





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.

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# Orion in brief



## Key messages



- Orion develops, manufactures and markets human and animal pharmaceuticals, and APIs. Products marketed in >100 countries.
- Balanced business model: Both proprietary drugs and generics.



Growth targeted through new inhouse developed drugs.

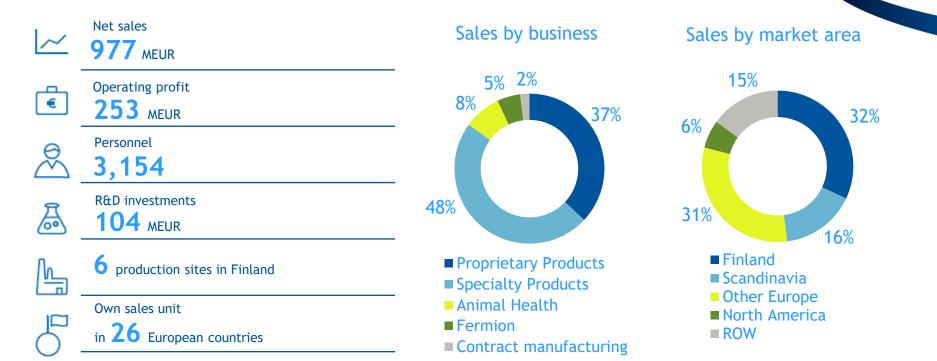
Core therapy areas in R&D: oncology, CNS and respiratory diseases (Easyhaler family).

5 Strong position in the Nordic generics market.

6 Strong profitability, stable dividends.







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.









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# Orion's product mix has changed



#### Our businesses





#### **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

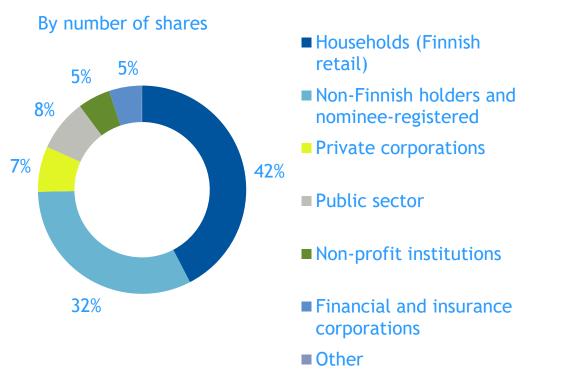


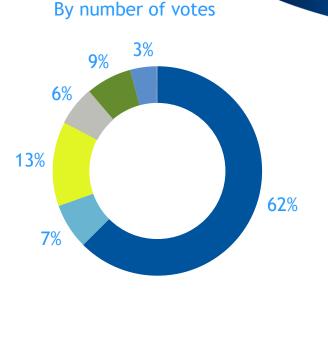
# Orion's strategy - Mission to build well-being

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	May 1	Quality and safety	Productivity and flexibility	
	Strong development of <b>profitability</b> is a target		Partnerships	Competitive product portfolio		Growth
Megatrends	St	rategic targets			Sustainability	
Focus areas	St	rategic developmen	t projects		Sustamasmity	



# Orion had ~73,000 shareholders on 31 December 2018







Research and development

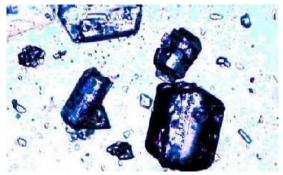












#### **Proprietary products**

- Central nervous system
- 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

# Together we can achieve more in R&D



Research			Early	/ development	Late stage development		
Target identification and validation	Hit to Lead generation	Lead optimisation	Candidate selection, preclinical development	Phase I	Phase II	Phase III	
8–24 mo.	12–24 mo.	18–36 mo.	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	Bioequivalence study			
Darolutamide 1)	Prostate cancer (nmCRPC)	1	II	III	
Darolutamide 1)	Prostate cancer (mHSPC)	1	II	III	
ODM-109 (oral levosimendan)	ALS	1	II	III	
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	1	II		
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumours	1	H		
ODM-207 (BET protein inhibitor)	Cancer	1			
ODM-208 (CYP11A1 inhibitor)	Prostate cancer (CRPC)	1			
1) In collaboration with Bayer		= Completed = Ongoing			
More information on R&D projects: https://www.orion.fi/en/rd/orion-rd/pipeline/		= Status changed			



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 safety and tolerability were consistent with previously published data.
- The full data will be presented at the ASCO GU on 14 February 2019. An abstract will be published on 11 February 2019.
- Bayer is having discussions with health authorities regarding the submission for marketing authorisation application.
- Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA). If the process proceeds as planned, the sales could in the best-case scenario start in the US already at the end of 2019.
- Phase III ARASENS trial for metastatic prostate cancer continues.



