

Orion Group Interim Report 1-9/2018





ORION CORPORATION INTERIM REPORT JANUARY-SEPTEMBER 2018 24 OCTOBER 2018 at 12.00 EEST

# Orion Group Interim Report January-September 2018

Orion's net sales for continuing operations in January-September 2018 totalled EUR 715 million (net sales in January-September 2017 were EUR 768 million).

- Operating profit for continuing operations was EUR 184 (214) million.
- Profit for continuing operations before taxes was EUR 181 (209) million.
- Equity ratio was 69% (62%).
- ROCE before taxes was 50% (38%).
- ROE after taxes was 52% (37%).
- Basic earnings per share for continuing operations were EUR 1.02 (1.18) and basic earnings per share including also discontinued operations were EUR 1.97 (1.22).
- Cash flow per share before financial items was EUR 2.10 (0.86).
- The sale of the Orion Diagnostica business division was closed on 30 April 2018. Following the transaction, the Group has only one reporting segment, Pharmaceuticals business. In the Interim Report, Orion Diagnostica business is reported as a discontinued operation, and as a rule, the report only covers continuing operations.
- On 24 October 2018, Orion and Bayer announced that Phase III trial of prostate cancer drug darolutamide met primary endpoint.
- Outlook remains unchanged: Orion estimates that in 2018 the net sales excluding Orion
  Diagnostica will be at the same level or slightly lower than in 2017 and the operating profit
  excluding Orion Diagnostica and material capital gains is estimated to be lower than in 2017. The
  complete outlook estimate and the basis for it can be found in this report under 'Outlook for 2018'
  and 'Basis for outlook'.

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

Continuing operations	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Net sales, EUR million	221.8	241.5	-8.2%	715.1	767.6	-6.8%	1,033.6
Operating profit, EUR million	44.6	54.9	-18.7%	184.2	213.7	-13.8%	284.1
% of net sales	20.1%	22.7%		25.8%	27.8%		27.5%
Profit before taxes, EUR million	43.6	54.0	-19.3%	180.9	208.7	-13.3%	277.7
% of net sales	19.6%	22.4%		25.3%	27.2%		26.9%
Income tax expense, EUR million	9.3	11.4	-18.0%	37.3	44.0	-15.3%	58.6
R&D expenses, EUR million	24.5	23.3	+5.1%	76.2	72.6	+5.0%	99.1
% of net sales	11.1%	9.7%		10.7%	9.5%		9.6%
Capital expenditure, EUR million	9.6	21.5	-55.3%	29.4	60.1	-51.1%	75.0
% of net sales	4.3%	8.9%		4.1%	7.8%		7.2%
Basic earnings per share, EUR	0.24	0.31	-22.6%	1.02	1.18	-13.2%	1.56
Diluted earnings per share, EUR	0.24	0.31	-22.6%	1.02	1.18	-13.2%	1.56
Personnel at the end of the period				3,145	3,199	-1.7%	3,161
Average personnel during the period				3,188	3,219	-1.0%	3,205



Continuing and discontinued operations	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Assets total, EUR million				1,088.7	970.1	+12.2%	1,055.5
Equity ratio, %				69.1%	61.6%		64.6%
Gearing, %				-14.0%	3.1%		-1.9%
Interest-bearing liabilities, EUR million				151.5	151.4	+0.1%	151.3
Non-interest-bearing liabilities, EUR million				200.4	224.2	-10.6%	224.5
Cash and cash equivalents and money market investments, EUR million				254.8	133.1	+91.5%	164.1
ROCE (before taxes), %				49.7%	38.3%		36.2%
ROE (after taxes), %				52.2%	36.9%		34.2%
Basic earnings per share, EUR	0.24	0.31	-22.1%	1.97	1.22	+62.1%	1.61
Diluted earnings per share, EUR	0.24	0.31	-22.1%	1.97	1.22	+62.1%	1.61
Cash flow per share before financial items, EUR	0.36	0.47	-24.5%	2.10	0.86	+143.3%	1.09
Equity per share, EUR				5.24	4.23	+23.8%	4.83
Personnel expenses, EUR million				150.6	159.1	-5.3%	218.1
Discontinued operations	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Profit for the period as stated in the consolidated statement of comprehensive income, EUR million		1.4	-100.0%	133.4	6.2		6.9

Discontinued operations	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Profit for the period as stated in the consolidated statement of comprehensive income, EUR million		1.4	-100.0%	133.4	6.2		6.9
Capital gain, EUR million				128.4			
Sales-related expenses, EUR million				-0.8			
Item related to transfer of benefit pension plans, EUR million				4.5			
Basic earnings per share, EUR		0.01	-100.0%	0.95	0.04		0.05
Diluted earnings per share, EUR		0.01	-100.0%	0.95	0.04		0.05



#### President and CEO Timo Lappalainen:

# Phase III trial of prostate cancer drug darolutamide met primary endpoint

"The Phase III trial of darolutamide in patients with non-metastatic castration-resistant prostate cancer, which was carried out in cooperation with Bayer, met the primary endpoint: Darolutamide significantly extended metastasis-free survival compared to placebo. We are looking forward to the full data of the ARAMIS trial, to be presented at an upcoming scientific meeting. Discussions with authorities regarding the submission for marketing authorization application are about to start. Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). Besides royalties on product sales, we are eligible to receive significant milestone payments upon first commercial sales. In addition, Orion has the option of co-promoting the product in Europe. We wish to utilise the full potential of our own proprietary molecule, and we have another, ongoing Phase III trial (ARASENS) with Bayer which evaluates darolutamide in patients with metastatic prostate cancer. This trial is expected to be completed in 2022.

Our profitability in January-September was good: our operating profit margin for continuing operations was 26%, and above our financial target. Our cash flow was stronger than in the comparative period. Net sales and operating profit for continuing operations were lower than in the comparative period. Most of the profit decrease was due to unfavourable exchange rate changes as well as milestone payments and royalties being lower than in the previous year. Other than that, the profitability was only slightly below that of the comparative period despite many challenges, including price decreases in Finland and lower sales of biosimilars.

Profitability was also affected by the R&D expenses being higher than in the comparative period. The sale of Orion Diagnostica in April has provided an additional buffer and allowed us to engage more determinedly in accelerating Group growth. For example, we established a new responsibility area for this purpose in our Executive Management Board. Orion is currently working on numerous projects that target growth. For example, we are actively evaluating in-licensing opportunities of products in the late stage of development.

We are also investing in our own clinical trials, such as REFALS, which reached Phase III in the spring. The trial evaluates orally administered levosimendan (ODM-109) for the treatment of symptoms of ALS. We are conducting this trial on our own and are investing approximately EUR 60 million in it over the next three years.

Net sales of Proprietary Products were at the previous year's level. The Easyhaler product family for the treatment of asthma and COPD is a significant source of growth for Orion in the near term. Growth remained strong in the reporting period, especially due to the budesonide-formoterol product. We expect the growth of the product family to continue, for example with our new combined formulation: the launch of the salmeterol-fluticasone Easyhaler has commenced and the first deliveries in Europe started in October. The sales of branded Parkinson's drugs were lower than in the previous year, as anticipated. Their sales saw an unusual increase in the previous quarter, which was explained by the timing of deliveries and normal fluctuation between quarters. In the longer term, we expect sales of Parkinson's drugs to continue to decrease, as the products have generic competition in practically all markets. Sales of Dexdor intensive care sedative remained at a good level and grew in most of the countries despite generic competition having expanded to a few European countries. Sales of Simdax, a drug for treatment of acute decompensated heart failure, increased slightly.

Sales of Specialty Products decreased in Finland and Scandinavia. Tougher price competition continues in Finland following decisions made in 2016 regarding the pricing of substitutable generic drugs. This has led to an overall decrease in the reference priced prescription drugs market. The impact on Orion has been significant due to our broad product range and market share. We estimate tougher price competition to reduce our sales in Finland by EUR 15 million in 2018. The impact has sustained longer than anticipated, and price competition does not appear to be significantly slowing down yet.



The sales of Remsima biosimilar (infliximab), a driver of Specialty Products sales growth last year, were significantly lower than in the comparative period. Orion has not won national tendering competitions in Denmark and Norway since the comparative period, and due to this, did not deliver Remsima to these markets at all in the third quarter. Sales development of biosimilars will continue to fluctuate depending on our success in tendering competitions also in the future. In order to succeed in this competitive and volatile market, we need a broad portfolio. Our biosimilar range is expanding with the first biosimilar for outpatient use; after the review period we have signed an agreement with Amgen on the sales and marketing of Amgevita biosimilar (adalimumab) in Finland.

