



# Orion Interim Report 1-9/2018

# 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 2018

# Orion and Bayer's Phase III trial of prostate cancer drug darolutamide met primary endpoint

**1** Darolutamide: Discussions with authorities regarding the submission for marketing authorization application are about to start. Darolutamide has been granted Fast Track designation by FDA.

**2** Profitability was good, and profit margin for continuing operations exceeded financial target. Cash flow was strong. Net sales and operating profit were lower than in the comparative period. R&D investments increased.



**3** Sales of Proprietary Products were at level with comparative period. Net sales of Specialty Products continued to decrease due to challenging operating environment, tougher price competition and lower sales of biosimilars.

**4** Outlook remains unchanged.

# Key figures 1–9/2018 (continuing operations)

Net sales

**715**

MEUR (768)  
-7%

Operating profit

**184**

MEUR (214)  
-14%

Operating profit  
margin

**26%**

(28%)

Cash flow per share  
before financial  
items\*\*

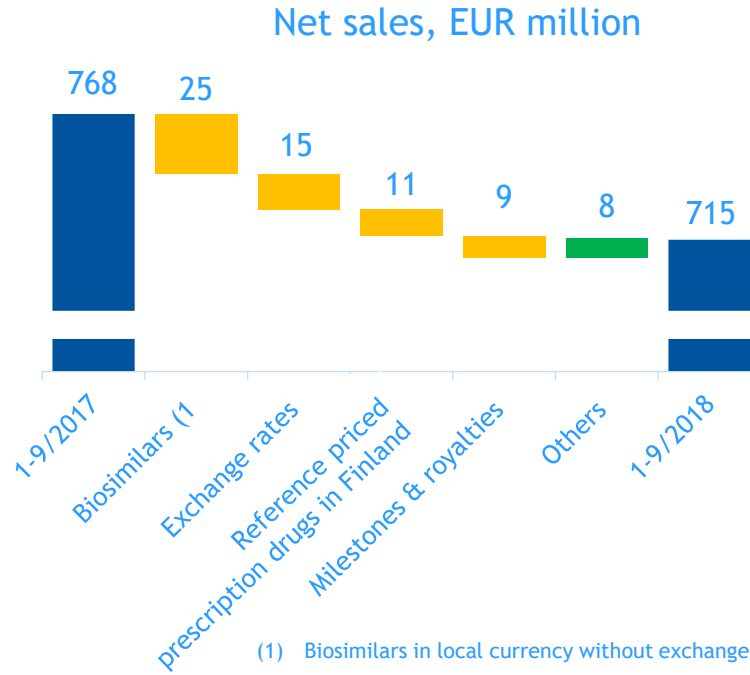
**2.10**

EUR (0.86)  
+143%

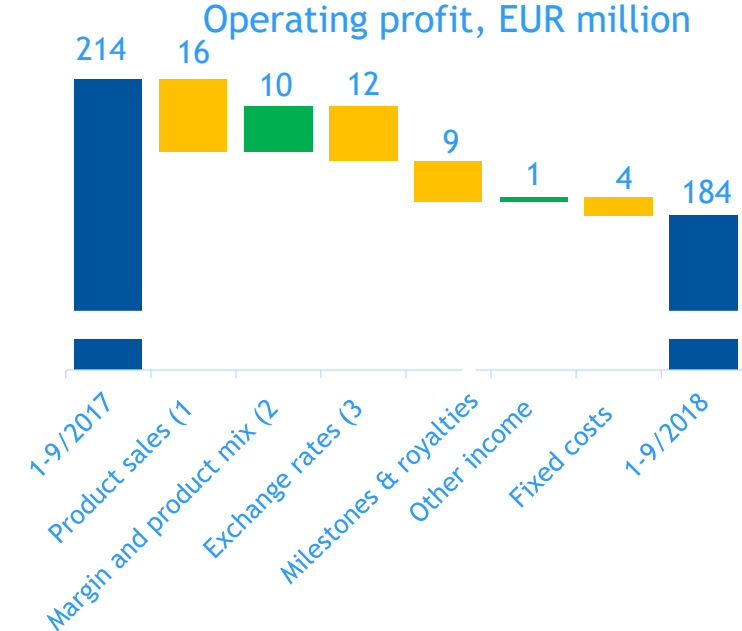
\*\* ) Cash flow per share before financial items: Continuing and discontinued operations

