



**Orion
Half Year Report
1-6/2019**

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-June 2019

Marketing authorisation applications for darolutamide submitted in the main markets

1 Marketing authorisation applications for the prostate cancer drug darolutamide submitted in the main markets USA, Japan and Europe. Priority Review granted in the USA.

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



3 Net sales of Proprietary Products on previous year's level. Easyhaler® and Simdax® showing strong sales. Specialty Products' net sales decline halted. Strong growth in Scandinavia.

4 REFALS patient recruitment completed. REFALS evaluates orally administered levosimendan (ODM-109) for the treatment of symptoms of ALS.

Key figures 1-6/2019

Net sales

493

MEUR (493)

Operating profit

107

MEUR (140)
-23%

Operating profit
margin

22%

(28%)

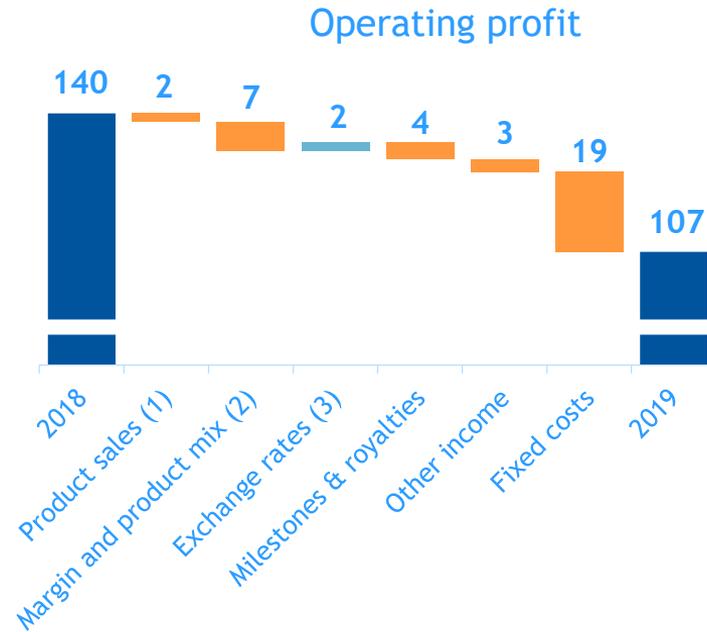
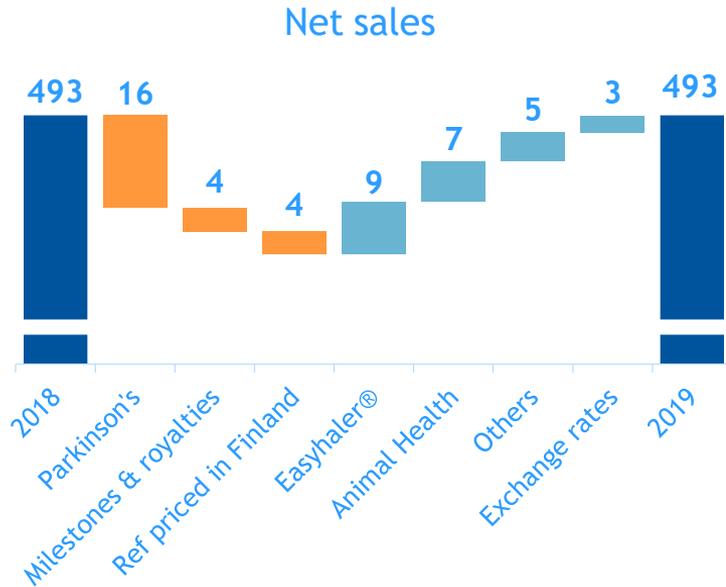
Cash flow per share
before financial
items*