The outlook remains unchanged. Orion estimates that in 2018 the net sales excluding Orion Diagnostica will be at the same level or slightly lower than in 2017 and the operating profit excluding Orion Diagnostica and material capital gains is estimated to be lower than in 2017. The complete outlook estimate and the basis for it can be found in this report under 'Outlook for 2018' and 'Basis for outlook'."



# Events during the period

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

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

# Events after the period

The deliveries of salmeterol-fluticasone Easyhaler, the sixth product in the Easyhaler product family for the treatment of asthma and COPD, started in the first countries in October.

Orion has signed an agreement with Amgen on the marketing and sales of the adalimumab biosimilar Amgevita® in Finland. This biosimilar is used in the treatment of chronic inflammatory diseases including for example moderate-to-severe rheumatoid arthritis and inflammatory intestinal diseases as well as psoriatic arthritis. Amgevita is Orion's first biosimilar for outpatient use.

On 24 October 2018 Orion and Bayer announced that they had completed the Phase III clinical trial (ARAMIS) of darolutamide, the novel oral androgen receptor antagonist for the treatment of patients with non-metastatic castration-resistant prostate cancer. The primary endpoint of the trial was met: Darolutamide significantly extended metastasis-free survival compared to placebo. The safety profile and the tolerability of darolutamide were consistent with previously published data.

The full data will be presented at an upcoming scientific meeting. Bayer plans to discuss the data from the trial with health authorities regarding the submission for marketing authorization application. Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment in men with non-metastatic castration-resistant prostate cancer.

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

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

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

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

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



#### News conference and teleconference

A news conference and teleconference on the published results will be held on Wednesday 24 October 2018 at 13.30 EEST at Orion's head office (address: Orionintie 1A, Espoo). President and CEO Timo Lappalainen will give a brief presentation in English on the financial review.

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

The conference call ID is 582178 and the telephone numbers to participate in the teleconference are:

Finland: +358 (0)9 7479 0360 Sweden: +46 (0)8 5033 6573

United Kingdom: +44 (0)330 336 9104 United States: +1 323-794-2558

#### **News conference recordings**

A recording of the webcast of the event in English and a recording of the presentation by the President and CEO in Finnish will be published on Orion's website during Wednesday 24 October 2018.

# Financial report material

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

#### Dates in Orion Calendar 2018-2019

Financial Statement Release for 2018 Annual General Meeting 2019 Interim Report January-March 2019 Half-Year Financial Report January-June 2019 Interim Report January-September 2019 Wednesday 6 February 2019 Planned to be held on Tuesday 26 March 2019 Thursday 25 April 2019 Wednesday 17 July 2019 Wednesday 23 October 2019

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

# For additional information about the report:

Jari Karlson, CFO tel. +358 50 966 2883 Lilli Riikonen, Communications Manager tel. +358 50 966 2319

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



# Financial review for 1 January-30 September 2018

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

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

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

#### **Net sales**

Orion Group's net sales in January-September 2018 totalled EUR 715 million (EUR 768 million in January-September 2017), a decrease of 7%. Of the total net sales decrease of EUR 53 million, exchange rate changes accounted for EUR 15 million and lower royalties and milestone payments than in the comparative period for EUR 9 million.

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

#### **Operating profit**

The Orion Group's operating profit was down by 14% at EUR 184 (214) million.

Gross profit from product sales was EUR 18 million lower than in the comparison period. The negative effect of net sales calculated in local currencies on gross profit was EUR 16 million. On the other hand, higher margin level and favourable product mix increased the gross profit by EUR 10 million. The single greatest cause for the decline were exchange rate changes, with a net negative effect of EUR 12 million on the gross profit.

Milestone payments and royalties were also lower than in the comparative period. Milestone payments accounted for EUR 4 (9) million and royalties for EUR 14 (18) million of net sales and operating profit. The net effect of these was EUR 9 million negative.

#### Profit impact of the sale of Orion Diagnostica

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

#### **Operating expenses**

The Group's sales and marketing expenses totalled EUR 140 (139) million.

R&D expenses were up by 5% at EUR 76 (73) million and accounted for 11% (9%) of the Group's net sales. Research projects are reported in more detail under 'Business Review'.

Administrative expenses were EUR 32 (33) million, down by 2%.

Other operating income and expenses were EUR 4 (3) million.

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

The profit of the Group's continuing operations was EUR 144 (165) million and the profit of discontinued operations was EUR 133 (6) million.



Basic earnings per share for continuing operations were EUR 1.02 (1.18) and basic earnings per share including continuing and discontinued operations were EUR 1.97 (1.22). Equity per share was EUR 5.24 (4.23).

The return on capital employed before taxes (ROCE) was 50% (38%) and the return on equity after taxes (ROE) 52% (37%).

#### Financial position including both continuing and discontinued operations

The Group's gearing was -14% (3%) and the equity ratio 69% (62%).

The Group's total liabilities at 30 September 2018 were EUR 352 (376) million. At the end of the period, interest-bearing liabilities amounted to EUR 152 (151) million, including EUR 1 (150) million of long-term loans.

The Group had EUR 255 (133) million of cash and cash equivalents and money market investments at the end of the period. The cash and cash equivalents are invested in short-term money market instruments issued by financially solid financial institutions and corporations.

#### Cash flow including both continuing and discontinued operations

Cash flow from operating activities was EUR 167 (181) million. The decrease was due to the reduction in profit. Less cash than in the comparative period was tied up in working capital.

The cash flow from investing activities was EUR 129 (-60) million positive following the sale of Orion Diagnostica. Excluding the sale of Orion Diagnostica, cash flow from investing activities was EUR -32 (-60) million, i.e. cash flow before cash flow from financing activities was better than in the comparative period even without proceeds from the sale of Orion Diagnostica.

The cash flow from financing activities was EUR -204 (-219) million.

#### Capital expenditure

The Group's capital expenditure in continuing operations totalled EUR 29 (60) million, down by 51%. This comprised EUR 26 (53) million on property, plant and equipment and EUR 4 (8) million on intangible assets. Fermion's significant expansion investment at its Hanko manufacturing plant was completed in June 2018.

#### Outlook for 2018

Due to generic and price competition Orion estimates that in 2018, the net sales excluding Orion Diagnostica will be at the same level or slightly lower than in 2017 (net sales were EUR 1,034 million excluding Orion Diagnostica in 2017).

Orion continues persistent actions to generate growth. Due to the estimated sales development and these actions the operating profit excluding Orion Diagnostica and material capital gains is estimated to be lower than in 2017 (operating profit excluding Orion Diagnostica and capital gains was EUR 284 million in 2017).

As estimated earlier, Orion has recognised a EUR 128 million capital gain in other operating income from the sale of Orion Diagnostica. Due to the uncertainty relating to the variable component included in the transaction, the capital gain does not include any part of the variable component.

#### Basis for outlook in more detail

The outlook covers the Group's continuing operations excluding Orion Diagnostica.

Items related to the sale of Orion Diagnostica and the profit generated by Orion Diagnostica for the period from 1 January to 30 April 2018 are entered as part of discontinued operations. A capital gain of EUR 128 million was booked for the transaction closed on 30 April 2018. The departure of Orion Diagnostica from



the Orion pension fund caused one-off income of EUR 5 million and the transaction process incurred expenses of approximately EUR one million. In addition, Orion has the possibility to receive a variable component of EUR 60 million maximum. The payment of the variable component is based on the return on investment for the buyer (investment fund managed by Axcel Management A/S) at the time of the exit. Due to the uncertainty relating to the variable component, the capital gain does not include any part of the variable component.

#### **Net sales**

Orion's branded Parkinson's drugs are Comtess®, Comtan® and Stalevo®. Generic competition to these products commenced in the United States in 2012 and has already extended to nearly all markets. As a result of the competition, Orion's sales of these products have decreased to low levels in the United States and some other markets, and competition is expected to extend gradually. Sales of the Easyhaler® product family are forecast to continue to grow. In some European countries, marketing authorisation has been granted for a generic version of Dexdor®. Generic competition commenced in Germany in 2017 and has expanded to a few other European countries during 2018. It is to be assumed that generic competition to the product will continue to gradually expand in the EU. Orion has also been informed that a marketing authorisation application has been filed for a generic version of Simdax® in Europe. The impact of generic competition on the sales of Dexdor and Simdax is still difficult to estimate at this stage. The patent for the Simdax molecule expired in September 2015 but this is still not expected to have a material impact on sales of the product in 2018. Orion is continuing actions to defend its rights.