# Most of the profit decrease due to exchange rate changes and lower milestone payments and royalties

– Otherwise, profitability only slightly below comparative period



(1) Biosimilars in local currency without exchange rate effect



(1) Product sales without sales margin and product mix change and exchange rate effect

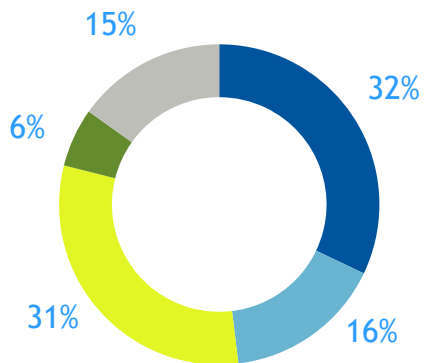
(2) Product sales margin and product mix change without exchange rate effect

(3) Exchange rate effect on gross margin



# Geographical breakdown and development of net sales

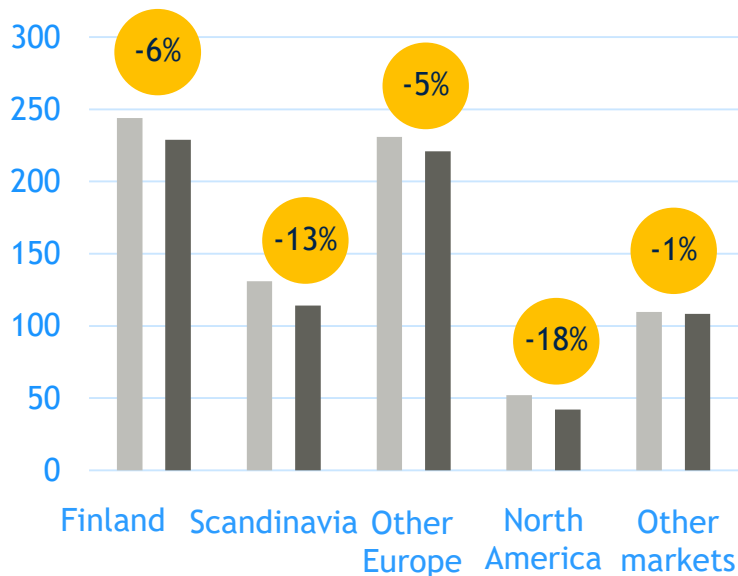
1-9/2018



- Finland
- Scandinavia
- Other Europe
- North America
- Other markets

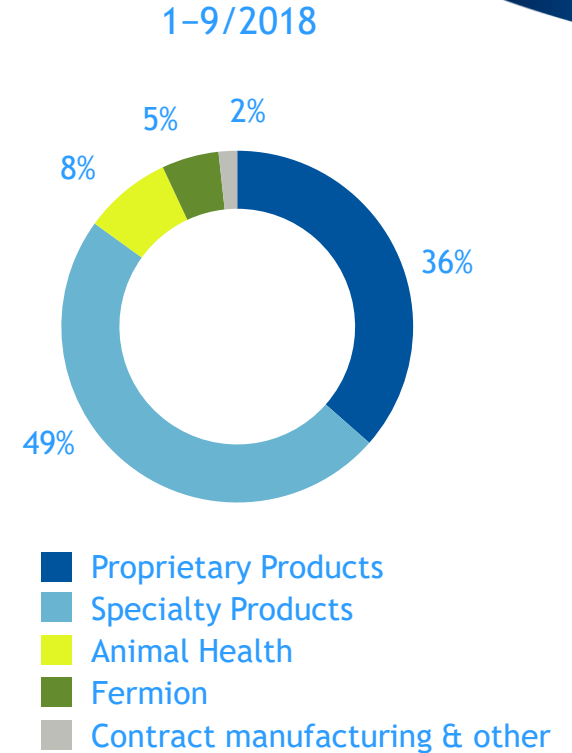
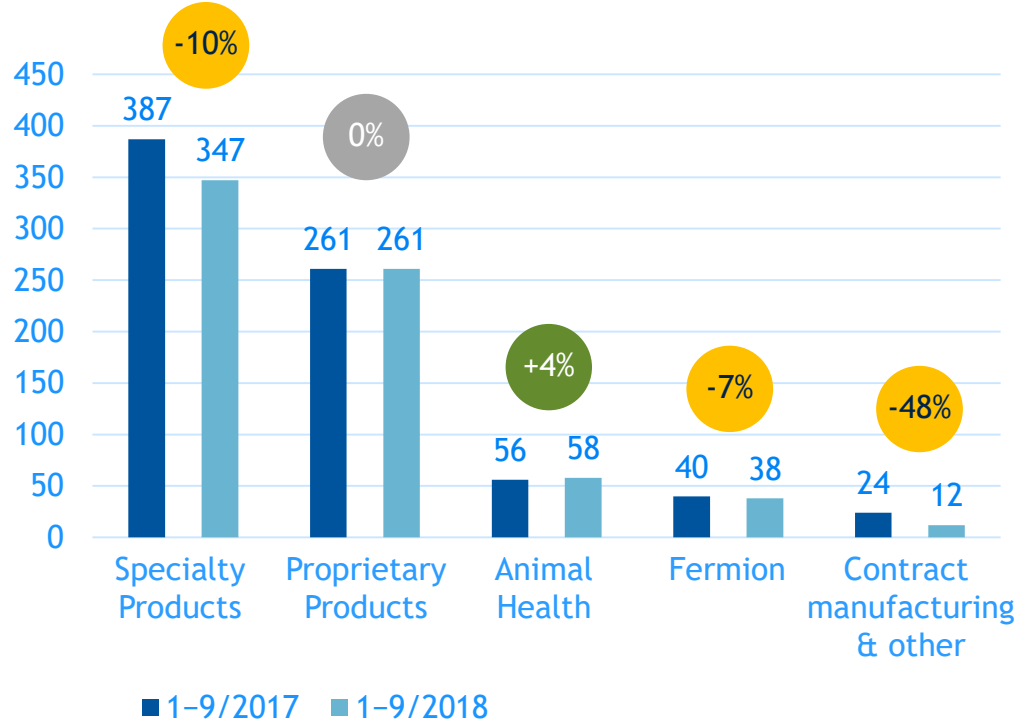
■ 1-9/2017 ■ 1-9/2018