# 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 the US, 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.



## Two trials with Bayer on darolutamide





- Patients: men with non-metastatic, castration-resistant prostate cancer treated with androgen deprivation therapy (hormonal therapy) and at risk of developing metastatic disease
- Treatment: 600 mg of darolutamide or matching placebo twice a day
- Endpoints:
  - Primary: metastasis-free survival, defined as time between randomization and evidence of metastasis or death from any cause
  - 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
- Status: Trial completed, primary endpoint met. The full data presented at ASCO GU on 14 February.



- Patients: men with metastatic, hormonesensitive prostate cancer
- Treatment: Darolutamide with androgen deprivation 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
- Status: Recruitment finalized, estimated completion of the trial in 2022.

# ODM-109: Oral levosimendan for ALS

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- 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 (ALS): REFALS phase III trial



#### 450 patients

- Levosimendan1-2mg/day(300 patients)
- Placebo (150 patients)

#### Approx. 100 clinical sites

 US, Canada, Europe, Australia

#### **Primary endpoints**

- 12 weeks: Slow vital capacity (Breathing capacity compared to normal subjects)
- 48 weeks:
   ALS functional rating scale (Overall assessment of ALS symptoms)

www.clinicaltrials.gov: NCT03505021



1-2/ 100,000 Incidence ~16,800

Patients in the US in 2017

~12,500

Patients in Europe

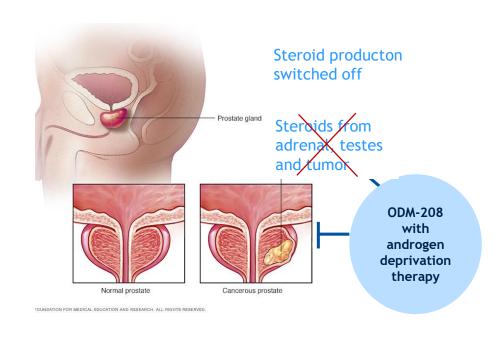
~450-500

Patients in Finland



# 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-December 2018



# Important year for future growth



- Profitability was good, 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.
- Net sales of Specialty Products declined due to continued intense price competition in generic drugs in Finland and anticipated lower sales of biosimilars.
- 5 Strategic target in 2019-2023: Growing more rapidly than the growth in the market.



- The net sales of Proprietary Products increased slightly particularly due to strong Easyhaler sales. Sales of Dexdor and Simdax remained at a good level. Sales of Parkinson's drugs declined as anticipated.
- Prostate cancer drug darolutamide met primary endpoint in October. Full data will be presented at ASCO GU on 14 February 2019.
- 6 Dividend proposal: EUR 1.50 share.

# Key strategic target in 2019–2023: Growing more rapidly than the growth in the market



Net sales target in 2025

1.5

billion EUR

Capital gain from the sale of Orion Diagnostica, EUR 128 million, supports growth opportunities.



Own investments in new clinical trials:

E.g. EUR 60 million investment in Phase III trial on ALS (REFALS).

Investments in sales and marketing:

E.g. strengthening the Easyhaler product family sales force in Germany.

In-licensing and product acquisitions:

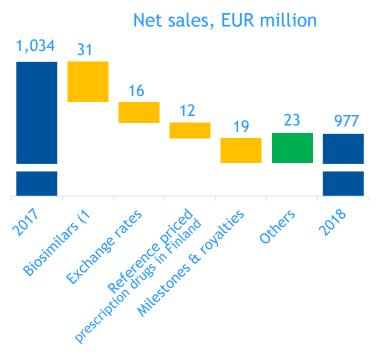
E.g. reacquisition of Stalevo sales rights in Europe.

Investments supporting growth estimated at EUR 30 million in 2019.



