



Orion Interim Report 1-3/2019

Disclaimer

This presentation contains forward-looking statements which involve risks and uncertainty factors. These statements are not based on historical facts but relate to the Company's future activities and performance. They include statements about future strategies and anticipated benefits of these strategies.

These statements are subject to risks and uncertainties. Actual results may differ substantially from those stated in any forward-looking statement. This is due to a number of factors, including the possibility that Orion may decide not to implement these strategies and the possibility that the anticipated benefits of implemented strategies are not achieved. Orion assumes no obligation to update or revise any information included in this presentation.



Highlights in January-March 2019

Marketing authorisation applications for darolutamide submitted in main markets

1 Marketing authorisation applications for the prostate cancer drug darolutamide submitted in the main markets US, Japan and Europe.

2 Net sales and operating profit were lower than in the comparative period.
R&D expenses increased.
Outlook remains unchanged.



3 Net sales of Proprietary Products slightly declined from the previous year. Easyhaler, Dexdor and Simdax sold well.

Net sales of Specialty Products decreased in Finland and Eastern Europe, but increased in Scandinavia.

4 Orion has launched a Phase I clinical trial on the ODM-209 molecule. This molecule is a selective hormone synthesis inhibitor much like the ODM-208.

Orion will not independently pursue a trial on ODM-104 for Parkinson's disease.

Key figures 1–3/2019

Net sales

241

MEUR (247)
-3%

Operating profit

55

MEUR (70)
-21%

Operating profit
margin

23%

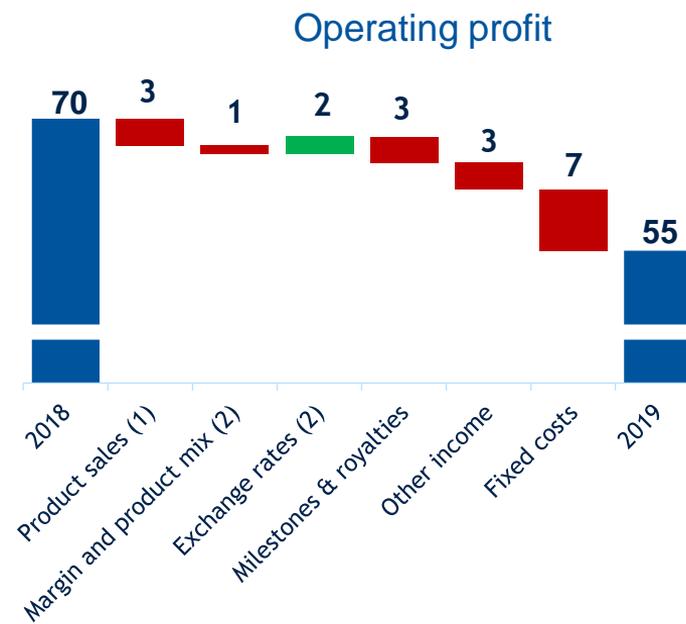
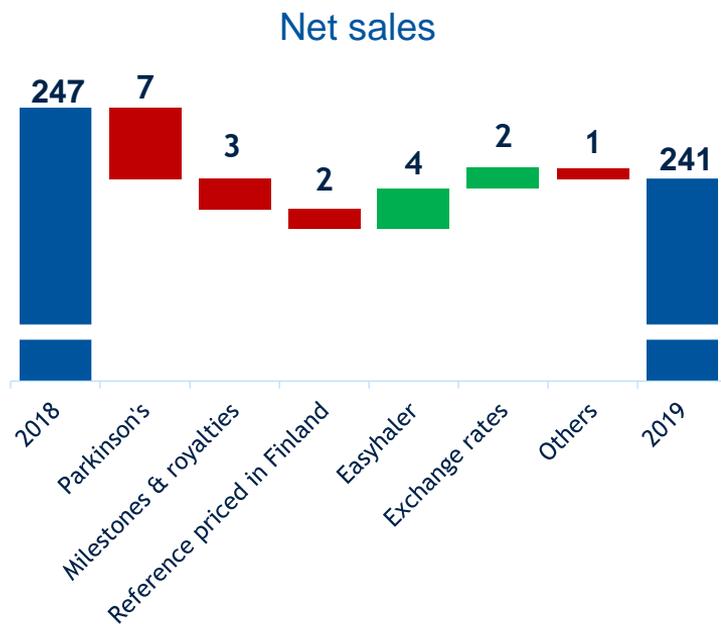
(28%)

