the Company. The shares will be acquired in accordance with the terms of the authorisation 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. Such shares held by the Company can be conveyed either against or without payment. Such shares held by the Company can be conveyed by selling them in the regulated market of the Stock Exchange; in a share issue placement to the Company's shareholders in proportion to their holdings at the time of the conveyance regardless of whether they own A or B shares; or in a share issue placement deviating from shareholders' pre-emptive rights if there is a weighty financial reason, such as the development of the capital structure of the Company, using the shares to finance possible corporate acquisitions or other business arrangements of the Company, financing capital expenditure or as part of the Company's incentive plan. The share issue placement can be without payment only if there is an especially weighty financial reason in the view of the Company and to the benefit of all its shareholders. The amounts paid for shares in the Company conveyed shall be recorded in a distributable equity fund. The Board of Directors shall decide on other matters related to the conveyance of shares held by the Company. The decision to authorise the share issue revoked the unexercised portion of the outstanding share issue authorisation approved at Orion Corporation's Annual General Meeting on 24 March 2010.

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

#### Orion Group's 2013 long-term incentive plan

In February 2013 Orion's Board of Directors 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 2013, 2014 and 2015. 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 approximately 35 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 5 February 2013.

#### 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 2013 Orion had a total of 56,142 (58,800) registered shareholders, of whom 95% (95%) were private individuals holding 46% (50%) of the entire share stock and 64% (65%) of the total votes. There were altogether 48 (44) million nominee-registered shares, which was 34% (31%) of all shares, and they conferred entitlement to 7% (6%) of the total votes.

At the end of September 2013 Orion held 188,991 (325,991) B shares as treasury shares, which is 0.1% (0.2%) of the Company's total share stock and 0.02% (0.03%) of the total votes.

### Personnel

The average number of employees in the Orion Group in January–September 2013 was 3,550 (3,500). At the end of September 2013 the Group had a total of 3,530 (3,489) employees, of whom 2,820 (2,788) worked in Finland and 710 (701) outside Finland.

Salaries and other personnel expenses in January–September 2013 totalled EUR 157 (155) million.

### Significant legal proceedings

#### Legal proceedings against the Sandoz companies

On 1 May 2012 Orion announced that it had been informed that the United States District Court for the District of New Jersey had given its decision on the patent infringement lawsuit that Orion Corporation and Hospira, Inc. filed on 4 September 2009 to enforce US Patents Nos. 4,910,214 and 6,716,867. The respondents in the case are Sandoz Inc., Sandoz International GmbH and Sandoz Canada Inc. (hereinafter collectively "Sandoz").

The court found that US Patent No. 4,910,214 is valid and enforceable. Sandoz is permanently enjoined from the commercial manufacture, use, sale or offer for sale in the United States or importation into the United States of its generic dexmedetomidine product until such time as US Patent No. 4,910,214 expires, including any applicable extensions. The Court also ordered that the effective date of Sandoz's Abbreviated New Drug Application No. 91-465 shall not occur until the expiration of Patent No. 4,910,214, including any applicable extensions. Separately, the court found that US Patent No. 6,716,867 is invalid as obvious.

Orion's licensee Hospira, Inc. sells Precedex<sup>®</sup> in the United States and in markets outside Europe.

Orion and Hospira have filed an appeal against the decision to the court of appeals, and so has Sandoz.

#### Legal proceedings against Caraco Pharmaceutical Laboratories, Ltd.

On 12 November 2010 Orion Corporation and Hospira, Inc. jointly filed a patent infringement lawsuit in the United States against Caraco Pharmaceutical Laboratories, Ltd. to enforce Orion's and Hospira's joint patent No. 6,716,867 valid in the United States. Gland Pharma Ltd. has since been added as a defendant in the lawsuit.

Caraco had submitted an application for authorisation to produce and market in the United States a generic version of Orion's proprietary drug Precedex<sup>®</sup> (dexmedetomidine hydrochloride 100 µg/ml), which is marketed in the United States by Orion's licensee Hospira.

Orion expects the costs of the legal proceedings against Caraco to be substantially less than the costs of the entacapone patent litigation that had previously been pending in the United States.



### **Business Reviews**

### **Pharmaceuticals**

#### Review of human pharmaceuticals market

According to statistics collected by Finnish Pharmaceutical Data Ltd, **Finnish wholesale of human pharmaceuticals** in January–September 2013 was up by 2% on the comparative period at EUR 1,520 (1,489) million.

Finland is the most important individual market for Orion, generating about one-quarter of the total net sales. Orion was able to increase its sales faster than the markets as a whole and strengthened its position as leader in marketing pharmaceuticals in Finland. According to statistics collected by Finnish Pharmaceutical Data Ltd, **Orion's wholesale of human pharmaceuticals in Finland** in January–September 2013 amounted to EUR 172 (162) million, up by 7% compared with the previous year. Orion's market share of Finnish pharmaceuticals markets was 11% (11%).

According to IMS Health pharmaceutical sales statistics, in the 12-month period ending in June 2013 the **total sales of Parkinson's drugs** in the United States were up by 8% at USD 791 million (USD 731 million in the previous 12-month period). The five largest European markets for Parkinson's disease drugs were Germany, the United Kingdom, France, Spain and Italy. In these countries, the combined sales of Parkinson's drugs totalled EUR 969 (951) million, and the average market growth was 2%. In Japan sales of Parkinson's drugs were down by 2% at EUR 553 (562) million.

According to IMS Health pharmaceutical sales statistics, in the 12-month period ending in June 2013 the **total sales of Parkinson's drugs containing entacapone** were USD 175 (193) million in the United States and EUR 153 (156) million in the five largest European markets.