0.57

EUR (1.75)
-67%

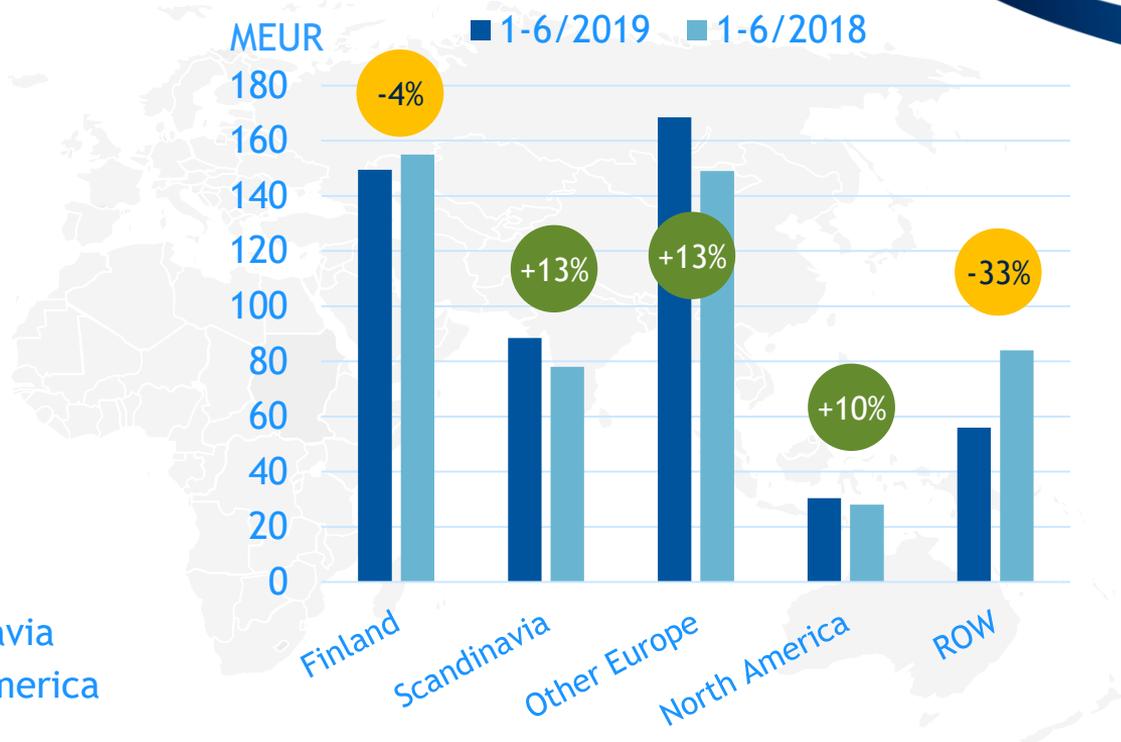
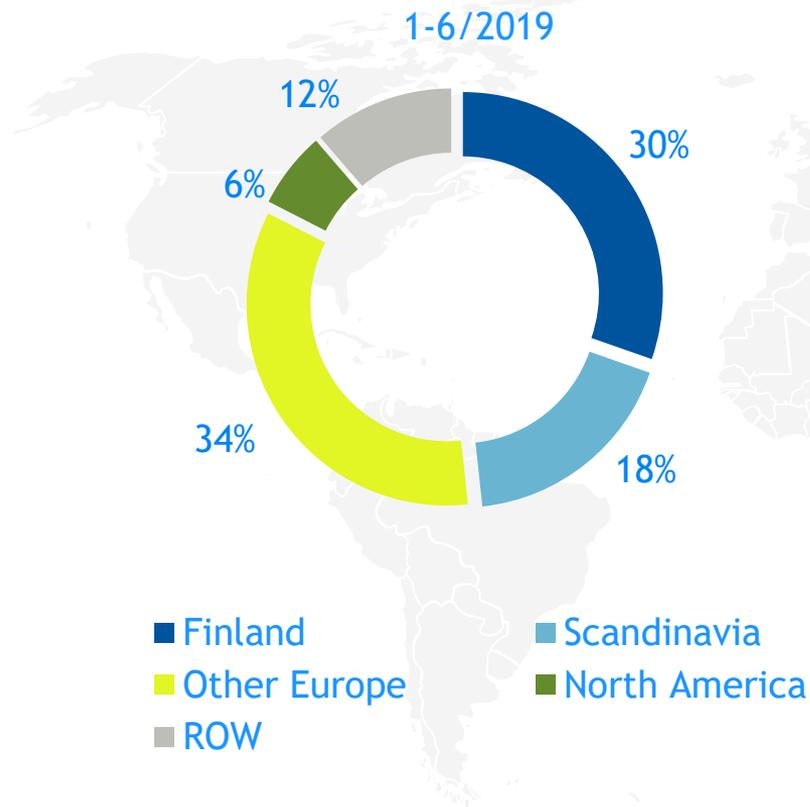
*) Comparison period cash flow per share before financial items includes both continuing and discontinued operations