EUR million


















# Net sales by business division

EUR million





# Best-selling pharmaceuticals 1–9/2018

		Indication	Net sales (EUR million)	Change vs 1–9/2017
1.	 <i>Stalevo</i>  <i>Comtess</i>  <i>COMTan</i>	Parkinson's disease	76	-5%
2.	 <b>EASYHALER</b>	Asthma, COPD	64	+17%
3.	 <i>dexdor</i>	Intensive care sedative	48	+2%
4.	 <b>SIMDAX</b> levosimendan	Acute heart failure	43	+2%
5.	 <b>DEXDOMITOR</b>  <b>DOMITOR</b>  <b>DOMOSEDAN</b>  <b>ANTISEDAN</b>	Animal sedatives	23	+6%
6.	Biosimilars  <b>Remsima</b> infiximab  <b>Ritemvia</b> Rituximab	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	19	-57%
7.	 <b>burana</b>	Inflammatory pain	17	-6%
8.	 <b>Precedex</b> (dexmedetomidine HCl injection)	Intensive care sedative	16	-14%
9.	Divina series  <i>Divina</i>	Menopausal symptoms	14	+4%
10.	<b>Marevan</b>	Anticoagulant	12	-11%

= Products of Proprietary Products business division



## Proprietary Products

# Proprietary Products

## Easyhaler

- Budesonide-formoterol Easyhaler continued strong growth.
- First deliveries of salmeterol-fluticasone Easyhaler have commenced.

## Dexdor

- Dexdor sales continued to grow in most countries. Significant generic competition only in Germany, but competition has now expanded to a few other countries as well.