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 about one-fifth of the Group's net sales. Sales of these products clearly decreased in the United States and slightly decreased in Europe. In Japan sales continued to grow better than the market as a whole. According to IMS Health pharmaceutical sales statistics, in the 12-month period ending in June 2013, **sales of Orion's branded Parkinson's drugs** in the United States were down by 60% at USD 71 (177) million. Sales were down by 3% at EUR 152 (156) million in the five largest markets in Europe, and in Japan sales were EUR 63 (62) million. The market share of Orion's branded Parkinson's drugs was 9% in the United States, on average 16% in the five largest European markets and 11% in Japan.

According to IMS Health pharmaceutical sales statistics, sales of Orion's **Precedex**<sup>®</sup> **intensive care sedative** (dexmedetomidine) were up by 39% at USD 321 million in the 12-month period ending in June 2013 (USD 231 million in the previous 12-month period). About four-fifths of the sales amounting to USD 262 (180) million were in the United States, where Precedex sales grew by 46%.

According to IMS Health pharmaceutical sales statistics, total sales of the most common intravenous anaesthetics and intensive care sedatives (propofol, midazolam, remifentanil and dexmedetomidine) in Europe in the 12-month period ending in June 2013 were EUR 474 (475) million. According to IMS Health pharmaceutical sales statistics, in the 12-month period ending in June 2013 sales of Orion's *dexdor*<sup>®</sup> intensive care sedative (dexmedetomidine) were up by 259% at EUR 18 (5) million in Europe.

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

Net sales of the Pharmaceuticals business in January–September 2013 were EUR 693 (687) million. The operating profit of the Pharmaceuticals business was down by 9% at EUR 205 (224) million. The operating profit of the Pharmaceuticals business was 30% (33%) of the segment's net sales.

Net sales of Orion's top ten pharmaceuticals in January–September 2013 were EUR 334 (347) million. They accounted for 48% (50%) of the total net sales of the Pharmaceuticals business.



#### **Proprietary Products**

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

Net sales of Proprietary Products in January-September 2013 were down by 5% at EUR 285 (300) million.

Orion's branded 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), and their net sales in January–September 2013 totalled EUR 156 (192) million. Sales of Parkinson's drugs were down by 19% and accounted for 22% (28%) of the total net sales of the Pharmaceuticals business. Net sales from deliveries of Stalevo and Comtan to Novartis were down by 27% at EUR 87 (119) million. Deliveries of Stalevo to Novartis were down by 24% at EUR 60 (78) million and deliveries of Comtan were down by 34% at EUR 27 (41) million. Total net sales generated by Stalevo and Comtess in Orion's own sales organisation were down by 6% at EUR 69 (73) million. Sales through Orion's own sales network were EUR 62 (63) million for Stalevo and down by 36% at EUR 6 (10) million for Comtess. The entacapone molecule patent will expire in October 2013 in the United States, where generic competition commenced in April 2012. Orion has delivered generic entacapone products to its partners in the United States and will continue these deliveries after the expiry of the patent. In Europe data protection of Stalevo will expire in October 2013, after which generic competitors can refer to results from Orion's clinical trials in their applications for marketing authorisation.

The US Food and Drug Administration (FDA) has an ongoing safety review of Stalevo, which began in spring 2009. Orion is assisting the FDA in undertaking the safety review. The FDA has requested additional data based on databases concerning the significance of the results of the STRIDE-PD study, and consequently Orion and Novartis have undertaken epidemiological studies and results from them were submitted to authorities for review in the third quarter of 2012.

Net sales of Simdax<sup>®</sup>, a drug for treatment of acute decompensated heart failure, in January–September 2013 were up by 3% at EUR 33 (32) million.

Total net sales of the Easyhaler<sup>®</sup> product family for treatment of asthma and chronic obstructive pulmonary disease were up by 3% in January–September 2013 at EUR 21 (20) million. Sales of Easyhaler products through Orion's own sales network in Europe continued to grow strongly. The repatriation of rights to Easyhaler products in 2012, especially in Poland and to some extent in Germany, and the related transitional phase slowed sales growth in the current year.

Net sales of the Precedex<sup>®</sup> intensive care sedative (dexmedetomidine) were up by 43% in January– September 2013 at EUR 41 (28) million. In the United States and markets outside Europe the sedative is sold by Orion's partner Hospira. US markets account for about four-fifths of net sales of Precedex. After the review period, Orion and Hospira announced that they have extended the licensing agreement concerning the sedative agent Precedex® in the markets outside the Europe.

Net sales of Orion's *dexdor<sup>®</sup>* intensive care sedative (dexmedetomidine) in January–September 2013 were up by 125% at EUR 18 (8) million. The product is still in the launching phase, which is apparent in the quarterly fluctuation in sales.

#### **Specialty Products**

Net sales of the Specialty Products business division's off-patent, i.e. generic prescription drugs and selfcare products in January–September 2013 were up by 4% at EUR 279 (270) million. Sales of generic entacapone products were down by 47% at EUR 7 (13) million. Sales of products from the rest of the portfolio were up by 6%.

Net sales of Orion's human pharmaceuticals in Finland in January–September 2013 were up by 7% at EUR 188 (175) million. Specialty Products accounted for the majority of sales. Orion managed to increase its sales, especially in prescription drugs.

Net sales of Orion's human pharmaceuticals in Eastern Europe and Russia in January–September 2013 were up by 14% at altogether EUR 50 (44) million. Specialty Products account for the majority of sales in the region.