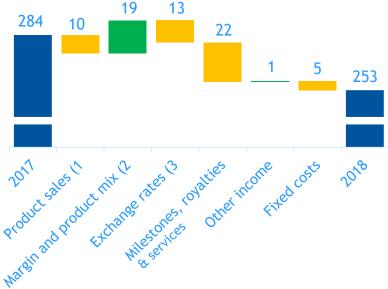
# Without the negative impact of exchange rate changes and lower milestone payments and royalties, profitability would have slightly improved from 2017







#### Operating profit, EUR million



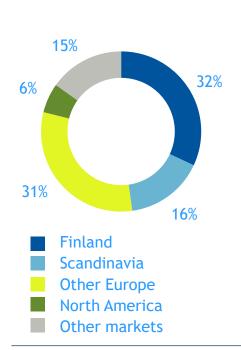
- (1) Product sales without sales margin and product mix change and exchange rate effect
- (2) Product sales margin and product mix change without exchange rate effect
- (3) Exchange rate effect on gross margin

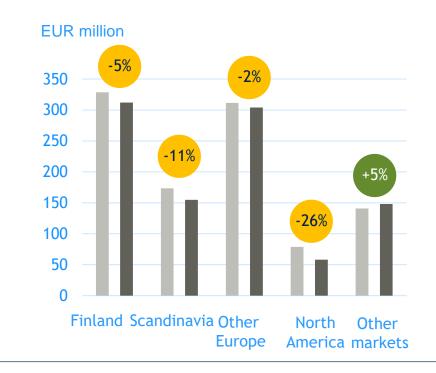
# Geographical breakdown and development of net sales





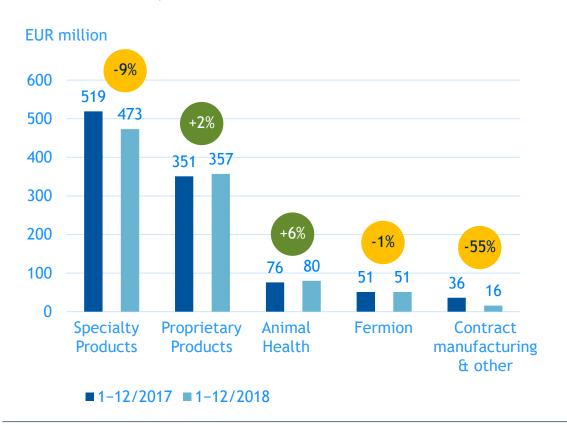


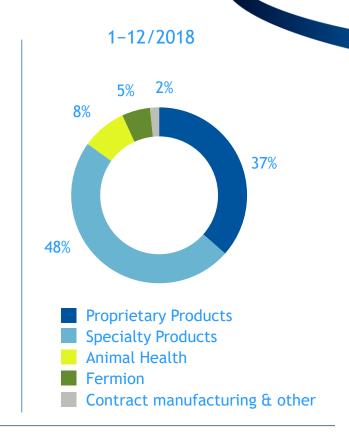






# Net sales by business division





# Best-selling pharmaceuticals 1-12/2018

= Products of Proprietary Products business division

		Indication	Net sales (EUR million)	1-12/2017
1.	Stalevo Comtess COMTan	Parkinson's disease	100	-3%
2.	<b>₹</b> EASYHALER	Asthma, COPD	90	+18%
3.	dexdor	Intensive care sedative	63	-2%
4.	SIMDAX'	Acute heart failure	59	+4%
5.	DEXDOMITOR DOMITOR DOMOSEDAN & ANTISEDAN	Animal sedatives	34	+10%
6.	Precedex* (dexmedetomidine HCI Injection)	Intensive care sedative	26	+3%
7.	Biosimilars	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	25	-56%
8.	burana	Inflammatory pain	23	0%
9.	Divina series Divina	Menopausal symptoms	19	+1%
10.	Marevan <sup>e</sup>	Anticoagulant	18	-7%

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**Proprietary Products** 



# **Proprietary Products**



#### Easyhaler

- Strong growth, investments in sales and marketing particularly in Germany.
- Salmeterol-fluticasone Easyhaler sales started.

#### Dexdor

 Dexdor sales continued to grow in most of the countries. In 2018 there was significant generic competition only in Germany, but competition is expected to expand in 2019.



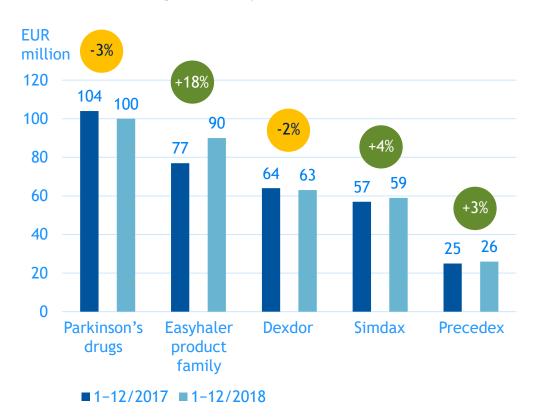
#### Simdax

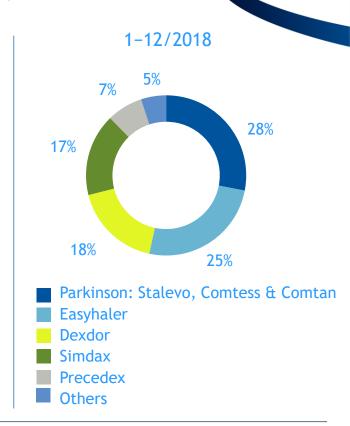
Sales increased slightly.
 Possible generic competition is not estimated to have a material impact on sales in 2019.

