



# Orion Interim Report 1-3/2018

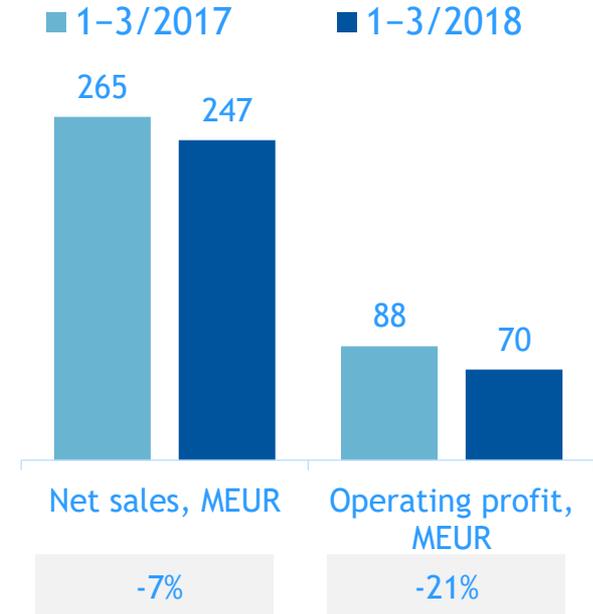
# Disclaimer

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.

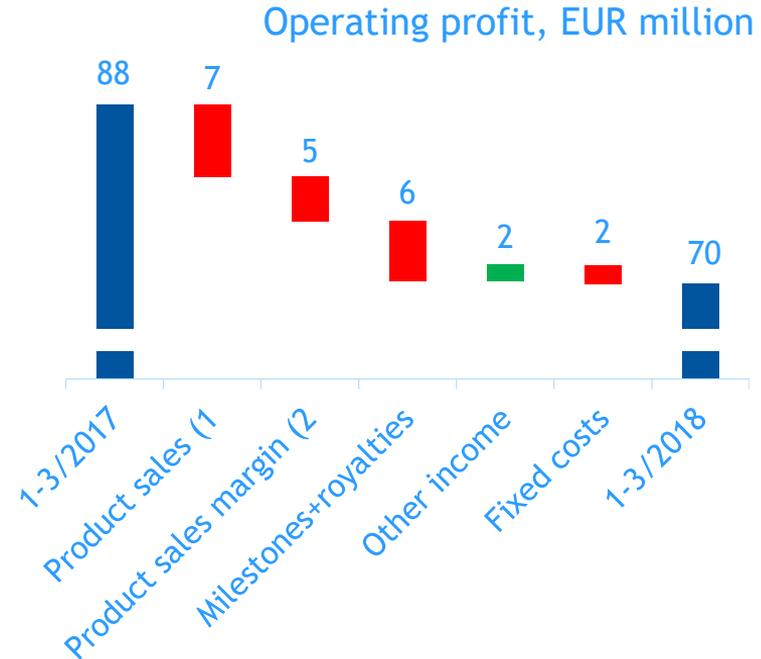
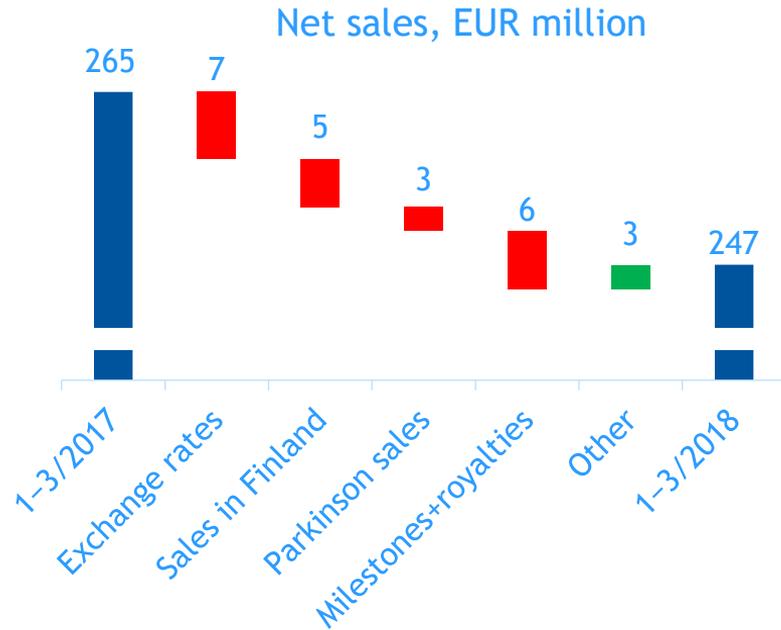
## A good start for the year

