



### 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.





## Orion in brief











On 21 April 2018, Orion signed an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business division). Following the transaction, that was completed on 30 April 2018, Orion Diagnostica business is reported as discontinued operation. All figures in this presentation are for continuing operations, if not otherwise stated.

### Steady development despite patent expiries







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### Orion's product mix has changed









### **Proprietary Products**

In-house developed drugs and other drugs with valid product protection



### **Specialty Products**

Generic prescription drugs, OTC and non-medicinal products, biosimilars



#### **Animal Health**

Medicine and well-being products for animals



#### Fermion

Active pharmaceutical ingredients (APIs)



**Contract Manufacturing** 

Production for other pharmaceutical companies

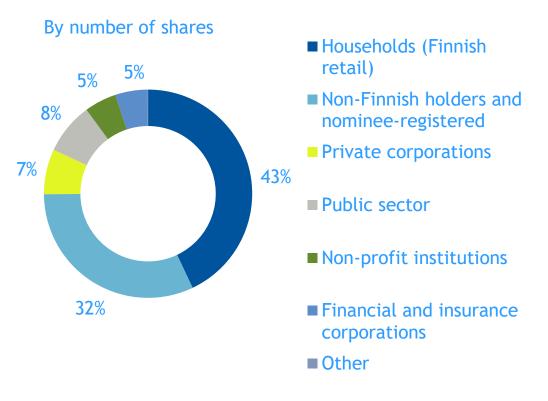


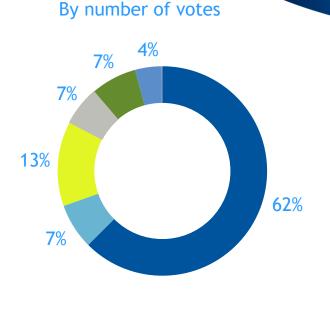
## Orion's strategy - Mission to build well-being

Ageing population	Advancements in science					
Cost burden in healthcare	Launching innovative and cost-effective pharmaceuticals and treatment methods for patients		Working together for our <b>customers</b>		Succeeding together!	
Increased personal responsibility for health	Continuously improving our performance in sustainability	Growing faster than the market		Quality and safety	Productivity and flexibility	
	Strong development of <b>profitability</b> is a target		Partnerships	Competitive product portfolio		Future R&D
Megatrends	S	trategic targets			Top Supply Chain	
Focus areas	S	trategic developmen	t projects			



## Orion had ~73,000 shareholders on September 30, 2018







Research and development







### **Proprietary Products**



- CNS
- Oncology
- Respiratory (Easyhaler® product family)

#### Animal Health



Orion utilises the R&D of proprietary products to develop new medicines for animals.

#### Fermion



- APIs to Orion's proprietary products
- Generic APIs
- Contract development for pharmaceutical companies





Research			Early	Early development		Late stage development	
Target identification and validation	Hit to Lead generation	Lead optimisation	Candidate selection, preclinical	Phase I	Phase II	Phase III	
8–24 mo.	12–24 mo.	18–36 mo.	development 12–24 mo.	12–14 mo.	12–36 mo.	18–48 mo.	

Collaboration with partners

Collaboration with partners









## Orion's key clinical drug development projects

Project	Indication		Phase		Registration
Easyhaler® tiotropium	COPD	Bioe	quivalence s	study	
Darolutamide 1)	Prostate cancer (nmCRPC)	1	Ш	III	
Darolutamide 1)	Prostate cancer (mHSPC)	1	II	111	
ODM-109 (oral levosimendan)	ALS	1	П	111	
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	- 1	П		
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumours	- 1	П		
ODM-207 (BET protein inhibitor)	Cancer	- 1			
ODM-208 (CYP11A1 inhibitor)	Prostate cancer (CRPC)	1			
1) In collaboration with Bayer			= Complete	d	
More information on R&D projects: https://www.orion.fi/en/rd/orion-rd/pipeline/			= Ongoing = Status cha	anged	

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

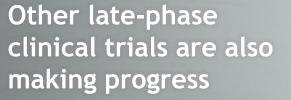
- Darolutamide significantly extended metastasisfree survival compared to placebo.
- The full data will be presented at an upcoming scientific meeting.
- Bayer plans to discuss the data from the trial with health authorities regarding the submission for marketing authorization application.
   Darolutamide 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.







