



Orion Group
Financial Statement Release 2019



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Orion Group Financial Statement Release for 2019

- Net sales totalled EUR 1,051 million (EUR 977 million in 2018).
- Operating profit was EUR 253 (253) million.
- Profit before taxes was EUR 251 (248) million.
- Net sales and operating profit include the EUR 45 million milestone payment received from Bayer.
- Equity ratio was 77% (69%).
- ROCE before taxes was 30% (44%).
- ROE after taxes was 26% (45%).
- Basic earnings per share were EUR 1.43 (1.40).
- Cash flow per share before financial items was EUR 1.68 (2.32).
- The Board of Directors proposes payment of a dividend of EUR 1.50 (1.50) per share.
- Orion estimates that in 2020 net sales will be at a similar level as in 2019 (net sales in 2019 were EUR 1,051 million). Operating profit is estimated to be lower than in 2019 (in 2019 operating profit was EUR 253 million).

Key figures

	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Net sales, EUR million	274.5	262.4	+4.6%	1,051.0	977.5	+7.5%
EBITDA, EUR million	69.5	79.7	-12.8%	308.9	293.9	+5.1%
% of net sales	25.3%	30.4%		29.4%	30.1%	
Operating profit, EUR million	55.0	68.6	-19.9%	252.8	252.8	
% of net sales	20.0%	26.1%		24.1%	25.9%	
Profit before taxes, EUR million	54.7	67.5	-19.0%	250.8	248.4	+1.0%
% of net sales	19.9%	25.7%		23.9%	25.4%	
Profit for the period, EUR million	45.2	53.7	-15.9%	200.4	197.3	+1.6%
% of net sales	16.4%	20.5%		19.1%	20.2%	
R&D expenses, EUR million	32.8	27.8	+18.1%	119.3	104.0	+14.7%
% of net sales	11.9%	10.6%		11.3%	10.6%	
Capital expenditure, EUR million	14.5	35.4	-59.0%	42.6	64.8	-34.3%
% of net sales	5.3%	13.5%		4.0%	6.6%	
Interest-bearing net liabilities, EUR million				-139.1	-132.1	-5.2%
Basic earnings per share, EUR million	0.32	0.38	-14.9%	1.43	1.40	+2.0%
Cash flow per share before financial items, EUR	0.40	0.22	+84.6%	1.68	2.32	-27.4%
Equity ratio, %				76.7%	68.8%	
Gearing, %				-17.8%	-17.1%	
ROCE (before taxes), %				29.9%	44.3%	
ROE (after taxes), %				25.8%	45.5%	
Average personnel during the period				3,251	3,179	+2.3%

The Diagnostics business, sold on 30 April 2018, has been reported as a discontinued operation since the interim report 1-3/2018 and is not included in consolidated statement of comprehensive income. The return on capital and cash flow per share figures in the comparative period also contain discontinued operations, including the capital gain from the sale of Orion Diagnostica.

President and CEO Timo Lappalainen: Darolutamide dominated the headlines in 2019

“In 2019 Orion's net sales increased by 8% to EUR 1,051 million and operating profit was at previous year's level at EUR 253 million. The operating profit level was affected by planned additional investments in research and development as well as sales and marketing. All our business units reported an increase in net sales in 2019.

Growth of the Proprietary Products business unit was boosted by the EUR 45 million milestone payment from Bayer, but it is worth noting that net sales increased even without that payment. The growth in sales of proprietary products was driven by the Easyhaler® product family, and the budesonide-formoterol combined formulation in particular. The overall trend in net sales was also boosted by the sales and marketing efforts made to promote the product portfolio. The net sales of the Parkinson's disease drugs Stalevo® and Comtess®/Comtan® remained at previous year's level as predicted following the reacquisition of their European sales and distribution rights. The sales of Simdax® continued to develop well, but the sales of Dexdor® turned to decline following generic competition, as expected.

Growth in the Specialty Products division's net sales was mostly due to biosimilars, prescription drugs in Scandinavia and self-care products in Finland. Disruptions in product availability and tougher price competition in generic drugs had a negative effect on the business division's net sales in all markets. The prices of reference-priced prescription drugs in Finland continued to decline compared with 2018, but in 2019 the price decline appeared to be levelling off. At the same time, availability disruptions have increasingly affected our net sales.

The Animal Health business division achieved its best net sales of all times so far, and sales by active pharmaceutical ingredients manufacturer Fermion and by Contract manufacturing also developed positively.

Darolutamide, invented by Orion and developed in collaboration with Bayer for the treatment of prostate cancer, dominated Orion's media releases in 2019. The key results of the ARAMIS trial were published and marketing authorisation applications were submitted in the United States, EU and Japan, among others. As a highlight, in July the United States Food and Drug Administration (FDA) granted marketing authorisation under the Priority Review designation to darolutamide for the treatment of non-metastatic castration-resistant prostate cancer, under the trade name Nubeqa®.

We have received many news on darolutamide also after the review period. New results from ARAMIS trial, published in January 2020, demonstrate that darolutamide plus androgen deprivation therapy show statistically significant improvement in overall survival (OS) in men with non-metastatic castration-resistant prostate cancer compared to placebo plus androgen deprivation therapy. Detailed data on the updated OS and other additional endpoints as well as an update on longer term safety will be presented at an upcoming scientific meeting.

In addition, in January 2020 Bayer received marketing authorisation for darolutamide in Japan, where market launch is now pending price decision. The Human Pharmaceutical Committee of the European Medicines Agency gave a positive recommendation for darolutamide, so we anticipate the Commission's marketing authorization decision in the next few months. Orion is due to receive milestone payments for darolutamide from Bayer, EUR 8 million upon first commercial sales in Japan and EUR 20 million in Europe.

We are continuing the Phase III clinical trial ARASENS with Bayer, evaluating 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. Darolutamide's commercial potential will increase significantly if the ARASENS trial yields positive results in around 2022.

Besides ARASENS, Orion has another ongoing Phase III clinical trial investigating orally administered levosimendan (ODM-109) in the treatment of amyotrophic lateral sclerosis. Patient recruitment for this REFALS trial was finalised in July 2019. The patients will be followed for a period of roughly one year, so the trial will be completed in the coming summer. We are conducting this trial alone and, if the findings are positive, it is possible that Orion will commercialise the product on its own not just in Europe but also in the United States.

The ODM-208 and ODM-209 molecule development projects proceeded as expected in 2019. We have decided to expand these ongoing Phase I projects to ensure that we have sufficient data to make informed decisions regarding subsequent phases.

With regard to other earlier phase development projects, we are looking for partners for possible next development phases of the ODM-203 and ODM-207 molecules.

A year ago, we set ourselves the target of increasing Orion's net sales to EUR 1.5 billion by 2025. To achieve this, we would need to grow net sales at an average rate of 6 per cent a year from the 2019 level. However, growth will not follow a straight line. While darolutamide and ODM-109 are crucial, they are not the only sources of aspired growth. We estimate that Nubeqa® will start to generate more substantial net sales growth starting from 2021-2022 and ODM-109, if successful, to have a significant impact on net sales growth from around 2022-2023. We see growth prospects in all our business units and we are actively seeking opportunities to grow through targeted product or company acquisitions. We are also seeking to grow by expanding our own sales network outside Europe. In the context of the REFALS trial, we have initiated an assessment on the prospects of launching the product in the United States on our own. We are also in the process of launching sales ventures in certain Southeast Asian countries.

Orion's solid balance sheet enables investments in growth without jeopardising our ability to distribute dividends or our equity ratio. However, significant growth investments to be made in research and development and sales and marketing in 2020-2021 will have a reducing effect on annual profitability.

Outlook for 2020

Orion estimates that in 2020 net sales will be at a similar level as in 2019 (net sales in 2019 were EUR 1,051 million).

Operating profit is estimated to be lower than in 2019 (in 2019 operating profit was EUR 253 million).

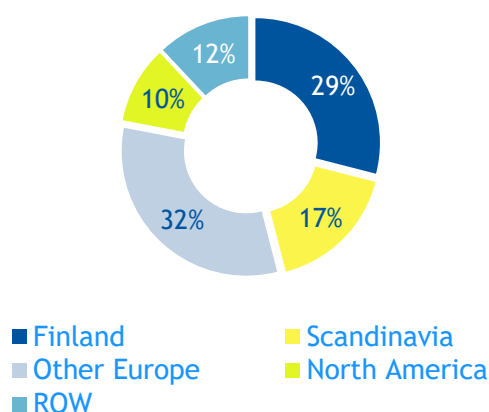
Basis for the outlook and an overview of near-term risks and uncertainties are provided on the pages 22-24 of this review.

Financial review for 1 January-31 December 2019

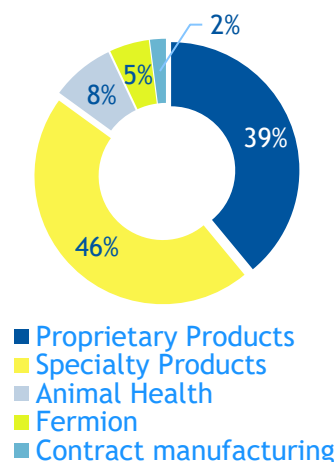
Net sales

Orion Group's net sales in 2019 totalled EUR 1,051 (977) million, an increase of 8%. The net sales include the EUR 45 million milestone payment received from Bayer. Exchange rates impacted net sales positively by EUR 5 million. Net sales of Orion's top ten pharmaceuticals in 2019 amounted to EUR 474 (444) million. They accounted for 45% (45%) of the total net sales.

Net sales split by region



Net sales split by business units



Operating profit

Orion Group's operating profit was EUR 253 (253) million. EBITDA was up by 5% at EUR 309 (294) million. Operating profit and EBITDA include the EUR 45 million milestone payment received from Bayer.

The positive effect of the increase in product and service sales calculated in local currencies on gross profit was EUR 19 million. On the other hand, the combined effect of changes in prices, costs and product mix was EUR 18 million negative and the impact of changes in exchange rates EUR 3 million positive. Taken together, these items resulted in total EUR 4 million higher gross profit from product and service sales than in the comparative period.

Milestone payments accounted for EUR 51 (5) million and royalties for EUR 11 (17) million of net sales and operating profit. The decline in other operating income had a EUR 3 million negative impact on the operating profit.