#### **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 international 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 2013 were up by 2% at EUR 53 (52) million. Sales of the animal sedatives at EUR 18 (16) million accounted for 34% (32%) of the division's net sales. Orion's animal sedatives are Dexdomitor<sup>®</sup> (dexmedetomidine), Domitor<sup>®</sup> (medetomidine), Domosedan<sup>®</sup> (detomidine) and Antisedan<sup>®</sup> (atipamezole).

#### Fermion

Fermion manufactures active pharmaceutical ingredients for Orion and other pharmaceutical companies. Its product range comprises nearly 30 pharmaceutical ingredients. Fermion's net sales in January–September 2013 excluding pharmaceutical ingredients supplied for Orion's own use were up by 27% at EUR 46 (36) million and accounted for about two-thirds of Fermion's entire net sales. Several key products performed well, even though competition in the markets remained intense. Capacity utilisation at Fermion's plants continued to be very high during the review period. Capacity utilisation was increased by manufacturing active ingredients required for development work on Orion's own proprietary drugs, in addition to the normal product range.

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

The Group's *R&D* expenses in January–September 2013 were down by 2% at EUR 72 (74) million, of which the Pharmaceuticals business accounted for EUR 66 (68) 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.

The Phase II clinical trial of an *androgen receptor antagonist* (ODM-201) for the treatment of advanced prostate cancer showed that initial results concerning efficacy were promising, and the product was well tolerated with no significant adverse events detected. The results were presented at the international ECCO oncology congress at the end of September 2013. Orion and Endo Pharmaceuticals, which is part of Endo Health Solutions Inc., have terminated their collaboration agreement concerning development of ODM-201. Subject to an ongoing royalty obligation due Endo, all rights to ODM-201 revert to Orion and ending the collaboration with Endo will not affect progress of the project. Orion has commenced preparations for a Phase III clinical trial and also continues negotiations to find a suitable partner for collaboration agreement between the companies concerning oncology drug research, development and commercialisation has also been terminated. All the drug candidates covered by the agreement and all their rights will revert to respective originators.

Orion has ongoing projects to broaden the range of the inhalable *Easyhaler<sup>®</sup> drugs* product family. Orion submitted an application for marketing authorisation for a combined *budesonide-formoterol formulation* in Europe in March, and the application is being processed. In this formulation, budesonide acts as an anti-inflammatory agent and formoterol acts as a long-acting bronchodilator.

In addition, Orion has another Easyhaler research programme in progress to develop a combined *fluticasone-salmeterol formulation* for European markets. In this formulation fluticasone acts as an anti-inflammatory agent and salmeterol acts as a long-acting bronchodilator.

Orion is collaborating with Novartis to develop *Stalevo<sup>®</sup> drug* for the Japanese markets. Novartis submitted an application for marketing authorisation for the product in June.

Orion has completed Phase II clinical trials with an *alpha-2c adrenoceptor antagonist* (ORM-12741). The trials investigated the efficacy and safety of the drug candidate in treatment of cognitive and behavioural symptoms related to Alzheimer's disease. Positive results from Phase IIa clinical trials were presented at the



22 October 2013

annual meeting of the American Academy of Neurology in mid-March 2013. Negotiations to find a suitable partner for the next development phase are ongoing. In addition, Orion has Phase I clinical pharmacokinetic trials ongoing with another *alpha-2c adrenoceptor antagonist* (ODM-102), a backup molecule to ORM-12741.

Orion is developing a new *more effective levodopa product* (ODM-101) based on optimised new formulations and doses of known compounds. Results obtained from Phase II clinical trials in 2012 were positive, and they were presented at the annual meeting of the American Academy of Neurology in mid-March 2013. The search for a suitable collaboration model for the next development phase is ongoing.

Orion has ongoing Phase I clinical safety trials initiated in summer 2012 with a new **COMT inhibitor (ODM-103)**. In addition, Orion has started Phase I clinical safety trials with another new **COMT inhibitor (ODM-104)**. ODM-103 and ODM-104 are new molecules that enhance the therapeutic effects of levodopa used to treat Parkinson's disease by blocking the COMT enzyme. The pre-clinical study results indicated that they are more effective than the COMT inhibitor entacapone, which is already in the markets.

After the review period, Orion and Phyxius Pharma, Inc. entered into a licensing agreement for levosimendan injection. According to the agreement Phyxius Pharma will develop and commercialize levosimendan in the USA and Canada for a new cardiovascular indication, prevention of Low Cardiac Output Syndrome (LCOS) in cardiac surgery patients.

In addition, Orion has several projects in the early research phase investigating cancer, neuropathic pain, Parkinson's disease and Alzheimer's disease, 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 2013 were up by 6% at EUR 43 (41) million.

QuikRead<sup>®</sup> infection tests remained the main product, with sales continuing strong. Launching of the QuikRead go<sup>®</sup> hsCRP+Hb test progressed as planned. Two results, for CRP and haemoglobin, can be obtained from a single sample with the test.

Through the measures decided following the co-operation negotiations, Orion Diagnostica continued streamlining its operations according to the planned schedule during the review period.

The operating profit of the Diagnostics business was up by 33% at EUR 3.9 (2.9) million due to good growth in sales. The profit includes EUR 1.6 million of expenses related to contraction of the product portfolio, closure of the Turku manufacturing plant and personnel reductions.