- ODM-201/darolutamide for metastatic hormone-sensitive prostate cancer:
  - Phase III trial ARASENS in collaboration with Bayer on-going.
  - 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:
  - 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.

## Two trials with Bayer on darolutamide





- Patients with non-metastatic, castrationresistant prostate cancer who were being treated with androgen deprivation therapy as standard care and at risk of developing metastatic disease
- Endpoints:
  - Primary: Darolutamide over placebo in metastasis-free survival
  - Secondary: Overall survival, time to first symptomatic skeletal event, time to first initiation of cytotoxic chemotherapy, time to pain progression, and to characterize the safety and tolerability of darolutamide
- Headline results published in October 2018: Primary endpoint met. The full data will be presented at an upcoming scientific meeting.



- Patients with metastatic, hormone-sensitive prostate cancer
- Treatment: Darolutamide with androgen deprivation therapy (hormonal therapy) and six cycles of docetaxel (chemotherapy)
- Endpoints:
  - Primary: Darolutamide over placebo in overall survival
  - Secondary: Time to castration resistance, time to antineoplastic therapy, time to first symptomatic skeletal event, time to initiation of opioids, time to pain progression, and to characterize the safety and tolerability of darolutamide
- Recruitment finalized, estimated completion of the trial in 2022.

# ODM-109: Oral levosimendan for ALS

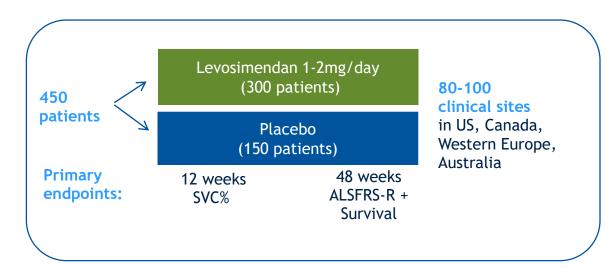


- First patients recruited in July for the Phase III clinical trial (REFALS).
- By enhancing respiratory muscle function in ALS patients, orally administered levosimendan can help maintain breathing capacity and benefit overall functioning of ALS patients.
- Orion is investing approximately EUR 60 million over three years in the trial.

- The aim is to apply for marketing authorisation in the US and Europe.
- Levosimendan has been granted an Orphan Drug Designation in the US and in the EU.
- It is a molecule originally developed by Orion for the treatment of acute decompensated heart failure. Simdax has been in the market for this indication since 2000.

### ODM-109: REFALS phase III trial





Costs of the trial:

~ EUR 60 million

approximately over three years

- = SVC% (slow vital capacity) measure of breathing capacity compared to normal subjects
- = ALSFRS-R (ALS functional rating scale) overall assessment of ALS symptoms

More information about the study: www.clinicaltrials.gov, Indentifier: NCT03505021



1-2/ 100,000

~16,800

Patients in the US in 2017

~12,500

Patients in Europe

~450-500

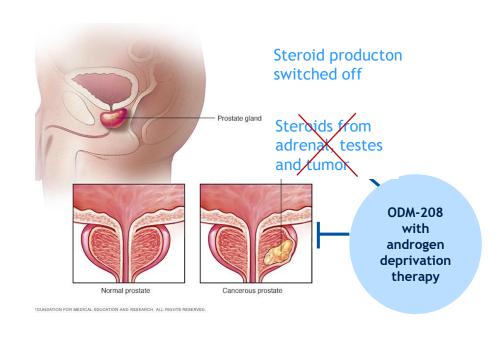
Patients in Finland

ORION



# ODM-208: Pan-steroid hormone synthesis inhibitor (CYP11A1 inhibitor) for castration-resistant prostate cancer

- Steroid hormones stimulate the growth of hormonally regulated cancers, such as most prostate and breast cancers.
- Hormonal treatments are highly effective, but drug resistance will often eventually emerge and cancer will start growing again.
- Preclinical studies have shown that ODM-208 inhibits the synthesis of steroids hormones. It has potential efficacy also for those cancers that have become resistant to the standard hormonal treatments.
- The steroid hormones that are needed and do not promote cancer growth are replaced with additional medication.





Highlights in January-September 2018







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

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.