- **Strong cash flow and good profitability**, 28% operating profit margin exceeded financial objectives.
- Net sales and profit affected by tightening generic and price competition, smaller milestone payments and exchange rate changes. Comparative period was exceptionally strong.
- Easyhaler product family and Dexdor grew.
- Positive conclusions received for the salmeterol-flucatisone Easyhaler under the decentralised EU marketing authorisation procedure.
- **Two new clinical trials:**
  - CYP11A1 inhibitor for prostate cancer (ODM-208) - Phase I
  - Oral levosimendan (ODM-109) - Phase III
- Alzheimer's research project (ORM-12741) discontinued.
- Orion to sell Orion Diagnostica to an investment fund managed by Axcel Management A/S. Orion Diagnostica business is reported as a discontinued operation.



The presentation only covers continuing operations without Orion Diagnostica.

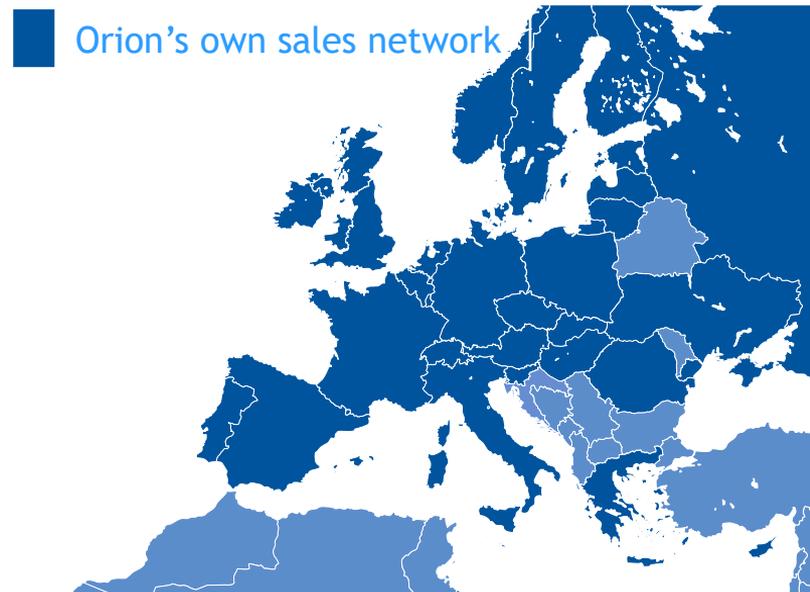
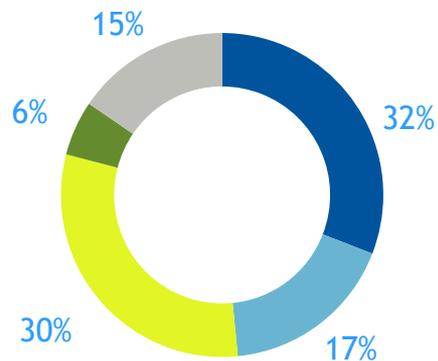
# Development of net sales and operating profit



- 1) Product sales without change in margins
- 2) Change in margin of product sales
- 1-2) Exchange rates generate about EUR 5 million of the overall decline (MEUR 12) in gross profit

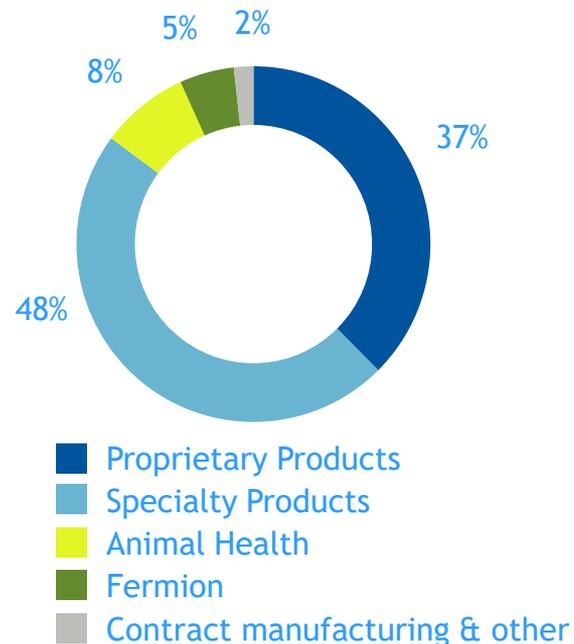
# Geographical breakdown of net sales

1-3/2018



## Net sales by business division

Net sales, EUR million	1-3/ 2018	1-3/ 2017	Change
Specialty Products	118	122	-3%
Proprietary Products	93	98	-6%
Animal Health	20	19	+5%
Fermion	12	16	-20%
Contract manufacturing & other	4	11	-59%