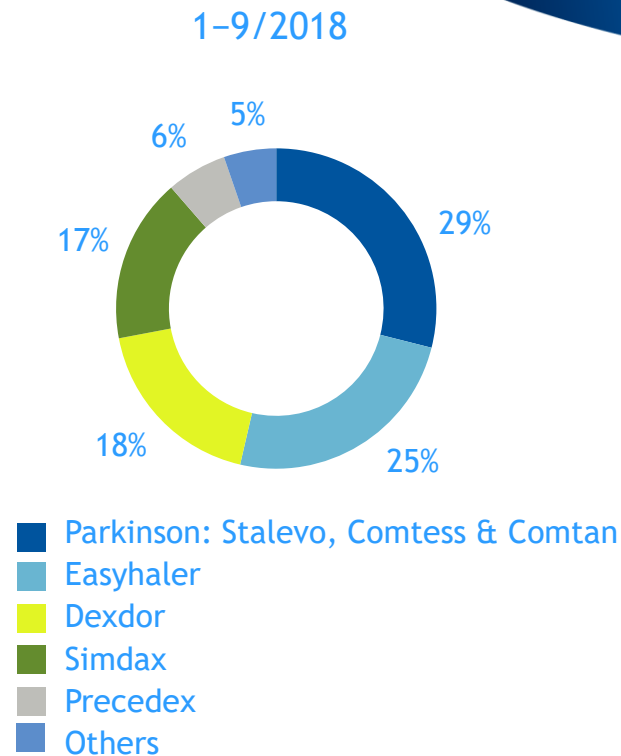
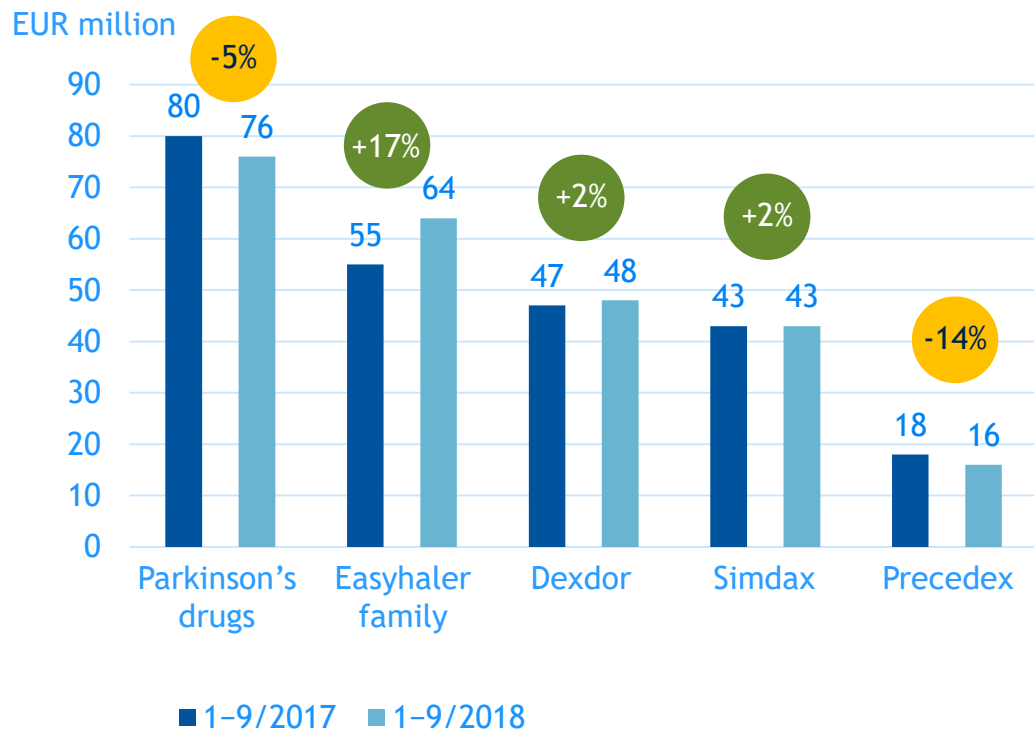
## Simdax

- Sales increased slightly.

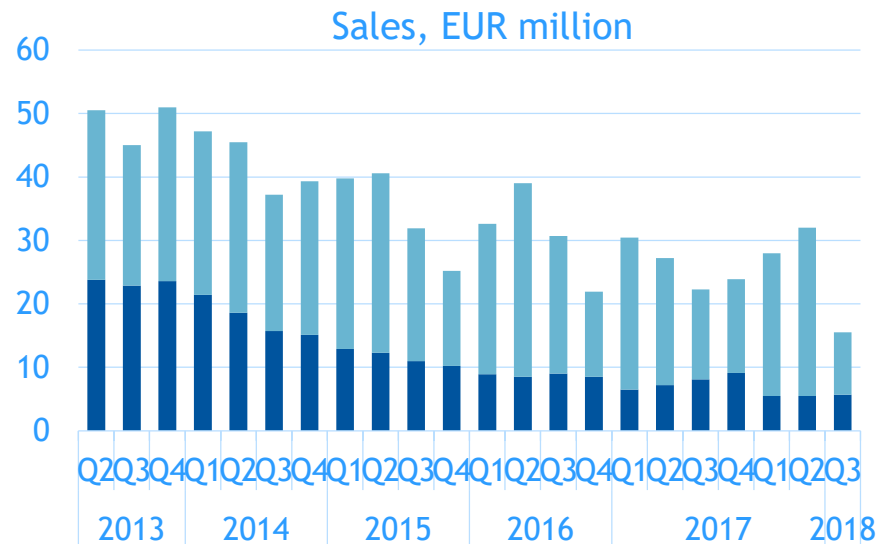
## Parkinson's drugs

- Sales lower than in comparative period, as anticipated. Sales are expected to continue to decrease in the long term, as well.