Operating expenses increased by EUR 41 million. Majority of the growth was due to planned sales and marketing as well as in research and development costs.

Operating expenses

The Group's sales and marketing expenses totalled EUR 216 (195) million. The growth was mostly due to depreciation associated with the reacquisition of European rights for Stalevo® and Comtan®, which in 2019 was approximately EUR 12 million, as well as investments in the sales of the Easyhaler® product portfolio in particular.

R&D expenses were EUR 119 (104) million. They accounted for 11% (11%) of the Group's net sales. Research projects are reported in more detail under the 'Research and development' section of this review.

Administrative expenses were EUR 48 (43) million.

Other operating income and expenses amounted to EUR 2 (5) million (positive).

Group's profit

Profit for the period was EUR 200 (197) million.

Basic earnings per share were EUR 1.43 (1.40). Equity per share was EUR 5.55 (5.50).

The return on capital employed before taxes (ROCE) was 30% (44%) and the return on equity after taxes (ROE) 26% (45%). The high figures in the comparative period are explained by the EUR 128 million capital gain recognised for the sale of Orion Diagnostica.

Financial position

The Group's gearing was -18% (-17%) and the equity ratio 77% (69%).

The Group's total liabilities at 31 December 2019 were EUR 256 (374) million. At the end of the period, interest-bearing liabilities amounted to EUR 10 (152) million, including EUR 7 (1) million of long-term loans. The change in interest-bearing liabilities was mostly due to the fact that the EUR 150 million bond loan issued by Orion in 2013 matured in June 2019.

After the matured bond was paid off, the Group had EUR 149 (284) 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.

Orion signed a EUR 100 million loan agreement with the European Investment Bank in January 2019. The loan has not yet been raised.

Cash flow

Cash flow from operating activities was EUR 271 (231) million. Cash flow improved both due to increased EBITDA and decrease in working capital.

The cash flow from investing activities was EUR -34 (95) million. The cash flow from investing activities was positive in the comparative period due to the sale of Orion Diagnostica.

The cash flow from financing activities was EUR -371 (-205) million. The difference to the comparative period is mostly due to the repayment of the bond that matured in June 2019. Orion also bought back its own shares by EUR 7 million in the course of the year.

Capital expenditure

The Group's capital expenditure totalled EUR 43 (65) million. This comprised EUR 35 (36) million on property, plant and equipment and EUR 7 (29) million on intangible assets.

Key business targets for 2019-2020

TARGET	DEVELOPMENT 1-12/2019
Launch and commercialisation of the prostate cancer drug darolutamide jointly with Bayer. Continued research and development collaboration in the ARASENS trial (metastatic prostate cancer) to expand the indication.	<ul style="list-style-type: none"> ○ In the United States, the FDA granted marketing authorisation under the Priority Review designation. ○ Marketing authorisation was also acquired in Brazil and, after the review period, in Japan. ○ The recommendation for darolutamide by the Committee for Medicinal Products for Human Use of the European Medicines Agency after the review period. ○ With recruitment completed, the ARASENS trial continues as planned.
Development of orally administered levosimendan (ODM-109) for the treatment of symptoms of ALS in Phase III clinical trial (REFALS) and preparation for its possible commercialisation. In research and development, the potential of different projects are reviewed with consideration of the total research portfolio.	<ul style="list-style-type: none"> ○ Patient recruitment was finalized for REFALS trial in July 2019. ○ Orion has initiated an assessment on the prospects of launching the product in the United States on its own. ○ Partners are being sought for the development of ODM-203 and ODM-207.
Strengthening Orion's position as the most significant provider of generic drugs in Finland and competitive pricing. Development of a competitive product portfolio in Specialty Products and strengthening of product launches.	<ul style="list-style-type: none"> ○ Orion was clear market leader in reference-priced prescription drugs in Finland in 2019. ○ In self-care products Orion grew faster than the market.
Accelerating the growth of the Easyhaler® product family and strengthening its market position. Progress on the launch of the salmeterol-fluticasone Easyhaler® product in Europe.	<ul style="list-style-type: none"> ○ Easyhaler® product family sales increased by 16%. ○ Sales of salmeterol-fluticasone have increased more slowly than anticipated.
Evaluation of new in-licensing opportunities in Europe, particularly in the area of hospital care.	<ul style="list-style-type: none"> ○ The work continues.

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

Business review

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 Pharmarket 2019 statistics, the total sales of Orion's human pharmaceuticals, including both medicinal and non-medicinal products, was behind market trend. The growth in the Finnish pharmaceuticals market has mostly been generated by proprietary products, while they only account for a small share of Orion's net sales in Finland.

Orion's biggest product group in Finland are reference-priced prescription drugs in the pharmacy channel. The sales of Orion's reference-priced prescription drugs declined from the comparative period due to continuing tough price competition and availability disruptions. However, sales volume still continued to increase, albeit slightly more slowly than the market. The average price of reference-priced drugs in the market declined in 2019 by approximately 8% from the comparative period (Source: Pharmarket). The impact of price competition on Orion has been significant due to the Company's broad product range and significant market share in Finland.

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 quarter of the market in each.

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

EUR million	1-12/19	1-12/18	Change %
Total sales of human pharmaceuticals (hospital and pharmacy channel)			
Market	2,859	2,715	+5%
Orion	314	314	-0%
Prescription drugs total (pharmacy channel)			
Market	1,602	1,533	+4%
Orion	178	183	-3%
Reference priced prescription drugs (pharmacy channel)			
Market	436	455	-4%
Orion	116	123	-6%
Self-care products (pharmacy channel)			
Market	399	389	+2%
Orion	100	96	+5%

Source: Pharmarket sales statistics 1-12/2019

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

Orion's market share, %	1-12/19	1-12/18
Human pharmaceuticals in total (hospital and pharmacy channel)	11%	12%
Prescription drugs total (pharmacy channel)	11%	12%
Reference priced prescription drugs (pharmacy channel)	27%	27%
Self-care products (pharmacy channel)	25%	25%

Source: Pharmarket sales statistics 1-12/2019

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

According to IQVIA pharmaceutical sales statistics, in Europe total sales of the most common intravenous anaesthetics and intensive care sedatives (propofol, midazolam, remifentanyl and dexmedetomidine) in the 12-month period ending in September 2019 were up by 4% at EUR 595 (570) million. The active ingredient in Orion's Dexdor® intensive care sedative is dexmedetomidine. The total sales of dexmedetomidine was EUR 72 (69) million in Europe, according to IQVIA pharmaceutical sales statistics.

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.

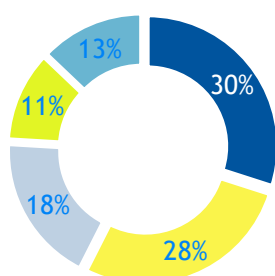
Net sales of the Proprietary Products division in 2019 were EUR 406 (357) million. The increase in net sales is mainly explained by the EUR 45 million milestone payment from Bayer, but product sales grew as well.

Net sales by product

EUR million	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Easyhaler® product family	29	26	+13%	104	90	+16%
Stalevo®, Comtess®, Comtan® (Parkinson's disease)	27	25	+10%	98	100	-3%
Simdax®	18	16	+13%	68	59	+14%
Dexdor®	11	15	-27%	57	63	-10%
Other*	13	14	-10%	80	44	+82%
TOTAL	99	96	+3%	406	357	+14%

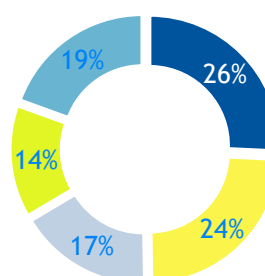
*1-12/19 figure includes EUR 45 million milestone from Bayer and several products such as Enanton®, Nubeqa® and Precedex®

Net sales split 10-12/2019



- Easyhaler®
- Parkinson's products
- Simdax®
- Dexdor®
- Other

Net sales split 1-12/2019



- Easyhaler®
- Parkinson's products
- Simdax®
- Dexdor®
- Other

Total net sales of the Easyhaler® product family for treatment of asthma and chronic obstructive pulmonary disease were up by 16% in 2019 at EUR 104 (90) million. The good development was mainly due to the strong sales of the budesonide-formoterol combined formulation, up by 21% at EUR 62 (52) million. The growth was supported by increased resources in the sales and marketing of the product family. Besides Orion's sales, co-marketing partner Menarini sells the budesonide-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.

The sales of salmeterol-fluticasone combined formulation have also started in several European countries, but they have initially developed more slowly than anticipated and for the time being, the product has no material impact on the net sales of the product family.

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 pharmaceutical ingredients (salbutamol, beclometasone, budesonide, formoterol, salmeterol and fluticasone).

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 2019 were down by 3% at EUR 98 (100) million. In 2019, Orion reacquired the European sales and distribution rights to Stalevo® ja Comtan®, which resulted in a sharp decline in deliveries to key partners and doubled Orion's own sales.

Except for Japan, Orion's arrangements with Novartis in other markets will expire during 2020 and in most of these markets, Orion is transferring the distribution to new partners. In the end of 2019, Orion and Lotus Pharmaceutical Co., Ltd. ("Lotus") made a marketing and distribution agreement according to which Lotus will, starting Q3 2020 and depending on transfer of the regulatory approvals, have the right to sell and market Stalevo® in Bangladesh, Hong Kong, Indonesia, Philippines, South Korea, Taiwan and Vietnam and Comtan® in Hong Kong, Philippines, South Korea and Taiwan. In a few Southeast Asian markets, Orion is planning to sell these products through its own sales organisations, which are being set up.

Breakdown of sales of Parkinson's drugs:

EUR million	1-12/2019	1-12/2018	Change %
Deliveries to key partners	52	78	-33%
Orion's own sales	46	22	+104%

Net sales of Orion's Dexdor® intensive care sedative (dexmedetomidine) decreased by 10% to EUR 57 (63) million. The decline in sales followed directly from the onset of generic competition and its expansion in Europe. Sales of the Precedex® intensive care sedative were down by 50% at EUR 13 (26) million. The sales comprise both royalties and sales of the pharmaceutical ingredient.