## Pharmaceuticals business

# Best-selling pharmaceuticals 1–3/2018

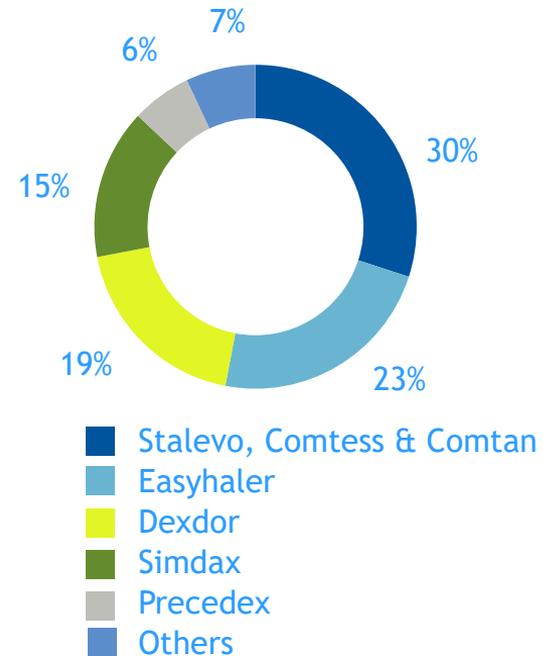
	Product	Indication	Net sales (EUR million)	Change vs 1–3/2017
1.	 <i>Stalevo</i> <i>Comtess</i> <i>COMTan</i>	Parkinson's disease	28	-8%
2.	 Easyhaler®	Asthma, COPD	22	+20%
3.	 dexdor	Intensive care sedative	18	+5%
4.	 SIMDAX levosimendan	Acute heart failure	14	-7%
5.	Biosimilars	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	11	-4%
6.	 DEXDOMITOR  DOMITOR  DOMOSEDAN  ANTISEDAN	Animal sedatives	8	+13%
7.	 burana®	Inflammatory pain	6	+2%
8.	 Precedex® (dexmedetomidine HCl injection)	Intensive care sedative	5	-24%
9.	<b>Marevan®</b>	Anticoagulant	4	+8%
10.	Divina series	Menopausal symptoms	4	+13%

= Products of Proprietary Products business division

# Proprietary Products

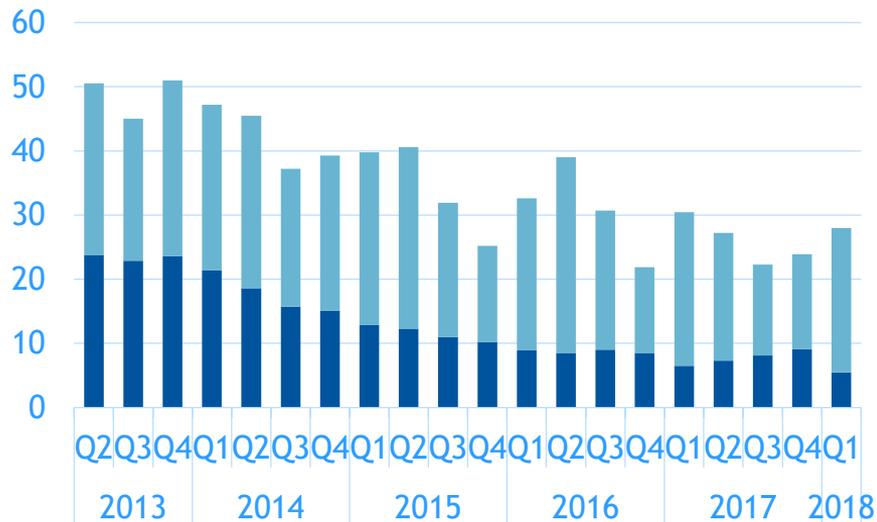
- As expected, sales of Stalevo, Comtess and Comtan continued to decline.
- The Easyhaler product family continued to grow. Positive conclusions received for the salmeterol-flucatisone formulation under the decentralised EU marketing authorisation procedure.
- Dexdor sales continued to grow in most European markets despite the commencement of generic competition in Germany.
- Simdax sales declined. The basic patent has expired, but this is not estimated to materially impact Simdax sales in 2018.