# Sales of Proprietary Products at level with comparative period

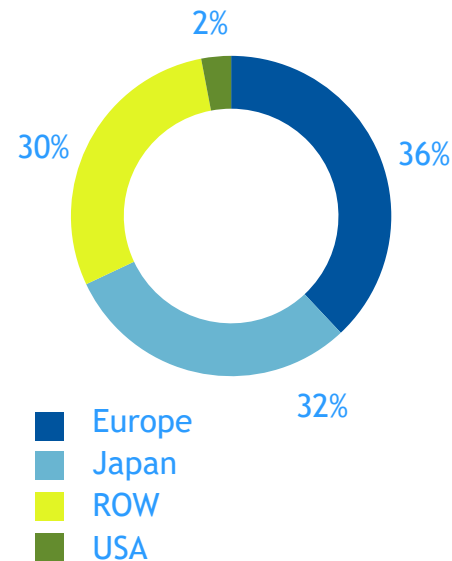


# Sales of Parkinson's drugs decreased from comparative period, as anticipated



- Deliveries of Parkinson's drugs (Stalevo, Comtess/Comtan) to key partners
- Orion's own sales

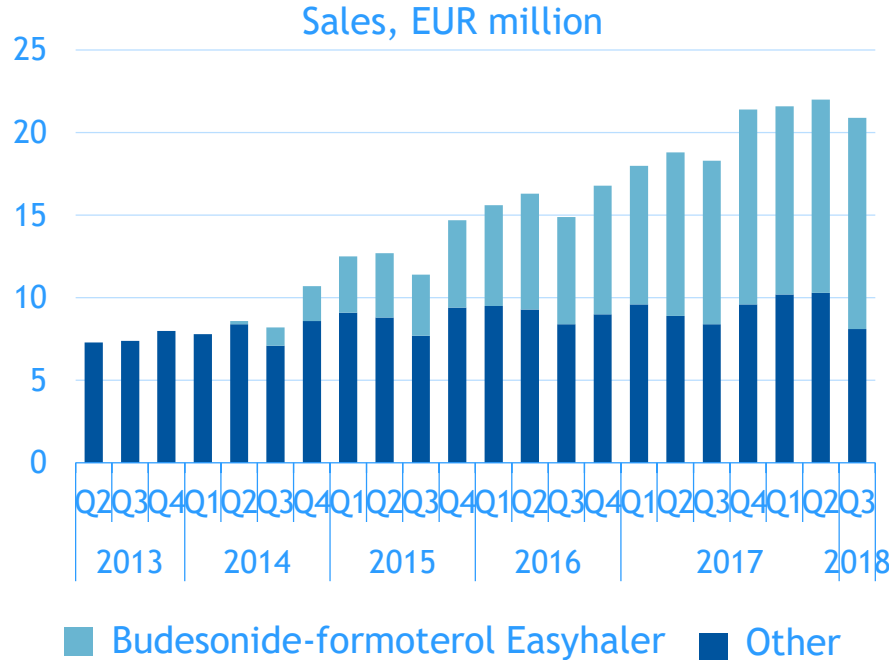
Sales of Orion's branded Parkinson's drugs by market area, MAT6/2018