Cash flow per share
before financial
items

0.40

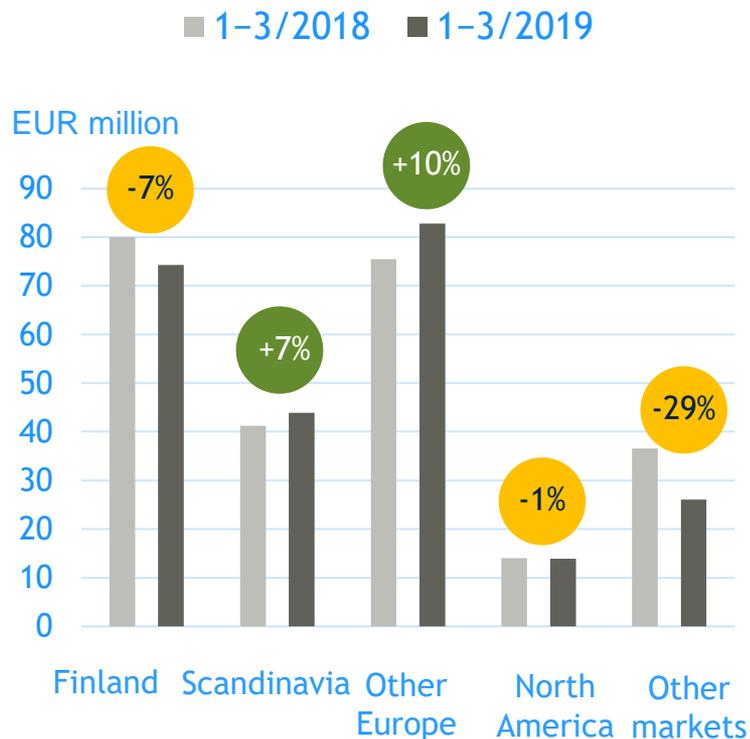
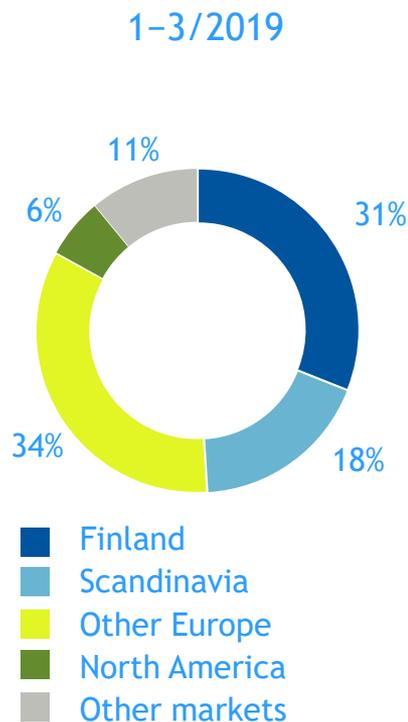
EUR (0.39)
+3%