Breakdown of net sales



# As expected, sales of Parkinson's drugs continued to decline

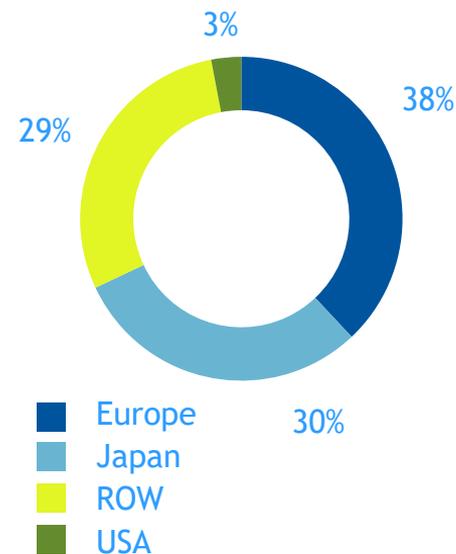
Sales, EUR million



■ Deliveries of Parkinson's drugs (Stalevo, Comtess/Comtan) to key partners

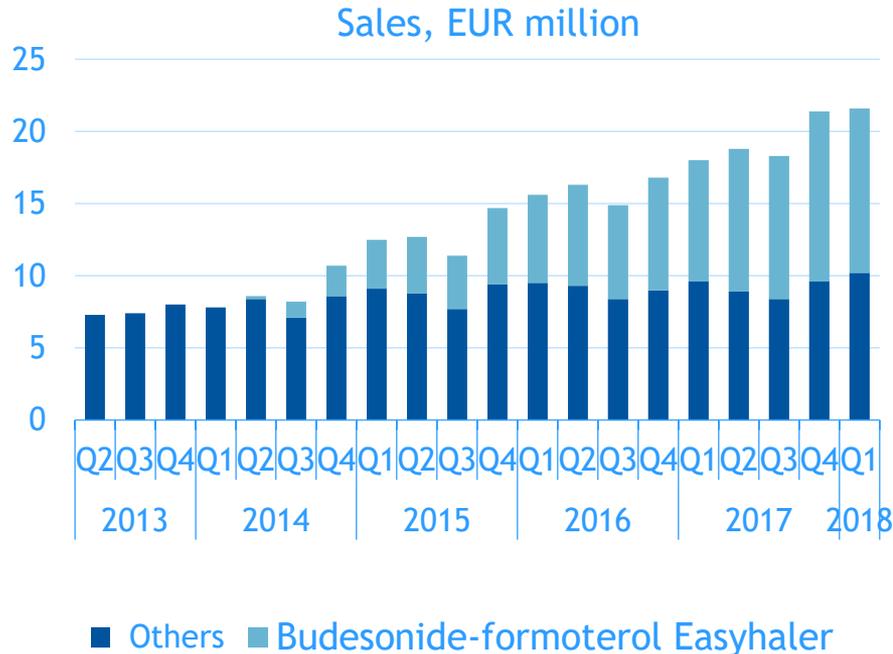
■ Orion's own sales

Sales of Orion's branded Parkinson's drugs by market area MAT12/2017



Source: IQVIA MAT12/2017

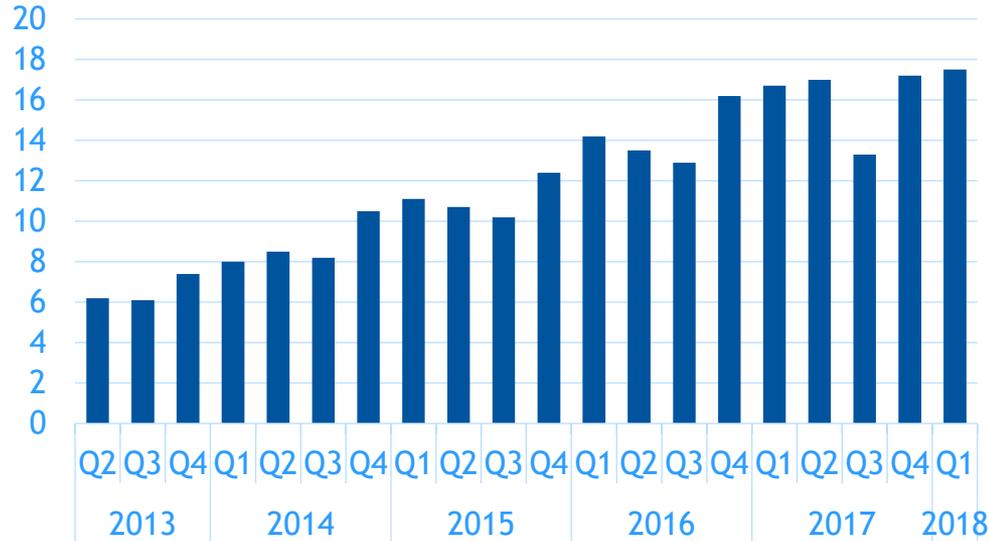
# Easyhaler product family is growing



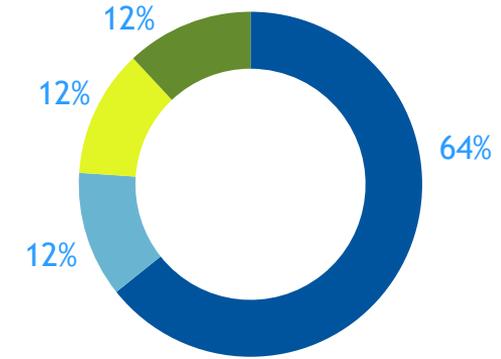
- The product family sales grew by 20%, driven by budesonide-formoterol Easyhaler, which grew by 36%.
- **Budesonide-formoterol Easyhaler** is now launched in all key European markets:
  - Menarini launched the product in France in Q1/2018.
  - First marketing authorisation applications submitted outside Europe (APAC, MENA).
  - Orion's market share varies: Sweden 37%, Germany 6%.
- **Salmeterol-flucatisone Easyhaler** received positive conclusions under the decentralised EU marketing authorisation procedure. National approval procedures have started in 23 countries.