Sales of generic products account for a significant proportion of Orion's total sales. Competition in Finland, the most important generic market for Orion, remains intense in 2018. However, product launches continue to support Orion's position as market leader in Finland. At the beginning of 2017, changes were made to the pricing system for substitutable prescription drugs in Finland by narrowing the so-called price band. The decrease in sales caused by this change was estimated at about EUR 15 million in 2017. The outlook for 2018 assumes that the change in the system and its effect in lowering prices will be at the same level as in 2017. The sales of reference priced pharmaceuticals declined by 9% in the Finnish pharmaceuticals market in 2017 and the sales of Orion's reference priced pharmaceuticals declined by 6% (Source: IQVIA).

In 2017, sales of the biosimilar Remsima® generated a significant portion of the growth in net sales of the Specialty Products business division. Sales of Remsima in 2018 are expected to be materially lower than in the previous year because Orion did not win the national tendering competition for 2018 in Norway, nor the national tendering competition held in autumn 2017 in Denmark. In addition, the price level has declined significantly due to intensified competition. Orion has launched a new biosimilar, Ritemvia® (rituximab). However, sales have just commenced, and the product is not expected to compensate for the decline in Remsima sales in 2018. Orion estimates that the sales potential of Ritemvia will be lower than that of Remsima.

Orion's contract manufacturing sales will significantly decline due to ending of the largest individual collaboration agreement at the end of 2017 as the collaboration partner stopped selling the product manufactured by Orion. Net sales generated by this agreement were EUR 16 million in 2017. It included, among other things, a EUR 4 million advance payment late in the year that was entered as income earlier than planned.

Collaboration agreements with other pharmaceutical companies are an important component of Orion's business model. These agreements often include payments recorded in net sales that vary greatly from year to year. 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 or findings of research projects, 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. The outlook for 2018 does not include significant individual payments related to collaboration agreements. The new IFRS 15 standard that came into force at the beginning of 2018 changes the treatment of these payments. Some of the payments received, especially payments related to sales rights, will be entered as income over a longer period of time. Until now they have generally been recognised as one-off payments in sales.



#### Expenditure

Marketing expenditure will be higher than in the previous year due to additional promotion of sales of the Easyhaler product portfolio in countries where the product was launched in 2017 or will be launched in 2018. 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 2018 were planned mainly during the previous year.

Research and development costs are estimated to be slightly higher than in 2017. 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 2018 are either continuing from the previous year or at an advanced stage of planning, therefore their cost level can be estimated rather accurately. However, the accrued costs are materially affected by collaboration arrangements and how the costs arising are allocated between Orion and its collaboration partners. For instance, Bayer is paying the majority of the darolutamide research costs.

#### Investments

The Group's total capital expenditure in 2018 is expected to be lower than in 2017, when capital expenditure was EUR 75 million. The largest single ongoing investment project, the expansion of Fermion's Hanko manufacturing plant, was completed in June 2018.

#### Near-term risks and uncertainties

Sales of Orion's branded Parkinson's drugs will decrease in 2018 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 and elsewhere still entail uncertainty that may materially affect the accuracy of the estimate made at this stage. The basic Dexdor and Simdax patents have expired. However, the products have other product protection that is still valid. In some European countries marketing authorisation has been granted for a generic version of Dexdor. Generic competition commenced in Germany in 2017 and has expanded to a few other European countries during 2018. It is to be assumed that generic competition to the product will continue to gradually expand in the EU. Orion has also been informed that a marketing authorisation application has been filed for a generic version of Simdax in Europe. The impact of generic competition on the sales of Dexdor and Simdax is difficult to estimate at this stage. As regards Simdax, the possible generic competition is still not estimated to materially impact its sales in 2018. Orion is continuing actions to defend its rights.

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

The structural exchange rate risk due to the US dollar has decreased in recent years because the share of Orion's net sales invoiced in dollars has fallen to below ten per cent and at the same time the value of purchases in dollars has increased. The greatest exchange rate risk at present relates to European currencies such as the Swedish crown and British pound. However, the overall effect of the risk due to currencies of European countries will be abated by the fact that Orion has organisations of its own in most of these countries, which means that in addition to sales income, there are also costs in these currencies. Changes in the Japanese yen exchange rate have become more important as sales of Parkinson's drugs in Japan have increased. The exchange rate effect related to the Russian rouble has increased due to the



strong volatility of the currency. However, Russian sales are not a significant portion of Orion's entire net sales.

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

Research projects always entail uncertainty factors that may either increase or decrease estimated costs. The projects may progress more slowly or faster than assumed, or they may be discontinued. Nonetheless, changes that may occur in ongoing clinical studies are reflected in costs relatively slowly, and they are not expected to have a material impact on earnings in the current year. Owing to the nature of the research process, the timetables and costs of new studies that are being started are known well in advance. They therefore typically do not lead to unexpected changes in the estimated cost structure. Orion 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 2014-2017 the annual payments varied from EUR 8 million to EUR 39 million. The payments may be subject to certain conditions relating to the development of research projects or sales, and whether these conditions are triggered and the timing of triggering always entail uncertainties.

# 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 2018, Orion had a total of 141,257,828 (141,257,828) shares, of which 37,120,346 (37,120,346) were A shares and 104,137,482 (104,137,482) B shares. The Group's share capital is EUR 92,238,541.46 (92,238,541.46). At the end of September 2018, Orion held 562,440 (675,401) B shares as treasury shares. On 30 September 2018, the aggregate number of votes conferred by the A and B shares was 845,981,962 (845,869,001) excluding treasury shares.

At the end of September 2018, Orion had 73,337 (50,745) registered shareholders.

#### Voting rights conferred by shares

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

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



#### Conversion of shares

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

#### Trading in Orion's shares

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

On 30 September 2018, the market capitalisation of the Company's shares, excluding treasury shares, was EUR 4,585 million.

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

#### **Authorisations of the Board of Directors**

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

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

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

#### Share-based incentive plans

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

#### 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 2018, Orion had a total of 73,337 (50,745) registered shareholders, of whom 95% (96%) were private individuals. They held 43% (38%) of the entire share stock and had 62% (61%) of the total votes. There were 46 (63) million nominee-registered and foreign-owned shares, which was 32% (45%) of all shares, and they conferred entitlement to 7% (10%) of the total votes.

At the end of September 2018, Orion held 562,440 (675,401) B shares as treasury shares, which is 0.40% (0.48%) of the Company's total share stock and 0.07% (0.08%) of the total votes.

# Personnel

The average number of employees in the Orion Group in January-September 2018 was 3,188 (3,219). At the end of September 2018, the Group had a total of 3,145 (3,199) employees, of whom 2,473 (2,550) worked in Finland and 672 (649) outside Finland.

Salaries and other personnel expenses in January-September 2018 totalled EUR 151 (159) million.



# Significant legal proceedings

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



### **Business review**

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

#### Review of human pharmaceuticals market

Finland is the most important individual market for Orion, generating about one-third of the Group's net sales. According to IQVIA statistics, a significant share of Orion's prescription drug sales in the Finnish pharmacy channel, approximately 68%, were reference priced drugs in January-September 2018. The sales of Orion's reference priced prescription drugs decreased slightly more than the market. The decline was mostly due to the change made in the pricing system for substitutable prescription drugs at the beginning 2017, which was followed by toughened price competition. The average price of reference priced drugs has decreased during 2018 approximately 10% from the comparative period. The impact of price competition on Orion has been significant due to the company's broad product range and significant market share in Finland. The total sales of Orion's human pharmaceuticals, including both medicinal and non-medicinal products, was clearly behind market trend in January-September 2018. The growth in the Finnish pharmaceuticals market has mostly been generated by proprietary products, while proprietary products only account for a small share of Orion's net sales in Finland.