Development of net sales and operating profit



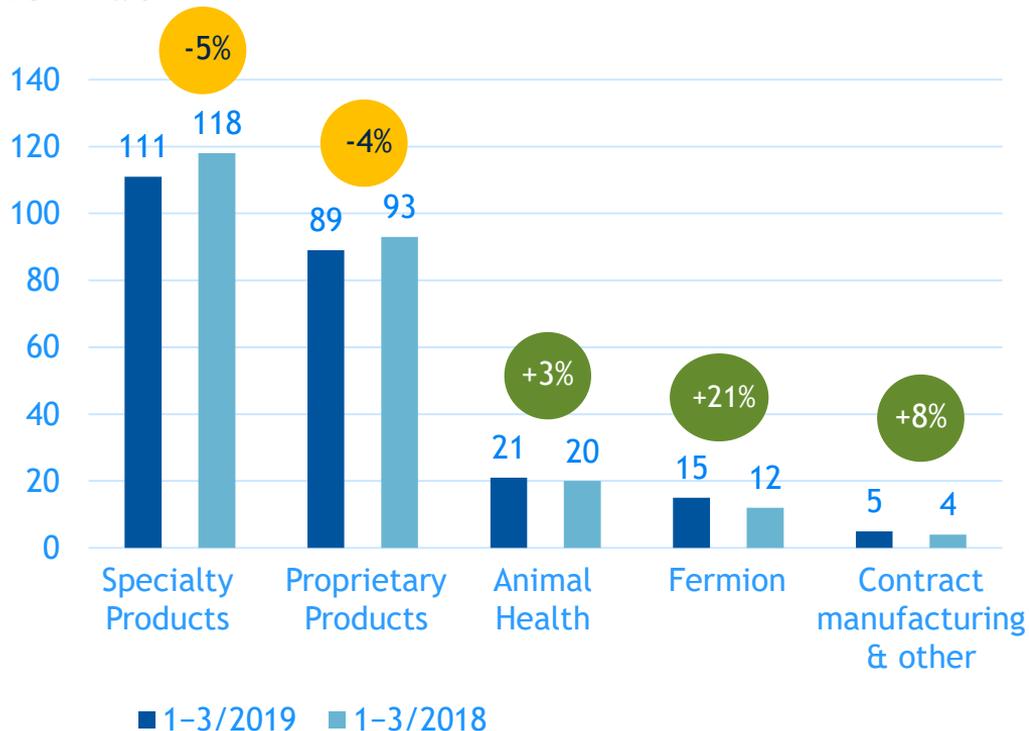
- (1) Product sales without sales margin and product mix change and exchange rate effect
- (2) Product sales margin and product mix change but without exchange rate effect
- (3) Exchange rate effect on gross margin

Geographical breakdown and development of net sales

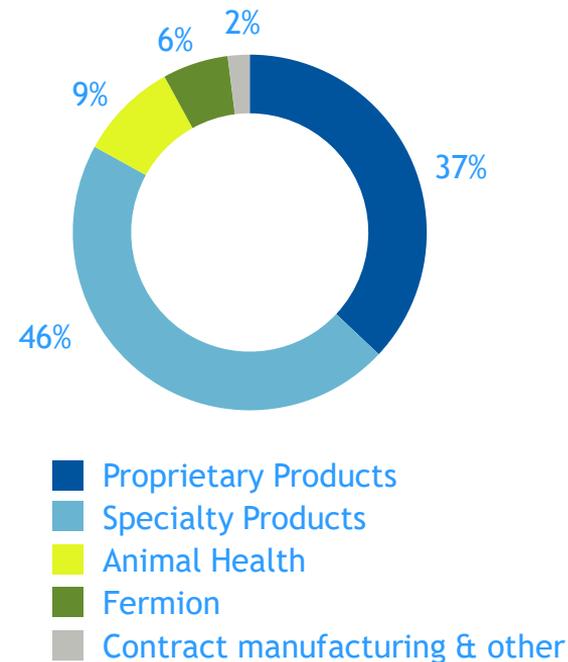


Net sales by business division

EUR million



1-3/2019



Best-selling pharmaceuticals 1-3/2019

		Indication	Net sales (EUR million)	Change vs 1-3/2018
1.		Asthma, COPD	26	+21%
2.	  	Parkinson's disease	21	-25%
3.		Intensive care sedative	19	+10%
4.		Acute heart failure	17	+16%
5.	   	Animal sedatives	10	+15%
6.	Biosimilars   	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	9	-12%
7.		Inflammatory pain	6	+5%
8.	Divina series 	Menopausal symptoms	5	+8%
9.		Anticoagulant	3	-24%
10.	Generic entacapone products	Parkinson's disease	3	-29%