- Development of the seventh product, tiotropium, is underway.

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

Sales, EUR million



Total value of the European sedatives market  
MAT12/2017:  
EUR 542 million (+4%)



- Propofol EUR 349 million (+2%)
- Midazolam EUR 64 million (-7%)
- Dexmedetomidine EUR 65 million (+34%)
- Remifentanyl EUR 65 million (+2%)

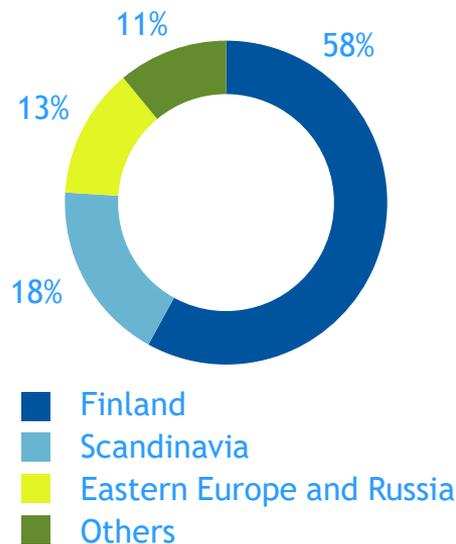
\*Source: IQVIA MAT12/2017

# Specialty Products

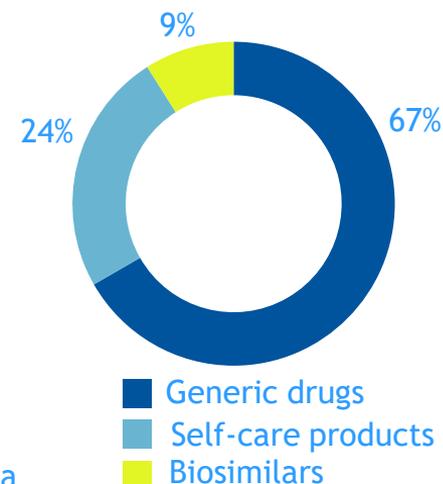
Net sales in key markets, EUR million	1-3/18	vs 1-3/17
Finland	68	-6%
Scandinavia	21	+6%
Eastern Europe and Russia	15	+11%

- The net sales of Specialty Products declined by 3%.
- Sales grew in Scandinavia and in Eastern Europe and Russia. In Finland, sales declined due to tightening price competition.
- Biosimilar sales declined by 4%. Ritemvia sales have commenced. The situation of tendering competitions, tougher competition and lower price level contributed to lower Remsima sales.