Source: IQVIA

# Easyhaler product family grows

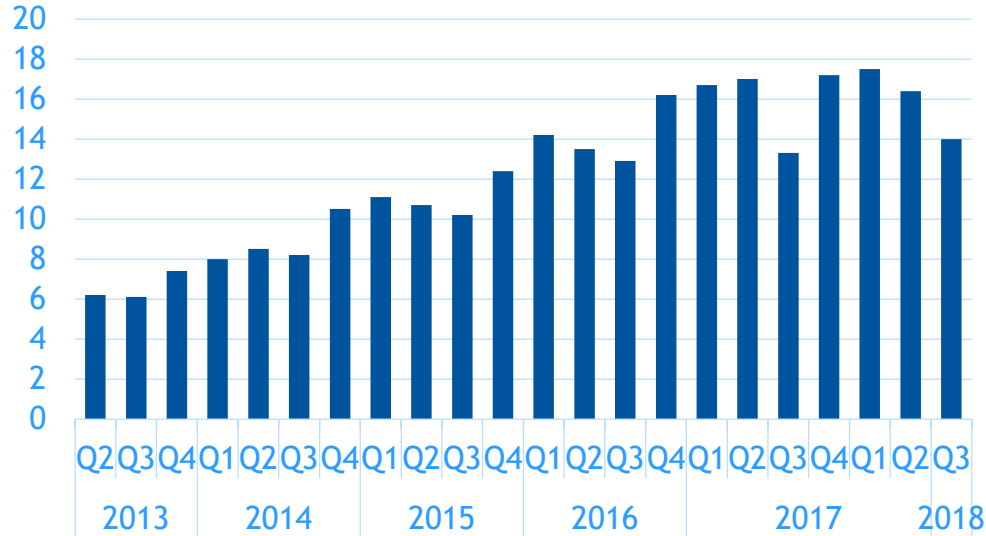
## – Salmeterol-fluticasone deliveries have commenced



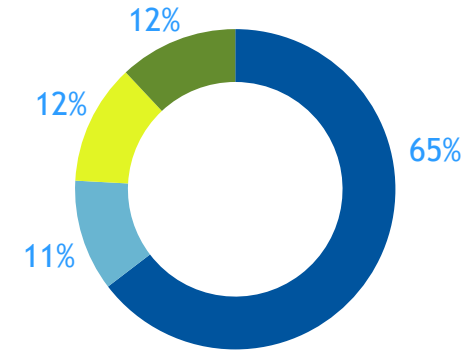
- Product family total sales: +17%
- Budesonide-formoterol Easyhaler: +27%
- Budesonide-formoterol Easyhaler
  - On sale in all key European markets.
  - Market share of volume varies: e.g. Sweden 38%, Germany 7%.
- Salmeterol-fluticasone Easyhaler
  - Launch started in first European countries. In March, positive conclusions received under the decentralised EU marketing authorisation procedure, and national approval procedures started in 23 countries.
- Development of the seventh product, **tiotropium**, continues.

# Sales of Dexdor intensive care sedative continued to grow in most European markets

Sales, EUR million



Total value of the European sedatives market: EUR 553 million (+3%)



- Propofol EUR 356 million (+3%)
- Midazolam EUR 62 million (-5%)
- Dexmedetomidine EUR 68 million (+16%)
- Remifentanyl EUR 66 million (-1%)

Source: IQVIA, MAT 6/2018





## Specialty Products



# Specialty Products

- Continued price competition in Finland has led to a decline in the entire reference priced prescription drug market.
  - Estimated impact on Orion EUR 15 million negative in 2018.

- In Scandinavia, sales decline was mainly due to the decreased sales of Remsima biosimilar.
- In Eastern Europe and Russia, sales were at level with the previous year.

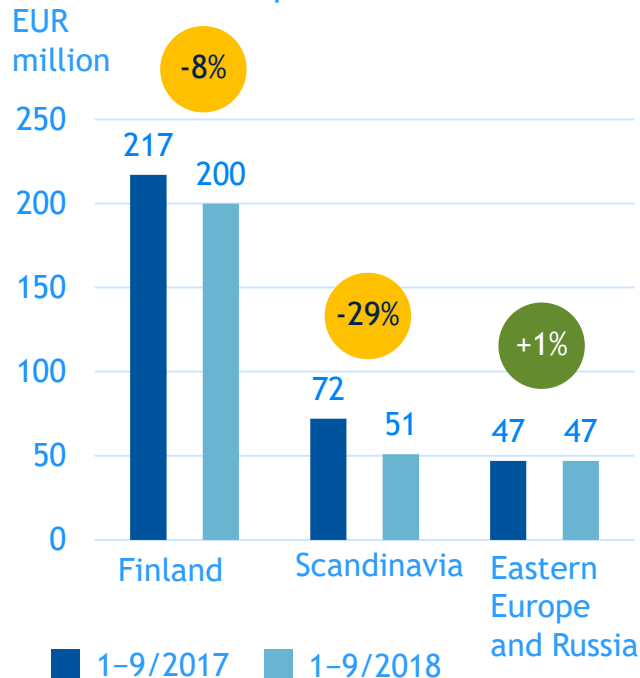


- Sales of biosimilars continued to decrease due to the situation of tenders, tightened competition and declined price level.