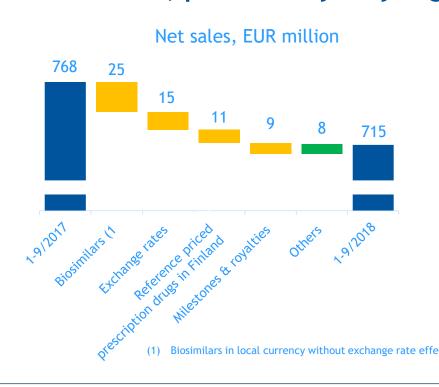
3 Sales of Proprietary Products were at level with comparative period. Net sales of Specialty Products continued to decrease due to challenging operating environment, tougher price competition and lower sales of biosimilars.

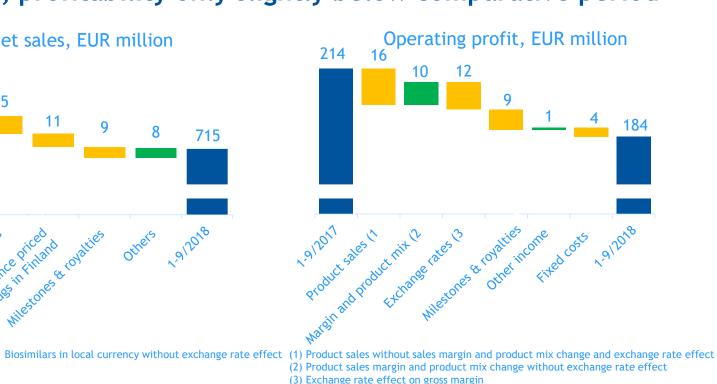
Outlook remains unchanged.



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







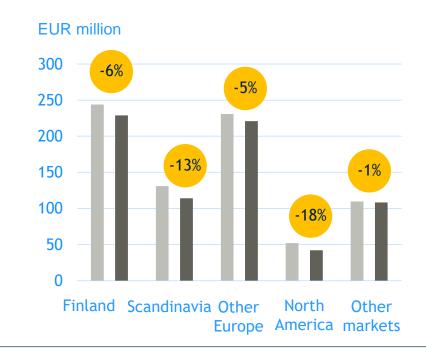
## Geographical breakdown and development of net sales





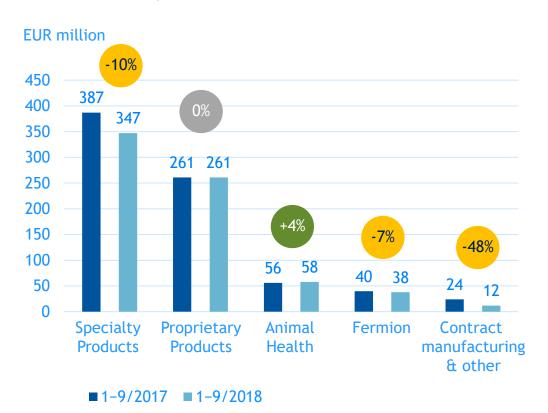


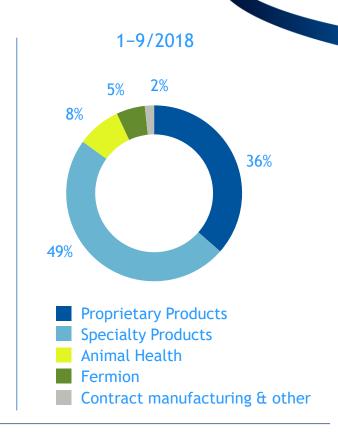
### **■** 1-9/2017 **■** 1-9/2018





### Net sales by business division





ckinson's disease chma, COPD ensive care sedative ute heart failure imal sedatives	Net sales (EUR million)  76 64 48 43	Change vs 1-9/2017 -5% +17% +2% +2% +6%
hma, COPD ensive care sedative ute heart failure	64 48 43	+17% +2% +2%
ensive care sedative ute heart failure	48	+2% +2%
ute heart failure	43	+2%
imal sedatives	23	+6%
eumatoid arthritis, inflammatory wel diseases, lymphoma	19	-57%
lammatory pain	17	-6%
ensive care sedative	16	-14%
nopausal symptoms	14	+4%
ticoagulant	12	-11%
֡	lammatory pain ensive care sedative nopausal symptoms ticoagulant	wel diseases, lymphoma  lammatory pain  ensive care sedative  nopausal symptoms  19  17  16



**Proprietary Products** 



### **Proprietary Products**



### Easyhaler

- Budesonide-formoterol Easyhaler continued strong growth.
- First deliveries of salmeterolfluticasone 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.



