



Orion Financial Statement Release 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-December 2018

Important year for future growth

1 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.

3 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.



2 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.

4 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
Diagnostics,
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.

Key figures 1–12/2018 (continuing operations)

Net sales

977

MEUR (1,034)
-5%

Operating profit

253

MEUR (284)
-11%

Operating
profit margin

26%

(27%)

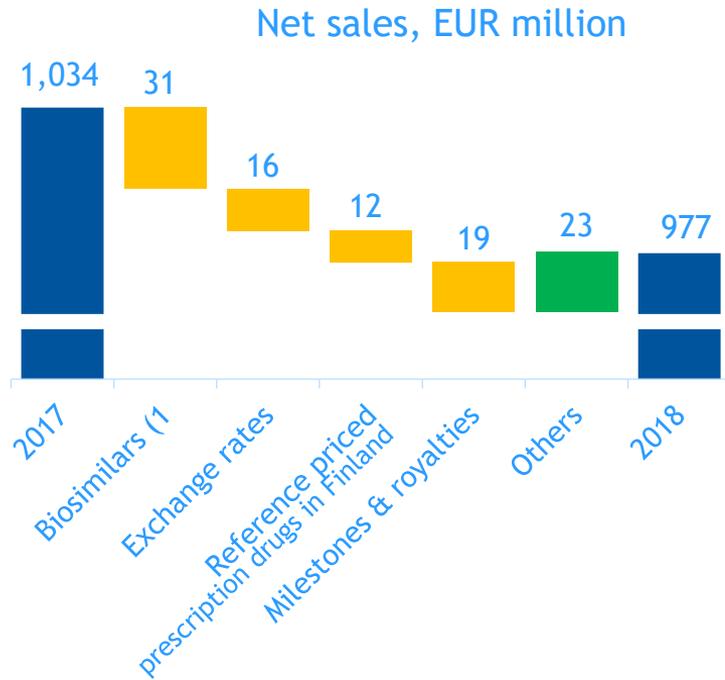
Cash flow per share
before financial
items**

2.32

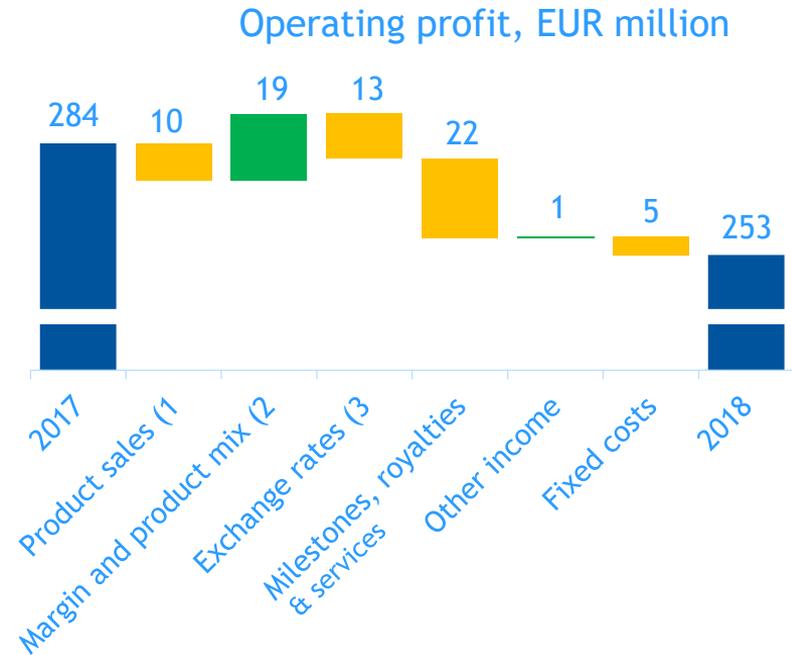
EUR (1.09)
+112%

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

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



(1) Biosimilars in local currency without exchange rate effect



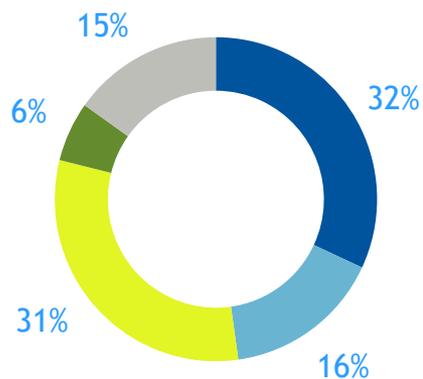
(1) Product sales without sales margin and product mix change and exchange rate effect