Espoo, 22 October 2013

Board of Directors of Orion Corporation

**Orion Corporation** 

Jari Karlson *CFO* 



### Tables

#### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

EUR million	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Net sales	236.9	245.8	-3.6%	734.3	726.0	+1.1%	980.4
Cost of goods sold	-96.3	-85.4	+12.7%	-286.9	-254.4	+12.8%	-350.8
Gross profit	140.6	160.4	-12.3%	447.4	471.6	-5.1%	629.6
Other operating income and expenses	1.7	0.7	+123.4%	3.4	2.1	+64.2%	6.3
Sales and marketing expenses	-45.1	-49.5	-8.9%	-144.7	-147.8	-2.0%	-206.1
R&D expenses	-21.2	-26.3	-19.5%	-72.2	-73.9	-2.3%	-105.8
Administrative expenses	-9.4	-9.7	-2.9%	-32.1	-32.5	-1.3%	-45.7
Operating profit	66.6	75.6	-11.9%	201.8	219.5	-8.1%	278.3
Finance income	0.6	1.4	-59.9%	3.4	4.8	-29.3%	4.9
Finance expenses	-1.9	-1.7	+12.0%	-5.9	-5.9	+0.5%	-6.6
Share of associated companies' results				0.3	0.1	+314.1%	0.1
Profit before taxes	65.3	75.3	-13.4%	199.6	218.5	-8.7%	276.6
Income tax expense	-16.2	-18.7	-13.4%	-49.1	-54.0	-9.2%	-69.7
Profit for the period	49.1	56.6	-13.3%	150.5	164.5	-8.5%	206.9

#### OTHER COMPREHENSIVE INCOME INCLUDING TAX EFFECTS

Personnel expenses	45.9	47.8	-3.9%	156.8	154.8	+1.3%	214.8
Depreciation, amortisation and impairment	9.2	10.7	-14.7%	27.6	28.6	-3.7%	40.0
Diluted earnings per share, EUR <sup>1)</sup>	0.35	0.40	-13.4%	1.07	1.17	-8.6%	1.47
Basic earnings per share, EUR <sup>1)</sup>	0.35	0.40	-13.4%	1.07	1.17	-8.6%	1.47
- · · · · · · · · · · · · · · · · · · ·							
Non-controlling interests	0.0	0.0		0.0	0.0		0.0
Owners of the parent company	49.9	63.6	-21.6%	149.6	185.5	-19.3%	233.7
COMPREHENSIVE INCOME ATTRIBUTABLE TO:							
Non-controlling interests	0.0	0.0		0.0	0.0		0.0
Owners of the parent company	49.1	56.6	-13.3%	150.5	164.5	-8.5%	206.9
PROFIT ATTRIBUTABLE TO:							
Comprehensive income for the period including tax effects	49.9	63.6	-21.6%	149.6	185.5	-19.3%	233.7
Other comprehensive income net of tax	0.8	7.0		-0.9	21.1		26.7
Items that will not be reclassified to profit and loss	0.0	6.4		0.0	19.2		25.6
Items due to remeasurement of defined benefit plans	0.0	6.4		0.0	19.2		25.6
Items that may be reclassified subsequently to profit and loss	0.8	0.6		-0.9	1.9		1.1
Translation differences	0.8	0.6		-1.0	1.8		1.1
Change in value of available-for-sale financial assets		0.0			0.3		0.3
Change in value of cash flow hedges	0.0	0.0		0.1	-0.3		-0.2

<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	9/13	9/12	Change %	12/12
Property, plant and equipment	236.3	201.7	+17.1%	205.3
Goodwill	13.5	13.5		13.5
Intangible rights	56.1	62.4	-10.0%	58.0
Other intangible assets	3.4	4.6	-25.8%	4.3
Investments in associates	1.7	1.4	+19.1%	1.4
Available-for-sale financial assets	0.5	1.1	-55.6%	0.5
Pension asset	38.6	30.1	+28.3%	38.4
Deferred tax assets	1.3	1.9	-27.9%	2.0
Other non-current assets	1.3	1.6	-20.6%	1.6
Non-current assets total	352.7	318.2	+10.8%	325.0
Inventories	199.6	170.2	+17.3%	179.2
Trade receivables	157.9	147.6	+7.0%	151.5
Other receivables	43.7	32.3	+35.2%	34.8
Money market investments	15.0			
Cash and cash equivalents	157.8	114.3	+38.0%	145.2
Current assets total	574.1	464.5	+23.6%	510.7
Assets total	926.8	782.7	+18.4%	835.7

#### EQUITY AND LIABILITIES

EUR million	9/13	9/12	Change %	12/12
Share capital	92.2	92.2		92.2
Expendable fund	0.5	0.5		0.5
Other reserves	1.6	0.8	+99.7%	0.8
Retained earnings	383.1	367.6	+4.2%	416.0
Equity attributable to owners of the parent company	477.4	461.1	+3.5%	509.5
Non-controlling interests	0.0	0.0	+6.4%	0.0
Equity total	477.4	461.1	+3.5%	509.6
Deferred tax liabilities	41.3	39.6	+4.5%	42.5
Pension liability	1.3	1.4	-5.3%	1.4
Provisions	0.1	0.1	-34.2%	0.1
Interest-bearing non-current liabilities	240.8	119.7	+101.2%	107.4
Other non-current liabilities	0.5	0.8	-43.7%	0.8
Non-current liabilities total	284.0	161.6	+75.8%	152.2
Trade payables	62.1	51.9	+19.6%	59.3
Current tax liabilities	0.2	10.2	-98.2%	8.0
Other current liabilities	72.9	67.8	+7.6%	77.4
Provisions	0.1	0.0		
Interest-bearing current liabilities	30.1	30.2	-0.5%	29.3
Current liabilities total	165.3	160.0	+3.3%	173.9
Liabilities total	449.3	321.6	+39.7%	326.1
Equity and liabilities total	926.8	782.7	+18.4%	835.7