Net sales by market area



Net sales by product

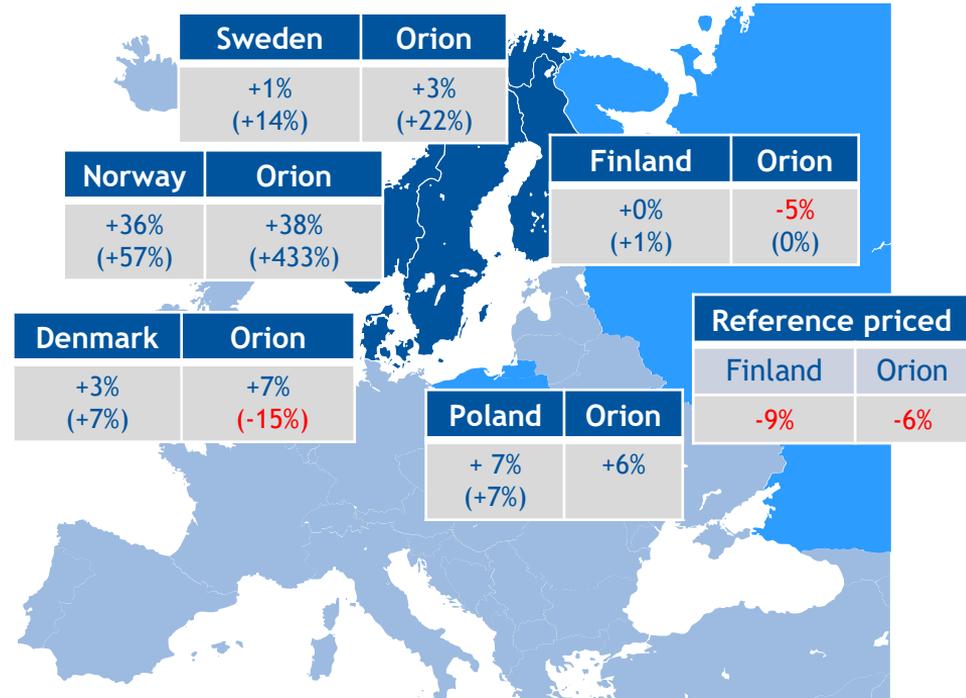


# Orion is a significant player in the Nordic generic drugs market

- Orion's market position in 2017: Finland #1, Sweden #2, Denmark #2, Norway #3
- Biosimilars drive market growth in Scandinavia:
  - The market of generic and self-care products grew by 9% in 2017, Orion's growth 8%.
  - When taking biosimilars into account, Orion grew faster than the market: Market growth was 21%, Orion's growth 34%.
- In the Finnish pharmaceuticals market, the sales of reference priced drugs declined by 9% in 2017.

## Generic and self-care product sales 2017

Orion vs market trend, (figure in brackets includes also biosimilars)