### Parkinson's drugs

 Sales were lower than in comparative period, as anticipated. However, the decline in sales was significantly slower than in the long term on average.

# Sales of Proprietary Products increased slightly

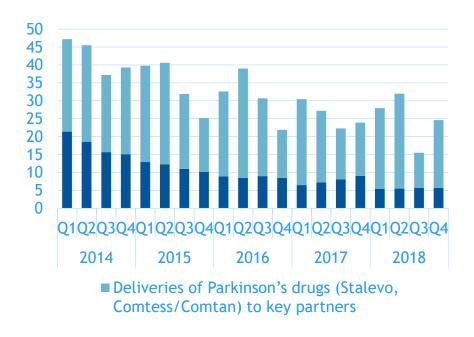




## Decrease in sales of Parkinson's drugs slowed down

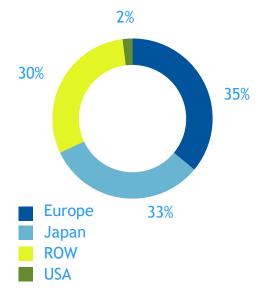






Orion's own sales

Sales of Orion's branded Parkinson's drugs by market area



Source: IQVIA, MAT9/2018



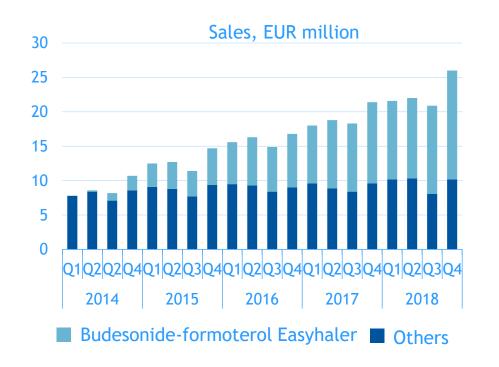




- The rights were transferred back from Novartis in December:
  - 18 EU countries and a few other European country.
- Added sales initially around EUR 20 million/year.
- Provides Orion with greater opportunities to promote Stalevo sales and to extend the product's life cycle.
- Orion paid USD 24.5 million for the transfer of sales rights, to be depreciated over two years.

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





- Continued strong growth for budesonideformoterol Easyhaler.
- Product family total sales: +18%

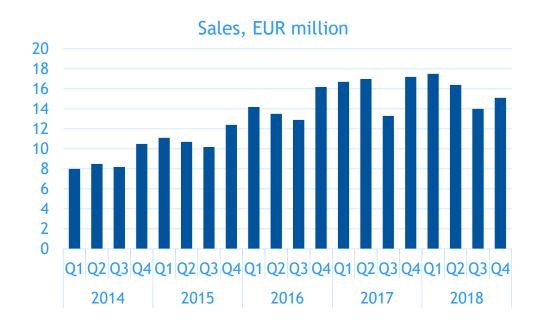


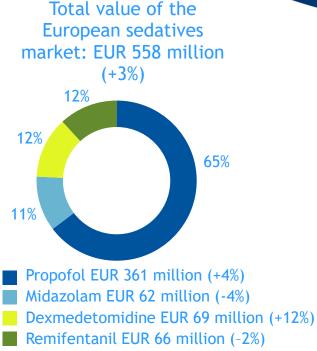
- Strong market position in some markets,
   e.g. in Sweden (40%).\*
- Growth still attainable in certain markets.
   Investments in sales and marketing made particularly in Germany (market share 7%).
- Salmeterol-fluticasone sales started in the first European countries in late 2018.
- Development of seventh product, tiotropium, continues.



Sales of Dexdor intensive care sedative continued to grow in most European markets - generic competition expected to expand in 2019

Total value o





Source: IQVIA, MAT 9/2018



**Specialty Products** 



## **Specialty Products**



 Net sales decreased in Finland and Scandinavia, and grew in Eastern Europe and Russia.