Development of net sales and operating profit

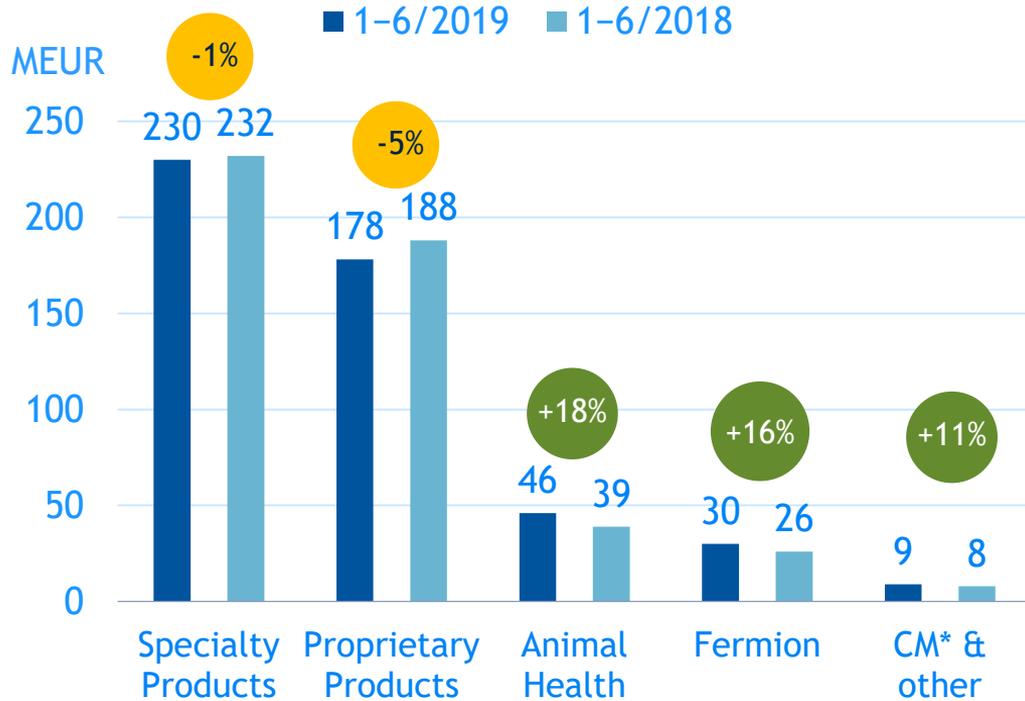


- (1) Product sales without sales margin and product mix change and exchange rate effect
- (2) Product sales margin and product mix change but without exchange rate effect
- (3) Exchange rate effect on gross margin

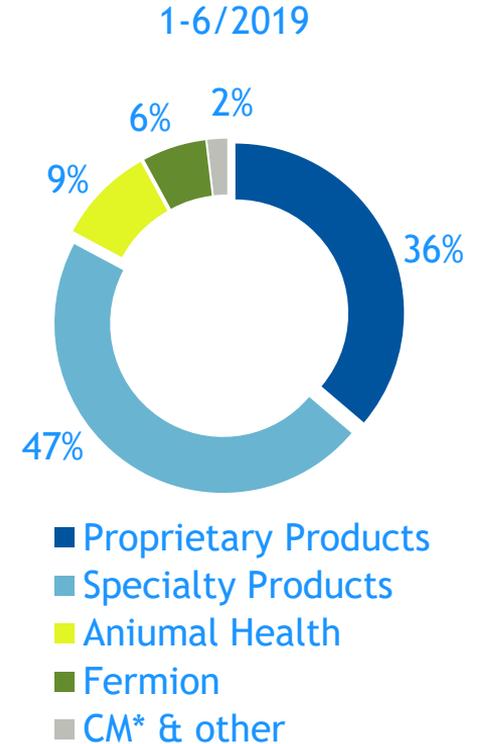
Geographical breakdown and development of net sales