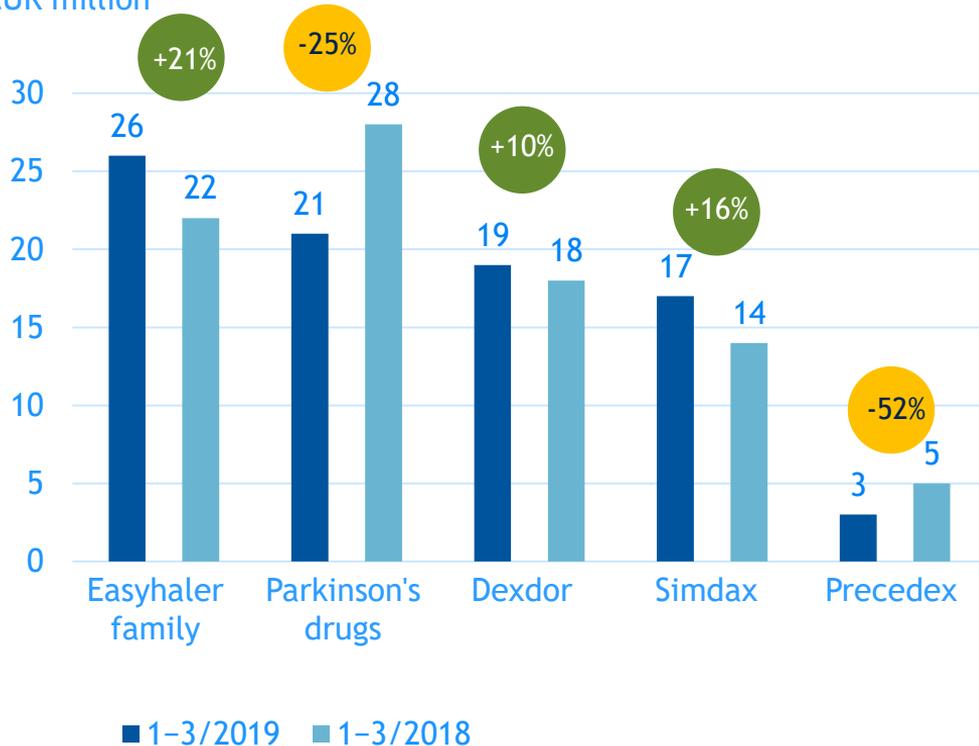
 = Products of Proprietary Products business division