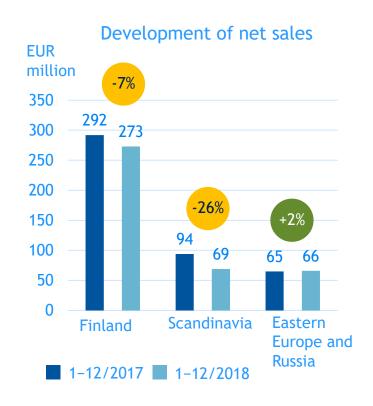
- In Finland, price competition has led to a decline in the entire market of reference priced prescription drugs. Impact on Orion's sales was EUR 15 million negative in 2018.
- Prices are expected to continue decline in 2019, but impact on sales is anticipated to be slightly lower than in 2018.

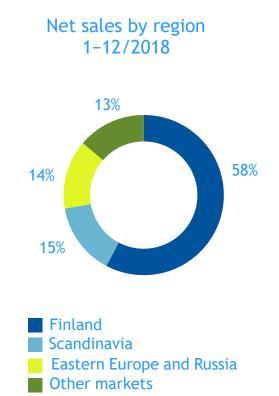


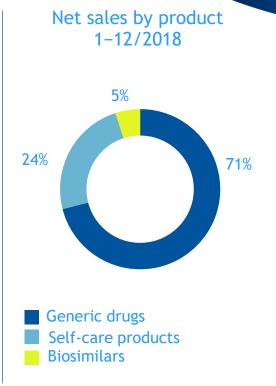
- Net sales of biosimilars decreased from record year 2017.
- The decrease was due to tightened competition, declined price level and the situation of tendering competitions.
- Orion won the national tender in Norway in late 2018, deliveries to start in Q1/2019.
- In Finland, sales of Amgevita (adalimumab), Orion's first biosimilar for outpatient use, started at the end of the year.

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









# 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 (1-12/2018)

490 MEUR (528)

Market development

**-7**%



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

126
MEUR (139)

Orion's development

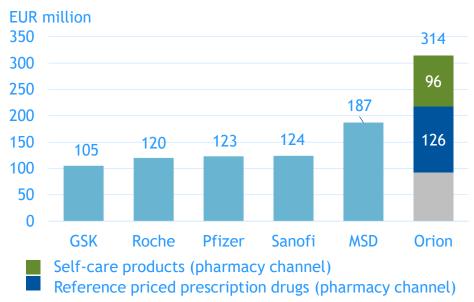
-9%





#### Human pharma market in Finland (1-12/2018)

Medicinal and non-medicinal products in hospital and pharmacy channels: EUR 2,746 million



Reference priced prescription drugs

Orion market share in pharmacy

26%

(26%)

## Self-care products

Orion market share in pharmacy

25%

(26%)

# Human pharmaceuticals total

Orion market share in pharmacy & hospital

11%

## 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.
- 2. Phase III clinical trial (REFALS) for orally administered levosimendan (ODM-109) in ALS and preparation for possible commercialisation.
- 3. Strengthening Orion's position as Finland's most significant provider of generic drugs; competitive pricing.
- 4. Competitive product portfolio in Specialty Products and strengthening of product launches.

5. Accelerating the growth of the Easyhaler product family and strengthening its market position. Salmeterol-fluticasone launch progressing in Europe.

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



• Daisy:

Optimising Parkinson's patient's quality ON-time (the period when medication is effective, and symptoms are under control) by gathering data on the patient's condition.

Orion and Fifth Corner Inc:

The research project aims to help prostate cancer patients manage the stress caused by their disease.

 ToxBuddy: Information and support for veterinary practitioners in the treatment of poisoning in dogs.

ORION



## Outlook







 The ongoing projects supporting growth are expected to burden Orion's profit in 2019 by an estimated EUR 30 million.  This comprises clearly increased depreciation as well as investments in sales and marketing and research.  At the same time, operating profit is burdened by intense price competition in the market and gradually expanding generic competition for Orion's old proprietary drugs.

#### **Outlook for 2019**



#### **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 (operating profit in 2018 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.





## **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.

<u>></u>

Keeping the equity ratio at least 50%.

