



Orion Interim Report 1-9/2019

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-September 2019

Marketing authorisation for darolutamide in the USA - application review ongoing in other main markets

1 Marketing authorisation granted for darolutamide in the USA. Application review ongoing in Europe, Japan and other core markets.

2 Net sales and operating profit were higher than in the comparative period. Both net sales and operating profit include EUR 45 million milestone from Bayer. Outlook remains unchanged.



3 Easyhaler® and Simdax® showing strong performance. Specialty Products' net sales turned to mild growth led by strong sales in Scandinavia. Price competition and disruptions in availability had a negative impact.

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

Key figures 1-9/2019

Net sales

776

MEUR (715)
+9%

Operating profit

198

MEUR (184)
+7%

Operating profit
margin

25%

(26%)

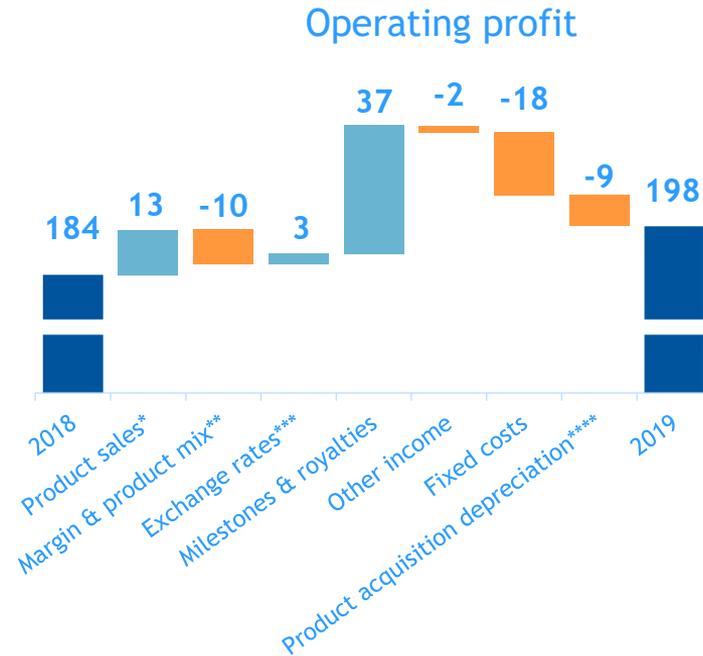
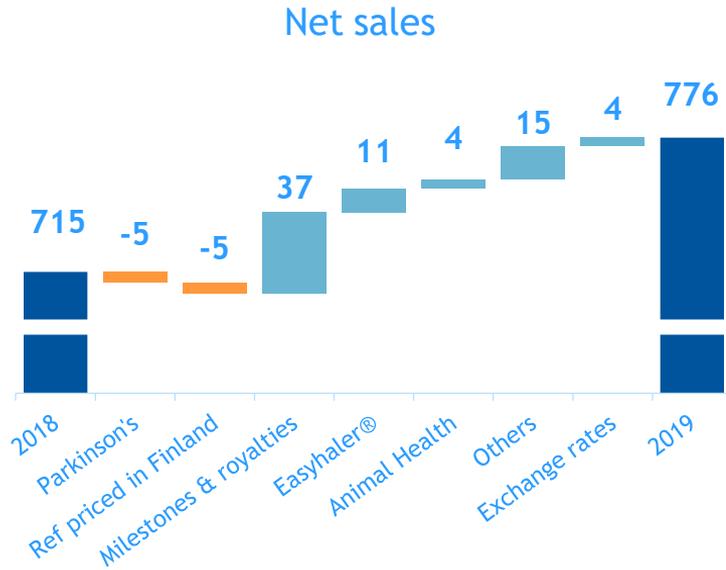
Cash flow per share
before financial
items*