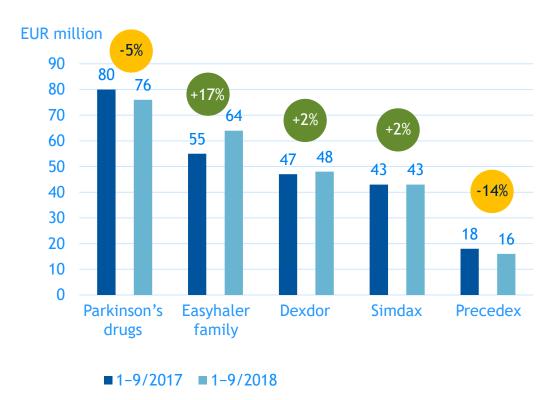
### Simdax

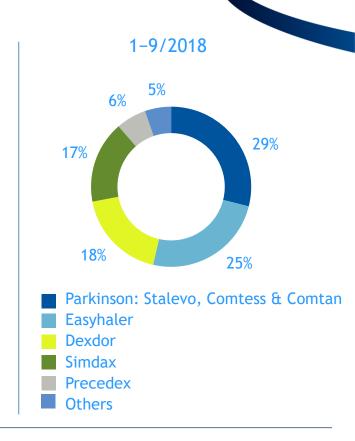
• Sales increased slightly.

### Parkinson's drugs

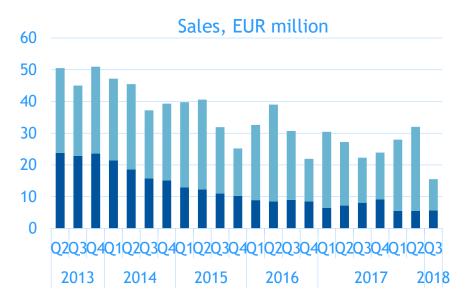
 Sales lower than in comparative period, as anticipated. Sales are expected to continue to decrease in the long term, as well.

# Sales of Proprietary Products at level with comparative period





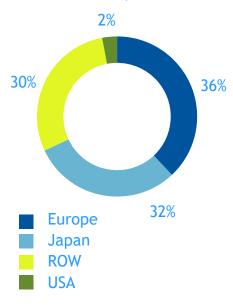
# Sales of Parkinson's drugs decreased from comparative period, as anticipated



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





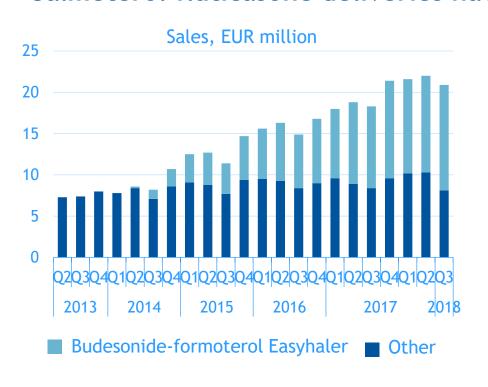


Source: IQVIA

## Easyhaler product family grows

## **ORION**

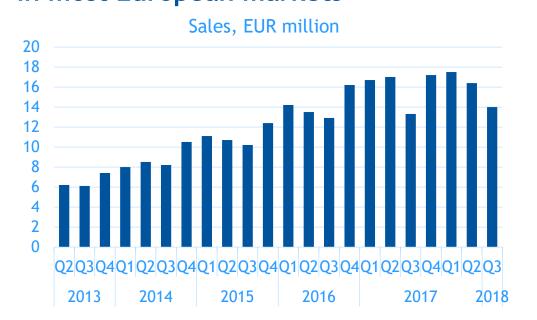
### Salmeterol-fluticasone deliveries have commenced