Net sales by business division



*) Contract manufacturing



Best-selling pharmaceuticals 1-6/2019

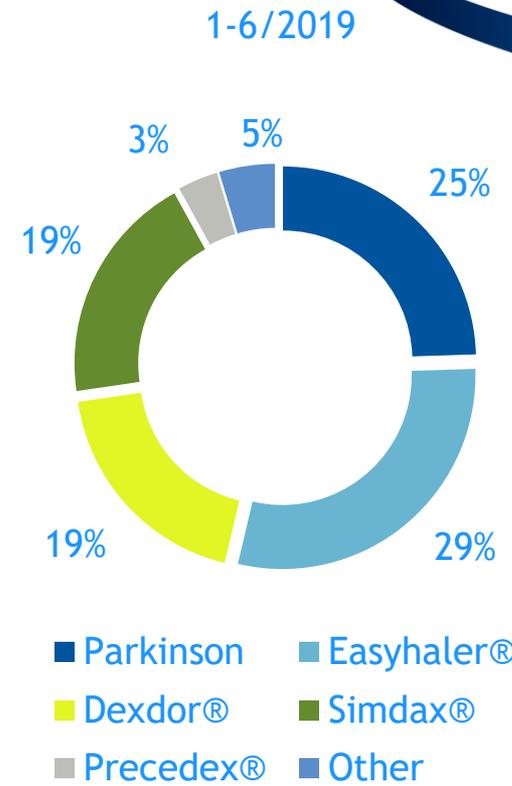
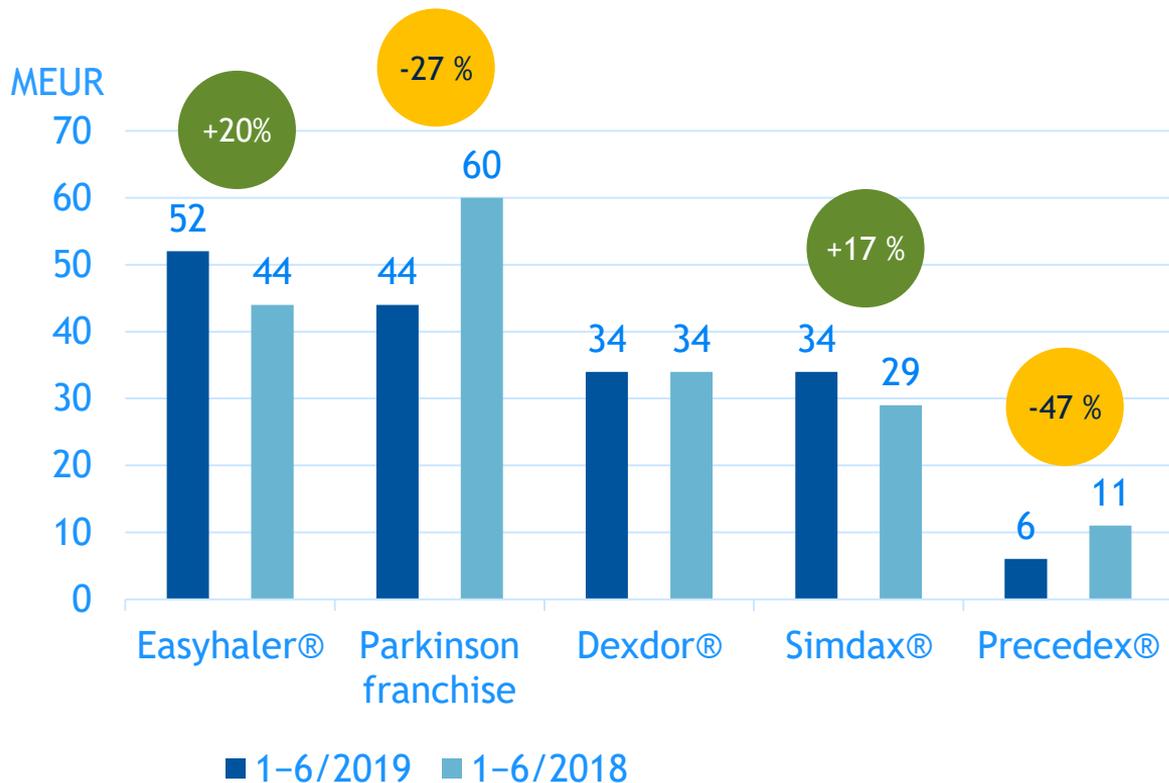
		Indication	Net sales (EUR million)	Change vs 1-6/2018
1.		Asthma, COPD	52	+20%
2.	  	Parkinson's disease	44	-27%
3.		Acute heart failure	34	+17%
4.		Intensive care sedative	34	-0%
5.	   	Animal sedatives	21	+46%
6.	Biosimilars   	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	18	+24%
7.		Inflammatory pain	12	+8%
8.	Divina series 	Menopausal symptoms	9	-4%
9.		Anticoagulant	7	-14%
10.	Solomet®	Inflammation	6	+3%