1.28

EUR (2.10)
-39%

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

Development of net sales and operating profit



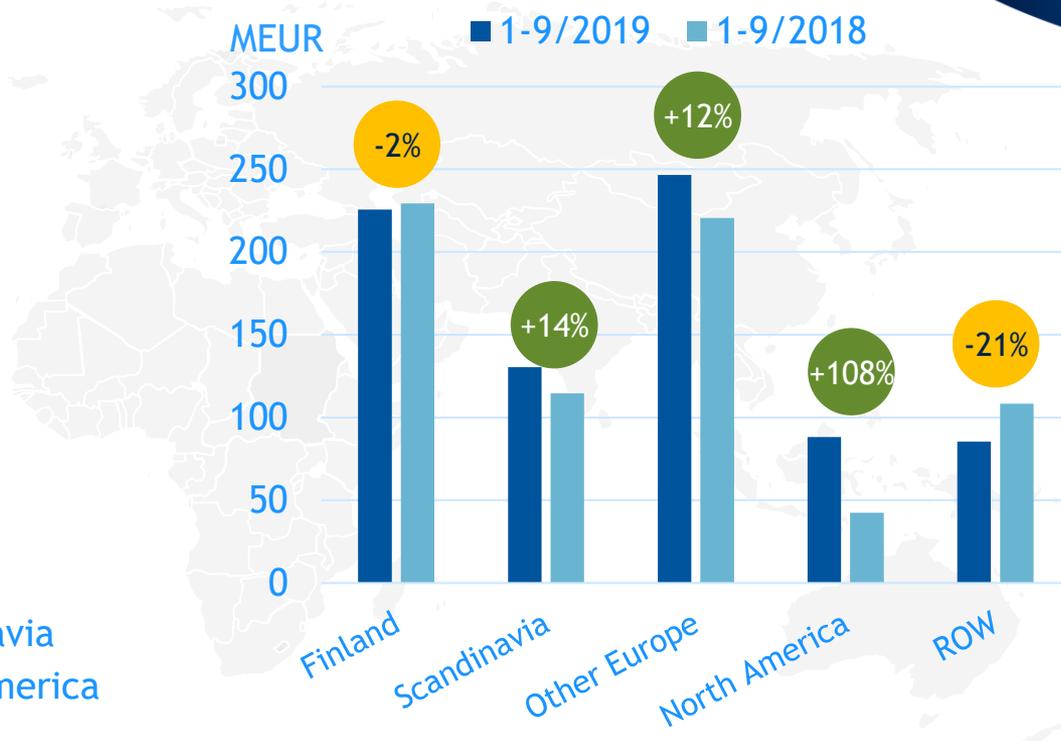
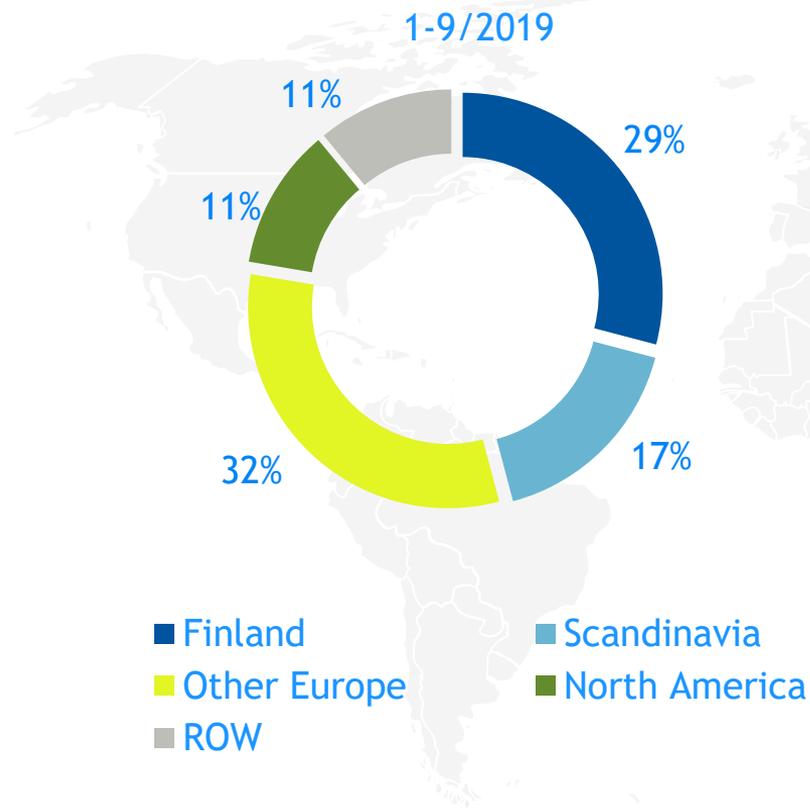
* Product sales without sales margin and product mix change and exchange rate effect