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

EUR million	1-9/18	1-9/17	Change %
Reference priced prescription drugs (pharmacy channel)			
Market	368	397	-7%
Orion	91	102	-11%
Self-care products (pharmacy channel)			
Market	286	277	+3%
Orion	71	71	-1%
Total sales of human pharmaceuticals (hospital and pharmacy channel)			
Market	1,990	1,855	+7%
Orion	230	253	-9%

Source: IQVIA pharmaceutical sales statistics 1-9/2018

Despite the challenging operating environment, Orion has maintained its position as leader in marketing pharmaceuticals in Finland. Orion has a particularly strong position in reference priced prescription drugs and in self-care product sales, with its market share being a guarter of the market in each.

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

Orion's market share, %	1-9/18	1-9/17
Reference priced prescription drugs		
(pharmacy channel)	25%	26%
Self-care products (pharmacy channel)	25%	26%
Human pharmaceuticals in total (hospital		
and pharmacy channel)	12%	14%

Source: IQVIA pharmaceutical sales statistics 1-9/2018

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



The most important individual therapy area for Orion is still the treatment of Parkinson's disease. Orion's branded Parkinson's drugs containing entacapone (Stalevo®, Comtess® and Comtan®) accounted for 11% of the Group's net sales in January-September 2018.

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

EUR or USD million	on	MAT6/2018	MAT6/2017	Change %
United States	USD	5	7	-27%
Europe TOP 5	EUR	45	60	-25%
Japan	EUR	69	77	-11%

Source: IQVIA pharmaceutical sales statistics MAT6/2018 (7/2017–6/2018) Europe TOP 5: Germany, United Kingdom, France, Spain and Italy

According to IQVIA pharmaceutical sales statistics, in Europe total sales of the most common intravenous anaesthetics and intensive care sedatives (propofol, midazolam, remifentanil and dexmedetomidine) in the 12-month period ending in June 2018 were up by 3% at EUR 553 (537) million. According to IQVIA pharmaceutical sales statistics, sales of Orion's Dexdor® intensive care sedative (dexmedetomidine) were up by 10% at EUR 64 (58) million in Europe.

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

Net sales of the Pharmaceuticals business in January-September 2018 were down by 7% at EUR 715 (768) million. The Pharmaceuticals business's operating profit was down by 13% at EUR 193 (221) million. Milestone payments and royalties accounted for EUR 18 (27) million of the net sales and operating profit.

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

Net sales of Orion's top ten pharmaceuticals in January-September 2018 were EUR 332 (354) million. They accounted for 46% (46%) of the total net sales of the Pharmaceuticals business.

#### **Proprietary Products**

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

Net sales of the Proprietary Products business division in January-September 2018 were at level with the previous year at EUR 261 (261) million.

Orion's drugs for treatment of Parkinson's disease are Stalevo® (active pharmaceutical ingredients carbidopa, levodopa and entacapone) and Comtess®/Comtan® (entacapone). Their total net sales in January-September 2018 were down by 5% at EUR 76 (80) million. As anticipated, deliveries to key partners over the summer were lower than in the previous year due to the timing of deliveries and normal fluctuation between quarters. There were more deliveries than is typical in the previous quarter. In the longer term, Orion expects sales of Parkinson's drugs to continue to decrease, as the products have generic competition in practically all markets. In the United States, Orion's Parkinson's drugs have several generic competitors, and competition is increasing in Europe and also in other markets. In Japan Comtan has generic competitors, but generic competition to Stalevo has not yet commenced.

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

EUR million	1-9/18	1-9/17	Change %
Deliveries to key partners	59	60	-1%
Orion's own sales	17	20	-18%

ORION INTERIM REPORT 1-9/2018



Total net sales of the Easyhaler® product family for treatment of asthma and chronic obstructive pulmonary disease were up by 17% in January-September 2018 at EUR 64 (55) million. The increase was mainly due to sales of the budesonide-formoterol combined formulation.

Sales of the budesonide-formoterol combined formulation were up by 27% in January-September 2018 at EUR 36 (28) million. The product was launched in several countries in 2017, and it is now on sale in all key European markets. Besides Orion's sales, co-marketing partner Menarini sells the budesodine-formoterol combined formulation in France and in a few Southern European countries. The first marketing authorisation applications have also been submitted outside Europe. Menarini is the distributor of the budesonide-formoterol combined formulation in the Asia and Pacific region, and Hikma Pharmaceuticals PLC in the Middle East and North Africa. Orion's market position in the budesonide-formoterol product varies considerably by country: for example in Sweden, Orion had a strong position with a 38% share of the market in the review period, while in Germany, Orion's share was just 7%. During this year, Orion has increased resources in the sales and marketing of the Easyhaler product family.

In March 2018, Orion received positive conclusions for the salmeterol-fluticasone Easyhaler under the decentralised EU marketing authorisation procedure, and the national approval procedures of the marketing authorisation applications started in 23 EU countries. National marketing authorisations have been acquired for several countries, and deliveries of the product to the first countries started after the review period in October. The salmeterol-fluticasone combined formulation is the sixth product of the Easyhaler product family. Orion is also currently engaged in developing a seventh Easyhaler product, with tiotropium as the active pharmaceutical ingredient, for the European market. The expansion of Easyhaler production facility at the Espoo pharmaceuticals production plant was completed in the first half of the year, which will allow production volumes to increase as the product family expands.

Net sales of Orion's Dexdor® intensive care sedative (dexmedetomidine) grew by 2% to EUR 48 (47) million in January-September 2018. Sales continued to grow in most of the European markets. In some European countries, marketing authorisation has been granted for generic versions of Dexdor, and it is to be assumed that generic competition to the product will continue to gradually expand in the EU. In January-September 2018 there was significant generic competition only in Germany, but competition has now expanded to a few other European countries as well. Orion is continuing actions to defend its rights. The impact of generic competition on sales is still difficult to estimate at this stage. Sales of the Precedex® intensive care sedative were down by 14% at EUR 16 (18) million.

Simdax®, a drug for treatment of acute decompensated heart failure is sold in some 60 countries worldwide. Net sales of the product in January-September 2018 were up 2% at EUR 43 (43) million. Orion was informed in the first quarter of this year that a marketing authorisation application has been filed for a generic version of Simdax in Europe. The patent for the product's molecule expired in September 2015, but possible generic competition is still not expected to have a material impact on sales of the product in 2018.

#### **Specialty Products**

Net sales of the Specialty Products business division's off-patent, i.e. generic prescription drugs, self-care products and biosimilars were down in January-September 2018 by 10% at EUR 347 (387) million.

70% of the net sales of Specialty Products came from generic drugs, 24% from self-care products and 6% from biosimilars.

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 2018 were EUR 200 (217) million, down by 8%. Sales declined in particular due to continued tough price competition, mostly resulting from the changing operating environment: the change made to the pricing system of substitutable prescription drugs in Finland at the beginning of 2017.

In Scandinavia, sales totalled EUR 51 (72) million, down by 29%. The decline in sales was in particular due to the decreased sales of the biosimilar Remsima®. In Eastern Europe and Russia, sales were at level with the previous year at EUR 47 (47) million.



The biosimilars net sales totalled EUR 19 (45) million, down by 57%. Net sales of Remsima® (infliximab), a biosimilar for the treatment of rheumatoid arthritis among other things, were EUR 14 (45) million. The sales declined by 68% due to the situation of tendering competitions, increasing competition with new competitors entering the market in the beginning of the year, and the subsequently significantly declined price level. Sales development will continue to fluctuate depending on the success in tendering competitions also in the future.

In the first quarter of 2018, Orion launched its second biosimilar, Ritemvia® (rituximab) for treatment of lymphoma, among other things. Orion has the distribution rights for the product in the Nordic countries and Estonia. Sales of Ritemvia are expected to be less than for Remsima, and it is not expected to compensate for the decline in Remsima sales in 2018. Orion estimates that the sales potential of Ritemvia will be lower than that of Remsima.

In the second quarter, Orion signed an agreement with Celltrion on the sales, marketing and distribution of the biosimilar trastuzumab in the Nordic countries and Estonia. The launch schedule of trastuzumab remains open and depends on the patent situation and on the timing of tendering competitions, among other things.

After the review period, Orion signed an agreement with Amgen on the marketing and sales of the biosimilar Amgevita® (adalimumab) in Finland. This biosimilar is used in the treatment of chronic inflammatory diseases including for example moderate-to-severe rheumatoid arthritis and inflammatory intestinal diseases as well as psoriatic arthritis. Amgevita is Orion's first biosimilar for outpatient use, the other biosimilars represented by Orion being solely for hospital use.