(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

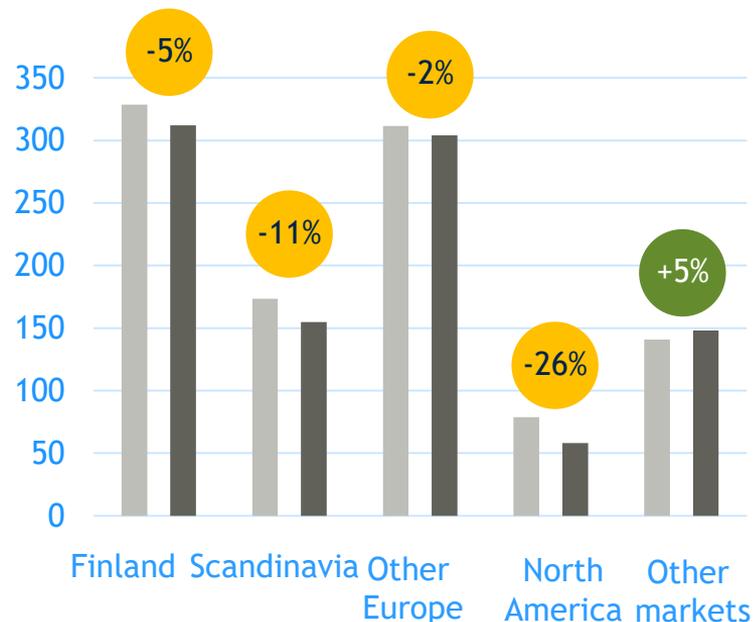
1-12/2018



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

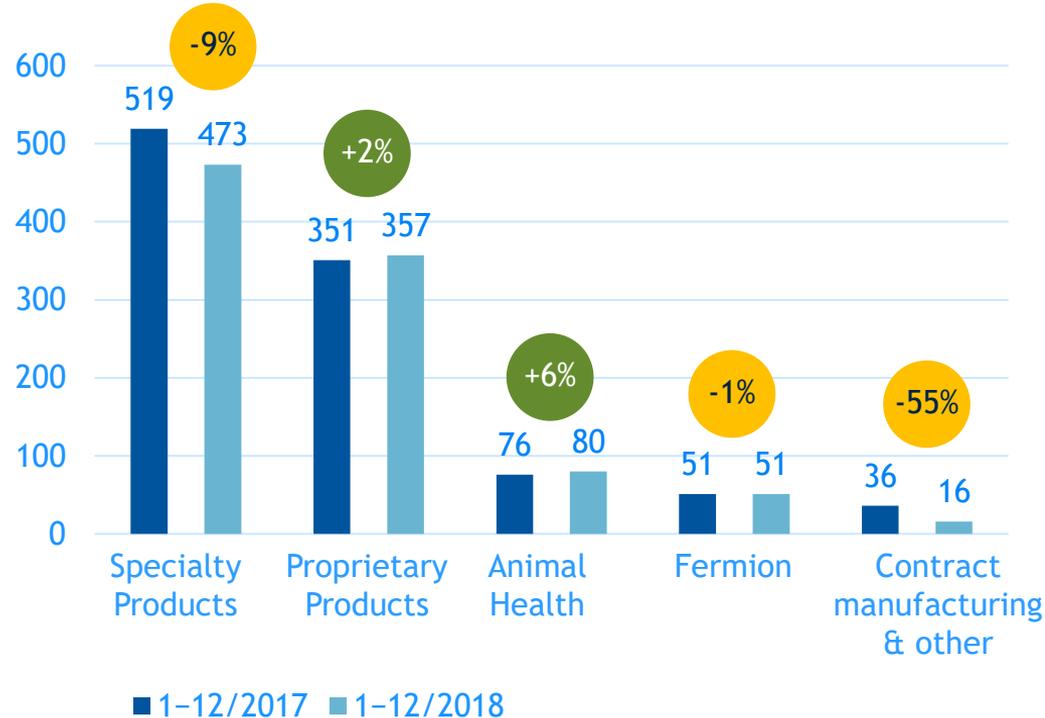
■ 1-12/2017 ■ 1-12/2018

EUR million

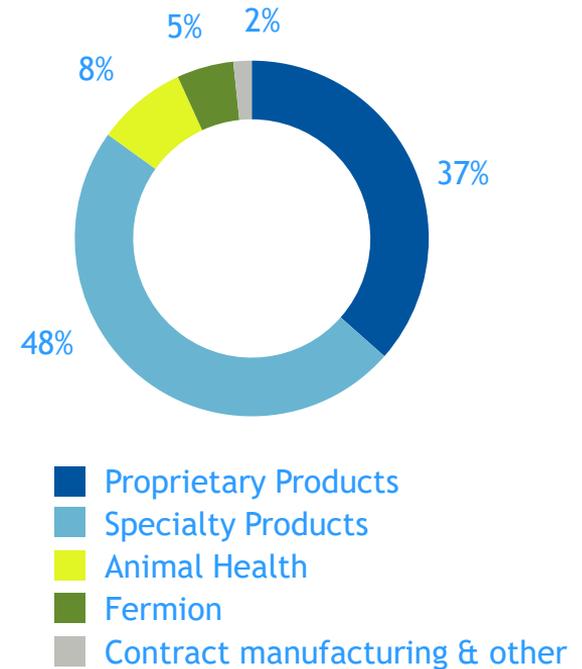


Net sales by business division

EUR million



1-12/2018



Best-selling pharmaceuticals 1–12/2018

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

 = Products of Proprietary Products business division



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.