** Product sales margin and product mix change but without exchange rate effect

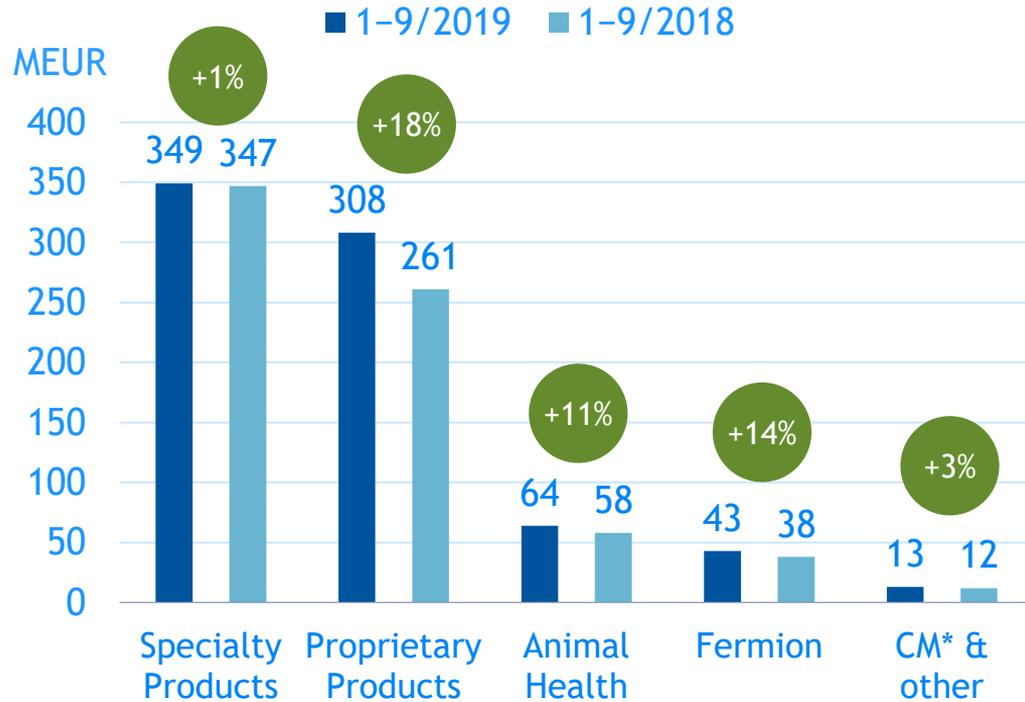
*** Exchange rate effect on gross margin

**** Acquisition of European sales and distribution rights for Stalevo® and Comtan®

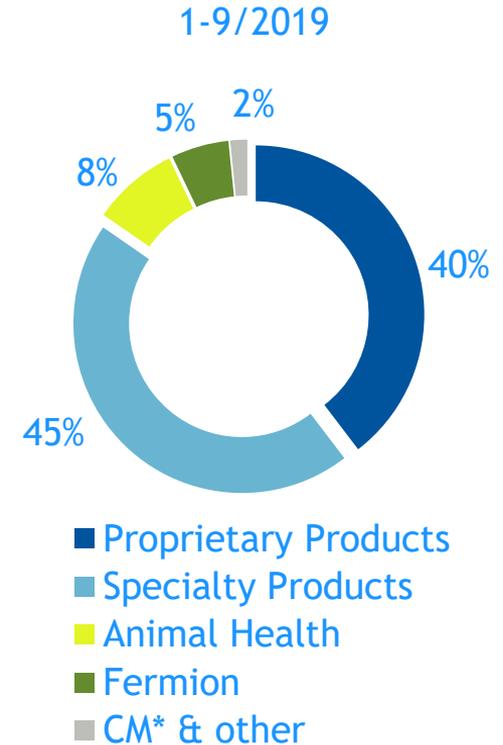
Geographical breakdown and development of net sales



Growth in all business divisions



*) Contract manufacturing



Best-selling pharmaceuticals 1-9/2019

		Indication	Net sales (EUR million)	Change vs 1-9/2018
1.		Asthma, COPD	75	+16%
2.	  	Parkinson's disease	70	-7%
3.		Acute heart failure	49	+14%
4.		Intensive care sedative	46	-5%
5.	Biosimilars   	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	28	+47%
6.	   	Animal sedatives	28	+20%
7.		Inflammatory pain	18	+10%
8.	Divina series 	Menopausal symptoms	14	+5%
9.		Anticoagulant	11	-7%
10.	Solomet®	Inflammation	10	+5%