Simdax® (levosimendan), a drug for treatment of acute decompensated heart failure is sold in some 60 countries worldwide. Net sales of the product in 2019 were up by 14% at EUR 68 (59) million. Orion has been informed that marketing authorisation applications have been filed for generic versions of Simdax® in Europe. The formulation patent of the product will expire in September 2020, but the timing of possible generic competition in the market is still difficult to predict.

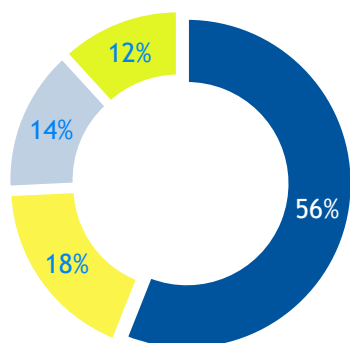
Nubeqa® (darolutamide) for the treatment of non-metastatic castration-resistant prostate cancer received marketing authorisation in July 2019 in the United States, where it is being sold by Orion's partner Bayer. Orion received a EUR 45 million milestone payment from Bayer for the successful commercialisation of darolutamide in the United States. Marketing authorisation has also been acquired in Brazil and, after the review period, in Japan. Likewise after the review period, the Committee for Medicinal Products for Human Use of the European Medicines Agency has issued a positive opinion and recommended that marketing authorisation be granted to darolutamide. The European Commission is expected to make the final decision regarding the granting of a marketing authorisation in the next few months. Orion is entitled to EUR 20 million milestone payment upon first commercial sales of darolutamide in the EU and to EUR 8 million upon first commercial sales in Japan.

Bayer holds global commercial rights to darolutamide. In Europe, however, Orion and Bayer have agreed on co-promotion. In addition, Orion will manufacture the product for global markets. Besides milestone payments, Orion will also receive tiered royalties on global darolutamide sales, which will be approximately 20% including production revenue. With sales increase, royalties may increase slightly. Orion also has the possibility to receive one-off payments from Bayer when certain global annual sales targets are met for the first time.

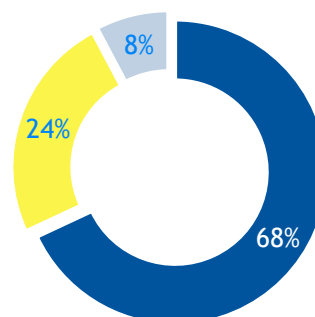
Specialty Products

Net sales of the Specialty Products division's off-patent, i.e. generic prescription drugs, self-care products and biosimilars amounted to EUR 486 (473) million in 2019.

Net sales split by region



Net sales split by product group



■ Finland ■ Scandinavia ■ Eastern Europe ■ Other ■ Generic prescription drugs ■ Self-care ■ Biosimilars

Breakdown of Specialty Products' net sales by product group 1-12/2019:

EUR million	1-12/2019	1-12/2018	Change %	Share of business unit net sales 1-12/2019	Share of business unit net sales 1-12/2018
Generic prescription drugs	331	334	-1%	68%	71%
Self-care (OTC)	118	114	+3%	24%	24%
Biosimilars	38	25	+52%	8%	5%
TOTAL	486	473	+3%		

Finland, Scandinavia and Eastern Europe and Russia are the most important markets for Specialty Products. In Finland, the business division's sales in 2019 totalled EUR 272 (273) million. Continued tough price competition in generic drugs and availability disruptions negatively affected net sales, but due to increased sales in self-care products and biosimilars overall net sales remained at previous year's level. Price competition in generic drugs has decreased Orion's sales in Finland by around EUR 15 million annually both in 2017 and 2018. In 2019, the system change and related price decrease had an impact of around EUR 10 million. In 2019, the decline in prices appears to have levelled off for the time being. At the same time, availability disruptions have increasingly affected net sales. Their negative impact in 2019 was roughly equal to that of the price decreases.

In Scandinavia the sales of Specialty Products totalled EUR 89 (69) million, up 28%. The growth was due to generic prescription drugs and biosimilars. In Eastern Europe and Russia, Specialty Products sales amounted to EUR 68 (66) million.

In Specialty Products, 68 (71)% of the net sales came from generic prescription drugs, 24 (24)% from self-care products and 8 (5)% from biosimilars. The biosimilars net sales totalled EUR 38 (25) million, up by 52%. The solid growth is explained by success in national or regional tendering competitions, which generated additional sales in 2019. However, Orion faced challenges in tendering competitions for this year, which is estimated to substantially decrease biosimilars net sales in 2020. Biosimilars distributed by Orion include Remsima® (infliximab), Ritemvia® (rituximab) and Amgevita® (adalimumab).

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.

The Animal Health division had a robust year, with the division's net sales in 2019 reaching their peak so far at EUR 86 (80) million. At EUR 36 (34) million, sales of animal sedative products accounted for 42% (42%) of the Animal Health business division's total net sales. The animal sedative product family comprises Orion's animal sedatives Dexdomitor® (dexmedetomidine), Domitor® (medetomidine) and Domosedan® (detomidine), and antagonist Antisedan® (atipamezole), which reverses the effects of the sedatives.

In February 2018, Orion received positive conclusions under the decentralised EU marketing authorisation procedure for Clevor®. Clevor, with ropinirole as the active pharmaceutical ingredient, is an eye-drop formula designed to treat poisoning in dogs. The product is expected to be launched during 2020. In June 2019 Orion launched the ToxBuddy® online service in Finland to provide veterinary practitioners with information and support for treating poisoning in dogs. The service gives tools for the practitioner to assess the severity of poisoning and receive treatment instructions, among other things. The plan is to launch the service in other markets later.

Fermion

Fermion manufactures active pharmaceutical ingredients for Orion and other pharmaceutical companies. Its product range comprises nearly 30 pharmaceutical ingredients. Fermion produces 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 excluding deliveries for Orion's own use were up 8% at EUR 55 (51) million and accounted for over one-half of Fermion's total net sales. In recent years order cycles in the trade in pharmaceutical raw materials have become ever shorter, and this has led to clearly greater fluctuation in business volume than before within each year and between different years.

Research and development

The Group's R&D expenses in 2019 totalled EUR 119 (104) million, up 15%. They accounted for 11% (11%) of the Group's net sales. R&D expenses also include expenses related to development of the current portfolio. In 2019 Orion strengthened its early phase research by recruiting new talent.

Key clinical development projects

Project	Indication	PHASE			Registration
		I	II	III	
Easyhaler® tiotropium	COPD	Bioequivalence study			
Darolutamide ¹⁾	Prostate cancer (nmCRPC)	I	II	III	Registration
Darolutamide ¹⁾	Prostate cancer (mHSPC)	I	II	III	
ODM-109 (oral levosimendan)	ALS	I	II	III	
ODM-203 (FGFR+VEGFR inhibitor) ²⁾	Solid tumours	I	II		
ODM-207 (BET protein inhibitor) ²⁾	Cancer	I			
ODM-208 (CYP11A1 inhibitor)	Prostate cancer (CRPC)	I			
ODM-209 (CYP11A1 inhibitor)	Breast cancer, prostate cancer (CRPC)	I			

¹⁾ In collaboration with Bayer

²⁾ Search for partner ongoing for the next possible phase

= Phase ready

= Phase ongoing

= Status changed

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

Darolutamide, developed jointly by Orion and Bayer, was granted marketing authorisation in the United States in July 2019 for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC). After the review period in January 2020, Japan granted a marketing authorisation and the Committee for Medicinal Products for Human Use of the European Medicines Agency issued a positive statement and recommended that marketing authorisation be granted to darolutamide. The European Commission is expected to make the final decision regarding the granting of a marketing authorisation in the next few months. The product has also been approved in Brazil, and marketing authorisation applications have been submitted in other markets as well.

New results from ARAMIS trial, published in January 2020, demonstrate that darolutamide plus androgen deprivation therapy show statistically significant improvement in overall survival (OS) in men with non-metastatic castration-resistant prostate cancer compared to placebo plus androgen deprivation therapy. Detailed data on the updated OS and other additional endpoints as well as an update on longer term safety will be presented at an upcoming scientific meeting.

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.

Orion has an ongoing the Phase III clinical trial (REFALS) evaluating orally administered levosimendan (ODM-109) in the treatment of symptoms of amyotrophic lateral sclerosis (ALS). Patient recruitment for the REFALS trial was completed in July, and the trial is expected to be completed in the summer of 2020. The trial involves 496 patients and 104 clinical sites in the United States, Canada, the EU and Australia.

The purpose of the REFALS 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 investing in it

around EUR 60 million in 2018-2020. 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. Levosimendan is a molecule developed by Orion and launched already in 2000 for the i.v. treatment of acute decompensated heart failure.

Orion has carried out a Phase II clinical trial with a new targeted FGFR+VEGFR inhibitor (ODM-203) for the treatment of cancers. The trial has investigated the efficacy of the drug candidate in slowing the growth of solid cancerous tumours in patients with detected FGFR changes in cancerous tumours. Orion is looking for a partner to the possible next development phase.

Orion has carried out a 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 has investigated the safety and tolerability of the drug candidate and provisionally its efficacy in cancer patients. Orion is looking for a partner to the possible next development phase.

Orion has an ongoing Phase I clinical trial for the development of a novel selective hormone synthesis inhibitor (CYP11A1 inhibitor) for castration-resistant prostate cancer. A decision has been made to expand the trial to ensure sufficient research data for making informed decisions regarding subsequent development phases. 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 that works 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 has an ongoing Phase I clinical trial on the ODM-209 molecule. This molecule is a selective hormone synthesis inhibitor (CYP11A1 inhibitor) much like the ODM-208. A decision has been made to expand this trial as well to ensure sufficient data for making informed decisions regarding subsequent research phases. In preclinical studies, the molecule (ODM-209) has shown antitumor activity. Like ODM-208, it has potential efficacy also for those hormone-dependent cancers that have become resistant to the standard hormonal treatments. The trial will investigate the safety and tolerability of the drug candidate in breast cancer and prostate cancer patients.

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.

Personnel

The average number of employees in the Orion Group in 2019 was 3,251 (3,179). At the end of December 2019, the Group had a total of 3,265 (3,154) employees, of whom 2,594 (2,485) worked in Finland and 671 (669) outside Finland.