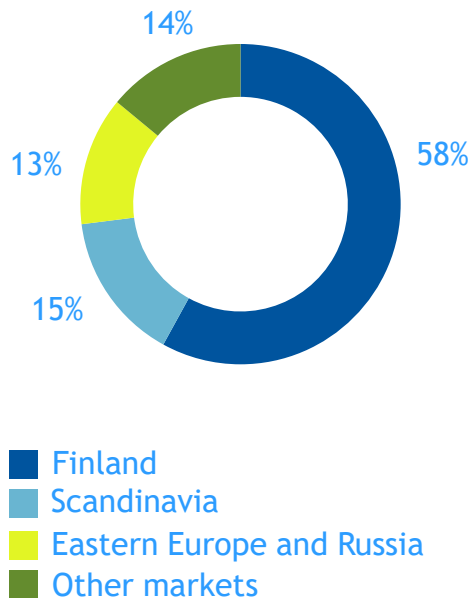
- Biosimilar portfolio expanding: In Finland, agreement with Amgen on the sales of Amgevita (adalimumab), Orion's first biosimilar for outpatient use.

# Specialty Products: tightened competition and lower sales of biosimilars showed as a decrease in sales

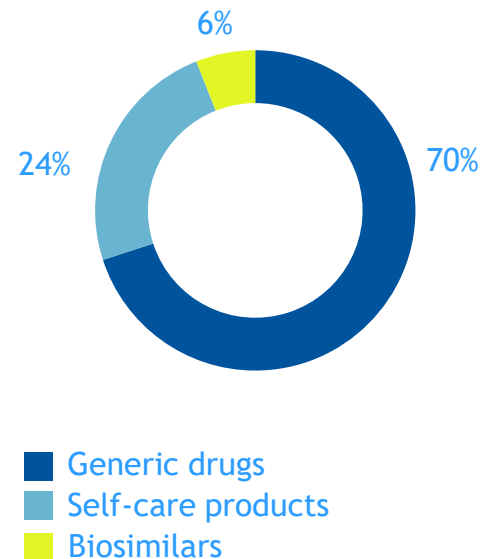
Development of net sales



Net sales by market area 1-9/2018



Net sales by product 1-9/2018



# 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 (1-9/2018)

368

MEUR (397)



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

91

MEUR (102)

Market development

-7%

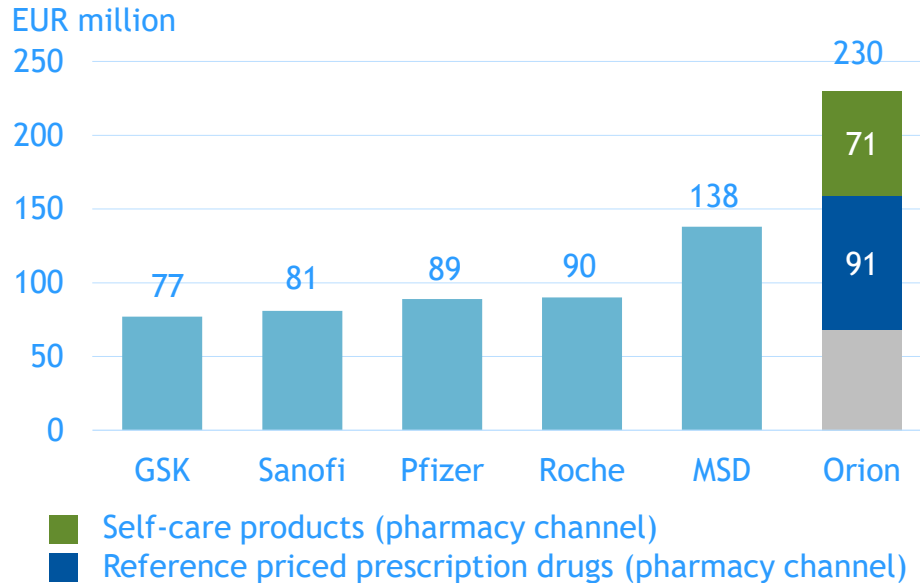
Orion's development

-11%

# Orion is strong in home market Finland

## Human pharma market in Finland (1-9/2018)

Medicinal and non-medicinal products  
in hospital and pharmacy channels: EUR 1,990 million



### Reference priced prescription drugs

Orion market share in pharmacy

**25%**  
(26%)

### Self-care products

Orion market share in pharmacy

**25%**  
(26%)

### Human pharmaceuticals total

Orion market share in pharmacy & hospital

**12%**  
(14%)



## Research and development



# Orion and Bayer's phase III trial of darolutamide for non-metastatic castration-resistant prostate cancer: Primary endpoint was met

- Darolutamide significantly extended metastasis-free survival compared to placebo.
- The full data will be presented at an upcoming scientific meeting.
- Bayer plans to discuss the data from the trial with health authorities regarding the submission for marketing authorization application. Darolutamide has been granted Fast Track designation by FDA.