#### 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 owners of the parent company							
EUR million	a.	b.	C.	d.	e.	f.	g.	h.
Equity at 31 December 2011 before change in accounting			47.0			000.4		500.0
policies	92.2	0.5	17.6		-3.8	393.4	0.0	500.0
Effect of change in accounting policies				-25.4				-25.4
Equity at 1 January 2012	92.2	0.5	17.6	-25.4	-3.8	393.4	0.0	474.6
Profit for the period						164.5		164.5
Other comprehensive income:								
Change in value of cash flow hedges			-0.3					-0.3
Change in value of available- for-sale investments			0.3					0.3
Translation differences					1.8			1.8
Items due to remeasurement of defined benefit plans				19.2				19.2
Transactions with owners								
Dividend and capital repayment			-16.9			-183.2		-200.1
Share-based incentive plan						1.3		1.3
Other adjustments						-0.3		-0.3
Equity at 30 September 2012	92.2	0.5	0.8	-6.1	-2.0	375.7	0.0	461.1
Equity at 31 December 2012 before change in accounting policies	92.2	0.5	0.8		-2.7	420.5	0.0	511.3
Effect of change in accounting policies				0.2		-2.0		-1.8
Equity at 31 December 2012	92.2	0.5	0.8	0.2	-2.7	418.5	0.0	509.6
Profit for the period						150.5		150.5
Other comprehensive income:								
Change in value of cash flow hedges			0.1					0.1
Change in value of available- for-sale investments								0.0
Translation differences					-1.0			-1.0
Items due to remeasurement of defined benefit plans					0.0			0.0
Transactions with owners								
Dividend and capital repayment						-183.4		-183.4
Share-based incentive plan						2.0		2.0
Other adjustments			0.6			-0.9	0.0	-0.3
Equity at 30 September 2013	92.2	0.5	1.6	0.2	-3.7	386.6	0.0	477.4



#### CONSOLIDATED STATEMENT OF CASH FLOWS

EUR million	Q1–Q3/13	Q1–Q3/12	2012
Operating profit	201.8	219.5	278.3
Adjustments	29.6	29.7	41.5
Change in working capital	-39.4	-28.8	-28.9
Interest paid	-4.9	-5.6	-6.1
Interest received	2.7	4.6	4.9
Dividends received	0.3		
Income taxes paid	-58.8	-51.9	-68.6
Total net cash flow from operating activities	131.4	167.6	221.0
Investments in property, plant and equipment	-47.8	-32.7	-42.4
Investments in intangible assets	-6.1	-6.5	-6.7
Sales of property, plant and equipment and available-for-sale investments	1.6	0.9	2.0
Sales of intangible assets	-0.1		
Total net cash flow from investing activities	-52.4	-38.3	-47.1
Current loans raised	40.8	0.7	1.0
Repayments of current loans	-40.8	-0.8	-2.2
Non-current loans raised	148.9	75.0	75.0
Repayments of non-current loans	-15.9	-14.1	-26.4
Dividends paid and other distribution of profits	-183.7	-200.0	-199.9
Total net cash flow from financing activities	-50.7	-139.1	-152.4
Net change in cash and cash equivalents	28.3	-9.9	21.5
Cash and cash equivalents at the beginning of the period	145.2	123.0	123.0
Foreign exchange differences	-0.7	1.3	0.8
Net change in cash and cash equivalents	28.3	-9.9	21.5
Cash and cash equivalents at the end of the period	172.8	114.3	145.2
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	157.8	114.3	145.2
Money market investments at the end of the period	15.0		
Cash and cash equivalents in the statement of cash flows	172.8	114.3	145.2

Following adoption of the amended IAS 19 Employee Benefits standard retrospectively, the operating profit for the Q1–Q3/2012 comparative period has been adjusted accordingly by EUR -2.0 million and the adjustments item by EUR 2.0 million. The operating profit for the 2012 comparative period has been adjusted by EUR -2.6 million and the adjustments item by EUR 2.6 million.



EUR million	NT 9/13	9/12	12/12
Carrying amount at the beginning of the period	205.3	190.7	190.7
Additions	51.5	29.7	40.1
Disposals	-1.4	-0.7	-1.1
Depreciation and impairments	-19.0	-18.1	-24.5
Carrying amount at the end of the period	236.3	201.7	205.3
CHANGES IN INTANGIBLE ASSETS (EXCLUDING	GOODWILL)		
EUR million	9/13	9/12	12/12
Carrying amount at the beginning of the period	62.3	71.3	71.3
Additions	6.0	6.3	6.6
Disposals	-0.3	-0.0	-0.0
Amortisation and impairments	-8.6	-10.6	-15.5
Carrying amount at the end of the period	59.5	67.0	62.3
EUR million	9/13	9/12	12/12
CONTINGENCIES FOR OWN LIABILITIES Mortgages on land and buildings	32.0	41.0	41.0
of which those to Orion Pension Fund	02.0	9.0	9.0
Guarantees	1.9	1.4	1.5
OTHER LIABILITIES Leasing liabilities (excluding finance lease contracts) Other liabilities	6.2 0.3	5.7 0.3	6.5 0.3
DERIVATIVES			
EUR million	9/13	9/12	12/12
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA		9/12	12/12
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA		<b>9/12</b> 0.6	
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million	PS		0.3
	PS 0.6	0.6	0.3
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS	PS 0.6	0.6	0.3 52.0
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS Fair value, EUR million	PS 0.6 53.2	0.6 51.3	0.3 52.0
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS Fair value, EUR million Nominal value, EUR million	PS 0.6 53.2 0.1	0.6 51.3 0.1	0.3 52.0 0.2
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS Fair value, EUR million Nominal value, EUR million	PS 0.6 53.2 0.1	0.6 51.3 0.1	0.3 52.0 0.2 51.3
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS Fair value, EUR million Nominal value, EUR million	PS 0.6 53.2 0.1 41.7	0.6 51.3 0.1 59.1	0.3 52.0 0.2 51.3 -0.3
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS Fair value, EUR million Nominal value, EUR million INTEREST RATE SWAPS Fair value, EUR million Nominal value, EUR million	PS 0.6 53.2 0.1 41.7 -0.2	0.6 51.3 0.1 59.1 -0.3	0.3 52.0 0.2 51.3 -0.3
CURRENCY FORWARD CONTRACTS AND CURRENCY SWA Fair value, EUR million Nominal value, EUR million CURRENCY OPTIONS Fair value, EUR million Nominal value, EUR million INTEREST RATE SWAPS Fair value, EUR million	PS 0.6 53.2 0.1 41.7 -0.2	0.6 51.3 0.1 59.1 -0.3	0.3 52.0 0.2 51.3 -0.3 22.3