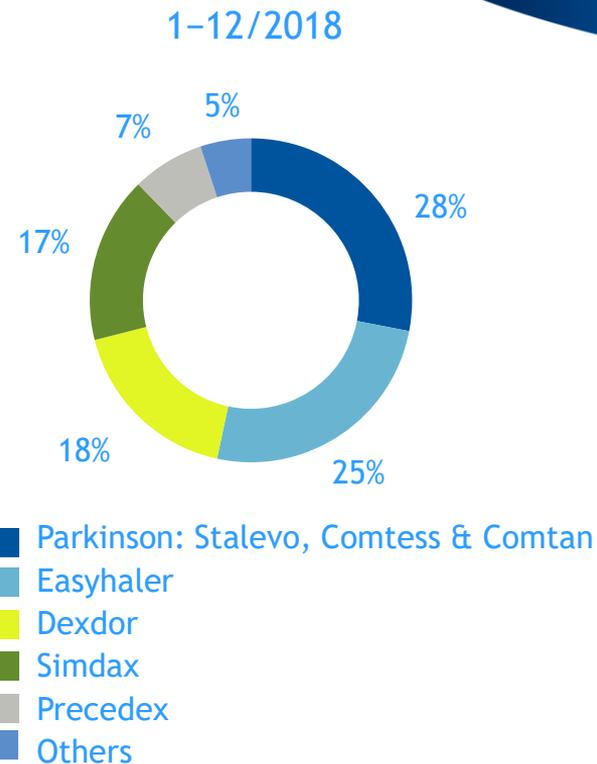
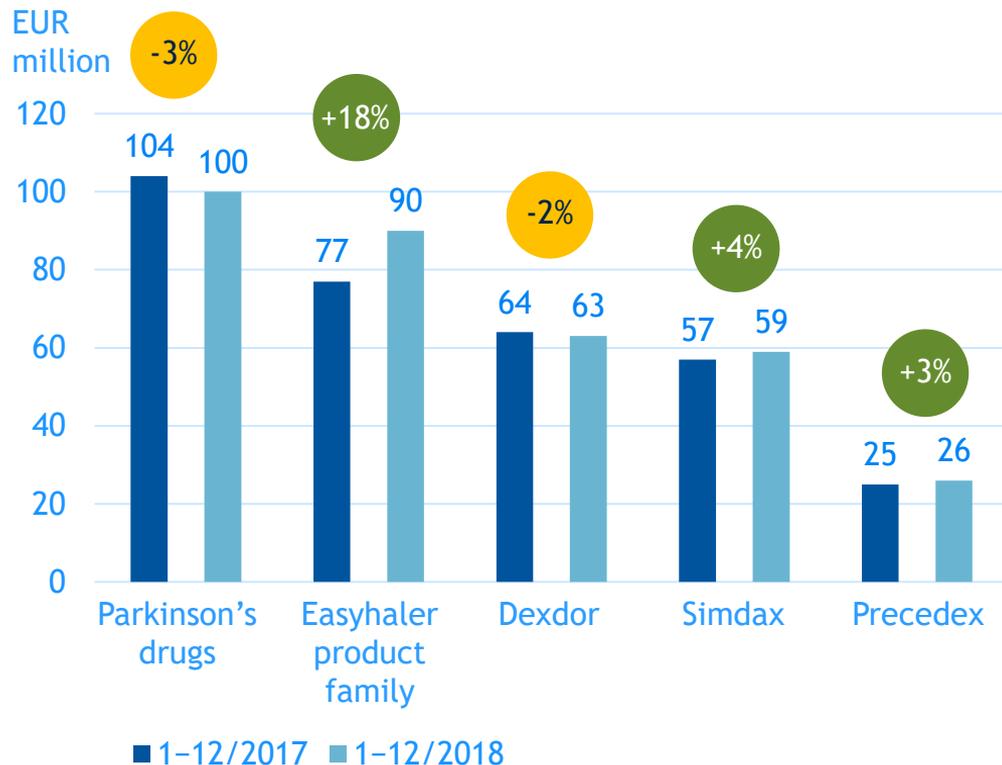
Simdax