#### **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 2018 were up by 4% at EUR 58 (56) million, mostly due to the timing of deliveries to partners. Sales of animal sedative products accounted for 40% (39%) of the division's net sales. The product family comprises Orion's animal sedatives Dexdomitor® (dexmedetomidine), Domitor® (medetomidine) and Domosedan® (detomidine), and antagonist Antisedan® (atipamezole), which reverses the effects of the sedatives. In February 2018, Orion received positive conclusions under the decentralised EU marketing authorisation procedure for Clevor®. Clevor, with ropinirole as the active ingredient, is an eye-drop formula designed to treat poisoning in dogs.

#### **Fermion**

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

Fermion's net sales in January-September 2018 excluding deliveries for Orion's own use were EUR 38 (40) million and accounted for over one-half of Fermion's total net sales. In recent years order cycles in the trade in pharmaceutical raw materials have become ever shorter, and this has led to clearly greater fluctuation in business volume than before within each year and between different years.

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



#### Research and development

The Group's R&D expenses totalled EUR 76 (73) million in January-September 2018, up 5%, and accounted for 11% (9%) of the Group's net sales. R&D expenses also include expenses related to development of the current portfolio.

In March 2018, Orion received positive conclusions for the salmeterol-fluticasone Easyhaler under the decentralised EU marketing authorisation procedure. The national approval procedures of the marketing authorisation applications started in 23 EU countries. The national marketing authorisations have been acquired already in several countries, and product deliveries to the first countries started after the review period in October. The inhaled salmeterol-fluticasone combined formulation is the sixth member of the Easyhaler product family for the treatment of asthma and COPD. In the salmeterol-fluticasone combined formulation, fluticasone acts as an anti-inflammatory agent and salmeterol acts as a long-acting bronchodilator. The Easyhaler product family offers diverse treatment options for asthma and COPD using the same inhaler technology. Orion's Easyhaler is a dry-powder inhaler developed in-house, for which Orion has developed Easyhaler-adapted dry powder formulations of several well-known generic active substances (salbutamol, beclometasone, budesonide, formoterol, salmeterol and fluticasone).

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

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

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

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



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

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

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

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

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

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



# Discontinued operations: Diagnostics

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

Espoo, 24 October 2018

Board of Directors of Orion Corporation

**Orion Corporation** 

Timo Lappalainen President and CEO Jari Karlson *CFO* 



# Tables CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

# **Continuing operations**

Continuing Operations		Adjusted			Adjusted		Adjusted
EUR million	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Net sales	221.8	241.5	-8.2%	715.1	767.6	-6.8%	1,033.6
Cost of goods sold	-99.2	-112.0	-11.5%	-286.7	-312.6	-8.3%	-417.6
Gross profit	122.6	129.5	-5.3%	428.4	455.0	-5.9%	616.0
Other operating income and expenses	0.4	1.5	-73.7%	4.0	3.2	+25.8%	4.9
Sales and marketing expenses	-43.4	-43.5		-139.9	-139.2	+0.5%	-188.9
R&D expenses	-24.5	-23.3	+5.1%	-76.2	-72.6	+5.0%	-99.1
Administrative expenses	-10.4	-9.3	+12.2%	-32.1	-32.8	-2.0%	-48.8
Operating profit	44.6	54.9	-18.7%	184.2	213.7	-13.8%	284.1
Finance income	0.1	0.1	-38.4%	0.0	2.0	-98.7%	0.1
Finance expenses	-1.2	-1.0	+11.7%	-3.3	-7.0	-52.3%	-6.6
Profit before taxes	43.6	54.0	-19.3%	180.9	208.7	-13.3%	277.7
Income tax expense	-9.3	-11.4	-18.0%	-37.3	-44.0	-15.3%	-58.6
Profit for the period for continuing operations	34.3	42.6	-19.5%	143.6	164.7	-12.8%	219.1
Profit for the period for discontinued operations		1.4	-100.0%	133.4	6.2		6.9
Profit for the period	34.3	44.1	-22.3%	277.1	170.8	+62.3%	226.0
OTHER COMPREHENSIVE INCOME INCLUDING TAX EF  Translation differences	-0.1	0.0		-1.2	-1.1		-1.4
Items that may be reclassified subsequently to profit and loss	-0.1	0.0		-1.2	-1.1		-1.4
Items due to remeasurement of defined benefit pension plans (continuing operations)				-4.5	0.0		27.4
Items due to remeasurement of defined benefit pension plans (discontinued operations)				2.9	0.0		2.5
Items that will not be reclassified to profit and loss				-1.6	0.0		29.9
Other comprehensive income net of tax  Comprehensive income for the period including tax	-0.1	0.0	+683.4%	-2.8	-1.1	+150.1%	28.5
effects	34.3	44.1	-22.4%	274.3	169.7	+61.7%	254.5
PROFIT ATTRIBUTABLE TO <sup>1</sup>			00.007		470.0	00.00/	
Owners of the parent company	34.3	44.1	-22.3%	277.1	170.8	+62.3%	226.0
Non-controlling interests  COMPREHENSIVE INCOME ATTRIBUTABLE TO¹		0.0			0.0		-0.0
Owners of the parent company	34.3	44.1	-22.4%	274.3	169.7	+61.7%	254.5
Non-controlling interests		0.0			0.0		-0.0
Continuing operations							
Basic earnings per share, EUR <sup>2</sup>	0.24	0.31	-22.6%	1.02	1.18	-13.2%	1.56
Diluted earnings per share, EUR <sup>2</sup>	0.24	0.31	-22.6%	1.02	1.18	-13.2%	1.56
Depreciation, amortisation and impairment	9.9	9.8	+1.6%	29.9	29.2	+2.7%	39.5
Personnel expenses	44.3	44.0	+0.7%	144.0	148.6	-3.1%	203.9



#### **Discontinued operations**

Basic earnings per share, EUR <sup>2</sup>	0.01	-100.0%	0.95	0.04		0.05
Diluted earnings per share, EUR <sup>2</sup>	0.01	-100.0%	0.95	0.04		0.05
Depreciation, amortisation and impairment	0.7	-100.0%	0.8	2.1	-66.7%	2.8
Personnel expenses	3.0	-100.0%	6.6	10.5	-36.6%	14.2

<sup>&</sup>lt;sup>1</sup>The figures in the table include both continuing and discontinued operations.

<sup>&</sup>lt;sup>2</sup> The figure has been calculated from the profit attributable to the owners of the parent company.

IFRS 15 and IFRS 9 standards have been adopted by using the cumulative effect method, and therefore figures of the comparative periods have not been adjusted.



# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

EUR million	9/18	9/17	Change %	12/17
Property, plant and equipment	314.7	317.7	-0.9%	323.1
Goodwill	13.5	13.5		13.5
Intangible rights	25.9	38.5	-32.8%	36.7
Other intangible assets	2.5	2.6	-3.5%	2.6
Investments in associates	0.1	0.1	-1.8%	0.1
Other investments	0.3	0.3	+0.9%	0.3
Pension asset	52.2	19.6	+166.2%	55.2
Deferred tax assets	5.2	1.1	+381.0%	1.3
Other non-current assets	1.0	2.5	-61.1%	1.9
Non-current assets total	415.3	395.8	+4.9%	434.7
Inventories	220.0	218.7	+0.6%	225.4
Trade receivables	165.4	187.8	-11.9%	199.0
Other receivables	33.2	34.8	-4.7%	32.4
Money market investments	22.0			
Cash and cash equivalents	232.8	133.1	+74.9%	164.1
Current assets total	673.4	574.4	+17.2%	620.8
Assets total	1,088.7	970.1	+12.2%	1,055.5
EQUITY AND LIABILITIES				
EUR million	9/18	9/17	Change %	12/1
Share capital	92.2	92.2		92.2
Expendable fund	0.5	0.5		0.5
Other reserves	2.4	2.4	+3.2%	2.4
Retained earnings	641.6	499.5	+28.5%	584.6
Equity attributable to owners of the parent company	736.8	594.5	+23.9%	679.7
Non-controlling interests		0.0	-100.0%	0.0
Equity total	736.8	594.5	+23.9%	679.7
Deferred tax liabilities	39.7	35.2	+12.9%	42.3
Pension liability	3.3	3.0	+10.6%	3.2
Provisions	0.5	0.3	+77.1%	0.3
Interest-bearing non-current liabilities	0.6	150.4	-99.6%	150.3
Other non-current liabilities	17.9	0.0		0.0
Non-current liabilities total	62.0	188.8	-67.2%	196.2
Trade payables	57.8	92.1	-37.3%	83.2
Current tax liabilities		3.0	-100.0%	3.0
Other current liabilities	81.2	90.5	-10.3%	92.4
Provisions		0.1	-100.0%	
Interest-bearing current liabilities	150.9	1.0		1.1
Current liabilities total	289.9	186.8	+55.2%	179.
Liabilities total	351.9	375.6	-6.3%	375.8



# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

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

Equity attributable to owners of the parent company								
EUR million	a.	b.	C.	d.	e.	f.	g.	h.
Equity at 1 January 2017	92.2	0.5	2.1	2.0	-5.0	549.5	0.0	641.4
Profit for the period						170.8		170.8
Other comprehensive income								
Translation differences					-0.7	-0.4		-1.1
Items due to remeasurement of defined benefit pension plans				0.0				0.0
Transactions with owners								
Dividend and capital repayment						-217.9		-217.9
Share-based incentive plan						1.9		1.9
Other adjustments			0.3			-0.8	0.0	-0.5
Equity at 30 September 2017	92.2	0.5	2.4	2.1	-5.7	503.0	0.0	594.5
Equity at 1 January 2018	92.2	0.5	2.3	31.9	-5.9	558.6	-0.0	679.7
Impact of adoption of the IFRS 15 and IFRS 9 standards						-16.5		-16.5
Adjusted equity at 1 January 2018	92.2	0.5	2.3	31.9	-5.9	542.1	-0.0	663.2
Profit for the period						277.1		277.1
Other comprehensive income								
Translation differences					-1.4	0.2		-1.2
Items due to remeasurement of defined benefit pension plans				-4.5		2.9		-1.6
Transactions with owners								
Dividend and capital repayment						-203.8		-203.8
Share-based incentive plan						3.4		3.4
Other adjustments			0.1			-0.5	0.0	-0.4
Equity at 30 September 2018	92.2	0.5	2.4	27.4	-7.3	621.5		736.8

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



# **CONSOLIDATED STATEMENT OF CASH FLOWS**

EUR million	1-9/18	1-9/17	1-12/17
Operating profit	319.1	219.9	293.0
Adjustments	-99.0	35.3	49.1
Change in working capital	-6.5	-17.7	-38.9
Interest paid	-5.9	-5.6	-6.2
Interest received	1.4	1.3	1.4
Dividends received	0.0	0.0	0.0
Income taxes paid	-42.6	-52.3	-70.0
Total net cash flow from operating activities	166.6	180.9	228.4
Investments in property, plant and equipment	-28.9	-52.1	-67.1
Investments in intangible assets	-3.9	-8.7	-9.4
Sales of property, plant and equipment and other investments	0.7	1.3	1.6
Sales of subsidiaries	161.3		
Total net cash flow from investing activities	129.2	-59.5	-74.9
Current loans raised	0.4	1.3	1.3
Repayments of current loans	0.0	-2.2	-3.5
Dividends paid and other distribution of profits	-203.9	-218.0	-218.0
Total net cash flow from financing activities	-203.6	-218.9	-220.3
Net change in cash and cash equivalents	92.2	-97.5	-66.8
Cash and cash equivalents at the beginning of the period	164.1	231.9	231.9
Foreign exchange differences	-1.4	-1.3	-1.0
Impact of discontinued operations	-0.8		
Net change in cash and cash equivalents	92.9	-97.5	-66.8
Cash and cash equivalents at the end of the period	254.8	133.1	164.1
Reconciliation of cash and cash equivalents in statement of financial position			
Cash and cash equivalents in statement of financial position at the end of the period	232.8	133.1	164.1
Money market investments at the end of the period	22.0		
Cash and cash equivalents in the statement of cash flows	254.8	133.1	164.1

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



#### **DISCONTINUED OPERATIONS**

On 23 January 2018, Orion announced that it had decided to investigate the possible sale of Orion Diagnostica or other transaction that would result in transfer of Orion Diagnostica outside the Orion Group. As a result of the investigation, an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business) was signed with an investment fund managed by Axcel Management A/S (Axcel) on 21 April 2018. The closing of the transaction took place on 30 April 2018. In the Financial Review and the tables of the Interim Report, the Orion Diagnostica segment is treated as a discontinued operation. The profit of discontinued operations in January-September 2018 was EUR 133.4 (6.2) million.

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

#### PROFIT FOR THE PERIOD FOR DISCONTINUED OPERATIONS

EUR million	1-9/18	1-9/17	Change %	1-12/17
Net sales	18.7	38.6	-51.7%	53.8
Capital gain from sale of discontinued operations	128.4			
Expenses related to sale of discontinued operations	-0.8			
Item related to fulfilment of an obligation under IAS 19	4.5			
Other operating expenses	-16.0	-32.4	-50.6%	-44.9
Operating profit	134.8	6.2		8.9
Income tax expense	-1.3	-0.1		-1.9
Profit for the period	133.4	6.2		6.9

#### CASH FLOW FROM DISCONTINUED OPERATIONS

EUR million	1-9/18	1-9/17	Change %	1-12/17
Cash flow from operating activities	-10.9	-2.4	-354.2%	8.9
Cash flow from investing activities	142.4	-1.1		-1.3

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



# CHANGES IN PROPERTY, PLANT AND EQUIPMENT

EUR million	9/18	9/17	12/17
Carrying amount at the beginning of the period	323.1	289.1	289.1
- discontinued operations	-10.1		
Additions	25.7	53.1	67.4
Disposals	-0.6	-0.6	-1.0
Amortisation and impairments	-23.1	-23.8	-32.1
Carrying amount at the end of the period	314.7	317.7	323.1

# **CHANGES IN INTANGIBLE ASSETS (EXCLUDING GOODWILL)**

EUR million	9/18	9/17	12/17
Carrying amount at the beginning of the period	39.4	40.4	40.4
- discontinued operations	-8.0		
Additions	3.8	8.3	9.1
Disposals		-0.0	-0.1
Amortisation and impairments	-6.9	-7.4	-10.2
Carrying amount at the end of the period	28.4	41.1	39.4

# **COMMITMENTS AND CONTINGENCIES**

EUR million	9/18	9/17	12/17
CONTINGENCIES FOR OWN LIABILITIES			
Guarantees	4.6	4.1	3.6
OTHER LIABILITIES			
Leasing liabilities (excluding finance lease contracts)	5.3	5.7	6.1
Other liabilities	0.3	0.3	0.3

# **DERIVATIVES**

EUR million	9/18	9/17	12/17
CURRENCY FORWARD CONTRACTS AND CURRENCY SWAPS			
Fair value, EUR million	-0.1	-0.8	0.1
Nominal value, EUR million	28.0	31.3	32.4
CURRENCY OPTIONS			
Fair value, EUR million	0.0	0.0	0.1
Nominal value, EUR million	42.5	44.0	45.4



#### FAIR VALUE MEASUREMENT AND HIERARCHY OF FINANCIAL INSTRUMENTS

EUR million	Level 1	Level 2	Level 3	Total
Derivatives				
Currency derivatives		0.2		0.2
Other investments				
Shares and investments			0.3	0.3
Assets total		0.2	0.3	0.5
Derivatives				
Currency derivatives		-0.3		-0.3
Liabilities total		-0.3		-0.3

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

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

No transfers between levels occurred during the reporting period.

#### **RELATED PARTY TRANSACTIONS**

EUR million	9/18	9/17	12/17
Management's employment benefits	4.9	6.5	7.1



# Operating segment performance for continuing operations

#### **NET SALES BY BUSINESS DIVISION**

			Change			Change	
EUR million	7-9/18	7-9/17	%	1-9/18	1-9/17	%	1-12/17
Pharmaceuticals	221.8	241.5	-8.2%	715.1	767.6	-6.8%	1,033.6
Proprietary Products 1)	72.4	75.2	-3.7%	260.9	261.1	-0.1%	351.4
Specialty Products	114.7	132.2	-13.3%	346.7	386.7	-10.4%	519.0
Animal Health	19.2	14.8	+30.1%	57.8	55.7	+3.9%	75.9
Fermion	11.6	12.4	-6.3%	37.5	40.5	-7.3%	51.0
Contract manufacturing and other	3.8	6.9	-44.5%	12.2	23.7	-48.4%	36.2
Group total	221.8	241.5	-8.2%	715.1	767.6	-6.8%	1,033.6

<sup>1)</sup> The net sales of Proprietary Products during the period 1-9/18 includes EUR 1.5 million of sales revenue for performance obligations to be transferred to customers that will be entered as income over time.