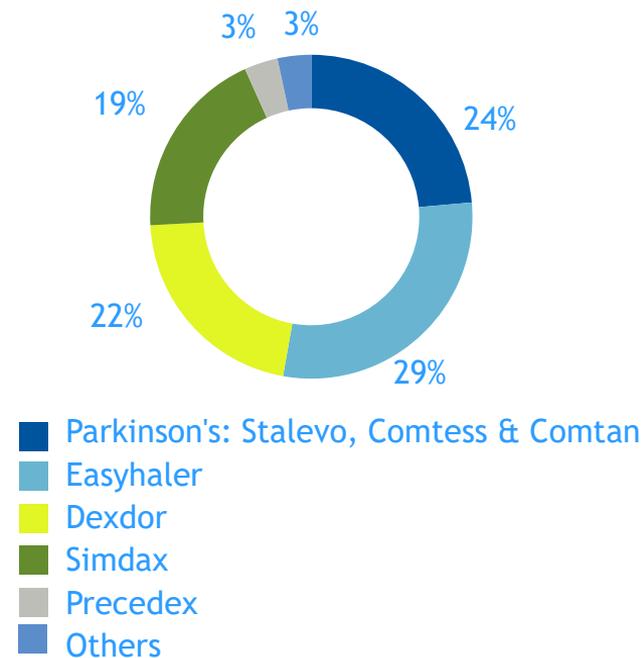
Proprietary Products

Easyhaler became the top proprietary product

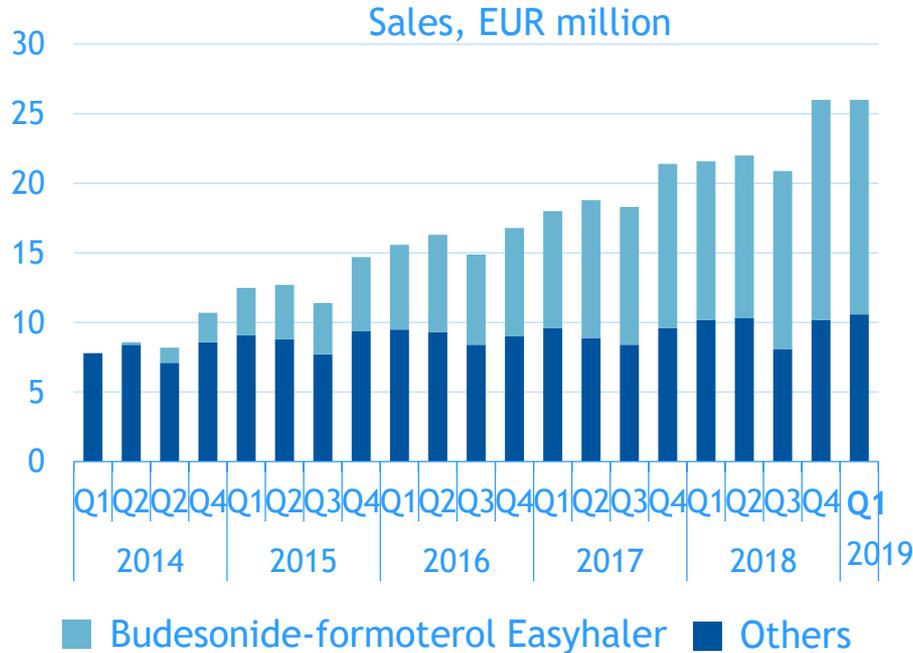
EUR million



1-3/2019



Easyhaler product family will be a key source of growth in the next few years

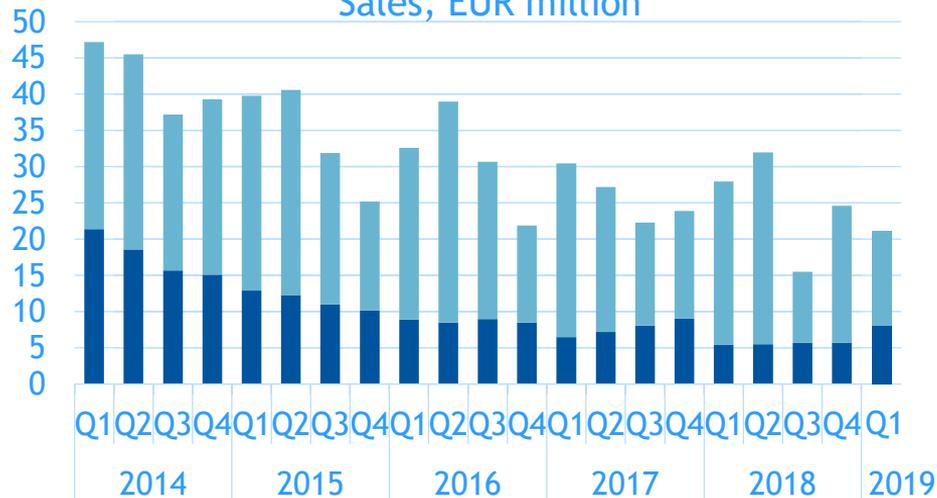


- Budesonide-formoterol Easyhaler continued strong growth.
- Product family total sales: **+21%**
- Budesonide-formoterol Easyhaler: **+35%**
 - Strong market position in some countries, such as Sweden (market share was 34%* in February).
 - Growth still attainable in certain markets. Investments in sales and marketing made particularly in Germany (market share was 7%* in February).
- Salmeterol-fluticasone sales started in the first European countries in late 2018.
- Development of seventh product, tiotropium, continues.

*) Market shares of sales in EUR.