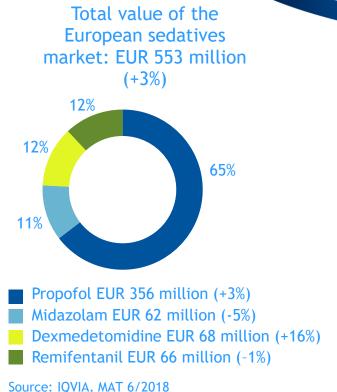


- Product family total sales:
- Budesonide-formoterol Easyhaler: +279
- Budesonide-formoterol Easyhaler
  - On sale in all key European markets.
  - Market share of volume varies:
     e.g. Sweden 38%, Germany 7%.
- Salmeterol-fluticasone Easyhaler
  - Launch started in first European countries. In March, 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







**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.

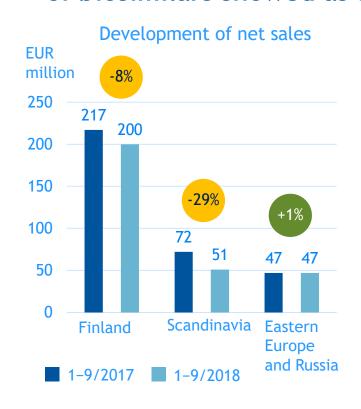


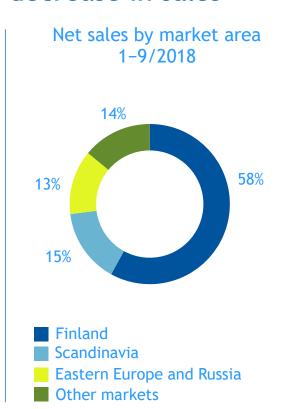
 Sales of biosimilars continued to decrease due to the situation of tenders, tightening competition and declined price level.

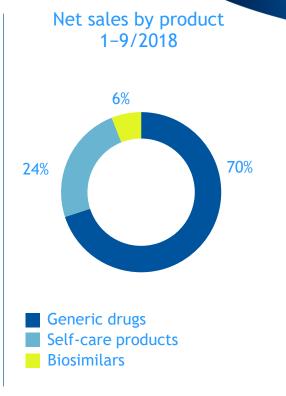
 Biosimilar portfolio expanding: In Finland, agreement with Amgen on the sales of Amgevita (adalimumab), Orion's first biosimilar for outpatient use.

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













The market of reference priced prescription drugs in Finland (1-9/2018)

368

**MEUR (397)** 

Market development

-7%



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

**91**MEUR (102)

Orion's development

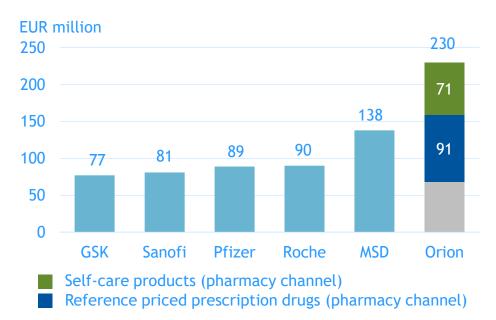
-11%

## 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%

# Self-care products

Orion market share in pharmacy

25%

# Human pharmaceuticals total

Orion market share in pharmacy & hospital

12%





## Outlook







#### **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.



## **Financials**







Growing net sales more rapidly than growth of the pharmaceuticals market. Achievement of this objective requires continuous investment in development of the product portfolio.

**>** 

Keeping the equity ratio at least 50%.

Maintaining profitability at a good level. The aim is operating profit that exceeds 25% of net sales.

€

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.





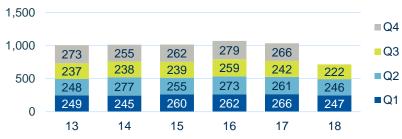
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\*) 2016: includes extra dividend EUR 0.20