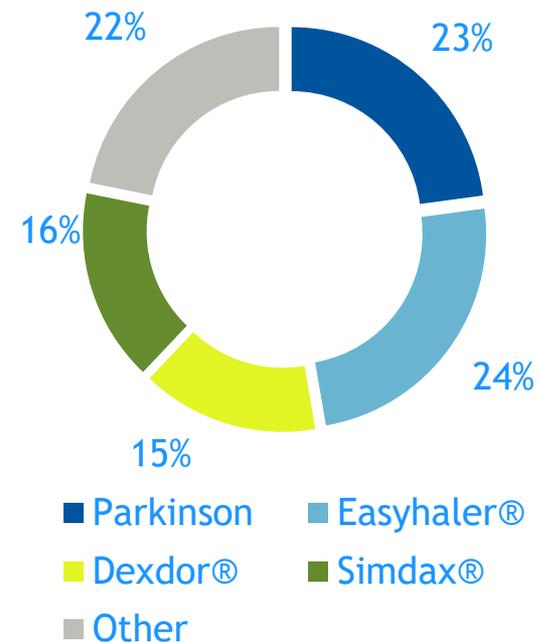
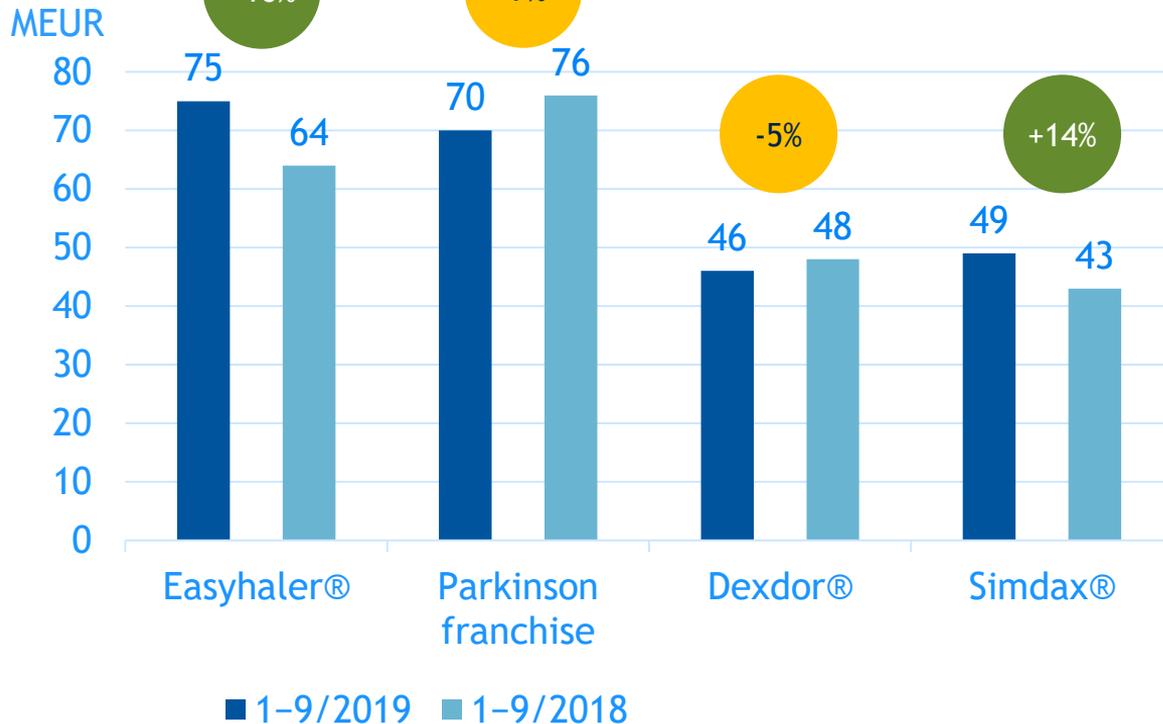
 = Products of Proprietary Products business division