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

		Change				Change			
EUR million	7-9/18	7-9/17	%	1-9/18	1-9/17	%	1-12/17		
Pharmaceuticals	47.2	57.4	-17.8%	193.3	221.1	-12.6%	296.3		
Group items	-2.6	-2.5	+1.7%	-9.1	-7.5	+21.6%	-12.2		
Group total	44.6	54.9	-18.7%	184.2	213.7	-13.8%	284.1		

#### **NET SALES BY ANNUAL QUARTERS**

		2018			201	7		2016
EUR million	7-9	4-6	1-3	10-12	7-9	4-6	1-3	10-12
Pharmaceuticals	221.8	246.1	247.2	265.9	241.5	260.7	265.5	267.1
Group total	221.8	246.1	247.2	265.9	241.5	260.7	265.5	267.1

# **OPERATING PROFIT BY ANNUAL QUARTERS**

		2018			2017	,		2016
EUR million	7-9	4-6	1-3	10-12	7-9	4-6	1-3	10-12
Pharmaceuticals	47.2	73.6	72.5	75.2	57.4	73.5	90.2	59.6
Group items	-2.6	-3.9	-2.7	-4.7	-2.5	-3.0	-2.0	-2.6
Group total	44.6	69.7	69.8	70.5	54.9	70.5	88.2	57.0

# GEOGRAPHICAL BREAKDOWN OF NET SALES BY ANNUAL QUARTERS

		2018			201	7		2016
EUR million	7-9	4-6	1-3	10-12	7-9	4-6	1-3	10-12
Finland	74.0	75.4	80.0	84.6	80.4	82.4	81.3	91.2
Scandinavia	36.4	36.9	41.2	42.4	44.0	46.6	40.5	41.6
Other Europe	72.0	73.0	75.5	80.5	73.2	78.7	79.2	85.7
North America	14.9	13.5	14.0	27.0	16.8	15.7	19.3	29.3
Other markets	24.4	47.3	36.6	31.4	27.1	37.2	45.2	19.3
Group total	221.8	246.1	247.2	265.9	241.5	260.7	265.5	267.1



# **Business review**

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

EUR million	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Net sales	221.8	241.5	-8.2%	715.1	767.6	-6.8%	1,033.6
Operating profit	47.2	57.4	-17.8%	193.3	221.1	-12.6%	296.3
% of net sales	21.3%	23.8%		27.0%	28.8%		28.7%
R&D expenses	24.5	23.3	+5.1%	76.2	72.6	+5.0%	99.1
% of net sales	11.1%	9.7%		10.7%	9.5%		9.6%
Capital expenditure	9.5	21.5	-55.7%	29.3	59.9	-51.1%	74.6
% of net sales	4.3%	8.9%		4.1%	7.8%		7.2%
Sales revenue from proprietary products	86.6	83.0	+4.4%	294.8	285.6	+3.2%	386.6
Assets				813.1	773.3	+5.2%	832.1
Liabilities				156.3	174.8	-10.6%	165.2
Personnel at the end of the period				3,119	3,175		3,138

# TOP TEN BEST-SELLING PHARMACEUTICAL PRODUCTS

EUR million	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Stalevo®, Comtess® and Comtan® (Parkinson's disease)	15.5	22.2	-30.2%	75.5	79.9	-5.4%	103.8
Easyhaler® product family (asthma, COPD)	20.9	18.3	+14.3%	64.4	55.2	+16.7%	76.6
Dexdor® (intensive care sedative)	14.0	13.3	+5.9%	48.0	47.0	+2.1%	64.1
Simdax® (acute decompensated heart failure)	13.8	12.9	+7.1%	43.3	42.6	+1.7%	57.2
Dexdomitor®, Domitor®, Domosedan® and Antisedan® (animal sedatives)	8.6	4.2	+104.3%	23.1	21.7	+6.1%	30.5
Biosimilars (rheumatoid arthritis, inflammatory bowel diseases, lymphoma)	4.5	16.9	-73.4%	19.1	44.6	-57.1%	56.7
Burana® (inflammatory pain)	5.5	6.3	-12.9%	16.6	17.7	-6.4%	23.4
Precedex® (intensive care sedative)	4.6	5.1	-8.8%	15.9	18.4	-13.6%	25.0
Divina series (menopausal symptoms)	4.6	4.6	-1.0%	13.8	13.2	+4.1%	18.6
Marevan® (anticoagulant)	4.1	4.4	-6.3%	12.3	13.8	-10.9%	19.2
Total	96.2	108.2	-11.1%	332.0	354.2	-6.3%	475.1
Share of pharmaceutical net sales	43%	45%		46%	46%		46%



# KEY CLINICAL PHARMACEUTICAL DEVELOPMENT PROJECTS

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



# Information on Orion's shares

# BASIC SHARE INFORMATION, 30 SEPTEMBER 2018

	A share	B share	Total
Trading code on Nasdaq Helsinki	ORNAV	ORNBV	
Listing day	1.7.2006	1.7.2006	
ISIN code	FI0009014369	FI0009014377	
ICB code	4500	4500	
Reuters code	ORNAV.HE	ORNBV.HE	
Bloomberg code	ORNAV.FH	ORNBV.FH	
Share capital, EUR million	24.2	68.0	92.2
Counter book value per share, EUR	0.65	0.65	
Total number of shares	37,120,346	104,137,482	141,257,828
% of total share stock	26%	74%	100%
Number of treasury shares		562,440	562,440
Total number of shares excluding treasury shares	37,120,346	103,575,042	140,695,388
Minimum number of shares			1
Maximum number of A and B shares, and maximum number of all shares	500,000,000	1,000,000,000	1,000,000,000
Votes per share	20	1	
Number of votes excluding treasury shares	742,406,920	103,575,042	845,981,962
% of total votes	88%	12%	100%
Total number of shareholders  Both share classes: A and B, confer equal rights to the Company's assets and dividends	20,152	59,682	73,337

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 2018

	A share	B share	Total
Shares traded	1,545,093	95,781,306	97,326,399
% of the total number of shares	4.2%	92.0%	68.9%
Trading volume, EUR million	45.4	2,613.5	2,658.9
Closing quotation on 31 December			
2017, ĔÚR	32.07	31.08	
Lowest quotation, EUR (A: 4 July 2018; B: 3 July 2018)	24.75	22.57	
Average quotation, EUR	29.40	27.29	
Highest quotation, EUR			
(A: 23 January 2018;			
B: 19 January 2018)	35.70	33.50	
Closing quotation on 30 September			
2018, ĔÚR	32.50	32.62	
Market capitalisation on 30 September 2018, EUR million	1,206.4	3,378.6	4,585.0



# PERFORMANCE PER SHARE

Continuing operations	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Basic earnings per share, EUR	0.24	0.31	-22.6%	1.02	1.18	-13.2%	1.56
Diluted earnings per share, EUR	0.24	0.31	-22.6%	1.02	1.18	-13.2%	1.56
Continuing and discontinued operations	7-9/18	7-9/17	Change %	1-9/18	1-9/17	Change %	1-12/17
Basic earnings per share, EUR	0.24	0.31	-22.1%	1.97	1.22	+62.1%	1.61
Diluted earnings per share, EUR	0.24	0.31	-22.1%	1.97	1.22	+62.1%	1.61
Cash flow per share before financial items, EUR	0.36	0.47	-24.5%	2.10	0.86	+143.3%	1.09
Equity per share, EUR				5.24	4.23	+23.8%	4.83
Average number of shares excluding treasury shares, 1,000 shares	140,695	140,582		140,679	140,559		140,565



# **Appendices**

# Reporting

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

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

Contract manufacturing and other, i.e. manufacturing for other companies, is included in the Pharmaceuticals business segment, but it is not a separate business division, it is part of the Group's Supply Chain organisation.