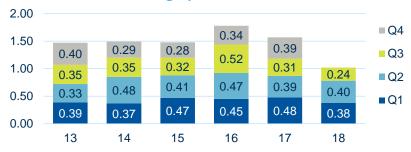




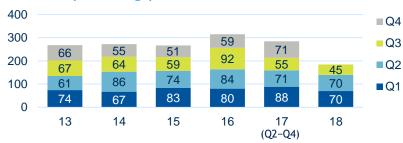




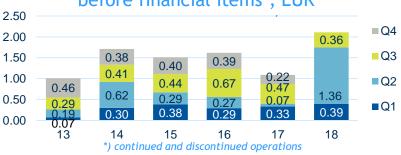
#### Basic earnings per share, EUR



#### Operating profit, EUR million



#### Cash flow per share before financial items\*, EUR



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Orion's key figures	2013	2014	2015	2016	ADJ.2017	1-9/2018	Change vs. 1-9/2017
Net sales, EUR million	1,006.9	1,015.3	1,015.6	1,073.5	1,033.6	715.1	-6.8%
Operating profit, EUR million	267.7	272.4	266.6	314.6	284.1	184.2	-13.8%
Profit before taxes, EUR million	264.0	267.8	262.3	310.9	277,7	180.9	-13.3%
R&D expenses, EUR million	101.9	106.2	108.1	118.2	99.1	76.2	+5.0%
Equity ratio, %	53.6%	52.3%	57.4%	60.8%	64.6%	69.1%	
Gearing, %	8.4%	-4.7%	-9.6%	-12.4%	-1.9%	-14.0%	
ROCE (before taxes), %	38.5%	36.6%	35.7%	40.9%	36.2%	49.7%	
Return on equity, %	40.3%	41.1%	37.5%	40.3%	34.2%	52.2%	
Basic earnings per share, EUR	1.46	1.50	1.48	1.77	1.61	1.97	+62.1%
Cash flow per share before financial items, EUR	1.02	1.72	1.51	1.62	1.09	2.10	+143.3%
Dividend per share, EUR	1.25	1.30	1.30	1.55*	1.45		

<sup>\*) 2016:</sup> dividend includes extra dividend of EUR 0.20

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#### Income statement

Formation of profits, EUR million	2013	2014	2015	2016	ADJ. 2017	1-9/2018	Change vs. 1-9/2017
Net sales	1,006.9	1,015.3	1,015.6	1,073.5	1,033.6	715.1	-6.8%
Cost of goods sold	-393.5	-401.7	-405.8	-421.7	-417.6	-286.7	-8.3%
Gross profit	613.4	613.6	609.8	651.8	616.0	428.4	-5.9%
Other operating income and expenses	5.6	1.7	1.5	24.3	4.9	4.0	+25.8%
Sales and marketing expenses	-204.9	-193.4	-190.4	-194.7	-188.9	-139.9	+0.5%
R&D expenses	-101.9	-106.2	-108.1	-118.2	-99.1	-76.2	+5.0%
Administrative expenses	-44.5	-43.3	-46.2	-48.7	-48.8	-32.1	-2.0%
Operating profit	267.7	272.4	266.6	314.6	284.1	184.2	-13.8%
Profit before taxes	264.0	267.8	262.3	310.9	277.7	180.9	-13.3%
Profit for the period for continuing operations					219.1	143.6	-12.8%
Profit for the period for discontinued operations					6.9	133.4	
Profit for the period	206.2	211.3	208.2	249.0	226.0	277.1	+62.3%

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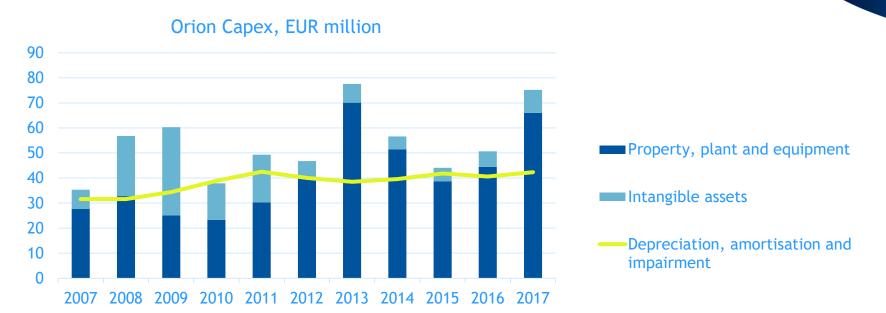