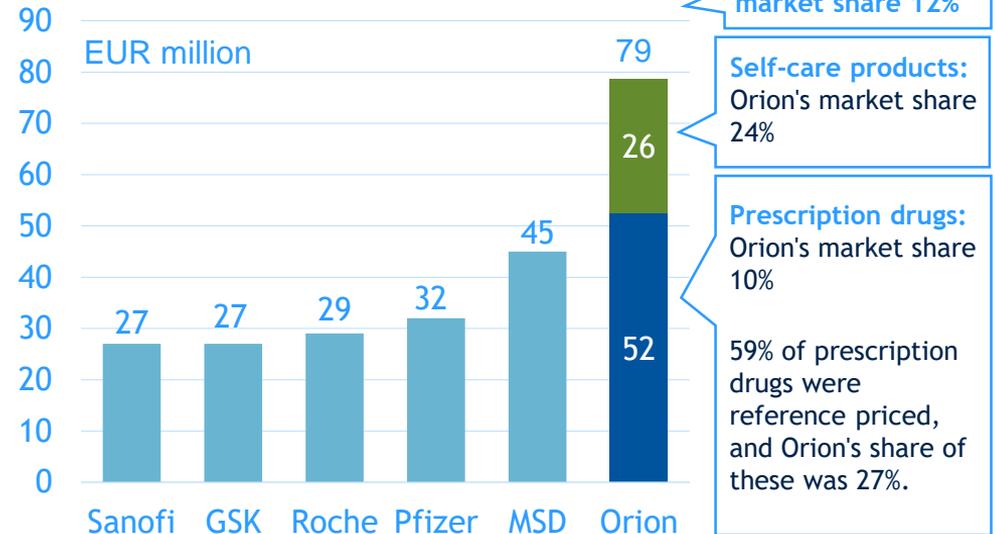
Source: IQVIA 2017

# Orion remains strong in home market Finland

## Human pharmaceuticals market in Finland 1–3/2018

- Total sales of medicinal and non-medicinal products EUR 652 million
- Orion's market share 12%
- Overall market growth +11%, Orion's sales declined 6% due to changing operating environment:
  - Tightening price competition reduced Orion's net sales in 2017 by EUR 15 million. The effect is expected to be as large in 2018.

## Leading pharmaceutical companies in Finland 1–3/2018 (medicinal and non-medicinal products)



Source: IQVIA



Research and development

# Key clinical pharmaceutical development projects

Project	Indication	PHASE			Registration
Easyhaler® salmeterol-fluticasone	Asthma, COPD	Bioequivalence study			Registration
Easyhaler® tiotropium	COPD	Bioequivalence study			
Darolutamide (ODM-201) <sup>1)</sup>	Prostate cancer (nmCRPC)	I	II	III	
Darolutamide (ODM-201) <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/>

- =Phase completed
- = Phase ongoing
- =Status changed

# Darolutamide: An androgen receptor targeted therapy for prostate cancer



Darolutamide (ODM-201) is an androgen receptor antagonist that

- Binds to the androgen receptor with high affinity
- Prevents efficiently androgen receptor signaling
- Low blood-brain barrier (BBB) penetration, potentially resulting in less side-effects in central nervous system.

# Darolutamide: Two trials in phase III proceeding

The logo for ARAMIS features the word "ARAMIS" in a bold, blue, sans-serif font. Above the letters "A" and "M" is a stylized green and blue arc with a small yellow starburst above the "A".

Androgen Receptor inhibiting Agent for Metastatic-free Survival

- Patients with **non-metastatic, castration-resistant prostate cancer** at high risk for 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
- Recruitment finalized, the trial proceeding as planned with estimated completion in September 2018.

The logo for ARASENS features the word "ARASENS" in a bold, blue, sans-serif font. Above the letters "A" and "S" is a stylized green and blue arc with a small yellow starburst above the "A".

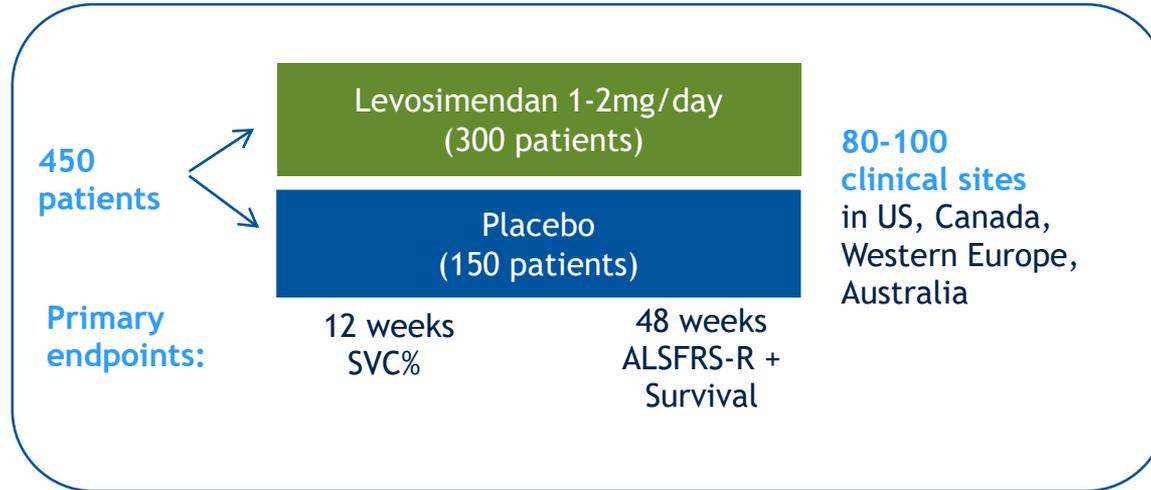
- Patients with **metastatic, hormone-sensitive prostate cancer**
- Treatment: Darolutamide with androgen deprivation therapy (hormonal therapy) and six cycles of docetaxel (chemotherapy)
- Endpoints:
  - Primary: Darolutamide over placebo in overall survival
  - Secondary: Time to castration resistance, 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 proceeding well, estimated completion of the trial in 2022.