Salaries and other personnel expenses in 2019 totalled EUR 217 (201) 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.

Key events in 2019

- 4 Feb 2019 Orion announced the intention to start an open label extension study to the REFALS Phase III clinical trial, studying the effect of oral levosimendan in patients with amyotrophic lateral sclerosis (ALS).
- 14 Feb 2019 The findings of the ARAMIS clinical trial were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2019.
- 27 Feb 2019 The rolling submission to FDA for darolutamide in the United States completed.
- 5 Mar 2019 Marketing authorisation application for darolutamide was submitted in Japan.
- 8 Mar 2019 Marketing authorisation application for darolutamide was submitted in Europe.
- 26 Mar 2019 Orion Corporation's Annual General Meeting was held in Helsinki.
- 1 Apr 2019 The sales and distribution rights in certain European countries for the Parkinson's disease drug Comtan®, developed by Orion, transferred back to Orion from Novartis. Orion estimates that the return of the sales rights will initially increase its Comtan sales by several million euros on annual level.
- 29 Apr 2019 The United States Food and Drug Administration (FDA) accepted the marketing authorisation application for darolutamide for review and granted it Priority Review status.
- 31 May 2019 New findings on darolutamide were presented at the American Society of Clinical Oncology (ASCO) annual meeting 2019.
- 15 Jul 2019 Patient recruitment for Orion's REFALS Phase III clinical trial studying the effect of orally administered levosimendan in patients with amyotrophic lateral sclerosis (ALS) was completed.
- 30 Jul 2019 The United States Food and Drug Administration granted marketing authorisation to darolutamide, a new drug for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC).
- 7 Aug 2019 Orion announced the start of darolutamide sales in the United States and that the company will enter the EUR 45 million milestone payment from Bayer for the successful commercialisation of the product in the United States in its third quarter profits.
- 30 Dec 2019 Orion announced signing an agreement with Lotus Pharmaceutical Co., Ltd for the marketing and distribution of Orion's Stalevo® and Comtan® drugs for the treatment of Parkinson's disease in parts of Asia.

Events after the period

- 23 Jan 2020 Japan's Ministry of Health granted marketing authorisation to darolutamide for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC).
- 30 Jan 2020 Orion and Bayer told that new results from ARAMIS trial demonstrate that darolutamide plus androgen deprivation therapy show statistically significant improvement in overall survival (OS) in men with non-metastatic castration-resistant prostate cancer compared to placebo plus androgen deprivation therapy. Detailed data on the updated OS and other additional endpoints as well as an update on longer term safety will be presented at an upcoming scientific meeting.
- 31 Jan 2020 The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive statement and recommended that marketing authorisation be granted to darolutamide.

Shares and shareholders

On 31 December 2019 Orion had a total of 141,257,828 (141,257,828) shares, of which 36,335,463 (37,120,346) were A shares and 104,922,365 (104,137,482) B shares. The Group's share capital is EUR 92,238,541.46 (92,238,541.46). At the end of 2019 Orion held 765,399 (562,440) B shares as treasury shares. On 31 December 2019, the aggregate number of votes conferred by the A and B shares was 830,866,226 (845,981,962) excluding treasury shares.

At the end of December 2019, Orion had 66,595 (72,802) 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. A total of 784,883 A shares were converted into B shares in 2019.

Trading in Orion's shares

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

On 31 December 2019, the market capitalisation of the Company's shares, excluding treasury shares, was EUR 5,786 million.

In 2019 a total of 2,149,046 A shares and 85,303,946 B shares were traded on Nasdaq Helsinki. The total value of the shares traded was EUR 2,920 million. During the year, 5.9% of the A shares and 81.3% of the B shares were traded. The average turnover in Orion's shares was 61.9%.

The price of Orion's A share increased by 35,1% and the price of its B share by 36,3% in 2019. On 31 December 2019 the closing quotation was EUR 40.95 for the A shares and EUR 41.27 for the B shares. The highest quotation for Orion's A shares was EUR 42.00 and the lowest quotation was EUR 28.20. The highest quotation for the B shares in 2019 was EUR 42.52 and the lowest quotation was EUR 28.19.

Orion shares are also traded on various alternative trading platforms in addition to Nasdaq Helsinki. In 2019, 18% of all trading in Orion's A share and 62% of all trading in its B share took place outside Nasdaq Helsinki Oy (Source: Fidessa Fragmentation Index).

Authorisations of the Board of Directors

On 26 March 2019, the Annual General Meeting of Orion Corporation authorised the Board of Directors to decide on an acquisition of no more than 350,000 Orion Corporation B shares. Based on this authorisation and a decision by the Board of Directors on 25 April 2019, Orion acquired a total of 250,000 B shares between 2 and 13 May 2019. The Board of Directors was authorised by Orion Corporation's Annual General Meeting on 26 March 2019 to decide on a share issue in which shares held by the Company can be conveyed. The Board of Directors is authorised to decide on a share issue in which no more than 850,000 B shares held by the Company can be conveyed. The authorisation to issue shares is valid for five years from the decision taken by the Annual General Meeting.

The terms and conditions of the authorisations are reported in more detail in a stock exchange release on 26 March 2019.

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 two currently operating share-based incentive plans for key persons of the Group: Orion Group's Long-Term Incentive Plan 2016, announced in a stock exchange release published on 2 February 2016 and Orion Group's Long-Term Incentive Plan 2019, announced in a stock exchange release published on 6 February 2019.

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 2019, Orion had a total of 66,595 (72,802) registered shareholders, of whom 96% (95%) were private individuals. They held 40% (43%) of the entire share stock and had 60% (62%) of the total votes. There were 53 (46) million nominee-registered and foreign-owned shares, which was 38% (32%) of all shares, and they conferred entitlement to 9% (7%) of the total votes.

At the end of December 2019, Orion held 765,399 (562,440) B shares as treasury shares, which is 0.5% (0.4%) of the Company's total share stock and 0.09% (0.07%) of the total votes.

Notification threshold

On 28 November 2019 Orion received a notification under Chapter 5, Section 9 of the Securities Market Act stating that the total share of voting rights of Orion shares owned by Maa- ja vesiteknikan tuki ry and a company controlled by it, Tukinvest Oy, exceeded 5% following the share conversion under the Articles of Association of Orion Corporation executed on 28 November 2019.

According to the notification, the total share of voting rights of Maa- ja vesiteknikan tuki ry and Tukinvest Oy was 5.01%.

Management's shareholdings

At the end of 2019, the members of the Board of Directors owned a total of 627,584 of the Company's shares, of which 564,228 were A shares and 63,356 B shares. At the end of 2019, the President and CEO owned 61,491 of the Company's shares, which were all B shares. The members of the Group's Executive Management Board (excluding the President and CEO) owned a total of 198,932 of the Company's shares, which were all B shares. Thus, the Company's executive management held 0.62% of all of the Company's shares and 1.39% of the total votes. These shareholdings include holdings by controlled corporations. The Company does not have stock option programmes.

Orion's dividend distribution policy

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

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

The parent company's distributable funds are EUR 468,363,703.16 or EUR 3.33 per share. This includes EUR 211,377,323.85 or EUR 1.50 per share, of profit for the financial year. These per share amounts are calculated excluding treasury shares held by the Company. The Board of Directors proposes payment of a dividend of EUR 1.50 (1.50) per share from the parent company's distributable funds.

No dividend shall be paid on treasury shares held by the Company on the dividend distribution record date. On the day when the profit distribution was proposed, the number of shares conferring entitlement to receive dividend totalled 140,492,429, on which the total dividend payment would be EUR 210,738,643.50. The Group's payout ratio for the financial year 2019 would be 105.2% (63.8%). The

dividend payment date would be 3 April 2019, and shareholders registered in the Company's shareholder register on 27 March 2020 would be entitled to the dividend payment.

The Board of Directors further proposes that EUR 250,000 (250,000) be donated to medical research and other purposes of public interest in accordance with a separate decision by the Board and that EUR 257,375,059.66 remain in equity.

Corporate responsibility: Material themes and indicators

Orion is committed to continuously improving its performance in sustainability. Based on a materiality assessment the Company has identified material themes and indicators for its corporate responsibility. They are prioritised in the development of operations, and the Company also regularly reports on the indicators. The key themes of Orion's corporate responsibility are ensuring patient safety and reliable supply of medications, in addition to which the Company has a responsibility for the environment, its employees, business ethics and transparency. In 2019, the Company progressed in integrating corporate responsibility into key processes, created a Sustainability Agenda and invested in increasing awareness of sustainability in-house and among stakeholders. A more extensive report of corporate responsibility is published as part of the Report by the Board of Directors in the Financial Statement, under 'Non-financial reporting'. A separate Sustainability Report for 2019 will be published in May.

	2019	2018
Total energy consumption, energy savings and greenhouse gas emissions		
Total absolute energy consumption (MWh)	158,442	155,198
Energy savings achieved by saving measures and efficiency improvements (MWh)	1,422	1,074
Energy Efficiency Programme targets achieved	51%	40%
Greenhouse gas emissions, scope 1 (tCO ₂ e)	2,838	2,788
Greenhouse gas emissions, scope 2 (tCO ₂ e)	17,285	36,793
Occupational well-being of personnel: Workplace injuries and sick leave of the personnel		
Lost time incident frequency, LTIF 1	6.3	5.5
Absence due to illness (hours of absence due to illness as percentage of total theoretical working hours)	3.3%	3.1%
Respect for human rights and prevention of corruption and bribery		
Human rights violations in own operations reported through the whistleblowing channel	0	0
Anti-corruption and anti-bribery training, number of participants	443	318
Product quality and safety		
Number of audits of Orion's operations, total	88	61
Audits by authorities	29	13
Audits by collaboration partners	59	48
Critical observations	1	0
Number of audits undertaken by Orion	251	238
Critical observations	9	10
Rejections	5	1
Number of customer complaints about the Pharmaceuticals business (ppm)	76	56

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

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

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

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

Strategy

Orion's Board of Directors has confirmed the Company's strategy for 2020-2024.