EUR million	9/ 2018	9/ 2017	Change %	EUR million	9/ 2018	9/ 2017	Change %
Non-current assets total	415.3	395.8	+4.9%				
Inventories	220.0	218.7	+0.6%	Equity total	736.8	594.5	+23.9%
Trade receivables	165.4	187.8	-11.9%	Interest-bearing non-current liabilities	0.6	150.4	-99.6%
Other receivables	33.2	34.8	-4.7%	Non-current liabilities total	62.0	188.8	-67.2%
Cash & cash equivalents & money market investments	254.8	133.1	+91.5%	Current liabilities total	289.9	186.8	+55.2%
Current assets total	673.4	574.4	+17.2%	Liabilities total	351.9	375.6	-6.3%
Assets total	1,088.7	970.1	+12.2%	Equity and liabilities total	1,088.7	970.1	+12.2%

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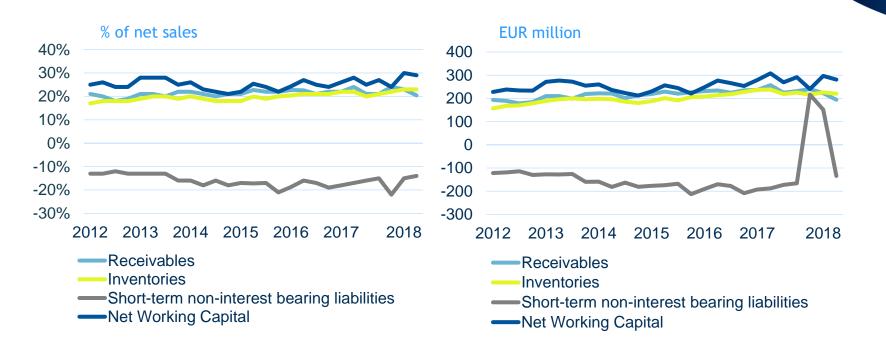








### Development of net working capital



### Dividend distribution policy

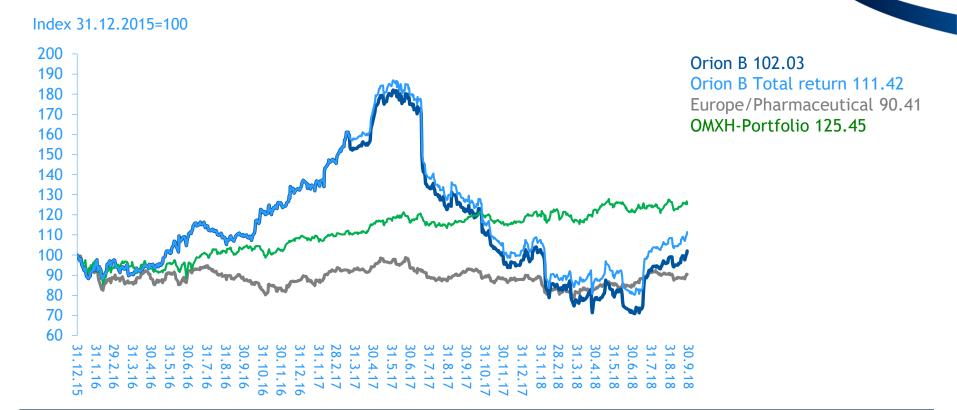


 Orion's dividend distribution takes into account distributable funds and capital expenditure and other financial requirements in medium and long term to achieve the financial objectives.





## Orion B share performance January 2016 - September 2018





## **Business units**



### **Proprietary Products**



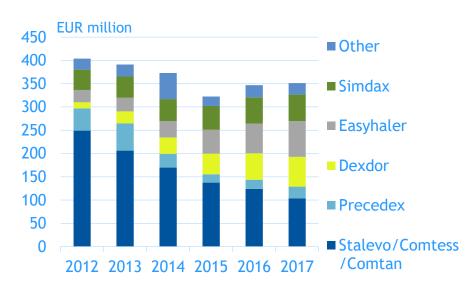
#### Mainly Orion in-house developed prescription drugs with valid product protection

• Global sales and R&D partner networks

#### Key drivers for business

- ▲ Easyhaler, Simdax
- Possible milestones from development pipeline projects
- New products from R&D pipeline
- Generic competition