# ODM-109: Oral levosimendan for ALS



- **ALS (Amyotrophic lateral sclerosis)** is a fast progressing and fatal neurodegenerative disease:
  - Leads to diaphragm and skeletal muscle weakness and eventually paralysis and death typically due to respiratory failure.
  - An orphan disease with incidence of 1-2 /100,000 (MS disease: 2.5/100,000)
- **Levosimendan** is developed for symptomatic treatment for muscle weakness, the main symptom of ALS:
  - Levosimendan has shown positive effect on diaphragm muscle function in experimental studies in animals and in humans.
  - Positive signal from a small phase II study in ALS patients.

# ODM-109: REFALS phase III trial



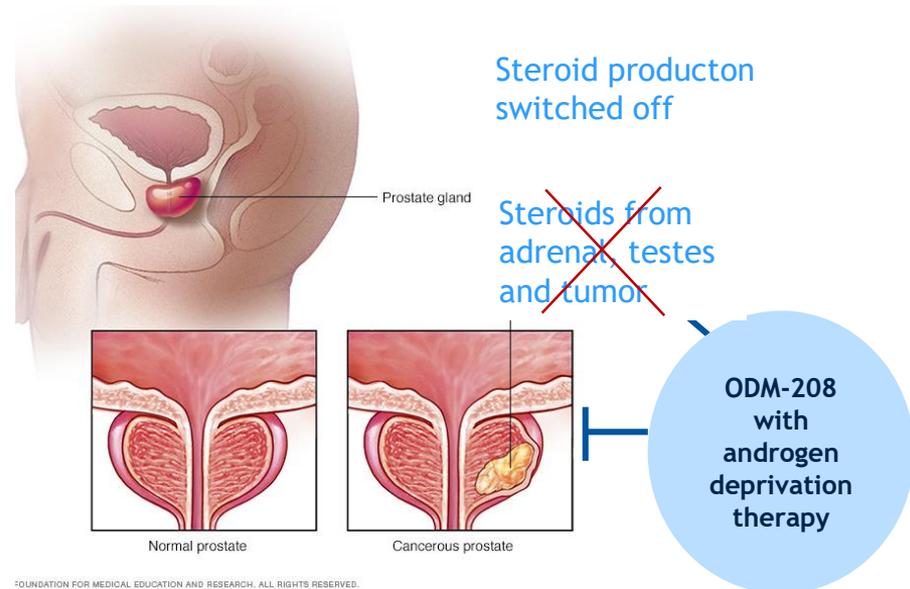
Costs of the trial:  
~ EUR 60 million  
approximately over three years

= **SVC% (slow vital capacity)** - measure of breathing capacity compared to normal subjects

= **ALSFRS-R (ALS functional rating scale)** - overall assessment of ALS symptoms

# 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 steroid 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.





**Discontinued operation: Diagnostics business**

# Orion to sell Orion Diagnostica to an investment fund managed by Axcel Management A/S

- Signed on 21 April 2018, estimated closing in Q2/2018
- Fixed purchase price ~EUR 163 million
- In addition, possible variable component of max. EUR 60 million, based on ROI at exit.
- Orion estimates to recognise a capital gain of about EUR 128 million in other operating income for 2018 (does not include any part of the variable component).
- The sale allows Orion to further focus on growth of Pharmaceuticals business.
- The capital gain will strengthen Orion's equity position and maintain the ability to achieve dividend distribution objective.





## Orion's outlook

## Outlook for 2018 (updated on 21 April 2018)

### 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).

Orion estimates to recognise EUR 128 million capital gain in other operating income from the sale of Orion Diagnostica at the closing of the transaction. Due to the uncertainty relating to the variable component included in the transaction, the estimated capital gain does not include any part of the variable component.



## Orion Calendar 2018

Half-Year Financial Report  
Interim Report 1-9/2018

18 July 2018  
24 October 2018



# Building well-being