# Accounting policies

This report has been prepared in accordance with the accounting policies set out in International Accounting Standard 34 on Interim Financial Reporting. The same accounting principles have been applied as in the 2017 financial statements, besides which the amendments to existing IFRS and IAS standards endorsed by the EU have been adopted as of 1 January 2018.

Orion Group adopted the new IFRS 15 standard and IFRS 9 standard as of 1 January 2018, which both impact the information provided in the consolidated financial statements.

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

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

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

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

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

The total net sales from the above-mentioned revenue flows on average account for less than five per cent of the Group's annual net sales. For the financial period 2017 net sales recorded from the revenue flows mentioned were EUR 12.1 million (2016: EUR 18.6 million), in other words 1.1 per cent (1.7 per



cent) of the total consolidated net sales. In the Group's view, the effect of IFRS 15 in recognising these revenue flows as revenue is not material in proportion to the total consolidated net sales.

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

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

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



. . . . . . .

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

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

4 0/47

4) Adjusted comparison information reported in this Interim Report, if impact of the IFRS 15 standard taken into consideration. Orion Diagnostica is reported as a discontinued operation.

	1-9/17				1-12/17				
	1)	2)	3)	4)	1)	2)	3)	4)	
Net sales, EUR million	804.3	799.5	767.7	762.9	1,084.6	1,077.2	1,033.6	1,026.2	
Operating profit, EUR million	219.9	215.1	213.7	208.9	293.0	285.6	284.1	276.7	
% of net sales	27.3%	26.9%	27.8%	27.4%	27.0%	26.5%	27.5%	27.0%	
Profit before taxes, EUR million	214.8	210.0	208.7	203.9	286.5	279.1	277.7	270.3	
% of net sales	26.7%	26.3%	27.2%	26.7%	26.4%	25.9%	26.9%	26.3%	
Income tax expense, EUR million	44.1	43.1	44.0	43.0	60.5	59.0	58.6	57.1	
Profit for the period, EUR million	170.8	167.0	169.4	165.6	226.0	220.1	219.1	213.1	
Other comprehensive income net of tax, EUR million	-1.3	-1.3	-1.1	-1.1	28.5	28.5	26.0	26.0	
Deferred tax assets, EUR million	1.1	5.3	1.1	5.3	1.3	5.4	1.3	5.4	
Other non-current liabilities, EUR million	0.0	19.2	0.0	19.2	0.0	18.7	0.0	18.7	
Other current liabilities, EUR million	90.5	92.4	90.5	92.4	92.4	94.3	92.4	94.3	
Non-interest-bearing liabilities, EUR million	224.2	245.3	224.2	245.3	224.5	245.1	224.5	245.1	
Equity total, EUR million	594.5	572.9	594.5	572.9	679.7	655.9	679.7	655.9	
Assets total, EUR million	970.1	969.5	970.1	969.5	1,055.5	1,052.4	1,055.5	1,052.4	
Equity ratio, %	61.6%	59.4%	61.6%	59.3%	64.6%	62.5%	64.6%	62.5%	
Gearing, %	3.1%	3.2%	3.1%	4.2%	-1.9%	-1.9%	-1.9%	-1.9%	
ROCE (before taxes), %	38.3%	38.5%	38.3%	38.2%	36.2%	36.4%	35.5%	35.1%	
ROE (after taxes), %	36.9%	37.0%	36.9%	37.3%	34.2%	34.4%	33.2%	33.3%	
Basic earnings per share, EUR	1.22	1.17	1.18	1.17	1.61	1.57	1.56	1.52	
Diluted earnings per share, EUR	1.22	1.17	1.18	1.17	1.61	1.57	1.56	1.52	
Equity per share, EUR	4.23	4.08	4.23	3.92	4.83	4.67	4.77	4.67	

#### Revenue recognition principles

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

#### Sales of goods

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



consideration is recognised as net sales that the Group expects to be entitled to taking into account the effects of discounts and incentives.

#### Transfer of sales rights to products already in the market

The Group enters into agreements in which it transfers the sales rights to a product already in the market to an external party outside the Group and agrees to manufacture the product for that external party. For transferring sales rights and manufacturing products, depending on the agreement the Group may receive milestone payments, revenue from manufacture and sales of the products and royalty income. Typically milestone payments are by their nature fixed payments that are received on signing of the agreement and payments related to commercialisation of the product.

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

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

# Clinical phase research and development work undertaken with collaboration partners

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

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

The agreements may also include a decision on arranging manufacture of finished product if it can be commercialised. For each agreement, considerations related to commercialisation are evaluated on the basis of whether the milestone payments and sales of finished products together constitute a performance obligation or whether the milestone payments can be identified as performance obligations distinct from sales of the finished product. Likewise, on the basis of each agreement, it is evaluated whether the performance obligation related to milestone payments will be satisfied at a single point of time or over a period of time. Royalty payments are recognised as revenue when the partner has sold products subject to royalties.



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

Following adoption of IFRS 15, comparative information reported by the Group have not been adjusted. The Group provides information on the impact of the adoption of IFRS 15 on the comparative period figures in a separate note to this report.

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

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

Adoption of the IFRS 9 standard the Group's financial items have been recognised according to the following principles:

- The Group's financial assets that are classified as loans and other receivables are measured at amortised cost. This does not affect the measurement of the items.
- Equity instruments included in other investments were recognised at fair value until 31 December 2017 and disclosed in the items under other comprehensive income. Since IFRS 9, these instruments are recognised at fair value through profit or loss, which changes the accounting on adoption of IFRS 9. Considering the current equity instruments of EUR 0.3 million in the statement of financial position, the Group does not expect the change in accounting to increase the volatility of the results.
- The accounting of financial liabilities did not change on adoption of IFRS 9 because the new requirements affect only the accounting of financial liabilities specifically classified at fair value through profit or loss. The Group does not have such liabilities.
- The Group does not currently apply hedge accounting, so the changes to hedge accounting due to IFRS 9 do not affect the Company.
- Measurement of financial assets for any impairment is based on whether there is a significant credit risk related to the receivable or not. The Group evaluates the risk related to a neglected payment on a financial instrument and recognises a provision for credit loss based on the assessment. Impairment of financial instruments is based on an expected credit loss model in which earlier and greater credit losses are recognised than under IAS 39.
- A simplified approach under IFRS 9 is applied for measurement of trade receivables through which impairment of trade receivables with various due dates is entered by reducing their value by a certain percentage allowance, which are determined based on actual credit losses taking into account economic conditions on the reporting day. The allowance percentages shall lead to impairment that corresponds to the expected credit losses of receivables over their lifetime. As regards impairment of trade receivables, the change to IFRS 9 had no material impact.

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

#### Other adjustments as of 1 January 2018

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



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

# Other matters

The figures in this Interim Report have not been 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	_ x 100					
= = = = = = = = = = = = = = = = = = = =	Total equity (average during the period)	_					
Equity ratio, %	Equity	_ x 100					
_	Total assets - Advances received						
Gearing, %	Interest-bearing liabilities - Cash and cash equivalents - Money market investments	_ x 100					
_	Equity						
Earnings per share, EUR	Profit available for the owners of the parent company	_					
_	Average number of shares during the period, excluding treasury shares						
Cash flow per share	Cash flow from operating activities + Cash flow from investing activities						
before financial items, EUR =	Average number of shares during the period, excluding treasury shares						
Equity per share, EUR	Equity attributable to owners of the parent company						
=	Number of shares at the end of the period, excluding treasury shares	_					
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 100					
- -	Earnings per share						
Effective dividend yield, %	Dividend per share	x 100					
	Closing quotation of the period						
Price/earnings ratio (P/E)	Closing quotation of the period						
=	Earnings per share						
Average share price, EUR	Total EUR value of shares traded						
=	Average number of traded shares during the period	_					
Market capitalisation, EUR million =	Number of shares at the end of the period × Closing quotation of the period						

Publisher:

Orion Corporation

http://www.orion.fi/en

http://www.twitter.com/OrionCorpIR

Orion is a globally operating Finnish pharmaceutical company - a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals and active pharmaceutical ingredients. The company is continuously developing new drugs and treatment methods. The core therapy areas of Orion's pharmaceutical R&D are central nervous system (CNS) disorders, oncology and respiratory diseases for which Orion develops inhaled Easyhaler® pulmonary drugs. Orion's net sales in 2017 amounted to EUR 1,034 million and the company had about 3,200 employees at the end of the year. Orion's A and B shares are listed on Nasdaq Helsinki.