Operating environment

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

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

Mission

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

Focus areas

The crucial focus areas for implementing the strategy are:

- **Quality and safety.** High quality, product safety and complying with requirements of authorities are indispensable in the pharmaceutical industry.
- **Competitive product portfolio** requires continuous renewal of the portfolio. Orion invests in product development, manufacturing, acquisition and effective launching of products and management of their life cycle.
- **Strong corporate culture of working together**, the basis of which is valuable and important work for the customer. Orion wants to be an excellent workplace and a responsible and attractive employer that continuously develops the well-being of its personnel at work and their expertise.
- **Partnerships.** Orion's operations are based on utilising worldwide networks. Well-managed partnerships and collaborations are a competitive advantage for the Company.
- **Productivity and flexibility.** Price pressure on drugs requires cost awareness and seamless cooperation between different parts of the Company to achieve the targeted profitability level. Flexibility to react rapidly to changes in the operating environment is also needed. Due to its size, Orion can be more agile than large companies and gain a competitive advantage from this.

Strategic targets

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

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

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

In the next few years, the most crucial individual growth projects will be the commercialisation of the prostate cancer drug darolutamide in cooperation with Bayer as well as finalising the development of orally administered levosimendan for the treatment of symptoms of amyotrophic lateral sclerosis (ALS) and getting the drug into market. Other than this, growth in the near future will be sought especially from the Easyhaler® product family and possibly through product acquisitions.

- **Providing new innovative and cost-effective drugs and treatments for patients.** The product development pipeline has balanced numbers of proprietary products and generic projects in different phases. In its research the Company aims for the best input/output ratio in the field.
- **Working together to benefit the customer.** Orion's personnel are committed and understand the needs of customers. The working atmosphere, customer satisfaction and Company image are at a high level.
- **Continuous improvement of performance in sustainability.** Patient safety is the most vital aspect of Orion's corporate responsibility, and managing the environmental responsibilities is an important part of the Company's sustainability. In addition, Orion aims to continuously develop the personnel's occupational safety and ability to cope with their work.
- **Strong development of profitability**

Financial objectives

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

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

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

Outlook for 2020

Orion estimates that in 2020 net sales will be at a similar level as in 2019 (net sales in 2019 were EUR 1,051 million).

Operating profit is estimated to be lower than in 2019 (in 2019 operating profit was EUR 253 million).

Basis for outlook in more detail

Orion continues persistent actions to generate growth more rapidly than growth of the market in the long term. However, significant growth investments to be made in research and development and sales and marketing in 2020-2021 will affect annual profitability.

At the same time, operating profit is burdened by intense price competition in the market and gradually expanding generic competition for certain proprietary products. It is estimated that this impact cannot be fully compensated by growing proprietary products in 2020. For example, sales of Nubeqa® is expected to start generating more revenue only from 2021 onwards.

The outlook does not include any income or expenses associated with possible product or company acquisitions.

Net sales

The sales of the Easyhaler® product family will continue to grow also in 2020 due to combined formulations (budesonide-formoterol and salmeterol-fluticasone) launched in the past few years.

Orion reacquired from Novartis the European sales and distribution rights for the Parkinson's drugs Stalevo® and Comtan® in December 2018 and April 2019, respectively. Except for Japan, Orion's arrangements with Novartis in other markets will expire during 2020 and in most of these markets, Orion is transferring the distribution to new partners. In a few Southeast Asian markets, Orion is planning to sell these products through its own sales organisations, which are being set up. After these changes, the sales of Orion's branded Parkinson's drugs (Comtess®, Comtan® and Stalevo®) are estimated to remain at the same level as in the previous year.

Generic competition for Dexdor® started in Germany in 2017 and has since expanded to most countries in the European Union, turning down sales of the product. Orion has also been informed that marketing authorisation applications have been filed for a generic version of Simdax® in Europe. It is, however, difficult to predict the impact of generic competition on the sales of Dexdor® and Simdax® in particular with any precision. The patent for the Simdax® molecule expired in September 2015 and its other product protection will expire in September 2020. The expiry of product protection is not estimated to materially affect Simdax® sales in 2020.

Sales of generic products account for a significant proportion of Orion's total sales. Disruptions in product availability and tougher price competition in generic drugs have had and will continue to have a negative effect on the business division's net sales in all markets. The prices of reference-priced prescription drugs in Finland, which is our biggest individual market, continued to decline in 2019 compared with 2018, but over the course of the year, the price decline levelled off. At the same time, the impact of availability disruptions on our net sales has intensified, and in 2019 their negative impact was roughly equal to that of the price decreases, at approximately EUR 10 million. The combined negative impact of price decline and product shortages is estimated to be slightly smaller in 2020 than in the previous year.

Net sales of Orion's biosimilars (Remsima®, Ritemvia® and Amgevita®) have fluctuated heavily in the past few years. Their net sales were EUR 57 million in 2017, EUR 25 million in 2018 and EUR 38 million in 2019. The changes are due to varying success in national or regional tendering competitions. Tendering competitions for this year have been challenging for Orion, and therefore the net sales of biosimilars are estimated to decline significantly in 2020.

Collaboration agreements with other pharmaceutical companies are an important component of Orion's business model. Agreements often include payments recorded in net sales that vary greatly from year to

year. Forecasting the timing and amount of these payments is difficult. In some cases they are conditional on, for instance, the progress or findings of research projects, which are not known until studies have been completed. On the other hand, neither the outcome nor the schedule of contract negotiations is generally known before the final signing of the agreement. In 2019, milestone payments amounted to EUR 51 million, including the EUR 45 million milestone payment from Bayer for the commercialisation of the prostate cancer drug darolutamide in the United States. The outlook for 2020 includes milestone payments worth around EUR 35 million, the largest single payments among which are EUR 20 million for the commercialisation of darolutamide in the EU and EUR 8 million for its commercialisation in Japan.

Expenditure

Sales and marketing expenditure for 2019-2020 includes a EUR 12 million annual depreciation related to the acquisition of the European sales and distribution rights for the Parkinson's drugs Stalevo® and Comtan®. Orion paid a total of USD 28 million for the transfer of the sales rights in December 2018 and in April 2019, and the investment will be depreciated over two years. The outlook also includes an estimated expenditure of EUR 5 million for preparing the launch of the ALS drug as well as costs associated with Orion's potential branching out to the United States. Most of these costs will only materialise in the second half of the year, provided that upon completion, the results of the ongoing Phase III REFALS clinical trial are considered sufficiently positive for obtaining marketing authorisation in the United States.

Because the registrations and launches of new products are projects that generally take more than a year, the increases in resources and other inputs required in 2020 were mainly planned during the previous year.

Research and development costs are estimated to be roughly equal to those in 2019. The expenses from the Phase III REFALS clinical trial investigating levosimendan (ODM-109) for the treatment of symptoms of amyotrophic lateral sclerosis (ALS) will slightly decline from previous year, since the trial will come to an end in 2020. However, investments in earlier research phases are set to increase. Research and development expenses 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 2020 are either continuing from the previous year or at an advanced stage of planning, therefore their cost level can be estimated rather accurately. However, the accrued costs are materially affected by collaboration arrangements and how the costs arising are allocated between Orion and its collaboration partners. For instance, Bayer is paying the majority of the darolutamide research costs.

Investments

The Group's total capital expenditure in 2019 is expected to be higher than in 2018, when capital expenditure was EUR 43 million.

Near-term risks and uncertainties

The reacquisition of European sales and distribution rights for Stalevo® and Comtan® has generated additional sales for Orion's branded Parkinson's drugs since 2019. With the expiration of the Novartis contract in 2020, the distribution of these products will be handed over to new partners in most non-European markets, with the exception of Japan. In a few Southeast Asian markets, Orion is also taking over sales on its own. Sales will continue to be negatively affected by continued generic competition. All these changes and impacts have been taken into account in the outlook for the current year. However, they still entail uncertainty that may materially affect the accuracy of the estimate made at this stage.

The basic Dexdor® and Simdax® patents have expired and Dexdor®'s indication patent expired at the end of March 2019. The last product protection for Simdax® will expire in 2020. Generic competition for Dexdor® started in Germany in 2017 and has since expanded to most countries in the European Union, turning down sales of the product. Orion has also been informed that marketing authorisation applications have been filed for a generic version of Simdax® in Europe. It is, however, difficult to predict the impact of generic competition on the sales of Dexdor® and Simdax® in particular with any precision. The expiry of product protection is not estimated to materially affect Simdax® sales in 2020.

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. Product deliveries to key partners are based on timetables that are jointly agreed in advance. Nevertheless, they can change, for example as a consequence of decisions concerning adjustments of stock levels. In addition, changes in market prices and exchange rates affect the value of deliveries.

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. The impact of availability disruptions on our net sales has increased in the past few years. 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 contains products manufactured by other pharmaceutical companies and products that Orion manufactures on its own but for which other companies deliver active pharmaceutical or other ingredients. Possible problems related to the delivery reliability or quality of the products of those manufacturers may cause a risk to Orion's delivery reliability. The single-channel system used for pharmaceuticals distribution in Finland, in which Orion's products have been delivered to customers through only one wholesaler, may also cause risks to delivery reliability. In 2020, there is a heightened risk of strikes or other industrial action in Finland. If strikes or industrial action do occur, they may place Orion's delivery reliability at risk. Potential production and financial impacts will depend on the extent and duration of the action, which are difficult to predict.

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

Collaboration arrangements are an important component of Orion's business model. Possible collaboration and licensing agreements related to these arrangements also often include payments to be recorded in net sales that may materially affect Orion's financial results. In 2014-2019 the annual payments varied from EUR 5 million to EUR 51 million. The payments may be subject to conditions relating to the progress of research projects or sales or to new contracts to be signed, and whether these conditions or contracts materialise and what their timing is will always entail uncertainties. The outlook for 2020 includes milestone payments worth around EUR 35 million, the largest single payments among which are EUR 20 million for the commercialisation of darolutamide in the EU and EUR 8 million for its commercialisation in Japan.

The spread of a new coronavirus creates uncertainty that can affect, among others, the supply and logistics chains.

Orion calendar

Annual General Meeting 2020	planned to be held on Wednesday 25 March 2020
Interim Report January-March 2020	Tuesday 28 April 2020
Half-Year Financial Report January-June 2020	Friday 17 July 2020
Interim Report January-September 2020	Wednesday 21 October 2020

The Financial Statements and Report by the Board of Directors for 2019 will be published on the Company's website at the latest in week 10/2020.