 = Products of Proprietary Products business division

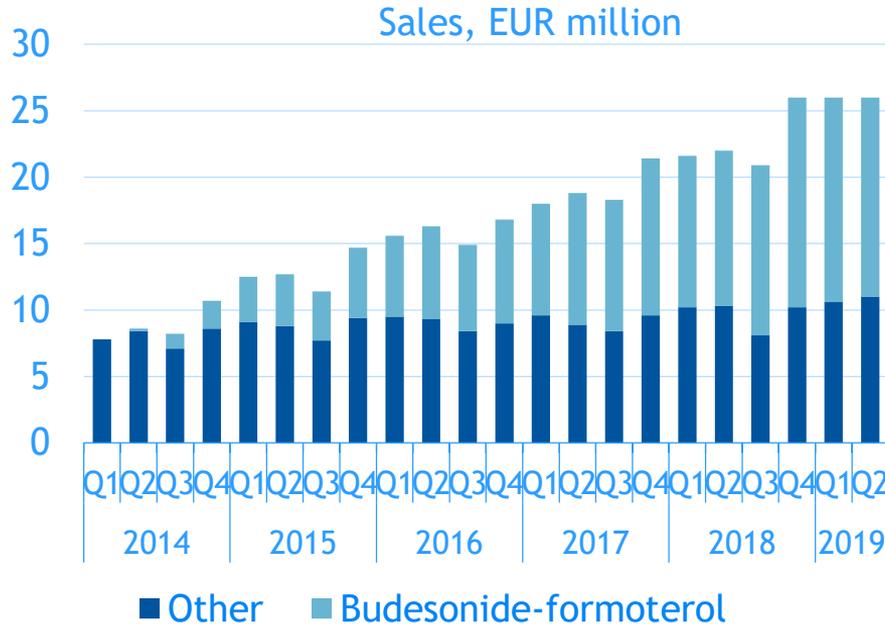


Proprietary Products

Easyhaler® product family continued strong growth



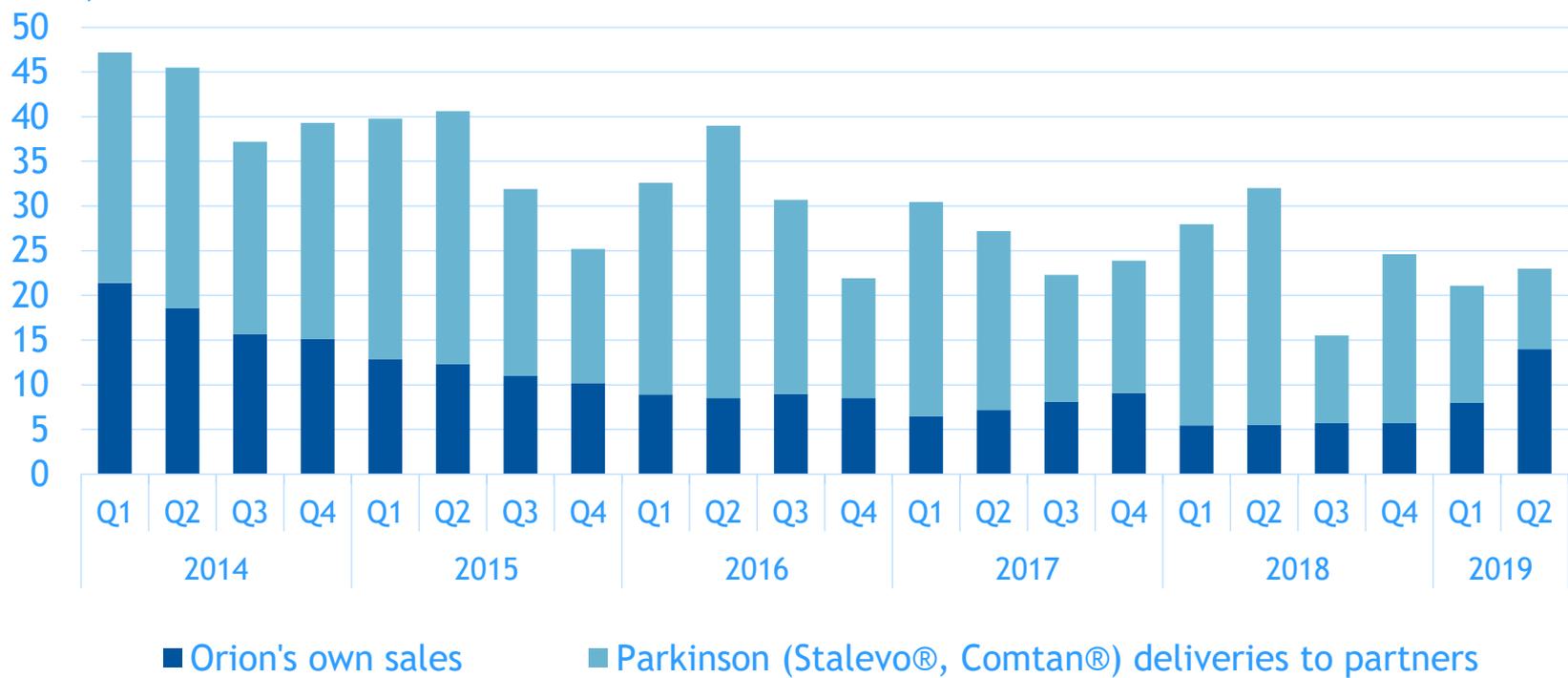
Easyhaler® product family will be a key source of growth in the next few years