#### ELECTRICITY DERIVATIVES

ELECTRICITY DERIVATIVES			
Fair value, EUR million	-0.4	-0.5	-0.6
Nominal amount, GWh	70	125	110



20 (26)

#### DERIVATIVE CATEGORIES USING FAIR VALUE HIERARCHY

EUR million	Level 1	Level 2	Level 3	Total
Currency forward contracts and currency swaps		0.6		0.6
Currency options		0.1		0.1
Interest rate swaps		-0.2		-0.2
Cross currency swaps		0.0		0.0
Electricity derivatives	-0.4			-0.4

All derivatives are OTC derivatives, and market quotations available at the end of the reporting period have been used as their fair value.

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 has occurred.

No transfers between levels occurred during the reporting period.

#### **RELATED PARTY TRANSACTIONS**

EUR million	Q1–Q3/13	Q1–Q3/12	2012
Management's employment benefits	5.4	3.9	4.4



## Operating segment performance

### NET SALES BY BUSINESS DIVISION

EUR million	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Pharmaceuticals	224.1	234.2	-4.3%	693.3	686.8	+0.9%	928.9
Proprietary Products	91.9	106.8	-14.0%	285.0	299.9	-5.0%	403.7
Specialty Products	91.3	92.7	-1.5%	279.0	269.6	+3.5%	367.2
Animal Health	18.0	17.5	+3.3%	52.6	51.6	+1.8%	69.2
Fermion	11.9	8.1	+47.0%	46.2	36.4	+26.9%	48.4
Contract manufacturing and other	11.0	9.2	+20.0%	30.6	29.3	+4.5%	40.5
Diagnostics	13.5	12.1	+11.3%	43.4	41.1	+5.6%	54.1
Group items	-0.7	-0.5	+25.1%	-2.3	-1.9	+21.9%	-2.7
Group total	236.9	245.8	-3.6%	734.3	726.0	+1.1%	980.4

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

EUR million	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Pharmaceuticals	66.7	78.0	-14.4%	205.0	224.3	-8.6%	286.5
Diagnostics	2.0	0.0		3.9	2.9	+33.0%	2.3
Group items	-2.2	-2.3	+7.3%	-7.1	-7.7	-8.2%	-10.6
Group total	66.6	75.6	-11.9%	201.8	219.5	-8.1%	278.3

### NET SALES BY ANNUAL QUARTERS

		2013			2012				
EUR million	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4	
Pharmaceuticals	224.1	235.0	234.2	242.1	234.2	220.1	232.5	223.8	
Diagnostics	13.5	14.0	15.9	13.1	12.1	13.4	15.5	12.9	
Group items	-0.7	-0.9	-0.8	-0.8	-0.5	-0.7	-0.6	-0.6	
Group total	236.9	248.0	249.4	254.4	245.8	232.8	247.4	236.1	

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

		2013			2012			
EUR million	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Pharmaceuticals	66.7	64.4	73.9	62.2	78.0	67.5	78.8	61.4
Diagnostics	2.0	-0.4	2.3	-0.6	0.0	0.5	2.5	0.7
Group items	-2.2	-2.9	-2.0	-2.9	-2.3	-2.7	-2.7	-2.5
Group total	66.6	61.1	74.1	58.8	75.6	65.3	78.6	59.6

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

		2013		2012				2011
EUR million	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Finland	67.6	67.7	67.8	67.3	63.3	62.7	64.0	61.7
Scandinavia	30.7	34.5	32.5	33.3	30.3	30.3	32.4	28.5
Other Europe	77.6	83.6	75.7	68.1	76.5	79.2	78.7	79.6
North America	32.7	33.6	34.5	54.7	27.1	30.4	38.4	36.0
Other markets	28.2	28.8	38.8	31.0	48.6	30.2	33.9	30.3
Group total	236.9	248.0	249.4	254.4	245.8	232.8	247.4	236.1