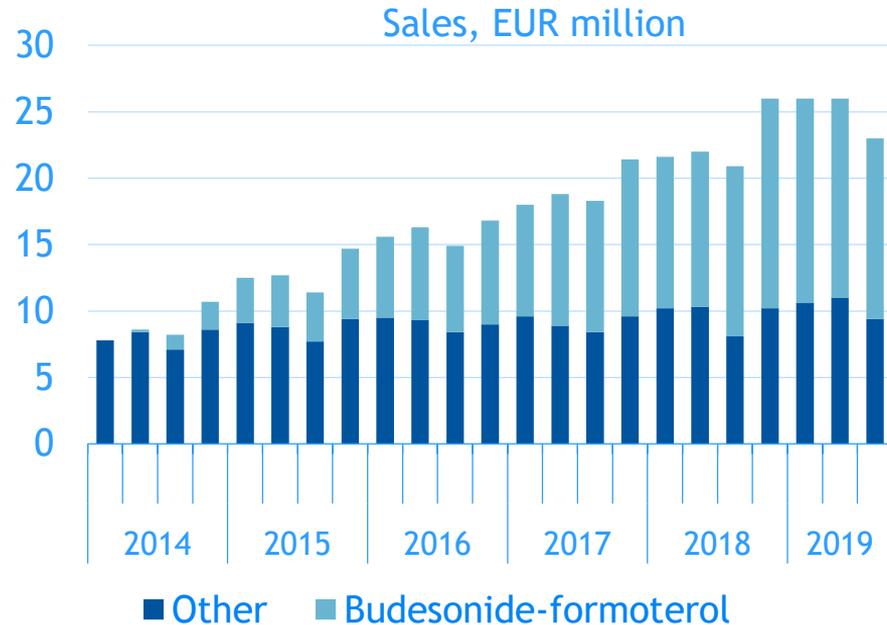
Proprietary Products

Easyhaler® product family and Simdax® growing

1-9/2019



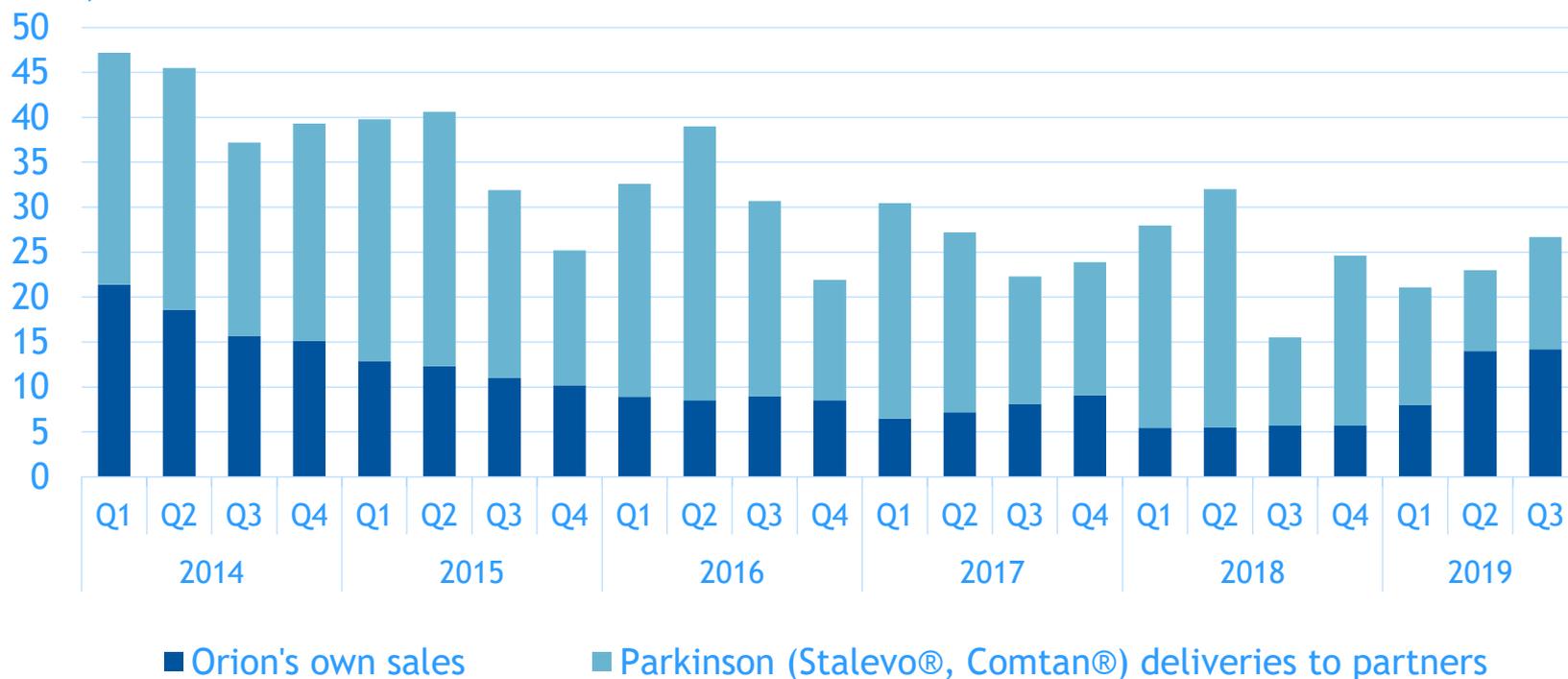
Easyhaler® product family will be a key source of growth in the next few years