Espoo, 5 February 2020

Board of Directors of Orion Corporation

Orion Corporation

Tables

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

EUR million	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Net sales	274.5	262.4	+4.6%	1,051.0	977.5	+7.5%
Cost of goods sold	-113.0	-101.2	+11.6%	-417.6	-387.9	+7.7%
Gross profit	161.5	161.2	+0.2%	633.4	589.6	+7.4%
Other operating income and expenses	0.4	1.4	-69.5%	2.2	5.5	-60.2%
Sales and marketing expenses	-60.8	-55.4	+9.9%	-215.7	-195.3	+10.5%
R&D expenses	-32.8	-27.8	+18.1%	-119.3	-104.0	+14.7%
Administrative expenses	-13.4	-10.9	+23.3%	-47.8	-43.0	+11.1%
Operating profit	55.0	68.6	-19.9%	252.8	252.8	
Finance income	0.1	0.3		0.7	0.3	
Finance expenses	-0.4	-1.4	-89.3%	-2.6	-4.7	-44.2%
Profit before taxes	54.7	67.5	-19.0%	250.8	248.4	+1.0%
Income tax expense	-9.5	-13.7	-30.4%	-50.5	-51.0	-1.0%
Profit for the period for continuing operations	45.2	53.7	-15.9%	200.4	197.3	+1.6%
Profit for the period for discontinued operations		-0.4			132.9	
Profit for the period	45.2	53.1	-14.9%	200.4	330.3	-39.3%
OTHER COMPREHENSIVE INCOME INCLUDING TAX EFFECTS¹						
Translation differences	1.1	-0.4		0.9	-1.7	
Items that may be reclassified subsequently to profit and loss	1.1	-0.4		0.9	-1.7	
Re-measurement of pension plans (continuing operations)	19.9	-16.9		19.9	-21.4	
Re-measurement of pension plans (discontinued operations)					2.9	
Items that will not be reclassified to profit and loss	19.9	-16.9		19.9	-18.5	
Other comprehensive income net of tax	21.1	-17.3	+221.4%	20.9	-20.1	+204.0%
Comprehensive income for the period including tax effects	66.2	35.8	+84.7%	221.2	310.1	-28.7%
PROFIT ATTRIBUTABLE TO¹						
Owners of the parent company	45.2	53.1	-14.9%	200.4	330.3	-39.3%
COMPREHENSIVE INCOME ATTRIBUTABLE TO¹						
Owners of the parent company	66.2	35.8	+84.7%	221.2	310.1	-28.7%
Continuing operations						
Basic earnings per share, EUR¹	0.32	0.38	-14.9%	1.43	1.40	+2.0%
Diluted earnings per share, EUR¹	0.32	0.38	-14.9%	1.43	1.40	+2.0%
Depreciation, amortisation and impairment	14.6	11.1	+30.8%	56.1	41.1	+36.5%
Personnel expenses	60.3	52.2	+15.6%	217.1	200.7	+8.2%

Discontinuing operations

	1-12/19	1-12/18
Basic earnings per share, EUR¹		0.95
Diluted earnings per share, EUR¹		0.95
Depreciation, amortisation and impairment		0.7
Personnel expenses		2.1

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

The Diagnostics business, sold on 30 April 2018, has been reported as a discontinued operation since the interim report 1-3/2018.

IFRS 16 has been adopted by using the simplified retrospective method, and therefore figures of the comparative periods have not been adjusted.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS

EUR million	12/19	12/18	Change %
Property, plant and equipment	320.9	316.9	+1.2%
Goodwill	13.5	13.5	
Intangible rights	34.8	47.5	-26.7%
Other intangible assets	2.8	2.7	+1.8%
Investments in associates	0.1	0.1	
Other investments	0.2	0.3	-19.0%
Pension asset	55.8	31.5	+77.1%
Deferred tax assets	6.8	5.1	+32.1%
Other non-current assets	0.8	0.9	-18.3%
Non-current assets total	435.6	418.5	+4.1%
Inventories	230.3	222.1	+3.7%
Trade receivables	196.5	188.8	+4.1%
Other receivables	24.3	33.7	-27.8%
Money market investments	35.0	35.0	
Cash and cash equivalents	114.0	248.7	-54.2%
Current assets total	600.1	728.2	-17.6%
Assets total	1,035.7	1,146.7	-9.7%

EQUITY AND LIABILITIES

EUR million	12/19	12/18	Change %
Share capital	92.2	92.2	
Other reserves ¹	3.0	2.9	+1.4%
Retained earnings	684.2	678.0	+0.9%
Equity attributable to owners of the parent company	779.4	773.1	+0.8%
Equity total	779.4	773.1	+0.8%
Deferred tax liabilities	41.2	37.8	+8.9%
Pension liabilities	3.4	3.6	-4.6%
Provisions	0.4	0.3	+5.2%
Interest-bearing non-current liabilities	6.7	0.6	
Other non-current liabilities	17.1	17.4	-1.8%
Non-current liabilities total	68.8	59.8	+15.1%
Trade payables	79.0	74.9	+5.4%
Current tax liabilities	2.6	1.5	+75.4%
Other current liabilities	102.6	86.4	+18.8%
Interest-bearing current liabilities	3.3	150.9	-97.8%
Current liabilities total	187.5	313.8	-40.2%
Liabilities total	256.3	373.6	-31.4%
Equity and liabilities total	1,035.7	1,146.7	-9.7%

The Group has combined the previously separately presented "Expendable fund" item under the item "Other reserves".

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

Equity attributable to owners of the parent company ¹							
EUR million	Share capital	Other reserves	Remeasurement of pension plans	Treasury shares	Translation differences	Retained earnings	Equity total
Equity at 1 January 2018	92.2	2.8	31.9	-20.1	-5.9	578.7	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	2.8	31.9	-20.1	-5.9	562.2	663.2
Profit for the period						330.3	330.3
Other comprehensive income							
Translation differences					-1.8	0.2	-1.6
Remeasurement of pension plans			-21.4			2.9	-18.5
Transaction with owners							
Dividend and capital repayment						-203.8	-203.8
Share-based incentive plan				2.1		1.8	3.9
Other adjustments		0.1				-0.4	-0.3
Equity at 31 December 2018	92.2	2.9	10.5	-18.0	-7.7	693.2	773.1
Equity at 1 January 2019	92.2	2.9	10.5	-18.0	-7.7	693.2	773.1
Impact of the adoption of the IFRS 16 standard						-0.2	-0.2
Adjusted equity at 1 January 2019	92.2	2.9	10.5	-18.0	-7.7	693.0	772.9
Profit for the period						200.4	200.4
Other comprehensive income							
Translation differences					0.7	0.2	0.9
Remeasurement of pension plans			19.9				19.9
Transaction with owners							
Dividend and capital repayment						-211.4	-211.4
Repurchase of own shares				-7.4			-7.4
Share-based incentive plan				0.9		1.6	2.5
Other adjustments		0.0				1.5	1.5
Equity at 31 December 2019	92.2	3.0	30.5	-24.5	-7.0	685.2	779.4

¹ The Group did not have portions attributable to non-controlling interests at 12/2019 and 12/2018.

² As of Q3/2019 reporting, the Group has combined the previously separately presented "Expendable fund" item under the item "Other reserves". The share of the expendable fund of other reserves at 31 December 2019 was EUR 0.5 million. There have been no changes in the expendable fund since 1 January 2018.

CONSOLIDATED STATEMENT OF CASH FLOWS

EUR million	1-12/19	1-12/18
Operating profit	252.8	387.3
Adjustments	56.7	-87.8
Change in working capital	14.5	-10.2
Net financial items	-3.9	-4.2
Income taxes paid	-49.3	-54.3
Total net cash flow from operating activities	270.8	230.9
Investments in property, plant and equipment	-28.7	-38.1
Investments in intangible assets	-7.5	-28.7
Sales of property, plant and equipment and other investments	0.7	0.9
Sales of subsidiaries	1.4	161.3
Total net cash flow from investing activities	-34.0	95.4
Cash flow from operating and investing activities, total	236.8	326.3
Current loans raised	-1.6	1.3
Repayments of current loans	-151.2	-2.6
Repurchase of own shares	-7.4	
Dividends paid and other distribution of profits	-211.2	-203.9
Total net cash flow from financing activities	-371.4	-205.3
Net change in cash and cash equivalents	-134.5	121.0
Cash and cash equivalents at the beginning of the period	283.7	164.1
Foreign exchange differences	-0.1	-1.5
Cash and cash equivalents at the end of the period	149.0	283.7
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	114.0	248.7
Money market investments at the end of the period	35.0	35.0
Cash and cash equivalents in the statement of cash flows	149.0	283.7

The Diagnostics business, sold on 30 April 2018, has been reported as a discontinued operation since the interim report 1-3/2018. The cash flow statement for the comparative period 1-12/2018 contain the assets and liabilities of the discontinued operation.

DISCONTINUED OPERATIONS

There are no discontinued operations during the financial year 2019.

At the outset of 2018 financial year, Orion announced that it had decided to investigate the possible sale of Orion Diagnostica or other arrangement. 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. In the Financial Review and in the comparative data of the tables of the Financial Statement Release, the Orion Diagnostica segment is treated as a discontinued operation. The of profit of discontinued operations in the comparative period, January-December 2018, was EUR 132.9 million.

The selling price of Orion Diagnostica was EUR 161.7 and Orion booked a EUR 128.4 million capital gain in the comparative period 2018, 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 the variable component is based on the return on investment for Axcel at the ime of the exit. Due to the uncertainty relating to the euro value and timing of the additional price, the estimated capital gain does not include any part of the additional price component. The management's evaluation on the realisation of the additional selling price has not changed during the financial period of 2019.