### **Business reviews**

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

EUR million	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Net sales	224.1	234.2	-4.3%	693.3	686.8	+0.9%	928.9
Operating profit	66.7	78.0	-14.4%	205.0	224.3	-8.6%	286.5
% of net sales	29.8%	33.3%		29.6%	32.7%		30.8%
R&D expenses	19.7	24.4	-19.2%	66.2	68.0	-2.5%	97.6
% of net sales	8.8%	10.4%		9.6%	9.9%		10.5%
Capital expenditure	20.0	11.7	+70.3%	55.1	32.6	+69.1%	42.0
% of net sales	8.9%	5.0%		8.0%	4.7%		4.5%
Sales revenue from proprietary products	98.3	114.0	-13.8%	304.6	318.7	-4.4%	429.0
Assets				688.0	605.9		627.3
Liabilities				125.6	112.5		128.4
Personnel at the end of the period				3,193	3,120		3,123

### TOP TEN BEST-SELLING PHARMACEUTICAL PRODUCTS

EUR million	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Stalevo <sup>®</sup> , Comtess <sup>®</sup> and Comtan <sup>®</sup> (Parkinson's disease)	45.0	74.1	-39.3%	155.8	192.2	-19.0%	250.1
Precedex <sup>®</sup> (intensive care sedative)	17.6	7.2	+143.0%	40.5	28.4	+42.5%	45.3
Simdax <sup>®</sup> (acute decompensated heart failure)	10.6	10.3	+2.7%	33.2	32.1	+3.4%	43.6
Easyhaler <sup>®</sup> product family (asthma, COPD)	7.4	6.2	+19.9%	20.9	20.4	+2.6%	26.8
Dexdomitor <sup>®</sup> , Domitor <sup>®</sup> , Domosedan <sup>®</sup> and Antisedan <sup>®</sup> (animal sedatives)	7.0	6.4	+10.7%	18.0	16.4	+9.8%	22.8
dexdor <sup>®</sup> (intensive care sedative)	6.1	3.2	+92.3%	18.0	8.0	+125.0%	13.0
Burana <sup>®</sup> (inflammatory pain)	5.9	6.1	-3.5%	17.1	17.5	-2.3%	23.3
Marevan <sup>®</sup> (anticoagulant)	3.7	3.9	-4.9%	11.8	12.2	-2.8%	15.8
Divina <sup>®</sup> range (menopausal symptoms)	3.1	3.4	-7.8%	10.5	11.5	-8.9%	15.5
Trexan <sup>®</sup> (rheumatoid arthritis, cancer)	3.0	3.1	-3.3%	8.6	8.0	+7.8%	10.7
Total	109.4	123.9	-11.7%	334.4	346.7	-3.5%	466.9
Share of pharmaceutical net sales	49%	53%		48%	50%		50%

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

EUR million	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Net sales	13.5	12.1	+11.3%	43.4	41.1	+5.6%	54.1
Operating profit	2.0	0.0		3.9	2.9	+33.0%	2.3
% of net sales	15.1%	0.1%		9.0%	7.1%		4.3%
R&D expenses	1.6	2.0	-18.7%	6.1	5.9	+3.2%	8.3
% of net sales	12.0%	16.4%		14.2%	14.5%		15.4%
Capital expenditure	0.8	0.6	+28.1%	2.1	2.9	-29.1%	4.2
% of net sales	6.0%	5.2%		4.8%	7.1%		7.7%
Assets				48.8	45.7		47.2
Liabilities				15.1	15.3		16.2
Personnel at the end of the period				314	346		340



### Information on Orion's shares

#### **BASIC SHARE INFORMATION 30 SEPTEMBER 2013**

	A shares	B shares	Total
Trading code on NASDAQ OMX 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	27.5	64.7	92.2
Counter book value per share, EUR	0.65	0.65	
Total number of shares	42,172,816	99,085,012	141,257,828
% of total share stock	30%	70%	100%
Number of treasury shares		188,991	188,991
Total number of shares excluding treasury shares	42,172,816	98,896,021	141,068,837
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	843,456,320	98,896,021	942,352,341
% of total votes	90%	10%	100%
Total number of shareholders	18,323	44,017	56,142

A shares and B shares confer equal rights to the Company's assets and dividends.

#### **INFORMATION ON TRADING ON NASDAQ OMX HELSINKI 1 JANUARY – 30 SEPTEMBER 2013**

	A shares	B shares	Total
Shares traded	2,362,006	63,061,262	65,423,268
% of the total number of shares	5.5%	64.0%	46.3%
Trading volume, EUR million	49.1	1,283.8	1,332.9
Closing quotation on 31 December 2012, EUR	22.05	22.18	
Lowest quotation, EUR (A 24 June and B 4 September 2013)	17.30	17.28	
Average quotation, EUR	20.80	20.36	
Highest quotation, EUR (A and B 8 March 2013)	24.42	24.58	
Closing quotation on 30 September 2013, EUR	18.66	18.62	
Market capitalisation on 30 September 2013			
excluding treasury shares, EUR million	786.9	1,841.4	2,628.4

#### PERFORMANCE PER SHARE

	Q3/13	Q3/12	Change %	Q1–Q3/13	Q1–Q3/12	Change %	2012
Basic earnings per share, EUR	0.35	0.40	-13.4%	1.07	1.17	-8.6%	1.47
Diluted earnings per share, EUR	0.35	0.40	-13.4%	1.07	1.17	-8.6%	1.47
Cash flow per share before financial items, EUR	0.29	0.42	-30.4%	0.56	0.92	-38.9%	1.23
Equity per share, EUR				3.38	3.27	+3.4%	3.62
Average number of shares excluding treasury shares, 1,000 shares	141,069	140,932		141,039	140,909		140,915



### 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 2012 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 2013. The amendments to IFRS standards had no effect on the Consolidated Financial Statements. The effects of the amendment to the IAS 19 standard on the Consolidated Financial Statements are described in more detail below.