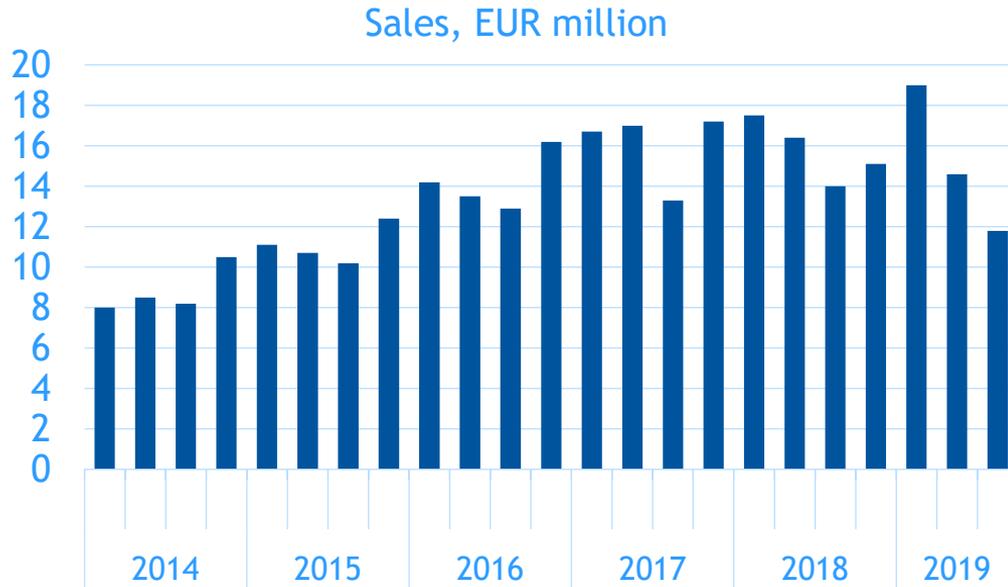
- Budesonide-formoterol Easyhaler® continued strong growth. +23%
- Product family total sales: +16%
- Salmeterol-fluticasone sales developed slower than anticipated.
- Development of Easyhaler® tiotropium continues.

Share of Orion's own sales in Parkinson growing

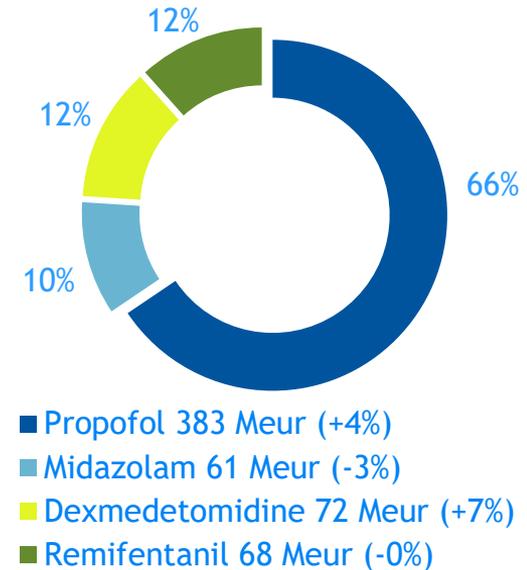
Sales, EUR million



Sales of Dexdor® declining due to generic competition



Total value of European sedatives market:
EUR 585 million (+4%)