Orion is taking over the sale of its proprietary Parkinson's drugs in Europe

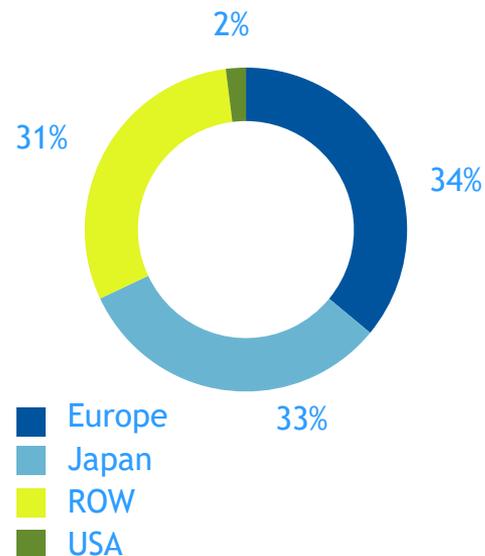
Sales, EUR million



■ Deliveries of Parkinson's drugs (Stalevo, Comtess/Comtan) to key partners

■ Orion's own sales

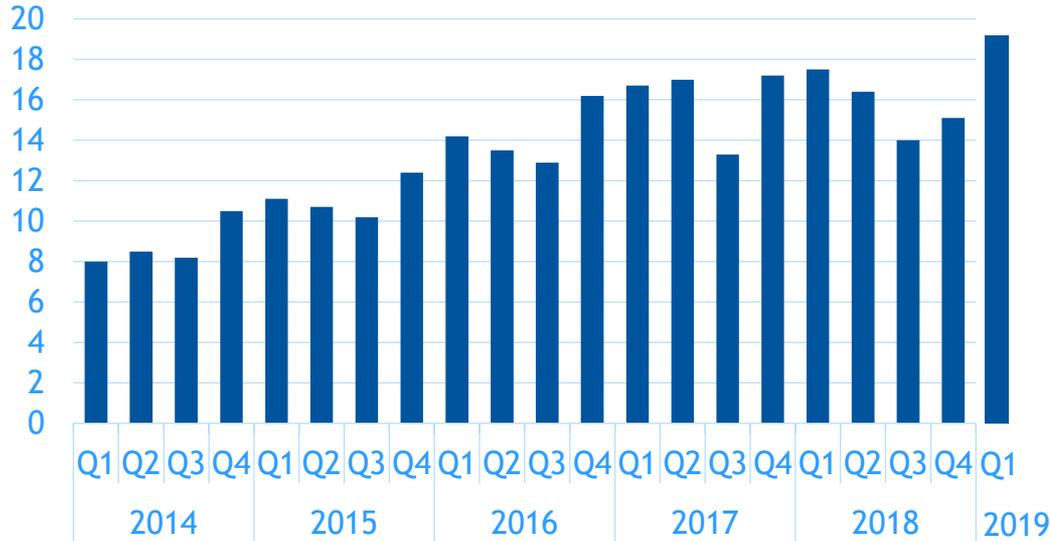
Breakdown of sales of Orion's branded Parkinson's drugs by market area



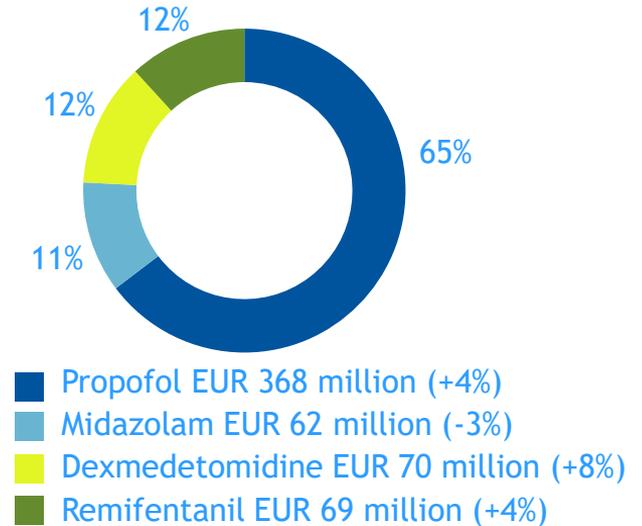
Source: IQVIA, MAT12/2018

Sales of Dexdor intensive care sedative continued to grow - patent expired at the end of March

Sales, EUR million



Total value of European sedatives market:
EUR 569 million (+3%)