- Budesonide-formoterol Easyhaler continued strong growth.
- Product family total sales: +20%
- Budesonide-formoterol Easyhaler: +33%
- Salmeterol-fluticasone sales developed slower than anticipated.
- Development of Easyhaler® tiotropium continues.

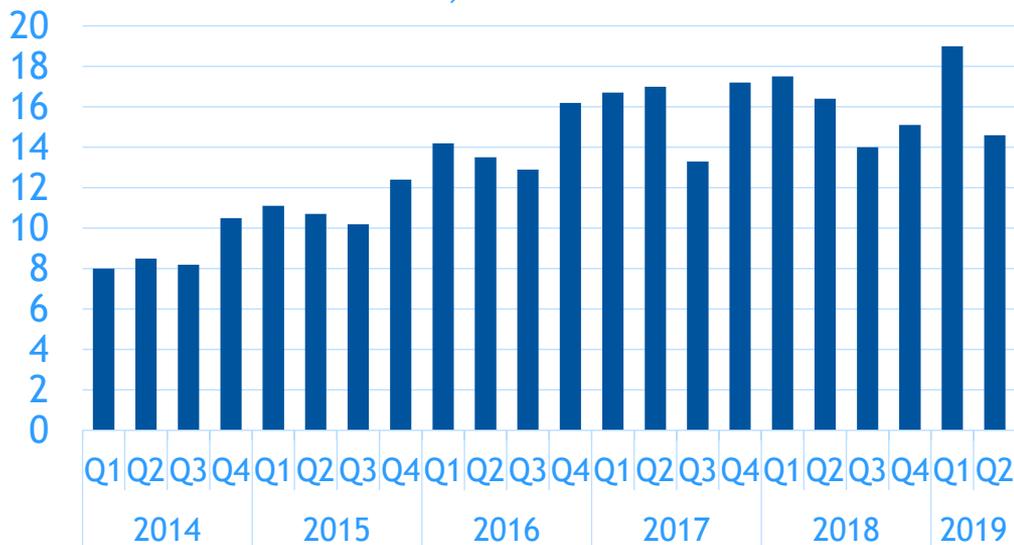
Share of Orion's own sales in Parkinson growing

Sales, EUR million

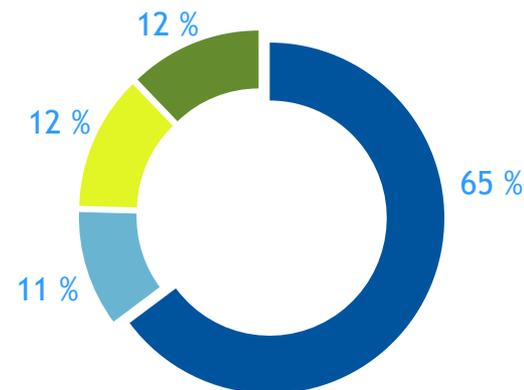


Sales of Dexdor intensive care sedative continued to grow - patent expired at the end of March

Sales, EUR million



Total value of European sedatives market:
EUR 574 million (+3%)



- Propofol 372 Meur (+4%)
- Midazolam 61 Meur (-3%)
- Dexmedetomidine 71 Meur (+7%)
- Remifentanyl 70 Meur (+5%)