Source: IQVIA, MAT 6/2019

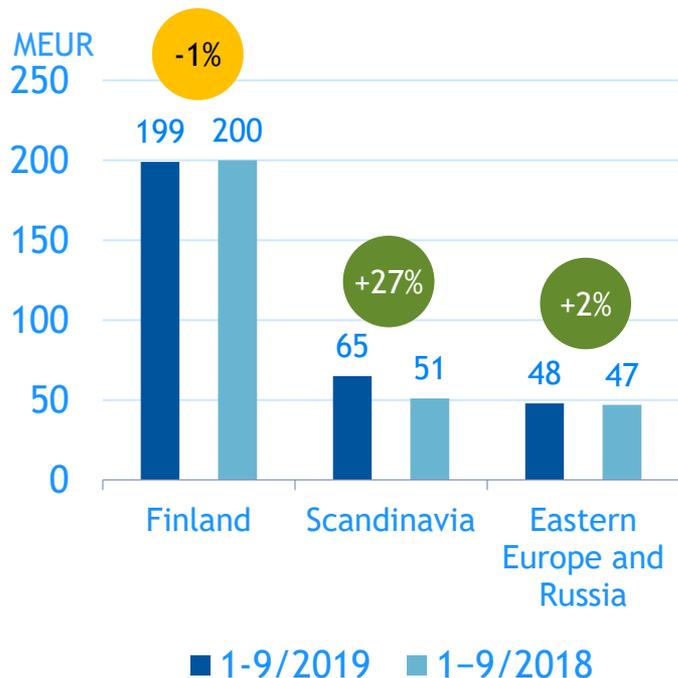


Specialty Products

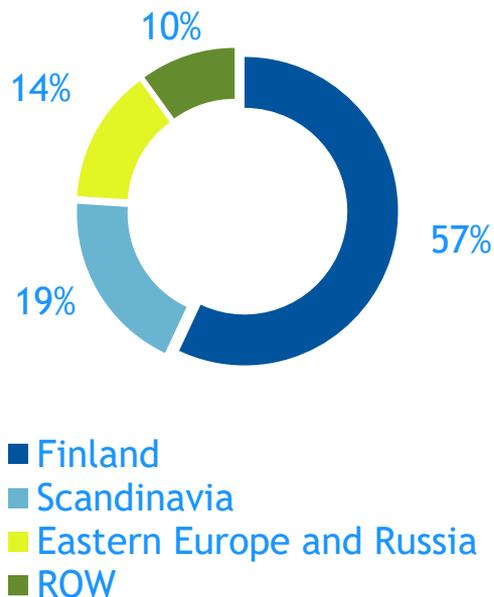


Specialty Products: tight price competition continued

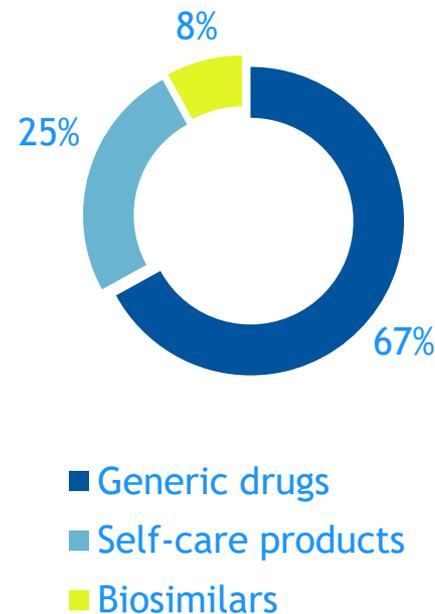
Development of net sales



Net sales by region 1-9/2019



Net sales by product 1-9/2019



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 (1-9/2019)

MEUR **319** (342)

Market development

-7%



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

MEUR **85** (90)

Orion's development

-5%

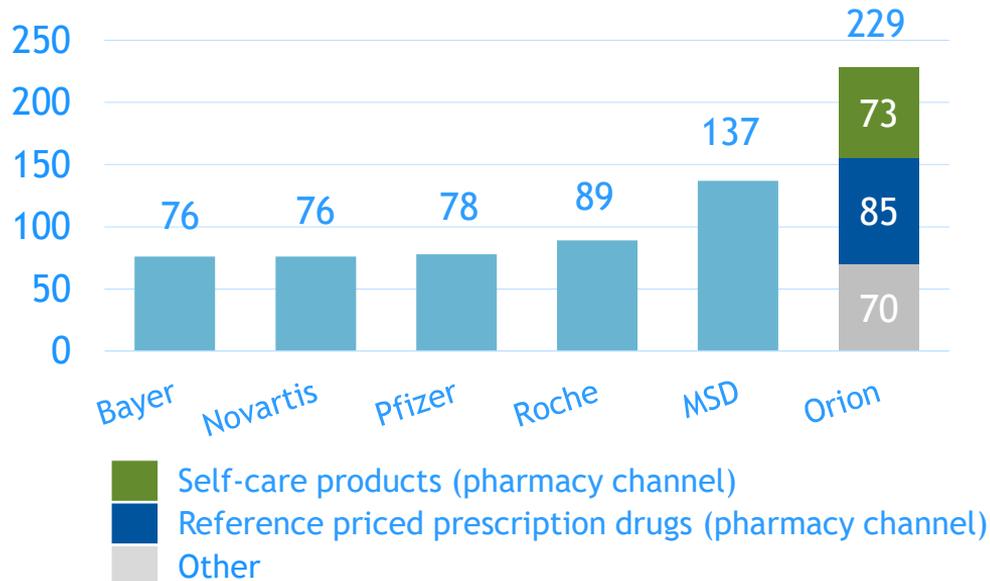
Orion is strong in home market Finland

Human pharma market in Finland 1-9/2019

Medicinal and non-medicinal products

in hospital and pharmacy channels: EUR 2,083 million

EUR million



Reference priced prescription drugs

Orion market share in pharmacy

27%
(26%)