#### Net sales





## Proprietary human pharmaceuticals developed by Orion

Product	Indication	Year	<b>Easyhaler</b> ®	Year	Indication
dexdor	Sedative for ICU use	2011	Salmeterol- fluticasone Easyhaler®	2018	
Stalevo	Parkinson's disease	2003	Budesonide-		
SIMDAX levosimendan	Acute decompensated heart failure	2000	6		
Precedex® (dexmedetomidine HCl Injection)	Sedative for ICU use	1999	Formoterol Easyhaler®	2004	Asthma and COPD
Comtess	Parkinson's disease	1998	Budesonid Easyhaler®	2002	
<u>COMTan</u>	Project concer		Beclomet Easyhaler®	1994	
FARESTON"	Breast cancer	1988	Buventol Easyhaler®	1993	

# Steady sales growth for Specialty Products Orion Specialty Products = Gx + OTC including also non-medicinal products









## **Specialty Products:** Portfolio of hundreds of different product

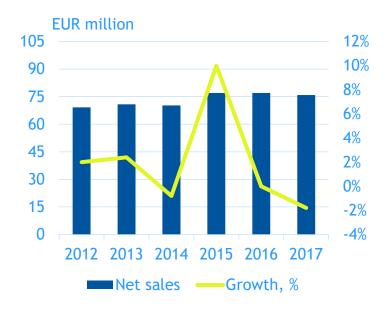






#### **Animal Health**





In-house developed proprietary products



- Medicinal and non-medicinal products for companion animals and livestock
- In-house developed proprietary products sold globally both through own sales network and through partners
- In-licensed products sold in own sales areas

## Fermion has an important strategic role











APIs for Orion's proprietary



Generic APIs for Orion and other pharmaceutical companies



Contract development and manufacturing

\*) Excluding supply to Orion

## Fermion's new production plant operational in Hanko

- nearly 100% of production is exported





**EUR** >30 million

Expansion investment 2016-2018

6,000

Production facility and equipment for the production of APIs

200-> 300 t

Enables capacity increase Number of APIs manufactured at Hanko

~ 20

- Special expertise in demanding production of active pharmaceutical ingredients (APIs), e.g. extremely potent substances.
- The aim is to captively manufacture the APIs for Orion's in-house developed proprietary drugs, such as darolutamide.
- Modernised, advanced technology at Hanko strengthens Fermion's global competitive position, meets increasingly strict regulatory requirements and provides the means to meet growing demand.
- The Hanko facility manufactures azathioprine and entacapone, among others, in which Fermion is the leading manufacturer globally.



### Contract manufacturing & other

#### **EUR** million









## Responsibility



## Patient safety, ethical operations and responsible supply chain - The cornerstones of Orion's corporate responsibility

#### In 2017:

- 31% of the energy savings target set for 2025 was achieved.
- New water collection systems were introduced in production to minimise pharmaceutical residue emissions.
- We worked to improve occupational safety and safety culture.
- Openness: Orion disclosed its financial collaboration with healthcare professionals.
  - In Finland, 90% (83%) gave their consent to publishing their speaker fees

Energy savings

MWh (2,068) +80%

Drug recalls

(9) -22%

Audits undertaken by Orion

(269) + 17%

Injury rate,



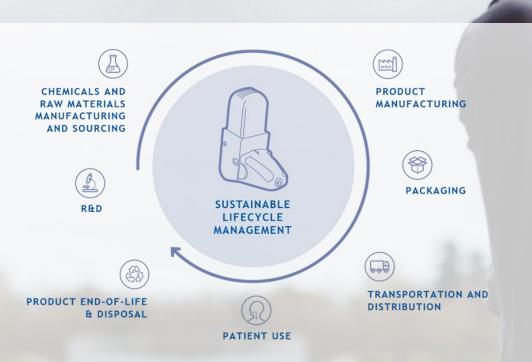


Patient safety is the guiding value in Orion's operations



**ORION** 

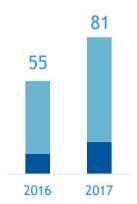
We assess product safety throughout the lifecycle





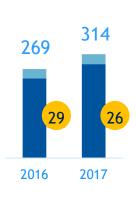






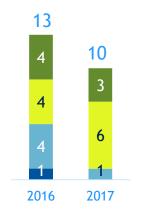
- ■GxP and EHS audits, partners and customers
- ■GxP and EHS audits, authorities





- GxP audits
- EHS audits
- Critical observations

## Product recalls



- 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)





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