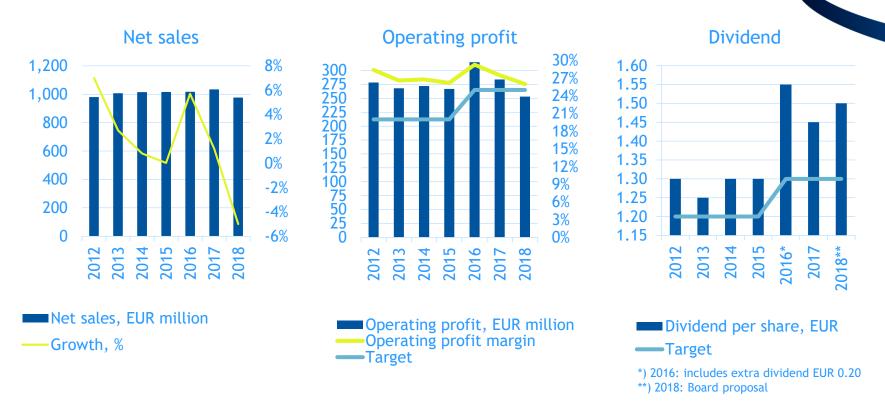
Maintaining profitability at a good level. The aim is operating profit that exceeds 25% of net sales.



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.

#### Financial objectives



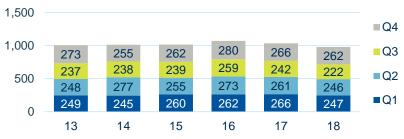


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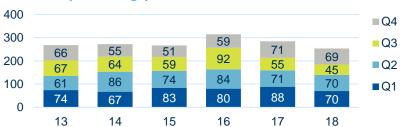




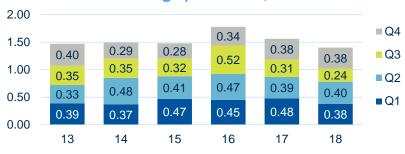




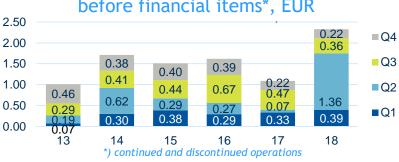
#### Operating profit, EUR million



#### Basic earnings per share, EUR



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



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							Change vs.
Orion's key figures	2013	2014	2015	2016	2017	2018	/2017
Net sales, EUR million	1,006.9	1,015.3	1,015.6	1,073.5	1,033.6	977.5	-5.4%
Operating profit, EUR million	267.7	272.4	266.6	314.6	284.1	252.8	-11.0%
Profit before taxes, EUR million	264.0	267.8	262.3	310.9	277.7	248.4	-10.6%
R&D expenses, EUR million	101.9	106.2	108.1	118.2	99.1	104.0	+4.9%
Equity ratio, %	53.6%	52.3%	57.4%	60.8%	64.6%	68.8%	
Gearing, %	8.4%	-4.7%	-9.6%	-12.4%	-1.9%	-17.1%	
ROCE (before taxes), %	38.5%	36.6%	35.7%	40.9%	36.2%	44.3%	
Return on equity, %	40.3%	41.1%	37.5%	40.3%	34.2%	45.5%	
Basic earnings per share, EUR	1.46	1.50	1.48	1.77	1.56	1.40	-10.3%
Cash flow per share before financial items, EUR	1.02	1.72	1.51	1.62	1.09	2.32	+112.4%
Dividend per share, EUR	1.25	1.30	1.30	1.55*	1.45	1.50	+3.4%

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

The figures in the table include both continuing and discontinued operations.



#### Income statement

							Change vs.
Formation of profits, EUR million	2013	2014	2015	2016	ADJ.2017	2018	2017
Net sales	1,006.9	1,015.3	1,015.6	1,073.5	1,033.6	977.5	-5.4%
Cost of goods sold	-393.5	-401.7	-405.8	-421.7	-417.6	-387.9	-7.1%
Gross profit	613.4	613.6	609.8	651.8	616.0	589.6	-4.3%
Other operating income and expenses	5.6	1.7	1.5	24.3	4.9	5.5	+10.8%
Sales and marketing expenses	-204.9	-193.4	-190.4	-194.7	-188.9	-195.3	+3.4%
R&D expenses	-101.9	-106.2	-108.1	-118.2	-99.1	104.0	+4.9%
Administrative expenses	-44.5	-43.3	-46.2	-48.7	-48.8	-43.0	-11.8%
Operating profit	267.7	272.4	266.6	314.6	284.1	252.8	-11.0%
Profit before taxes	264.0	267.8	262.3	310.9	277.7	248.4	-10.6%
Profit for the period for continuing operations					219.1	197.3	-9.9%
Profit for the period for discontinued operations					7.0	132.9	
Profit for the period	206.2	211.3	208.2	249.0	226.0	330.3	+46.2%

The figures in the table include both continuing and discontinued operations.