Self-care products

Orion market share in pharmacy

25%
(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/

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.
- Marketing authorisation granted in the USA by FDA in July 2019.
- With recruitment completed, the ARASENS trial continues as planned.
- Patient recruitment completed in July 2019.
- Orion has initiated an assessment on the prospects of launching the product in the United States on its own.

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 16 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.

Disruptions in drug availability a global topic

☰ POLITICO PRO 🔍 👤 🌐

Europe comes up short on drug supplies

France has joined the Netherlands in pushing for an EU-wide approach to stopping drug shortages.

By JILLIAN DEUTSCH | 7/10/19, 11:33 AM CET | Updated 7/22/19, 2:58 PM CET

Uutiset

Lääkkeet apteekkeissa jatkuvasti loppu: Ongelmia etenkin e-pillereiden ja verenpainelääkkeiden saannissa – Suomessa vaikea korjata tilannetta

Lääkkeiden saatavuushäiriöt ovat kasvaneet tällä vuosikymmenellä räjähdysmäisesti. Syyt ovat useimmiten lääkkeiden tuotannossa ja ongelmat näin ollen maailmanlaajuisia.

18.7.2019 09:32

The Economist Topics ▾ Current edition More ▾

☰ THE WALL STREET JOURNAL.

Drug Shortage Leaves Patients Without Immune-Disorder Treatment

A shortage of immune globulin has forced hospitals to ration treatments. 'For the patients affected, it's been very significant'



The parrots eat 'em all

A dire scarcity of drugs is worsening, in part, because they are so cheap

Many generic drugs have too few manufacturers

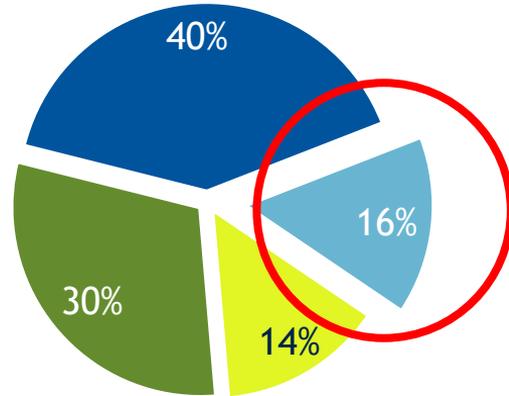
ÉDITORIAL

Le Monde

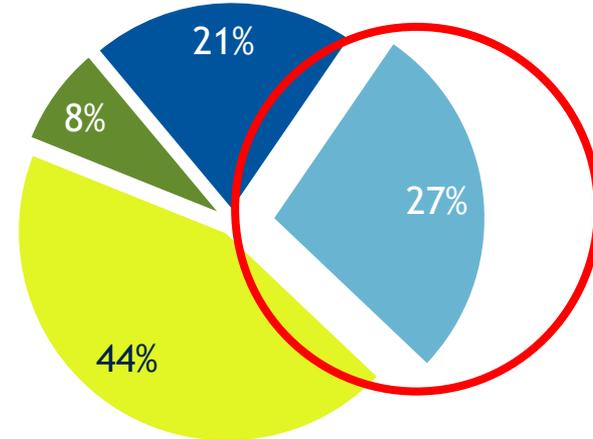
L'inquiétante pénurie de médicaments

In Finland deficiencies concern mainly reference priced prescription drug

Total sales of human pharmaceuticals 1-9/2019
(hospital and pharmacy channel) MEUR 2,083



Total volume of human pharmaceuticals
1-9/2019 (hospital and pharmacy channel)
~99 million packages



- Other than reference priced prescription drugs (pharmacy channel)
- Reference priced prescription drugs (pharmacy channel)
- Self-care products (pharmacy channel)
- Hospital channel

Key themes of corporate responsibility

Availability of
Orion products in
Finland
>96%

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





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

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