Source: IQVIA, MAT 3/2019



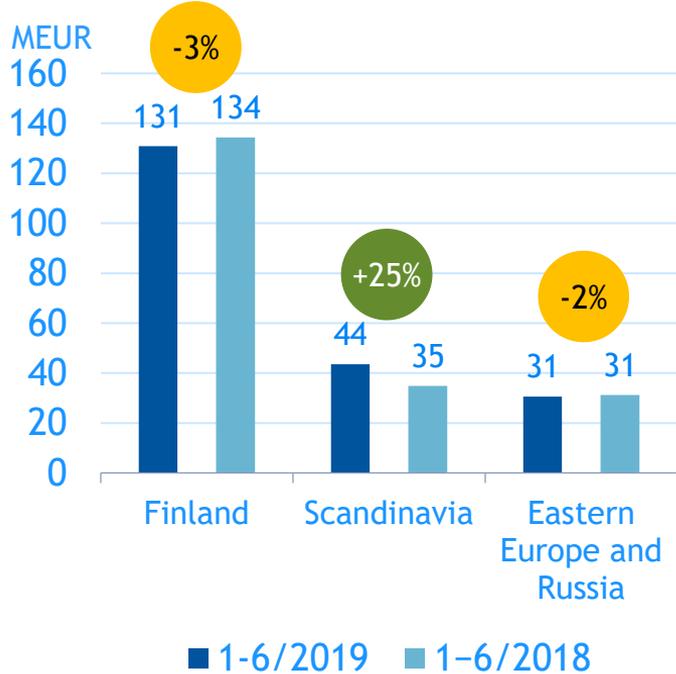
Specialty Products



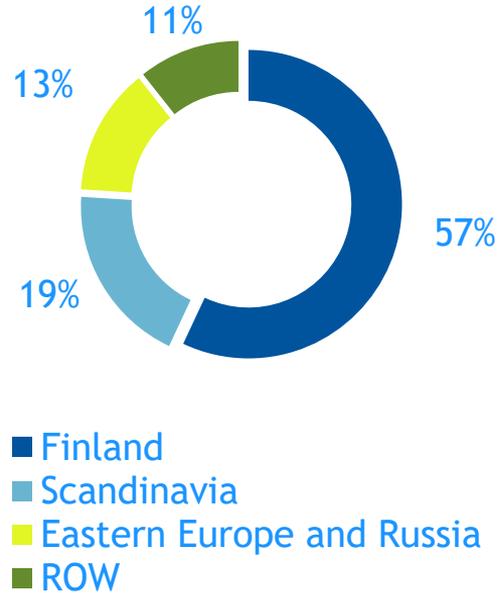
Specialty Products: price competition continued especially in Finland



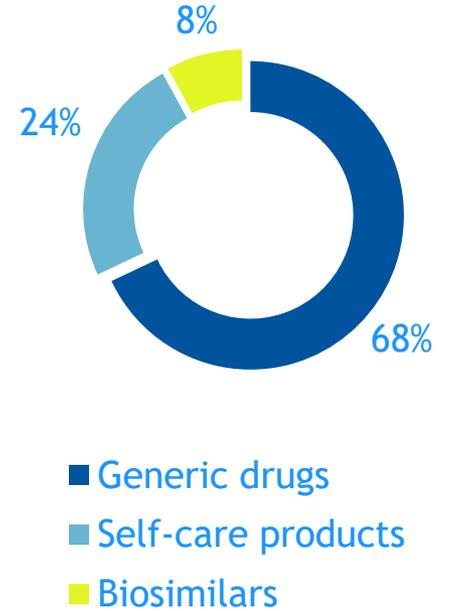
Development of net sales



Net sales by region 1-6/2019



Net sales by product 1-6/2019



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 (1-6/2019)

MEUR **216** (235)

Market development

-8%



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

MEUR **56** (60)