# Financial impacts of darolutamide

- Bayer covered the majority of the development costs and has the right to commercialize darolutamide globally. Orion has the option of co-promoting in Europe. Orion will manufacture the product.
- **Milestone payments** upon first commercial sales: EUR 45 million in USA, EUR 20 million in the EU and EUR 8 million in Japan.
- **Tiered royalties on product sales** approximately 20%, including production revenue.
- **Potential one-off payments** if certain sales targets are met.



## Other late-phase clinical trials are also making progress




- **ODM-201/darolutamide for metastatic hormone-sensitive prostate cancer:**
  - Phase III trial ARASENS in collaboration with Bayer ongoing.
  - Patient recruitment finalized. The trial is expected to be completed in 2022.
- **ODM-109/orally administered levosimendan for ALS:**
  - 3-year REFALS trial started in the spring, recruitment progressing.
  - Orion conducts the Phase III trial on its own.
- **ODM-104 for Parkinson's disease:**
  - Primary endpoint of Phase II met in Q2/2018. The results are being analysed and Orion is looking for a possible partner. Decision-making will also consider investment opportunities in other R&D projects.

# Orion's key clinical drug development projects

Project	Indication	Phase			Registration
Easyhaler® tiotropium	COPD	Bioequivalence study			
Darolutamide <sup>1)</sup>	Prostate cancer (nmCRPC)	I	II	III	
Darolutamide <sup>1)</sup>	Prostate cancer (mHSPC)	I	II	III	
ODM-109 (oral levosimendan)	ALS	I	II	III	
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	I	II		
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			

<sup>1)</sup> In collaboration with Bayer

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

	= Completed
	= Ongoing
	= Status changed





**Patient safety is the guiding value in Orion's operations**

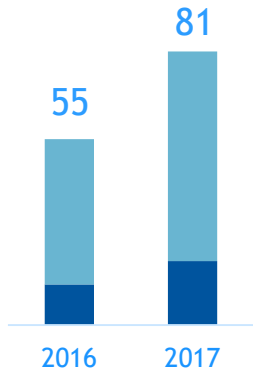


# We assess product safety throughout the lifecycle

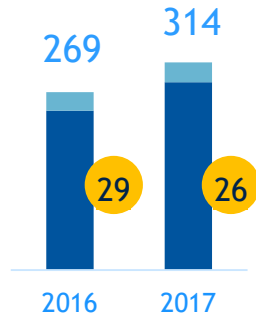


# In 2017 there were fewer product recalls than in the year before, number of audits increased

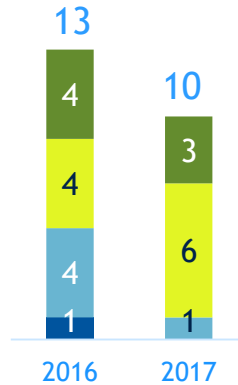
Audits by 3rd parties



Audits by Orion



Product recalls



■ GxP and EHS audits, partners and customers  
 ■ GxP and EHS audits, authorities

■ GxP audits  
 ■ EHS audits  
 ● Critical observations

■ Non-medicinal product  
 ■ Class 3 (minor)  
 ■ Class 2 (major)  
 ■ Class 1 (critical)

- No critical observations in audits carried out by authorities, customers and partners.
- Slightly less critical observations than in the previous year in audits carried out by Orion on partners.
- No product recalls related to critical defects (Class 1).



## Outlook



## Outlook for 2018 remains unchanged

### Net sales

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

### Operating profit

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

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



## Orion calendar

### 2019

Financial Statements Release 2018	6/2/2019
Annual General Meeting	26/3/2019
Interim Report 1-3/2019	25/4/2019
Half-Year Financial Report 1-6/2019	17/7/2019
Interim Report 1-9/2019	23/10/2019



**Building well-being**