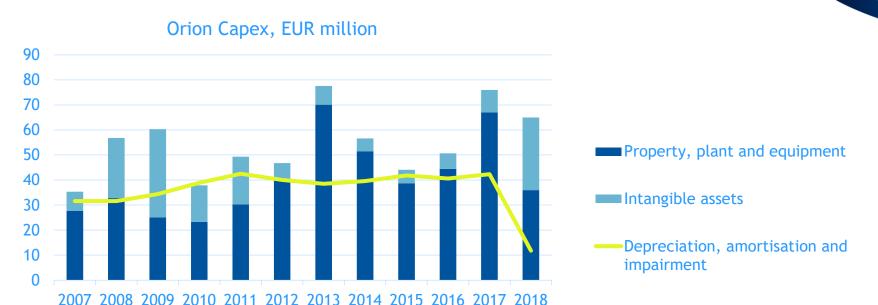


EUR million	12/18	12/17	Change %	EUR million	12/18	12/17	Change %
Non-current assets total	418.5	434.7	-3.7%				
Inventories	222.1	225.4	-1.5%	Equity total	773.1	679.7	+13.7%
Trade receivables	188.8	199.0	-5.1%	Interest-bearing non-current liabilities	0.6	150.3	-99.6%
Other receivables	33.7	32.4	+4.0%	Non-current liabilities total	59.8	196.2	-69.5%
Cash & cash equivalents & money market investments	283.7	164.1	+72.9%	Current liabilities total	313.8	179.7	+74.7%
Current assets total	728.2	620.8	+17.3%	Liabilities total	373.6	375.8	-0.6%
Assets total	1,146.7	1,055.5	+8.6%	Equity and liabilities total	1,146.7	1,055.5	+8.6%

The consolidated statement of financial position includes both continuing and discontinued operations.

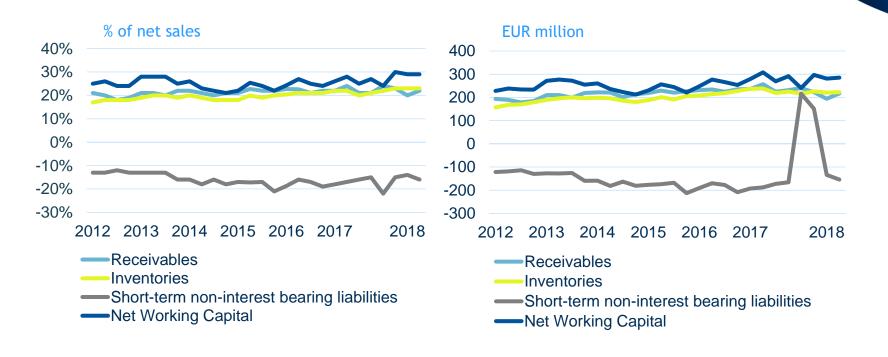








#### Development of net working capital



#### Dividend distribution policy

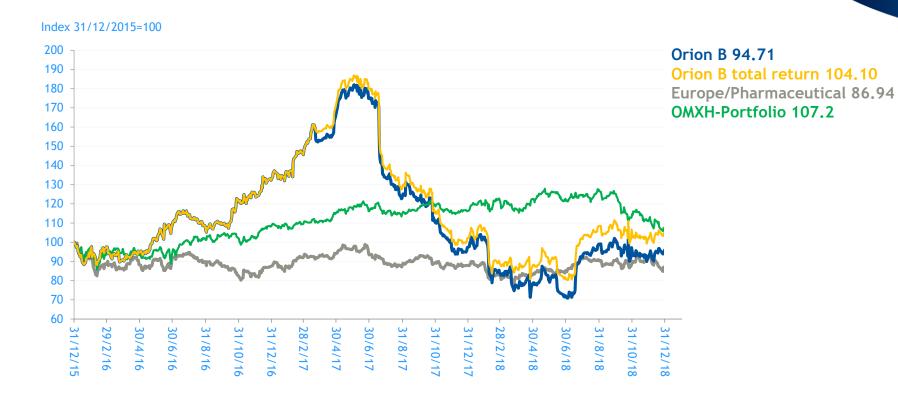


 Orion's dividend distribution takes into account distributable funds and capital expenditure and other financial requirements in medium and long term to achieve the financial objectives.