Orion's development

-7%

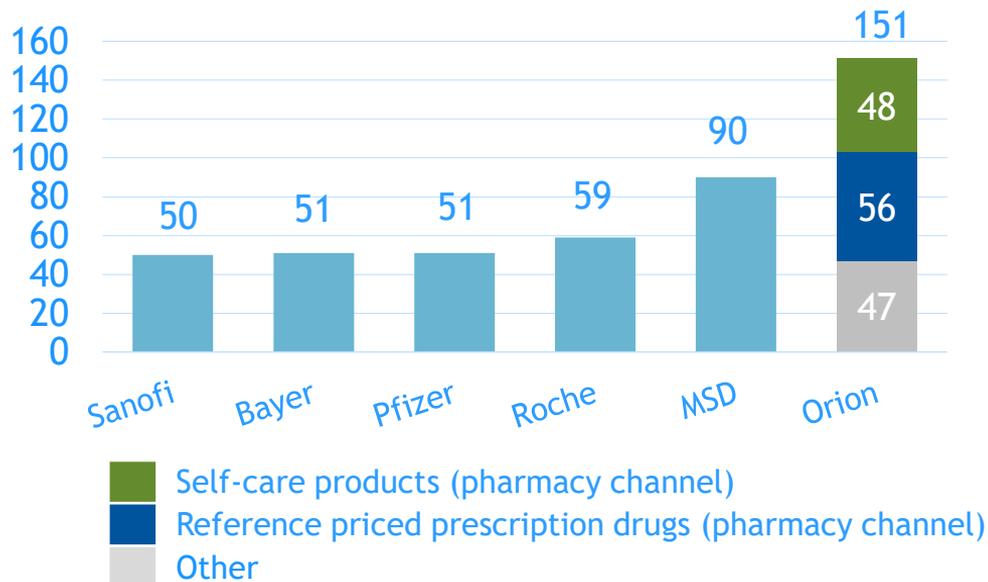
Orion is strong in home market Finland

Human pharma market in Finland 1-6/2019

Medicinal and non-medicinal products

in hospital and pharmacy channels: EUR 1,376 million

EUR million



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			

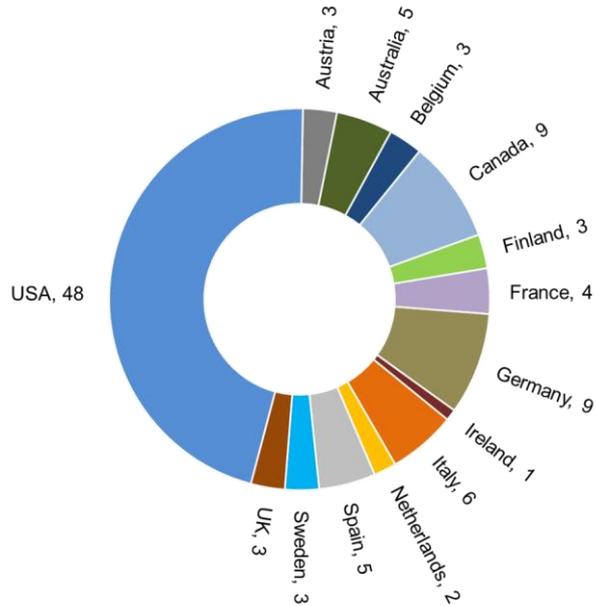
¹⁾ In collaboration with Bayer

	= Completed		= Status changed
	= Ongoing		

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

REFALS patient recruitment completed

104 ALS centres in 14 countries



- REFALS is an Orion study
- 1st patient randomised July 2018
- Last patient randomisation in July 2019
 - Last patient visit expected July 2020
 - Study results in H2 2020
- Number of patients in the study 496
- Objective to demonstrate benefit of oral levosimendan on respiratory and overall function in ALS
- And safety in prolonged use in ALS patients

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.

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

- Marketing authorisation applications submitted in the main markets.
- Priority Review granted in the USA.
- With recruitment completed, the ARASENS trial continues as planned.
- Patient recruitment completed in July 2019.

Orion's key business targets in 2019

3. Strengthening Orion's position as the most significant provider of generic drugs in Finland. Competitive product portfolio in Specialty Products and strengthening of product launches.

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

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

- Easyhaler® product family sales increased by 20 per cent.

Salmeterol-fluticasone launch in Europe.

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

- The work continues.



Orion's Sustainability Report for 2018 was published in May

Read more: <https://www.orion.fi/en/sustainability-report/>

Key themes of corporate responsibility

Ensure patient safety and availability of medicines

Responsibility for the environment - production according to the principles of sustainable development

Taking care of Orionees

Ethics and transparency of operations

This is how we are building well-being responsibly



WE PRODUCE
1/3 OF THE
GLOBAL SUPPLY
OF
METHOTREXATE



~200-300
AUDITS
ANNUALLY



NUMBER OF
CUSTOMER
COMPLAINTS IN
2018
56 (ppm)

ORION'S FOCUS ON QUALITY THROUGHOUT THE LIFECYCLE



PATIENT
NEEDS



R&D



RAW
MATERIALS



MANUFACTURING



PACKING



DELIVERY



SALES



PATIENT
USE



RECYCLING

REDUCING
PHARMACEUTICAL
RESIDUES E.G. BY
RENEWING WASTE
WATER SYSTEMS



ACTIONS ON
SERIALISATION
AND ANTI-
TAMPERING



CO₂e
REDUCTION
TARGET FOR
2025
-75%
FROM 2016



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

Interim Report 1-9/2019 23/10/2019

Financial Statement Release
for 2019 5/2/2020
AGM planned to be held 25/3/2020
Interim Report 1-3/2020 28/4/2020
Half-Year Report 1-6/2020 17/7/2020
Interim Report 1-9/2020 21/10/2020



Building well-being