PROFIT FOR THE PERIOD FOR DISCONTINUED OPERATIONS

EUR million	1-12/19	1-12/18	Change %
Net sales		18.7	
Capital gain from sale of discontinued operations		128.4	
Total expenses		-12.5	
Operating profit		134.6	
Income tax expense		-1.6	
Profit for the period		132.9	

Appendices

REVENUE BY REVENUE FLOWS

EUR million	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Sale of goods	267.3	257.5	+3.8%	988.6	953.7	+3.7%
Royalty income	3.2	3.4	-6.0%	11.5	17.4	-33.8%
Total sale of goods	270.5	260.9	+3.7%	1,000.1	971.0	+3.0%
Milestone payments	4.0	1.5	+172.9%	50.8	5.3	
Total sales of revenue flows	274.5	262.4	+4.6%	1,051.0	976.3	+7.7%
Sales for discontinued operations					1.2	
Group total	274.5	262.4	+4.6%	1,051.0	977.5	+7.5%

Revenue from clinical phase R&D collaboration with collaboration partners during the period 1-12/2019 was EUR 0.6 (0.5) million and is included in Milestone payments. EUR 2.0 (2.0) million of sales revenue for performance obligations to be transferred to customers were entered as income over time. The Group has recorded EUR 0.7 (-0.0) million of sales revenue for performance obligations satisfied during previous financial periods.

NET SALES BY BUSINESS DIVISION

EUR million	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Proprietary Products ¹⁾	98.5	96.0	+2.6%	406.1	356.9	+13.8%
Specialty Products	136.6	126.5	+8.0%	486.1	473.1	+2.7%
Animal Health	21.7	22.6	-4.0%	85.8	80.4	+6.7%
Fermion	12.3	13.2	-7.5%	55.0	50.7	+8.5%
Contract manufacturing and other	5.5	4.1	+33.9%	18.0	16.3	+10.6%
Group total	274.5	262.4	+4.6%	1,051.0	977.5	+7.5%

¹⁾ The net sales of Proprietary Products during the period 1-12/2019 includes EUR 2.0 (2.0) million of sales revenue for performance obligations to be transferred to customers that will be entered as income over time.

NET SALES AND OPERATING PROFIT BY QUARTER

EUR million	2019				2018			
	10-12	7-9	4-6	1-3	10-12	7-9	4-6	1-3
Net sales	274.5	283.7	251.7	241.0	262.4	221.8	246.1	247.2
Operating profit	55.0	90.7	52.1	55.0	68.6	44.6	69.7	69.8

GEOGRAPHICAL BREAKDOWN OF NET SALES BY QUARTER

EUR million	2019				2018			
	10-12	7-9	4-6	1-3	10-12	7-9	4-6	1-3
Finland	83.0	76.2	75.2	74.3	82.7	74.0	75.4	80.0
Scandinavia	46.2	42.0	44.6	43.9	40.4	36.4	36.9	41.2
Other Europe	87.5	78.1	85.7	82.8	83.5	72.0	73.0	75.5
North America	14.8	57.8	16.5	13.9	15.9	14.9	13.5	14.0
Other markets	42.9	29.6	29.9	26.1	39.7	24.4	47.3	36.6
Group total	274.5	283.7	251.7	241.0	262.4	221.8	246.1	247.2

TOP TEN BEST-SELLING PHARMACEUTICAL PRODUCTS

EUR million	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Easyhaler® product family (asthma, COPD)	29.5	26.0	+13.5%	104.5	90.4	+15.6%
Stalevo®, Comtess® and Comtan® (Parkinson's disease)	27.1	24.6	+10.2%	97.5	100.1	-2.6%
Simdax® (acute decompensated heart failure)	18.2	16.1	+13.1%	67.6	59.4	+13.8%
Dexdor® (intensive care sedative)	11.0	15.1	-27.3%	56.6	63.1	-10.2%
Biosimilars (rheumatoid arthritis, inflammatory bowel diseases)	9.6	5.7	+70.3%	37.7	24.8	+52.0%
Dexdomitor®, Domitor®, Domosedan® and Antisedan® (animal sedatives)	8.6	10.5	-18.2%	36.2	33.6	+7.7%
Burana® (inflammatory pain)	6.7	6.9	-2.9%	25.0	23.5	+6.5%
Divina series (menopausal symptoms)	4.6	5.0	-9.4%	19.0	18.8	+1.2%
Marevan® (anticoagulant)	4.4	5.5	-19.6%	15.9	17.8	-10.7%
Solomet® (inflammation, pain)	4.3	3.4	+25.6%	14.0	12.7	+10.6%
Total	124.0	118.8	+4.4%	474.2	444.2	+6.7%
Share of net sales	45%	45%		45%	45%	

CHANGES IN PROPERTY, PLANT AND EQUIPMENT

EUR million	12/19	12/18
Carrying amount at the beginning of the period	316.9	323.1
+ Impact of the adoption of the IFRS 16 standard	8.6	
- discontinued operations		-10.0
Additions	35.4	36.1
Disposals	-3.6	-0.9
Amortisation and impairment	-36.3	-31.1
Carrying amount at the end of the period	320.9	316.9

CHANGES IN INTANGIBLE ASSETS (EXCLUDING GOODWILL)

EUR million	12/19	12/18
Carrying amount at the beginning of the period	50.2	39.4
- discontinued operations		-8.0
Additions	7.2	28.7
Disposals	-0.0	-0.0
Amortisation and impairment	-19.8	-10.0
Carrying amount at the end of the period	37.6	50.2

COMMITMENTS AND CONTINGENCIES

EUR million	12/19	12/18
CONTINGENCIES FOR OWN LIABILITIES		
Guarantees	6.5	4.5
OTHER LIABILITIES		
Other liabilities	0.3	0.3

DERIVATIVES

EUR million	12/19	12/18
CURRENCY FORWARD CONTRACTS AND CURRENCY SWAPS		
Fair value, EUR million	-0.5	0.2
Nominal value, EUR million	56.2	32.6
CURRENCY OPTIONS		
Fair value, EUR million	-0.1	0.0
Nominal value, EUR million	44.6	31.8

FAIR VALUE MEASUREMENT AND HIERARCHY OF FINANCIAL INSTRUMENTS

EUR million	Level 1	Level 2	Level 3	Total
Derivatives				
Currency derivatives		0.1		0.1
Money market investments	35.0			35.0
Other investments				
Shares and investments			0.2	0.2
Assets total	35.0	0.1	0.2	35.3
Derivatives				
Currency derivatives		-0.7		-0.7
Liabilities total		-0.7		-0.7

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

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

No transfers between levels occurred during the reporting period.

RELATED PARTY TRANSACTIONS

EUR million	12/19	12/18
Management's employment benefits	4.9	5.9

BASIC SHARE INFORMATION, 31 DECEMBER 2019

	A share	B share	Total
Trading code on Nasdaq Helsinki	ORNAV	ORNBV	
Listing day	1 Jul 2006	1 Jul 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	23.7	68.5	92.2
Counter book value per share, EUR	0.65	0.65	
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	

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

KEY FINANCIAL FIGURES

	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Net sales, EUR million	274.5	262.4	+4.6%	1,051.0	977.5	+7.5%
EBITDA, EUR million	69.5	79.7	-12.8%	308.9	293.9	+5.1%
% of net sales	25.3%	30.4%		29.4%	30.1%	
Operating profit, EUR million	55.0	68.6	-19.9%	252.8	252.8	
% of net sales	20.0%	26.1%		24.1%	25.9%	
Profit for the period, EUR million	45.2	53.7	-15.9%	200.4	197.3	+1.6%
% of net sales	16.4%	20.5%		19.1%	20.2%	
R&D expenses, EUR million	32.8	27.8	+18.1%	119.3	104.0	+14.7%
% of net sales	11.9%	10.6%		11.3%	10.6%	
Capital expenditure, EUR million	14.5	35.4	-59.0%	42.6	64.8	-34.3%
% of net sales	5.3%	13.5%		4.0%	6.6%	
Amortisation and impairments, EUR million	14.6	11.1	+30.8%	56.1	41.1	+36.5%
Personnel expenses, EUR million	60.3	52.2	+15.6%	217.1	200.7	+8.2%
Equity total, EUR million				779.4	773.1	+0.8%
Interest-bearing net liabilities, EUR million				-139.1	-132.1	-5.2%
Assets total, EUR million				1,035.7	1,146.7	-9.7%
Cash flow from operating activities, EUR million				270.8	230.9	+17.3%
Equity ratio, %				76.7%	68.8%	
Gearing, %				-17.8%	-17.1%	
ROCE (before taxes), %				29.9%	44.3%	
ROE (after taxes), %				25.8%	45.5%	
Personnel at the end of the period				3,265	3,154	+3.5%
Average personnel during the period				3,251	3,179	+2.3%

PERFORMANCE PER SHARE

	10-12/19	10-12/18	Change %	1-12/19	1-12/18	Change %
Basic earnings per share, EUR	0.32	0.38	-14.9%	1.43	1.40	+2.0%
Diluted earnings per share, EUR	0.32	0.38	-14.9%	1.43	1.40	+2.0%
Cash flow per share before financial items, EUR	0.40	0.22	+84.6%	1.68	2.32	-27.4%
Equity per share, EUR				5.55	5.50	+1.0%
Proposed dividend per share, EUR				1.50	1.50	
Proposed payout ratio, %				105.2%	63.8%	
Total proposed dividend, EUR million				210.7	211.0	-0.2%
Effective dividend yield according to proposal, %						
A share				3.7%	5.0%	
B share				3.6%	5.0%	
Price/earnings ratio (P/E)						
A share				28.64	12.89	+122.2%
B share				28.86	12.89	+123.9%
A share						
Number of shares at the end of the period				36,335,463	37,120,346	-2.1%
% of total share stock				25.7%	26.3%	
Number of votes excluding treasury shares				726,709,260	742,406,920	-2.1%
% of total votes				87.5%	87.8%	
Total number of shareholders				19,990	20,368	-1.9%
Closing quotation at the end of previous financial year, EUR				30.30	32.07	-5.5%
Lowest quotation of review period, EUR				28.20	24.75	+13.9%
Average quotation of review period, EUR				34.26	29.63	+15.6%
Highest quotation of review period, EUR				42.00	35.70	+17.6%
Closing quotation at the end of review period, EUR				40.95	30.30	+35.1%
Trading volume, EUR million				73.5	63.2	+16.4%
Shares traded				2,149,046	2,131,981	+0.8%
% of the total number of shares				5.9%	5.7%	
B share						
Number of shares at the end of the period, including treasury shares				104,922,365	104,137,482	+0.8%
% of total share stock				74.3%	73.7%	
Treasury shares				765,399	562,440	+36.1%
Number of shares at the end of the period, excluding treasury shares				104,156,966	103,575,042	+0.6%
Number of votes excluding treasury shares				104,156,966	103,575,042	+0.6%
% of total votes				12.5%	12.2%	
Total number of shareholders				52,913	58,903	-10.2%
Closing quotation at the end of previous financial year, EUR				30.28	31.08	-2.6%
Lowest quotation of review period, EUR				28.19	22.57	+24.9%
Average quotation of review period, EUR				33.48	27.90	+20.0%
Highest quotation of review period, EUR				42.52	33.50	+26.9%
Closing quotation at the end of review period, EUR				41.27	30.28	+36.3%
Trading volume, EUR million				2,846.5	3,389.3	-16.0%
Shares traded				85,303,946	121,458,874	-29.8%
% of the total number of shares				81.3%	116.6%	