# Effect of amendment to IAS 19 Employee Benefits standard on the Orion Group's Consolidated Financial Statements

The Orion Group has changed its accounting procedure concerning defined benefit plans to comply with the requirements of the amended IAS 19 Employee Benefits standard. The Group has stopped using the corridor approach and, in accordance with the amended standard, recognises all amounts arising from remeasurement of defined benefit plan assets directly into the components of other comprehensive income. The Group continues the accounting procedure of function-based recognition of net interest arising from the plan assets through service costs above the operating profit. The accounting policy in accordance with the amended standard has been applied retroactively as of 1 January 2013.

The restated figures in the Orion Group's Consolidated Statement of Comprehensive Income and Statement of Financial Position and key figures for the financial year 2012 are presented by annual quarters in the table appended to this Interim Report. The amendment to the IAS 19 standard decreased the operating profit for the 2012 financial year by EUR 2.6 million. The net effect of the amendment on equity at 31 December 2012 was EUR -1.8 million. The amendment decreased the equity at 1 January 2012 by EUR 25.4 million, but increased the equity during the 2012 financial year by EUR 23.6 million.

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



Restated figures in Consolidated Statement of Comprehensive Income and Statement of Financial Position and other key figures for 2012

	Q1	/12	Q1	–Q2/12	Q	1–Q3/12	(	Q1–Q4/12
	Reported earlier	Restated	Reported earlier	Restated	Reported earlier	Restated	Reported earlier	Restated
Operating profit, EUR million	79.3	78.6	145.2	143.9	221.5	219.5	280.9	278.3
% of net sales	32.0%	31.8%	30.2%	30.0%	30.5%	30.2%	28.7%	28.4%
Profit before taxes, EUR million	79.3	78.7	144.5	143.2	220.5	218.5	279.3	276.6
% of net sales	32.1%	31.8%	30.1%	29.8%	30.4%	30.1%	28.5%	28.2%
Income tax expense, EUR million	19.7	19.5	35.6	35.3	54.5	54.0	70.4	69.7
R&D expenses, EUR million	22.8	23.1	47.1	47.5	73.2	73.9	104.8	105.8
% of net sales	9.2%	9.3%	9.8%	9.9%	10.1%	10.2%	10.7%	10.8%
Cost of goods sold, EUR million	86.6	86.8	168.5	169.0	253.7	254.4	350.0	350.8
% of net sales	35.0%	35.1%	35.1%	35.2%	34.9%	35.0%	35.7%	35.8%
Sales and marketing expenses, EUR million	49.2	49.3	98.1	98.3	147.5	147.8	205.7	206.1
% of net sales	19.9%	19.9%	20.4%	20.5%	20.3%	20.4%	21.0%	21.0%
Administrative expenses, EUR million	11.1	11.2	22.6	22.8	32.2	32.5	45.3	45.7
% of net sales	4.5%	4.5%	4.7%	4.7%	4.4%	4.5%	4.6%	4.7%
Profit for the period, EUR million	59.6	59.1	108.8	107.8	166.0	164.5	208.9	206.9
Other comprehensive income net of tax, EUR million	0.2	6.6	1.3	14.1	1.9	21.1	1.1	26.7
Pension assets, EUR million	38.0	13.0	38.7	21.5	39.3	30.1	39.6	38.4
Pension liabilities, EUR million	0.5	1.2	0.5	1.3	0.5	1.4	0.3	1.4
Deferred tax liabilities, EUR million	41.6	35.3	42.4	38.0	42.1	39.6	43.1	42.5
Equity total, EUR million	360.5	341.1	410.9	397.4	468.7	461.1	511.3	509.6
Assets total, EUR million	905.2	880.1	746.1	729.0	791.9	782.7	836.9	835.7
Equity ratio, %	39.8%	38.8%	55.1%	54.5%	59.2%	58.9%	61.1%	61.0%
Gearing, % Non-interest-bearing liabilities,	-20.0%	-21.2%	23.2%	24.0%	7.6%	7.7%	-1.7%	-1.7%
EUR million	380.9	375.4	177.5	174.1	173.0	171.7	189.0	189.5
ROCE (before taxes), %	57.8%	58.4%	51.4%	51.6%	50.0%	49.9%	46.2%	45.9%
ROE (after taxes), %	55.4%	56.2%	47.8%	48.1%	45.7%	45.6%	41.3%	41.0%
Basic earnings per share, EUR	0.42	0.42	0.77	0.77	1.18	1.17	1.48	1.47
Diluted earnings per share, EUR	0.42	0.42	0.77	0.77	1.18	1.17	1.48	1.47
Equity per share, EUR	2.56	2.42	2.92	2.82	3.33	3.27	3.63	3.62
Personnel expenses, EUR million	52.6	53.3	105.7	107.0	152.8	154.8	212.1	214.8

### 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 (ROCE), %	= -	Profit before taxes + Interest and other finance expenses Total assets - Non-interest-bearing liabilities (average during the period)			
Return on equity (ROE), %	= -	Profit for the period Total equity (average during the period)	— x 100		
Equity ratio, %	= -	Equity Total assets - Advances received	— x 100		
Gearing, %	=	Interest-bearing liabilities - Cash and cash equivalents - Money market investments 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 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 shares			
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 ${\bf x}$ Closing quotation of the period			

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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. Pharmaceutical R&D focuses on central nervous system drugs, oncology and critical care drugs, and Easyhaler<sup>®</sup> pulmonary drugs.

Orion's net sales in 2012 amounted to EUR 980 million and the Company had about 3,500 employees. Orion's A and B shares are listed on NASDAQ OMX Helsinki.