## Orion B share performance January 2016 - December 2018





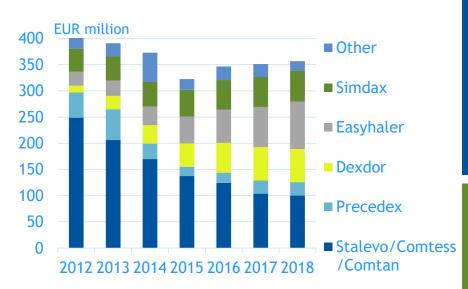
## **Business units**







Net sales



Global sales and R&D partner networks













#### Key drivers:

- Easyhaler, Simdax
- ✓ Possible milestones
- New products from R&D pipeline

**∀** Generic competition



## 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	formoterol Easyhaler®	2014	
Precedex® (dexmedetomidine HCl Injection)	Sedative for ICU use	1999	Formoterol Easyhaler®	2004	Asthma and COPD
<u>Comt</u> ess	Parkinson's disease	1998	Budesonid Easyhaler®	2002	
COMTan	_		Beclomet Easyhaler®	1994	
FARESTON'	Breast cancer	1988	Buventol Easyhaler®	1993	

# Diverse treatment options for asthma and COPD by utilizing the same inhaler technology

- Easyhaler is a dry-powder inhaler developed in-house
- Orion has developed Easyhaler-adapted dry powder formulations of several well-known generic active substances:
  - salbutamol, beclometasone, budesonide, formoterol, salmeterol and fluticasone
- Key benefits:
  - Dosing accuracy and consistent deposition
  - Easy to teach, learn and use
  - A wide range of products



## Easyhaler product family is expanding



#### **EASYHALER**



1984 The idea of Easyhaler is born



1993 Salbutamol Easyhaler



**1994**Beclometasone
Easyhaler



2002 Budesonide Easyhaler



**2004**Formoterol Easyhaler



**2014**Bufomix Easyhaler



2018 20 Salmeterol-Fluticasone Easyhaler sta



# Specialty Products: Generic prescription drugs, biosimilars and OTC including also non-medicinal products















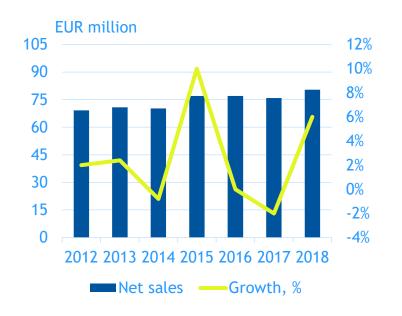






#### **Animal Health**







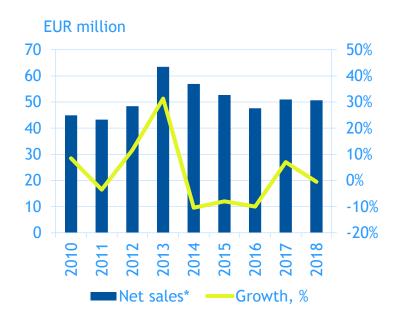
In-licensed products sold in own sales areas

In-house developed proprietary products sold globally through own sales network and through partners

Medicinal and nonmedicinal products for companion animals and livestock

#### Fermion has an important strategic role





\*) Excluding supply to Orion

Active pharmaceutical ingredients (APIs) for Orion's own Proprietary Products.



Generic APIs for Orion and other pharma companies.

Contract development and manufacturing of APIs.

### Fermion's new production plant operational in Hanko

- nearly 100% of production is exported





EUR >30 million

Expansion investment 2016–2018

6,000 m<sup>2</sup>

Production facility and equipment for the production of APIs 200->

Enables capacity increase

Number of APIs manufactured at Hanko

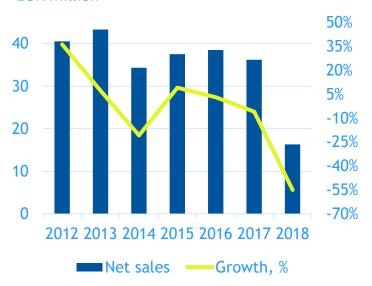
~ 20

- 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



Pharmaceutical manufacturing for other companies.







Sustainability is built into Orion's mission



### Material themes of Orion's sustainability

**ORION** 

Patient safety

Ensuring reliable supply of medications

 Manufacturing medications in an environmentally sustainable way: efficient use of materials, energy efficiency, wastewater management





Injury rate

Customer complaints (Pharmaceuticals)

**56** Ppm (64)

Audits undertaken by Orion

238

(314)

Energy savings

1,074

MWh (3,725)

40%

Energy savings

target set for 2025

achieved

(31%)

5.5

LTIF 1 (6.3)



## We assess product safety throughout the lifecycle







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