A and B share total			
Number of shares at the end of the period	141,257,828	141,257,828	
Average number of shares during the period excluding treasury shares	140,571,373	140,676,819	
Total number of votes conferred by the shares	830,866,226	845,981,962	-1.8%
Total number of shareholders	66,595	72,802	-8.5%
Trading volume, EUR million	2,920.0	3,452.5	-15.4%
Shares traded	87,452,992	123,590,855	-29.2%
Total shares traded, % of total shares	61.9%	87.5%	
Market capitalisation at the end of the period excluding treasury shares, EUR million	5,786.5	4,261.0	+35.8%

REPORTING

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

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

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

ACCOUNTING POLICIES

The Consolidated Financial Statements of the Orion Group have been prepared in accordance with International Financial Reporting Standards (IFRS) applying the IAS and IFRS standards as well as SIC and IFRIC interpretations effective at 31 December 2019.

The following new standards, interpretations and amendments to existing standards endorsed by the EU have been adopted as of 1 January 2019:

- IFRS 16 (new), Leases
- IAS 19 (amended), Employment benefits
- IFRIC 23 (new), Uncertainty over Income Tax Treatments

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 16 (Leases)

Information on transition on 1 January 2019

IFRS 16 (Leases) has replaced IAS 17 and related interpretations, which previously regulated the accounting treatment of leases, as of 1 January 2019. The Group has applied the simplified method permitted by IFRS 16 in the transition and recognised the cumulative effect in the opening balance sheet on 1 January 2019 as retained earnings and does not present comparative information.

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

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

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

Following the adoption of IFRS 16, the Group has recognised an increase of EUR 8.6 million in right-of-use assets. EUR 8.9 million has been recognised as increase in lease liabilities on the balance sheet. EUR 0.2 million has been recognised as decrease of retained earnings in equity. An increase of EUR 0.0 million has been recorded as deferred tax assets.

BALANCING LEASE COMMITMENTS ON 31 DECEMBER 2018 TO LEASE LIABILITIES ON 1 JANUARY 2019

EUR million	
Lease commitments on 31 December 2018	14.5
Discounted value on 1 January 2019	13.8
Finance lease liabilities on 31 December 2018	1.6
Short-term and low-value leases	-4.5
Leases commencing in 2019 not yet included in liabilities	-2.0
Lease liabilities on 1 January 2019	8.9

ADJUSTED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME, CONSOLIDATED STATEMENT OF FINANCIAL POSITION AND OTHER KEY FIGURES FOR THE FINANCIAL YEAR 2018

1) Comparative information previously reported in the interim report and financial statement release.

2) Comparative information previously reported in the interim report and financial statement releases, if impact of IFRS 16 is taken into account

	1-12/18	
	1)	2)
Net sales, EUR million	977.5	977.5
EBITDA, EUR million	293.9	293.9
% of net sales	30.1%	30.1%
Operating profit, EUR million	252.8	253.0
% of net sales	25.9%	25.9%
Profit for the period, EUR million	197.3	197.3
% of net sales	20.2%	20.2%
Other comprehensive income net of tax, EUR million	310.1	310.1
Deferred tax assets, EUR million	5.1	5.1
Interest-bearing non-current liabilities, EUR million	0.6	6.4
Interest-bearing current liabilities, EUR million	150.9	153.9
Equity total, EUR million	773.1	773.1
Assets total, EUR million	1,146.7	1,155.6
Equity ratio, %	68.8%	68.2%
Gearing, %	-17.1%	-15.9%
ROCE (before taxes), %	44.3%	43.9%
ROE (after taxes), %	45.5%	45.5%
Basic earnings per share, EUR	1.40	1.40
Diluted earnings per share, EUR	1.40	1.40
Equity per share, EUR	5.50	5.50

Accounting of leases under IFRS 16

Determining whether an arrangement contains a lease

The Group will assess at the time of inception whether a contract is, or contains, a lease. A contract contains a lease when it contains an identified asset and it conveys the right to direct the use of that asset for a specific period of time. The precondition is that the Group pays a consideration to the contracting party in exchange for this right.

The asset can be identified either explicitly, for example, based on a specific identification code, or implicitly, when the asset is not specified in the contract but in practice the contract can only be performed using a specific asset. The identified asset may also be a physically separable part of a larger asset, if it represents a substantial part of the total capacity of the asset. If the contracting party may substitute the asset with another one and gain financially in the process, the contract does not involve an identified asset and thus does not constitute a lease.

A contract conveys control to the Group when the Group gains substantially all the economic benefits from using the asset and has the right to direct the use of the identified asset during its useful life.

Determination of the Group's right to direct the use of an asset involves considering its right to change things such as:

- what type of output is generated;
- when the output is generated;
- where the output is generated; and
- how much output is generated

Separating components of a contract

In some cases, contracts may contain lease components, which is due to the fact that the contract obligates the contracting party to provide various obligations to the Group. In such multi-component arrangements, the Group will specify each lease component and process them separately in accounting. The right to use the underlying asset is a separate lease component when the Group is able to benefit from the use of the asset either as such or jointly with other easily accessible resources and the asset is not highly dependent on other assets stipulated by the contract or it is not strongly attached to them. The Group allocates the contractual consideration to each lease component in proportion to their relative individual prices.

Lease term

The lease term is the period during which the lease cannot be cancelled. The lease term is extended by the period covered by an extension or termination option, if the Group is reasonably certain to exercise the extension option or not to exercise the termination option.

Leases with a term of 12 months or less and leases of low-value assets are classified as operating leases. For these leases, the lease payable to the lessor is recorded as an expense on an accrual basis. The underlying assets are not capitalised in the balance sheet.

Recognition at the inception of the lease

At the commencement of a lease, the Group recognises a lease liability and a corresponding right-of-use asset.

The lease liability is measured at the present value of the lease payments payable over the lease term that have not yet been paid. The leases are discounted at the rate implicit in the lease or the Group's incremental borrowing rate. In practice, the Group discounts the leases using the Group's incremental borrowing rate, since the rates implicit in the Group's leases typically cannot be readily determined. The incremental borrowing rate is based on market rates plus a country risk associated premium.

The right-of-use asset is initially measured at acquisition cost, which includes the original amount of the lease liability plus any initial direct costs incurred by the Group, estimated restoration costs and any lease payments made at or prior to commencement, less lease incentives obtained.

Leases paid by the Group consist of fixed payments, variable leases, amounts payable based under residual value guarantees, purchase option exercise prices, if it is reasonably certain that the option will be exercised as well as of payments associated with termination sanctions if it has been taken into account in the lease term that the Group will exercise its lease termination option.

When a variable lease depends on an index or a rate, these are taken into consideration when determining lease liability. Variable lease payments are initially measured using the index or rate as at the commencement date. Other variable leases, such as leases to be payable based on asset performance, are not included in the lease liability. Factually fixed payments, which are dependent on the functioning of an asset, for example, are taken into consideration when measuring the lease liability.

Subsequent measuring of a lease

After lease commencement, the Group measures the right-of-use asset using the acquisition cost model. The right-of-use asset is measured at acquisition cost less accumulated depreciation and accumulated impairment, adjusted by any cost of remeasurement of the lease liability. Depreciation is recognised in accordance with IAS 16 (Property, plant and equipment). The residual value and useful life of the right-of-use asset is reviewed when necessary, but at least at every year end for the financial statements, and an impairment is recognised if expected economic benefits change.

The Group values the lease liability in subsequent periods using the effective interest method.

The lease liability is remeasured if actual lease payments materially differ from lease payments contained in the original measurement and if the change in lease payments is based on clauses of the lease agreement that were in force at the inception of the lease. The lease is subsequently remeasured, for

example, when there is a change in future lease payments due to a change in the index or rate used to determine those payments, or if there is a change in the amounts expected to be payable under a residual value guarantee. Changes in the assessment of a purchase option of an underlying asset or an extension or termination option may also lead to a remeasurement of the lease liability. The carrying amount of the right-of-use asset is adjusted by the lease liability amount following a remeasurement, or if the right-of-use asset has a carrying amount of zero, it is recognised through profit or loss.

The Group may re-negotiate leases during the lease term. Changes may lead to a revision of the duration of the lease term or to changing the underlying asset. The Group processes lease modifications in accordance with IFRS 16 as modifications of the scope of the lease or of the consideration payable, which were not part of the original terms agreed at the inception of the lease.

Other adjustments as of 1 January 2019

Other new IFRS standards, interpretations and amendments to existing IFRS standards adopted from 1 January 2019 have not affected the consolidated financial statements.

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

Other matters

The information published in this release is based on Orion's audited financial statement for 2019. Orion Corporation's financial statement release has been prepared in accordance with the accounting policies set out in International Accounting Standard 34 on Interim Financial Reporting. Orion has applied the same accounting principles in the preparation of the Financial Statement Release as in the Financial Statements for 2019.

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

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

Publisher:

Orion Corporation

<http://www.orion.fi/en>

<http://www.twitter.com/OrionCorplR>

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, Finnish heritage rare diseases and respiratory diseases for which Orion develops inhaled Easyhaler® pulmonary drugs. Orion's net sales in 2019 amounted to EUR 1,051 million and the company had about 3,300 employees at the end of the year. Orion's A and B shares are listed on Nasdaq Helsinki.