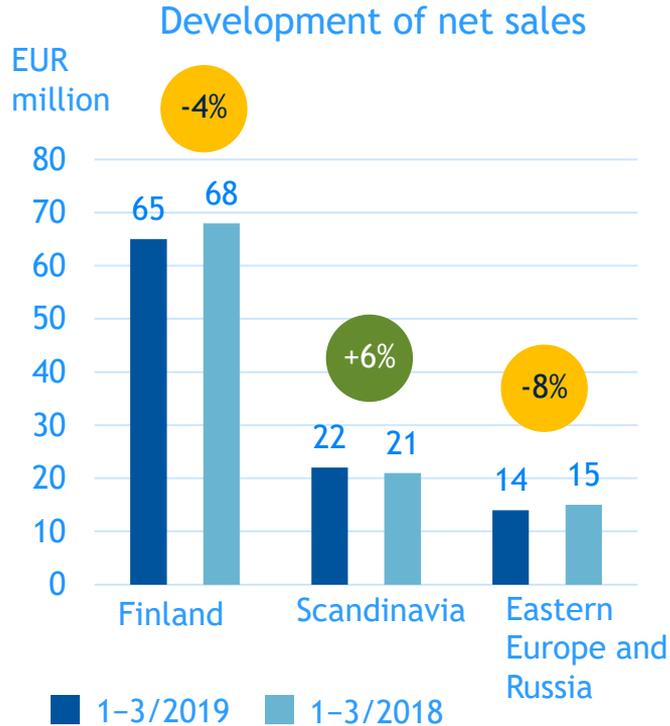
Source: IQVIA, MAT 12/2018



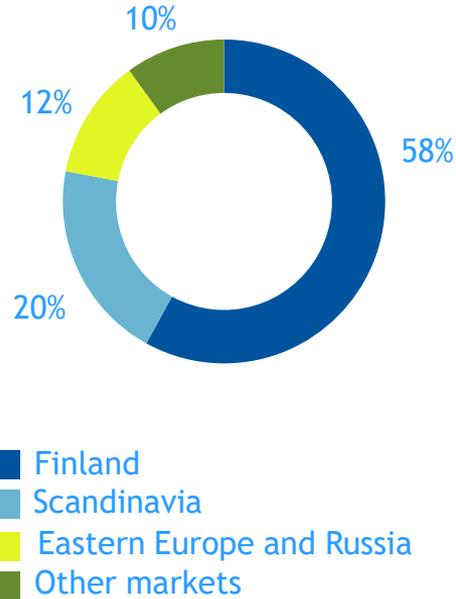
Specialty Products



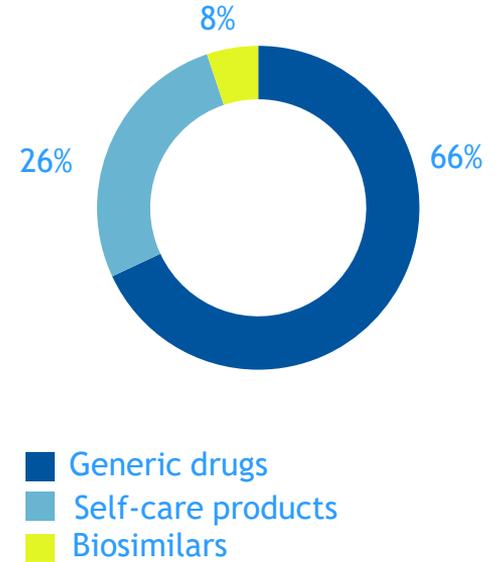
Specialty Products: price competition continued especially in Finland



Net sales by region 1-3/2019



Net sales by product 1-3/2019



In Finland, price competition has led to a decline in the entire market of reference priced prescription drugs

The market of reference priced prescription drugs in Finland (1-3/2019)

MEUR **106** (118)

Market development

-10%



The sales of Orion's reference priced prescription drugs in Finland

MEUR **28** (30)

Orion's development

-7%

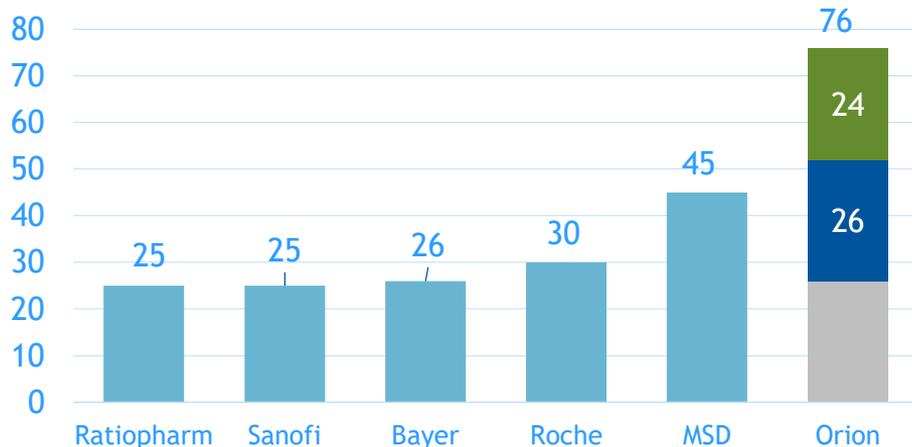
Orion is strong in home market Finland

Human pharma market in Finland 1–3/2019

Medicinal and non-medicinal products

in hospital and pharmacy channels: EUR 676 million

EUR million



- Self-care products (pharmacy channel)
- Reference priced prescription drugs (pharmacy channel)

Reference priced prescription drugs

Orion market share in pharmacy

26%
(26%)

Self-care products

Orion market share in pharmacy

24%
(24%)

Human pharmaceuticals total

Orion market share in hospital & pharmacy

11%
(12%)



Research and development

Orion's key clinical drug development projects

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

¹⁾ In collaboration with Bayer

More information on R&D projects: www.orion.fi/en/rd/orion-rd/pipeline/

 = Completed
 = Ongoing

 = Status changed

Progress in key development projects - new addition to portfolio: ODM-209

- **ODM-201/darolutamide for metastatic hormone-sensitive prostate cancer:**
 - Ongoing Phase III trial ARASENS in collaboration with Bayer.
 - Patient recruitment finalized. The trial is expected to be completed in 2022.
- **ODM-109/oral levosimendan for ALS:**
 - 3-year REFALS trial started in the spring, recruitment progressing.
 - Orion conducts the Phase III trial on its own.
- **ODM-209 for prostate and breast cancer:**
 - Orion has launched a Phase I clinical trial on the ODM-209 molecule. This molecule is a selective hormone synthesis inhibitor much like the ODM-208.
- **ODM-104 for Parkinson's disease:**
 - Orion has decided not to move on to Phase III on its own but is looking for a potential partner for the project.

Orion's key business targets in 2019

1. Preparation for the commercialisation of darolutamide. ARASENS trial (metastatic prostate cancer) continues in order to expand the indication for the molecule.

- Marketing authorisation applications submitted in main markets.
- With recruitment completed, the ARASENS trial continues as planned.

2. Development of orally administered levosimendan (ODM-109) (REFALS) for ALS in phase III clinical trial and preparation for its possible commercialisation.

- Patient recruitment is proceeding as planned

3. Strengthening Orion's position as the most significant provider of generic drugs in Finland. Competitive pricing.

- Orion's sales volume in Finland grew faster than the market.

Orion's key business targets in 2019

4. Competitive product portfolio in Specialty Products and strengthening of product launches.

- Orion's sales volume in Finland grew faster than the market.

5. Accelerating the growth of the Easyhaler product family and strengthening its market position.

Salmeterol-fluticasone launch in Europe.

- Easyhaler product family sales increased by 21 per cent.

6. Evaluation of new in-licensing opportunities in Europe, particularly in the area of hospital care.

- The work continues.

Current corporate responsibility themes at Orion

- Patient safety: New safety features for prescription drugs required in all European markets and implemented at Orion's production facilities.
- Orion's new values have been approved.
- We reduce the climate change impact of our own production. We have set ourselves an emissions target.
- Orion's Sustainability Report 2018 will be published in May.

550
products
serialized

Number of Orionees
responding
to the value survey

2,073
(65 %)

CO₂e reduction
target for 2025

-75%

against our 2016
baseline (current
reduction 11%)



Outlook

Outlook for 2019 remains unchanged

Net sales

Orion estimates that in 2019 net sales **will be slightly higher than** in 2018 (net sales in 2018 were EUR 977 million). The estimated net sales include the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide.

Operating profit

Operating profit is estimated to be **at the same level** as in 2018 (in 2018 operating profit was EUR 253 million). The estimated operating profit includes the possible EUR 45 million milestone payment associated with the commercialisation of darolutamide as well as significant investments in actions to generate growth.



Orion calendar

Capital Markets Day

Helsinki, 22 May 2019

Half-Year Financial Report	17/7/2019
Interim Report 1-9/2019	23/10/2019



Building well-being