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

Parkinson's drugs

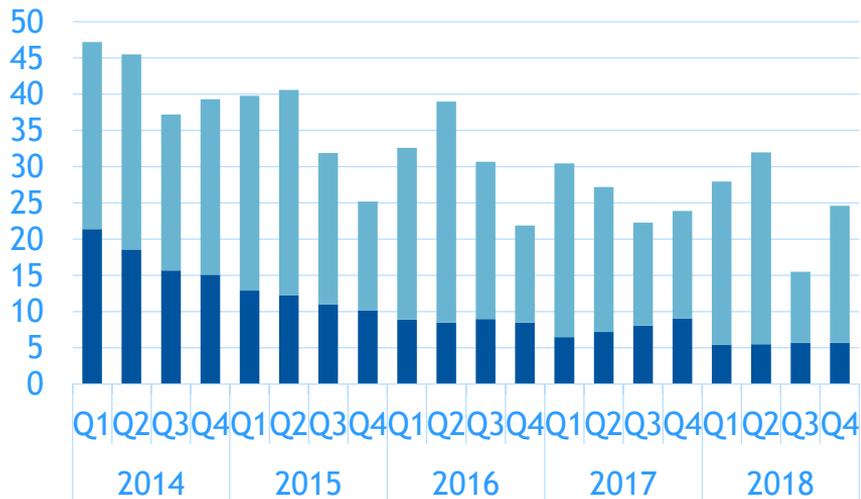
- Sales were lower than in comparative period, as anticipated. However, the decline in sales was significantly slower than in the long term on average.

Sales of Proprietary Products increased slightly



Decrease in sales of Parkinson's drugs slowed down

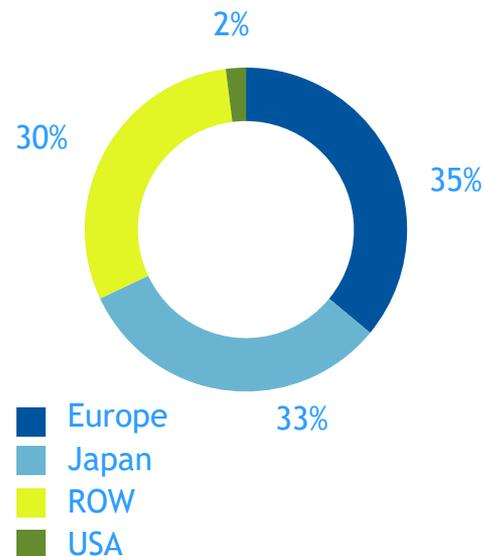
Sales, EUR million



■ 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

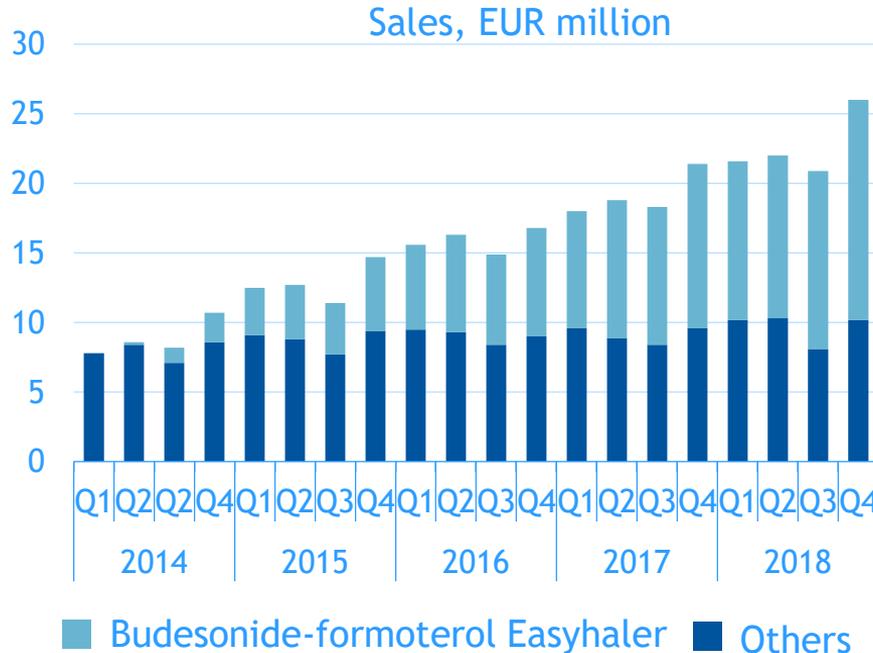


Source: IQVIA, MAT9/2018

Repatriation of Stalevo's sales and distribution rights in Europe reinforces Orion's growth targets

- 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 budesonide-formoterol Easyhaler.
- Product family total sales: +18%
- Budesonide-formoterol Easyhaler: +29%
 - 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.

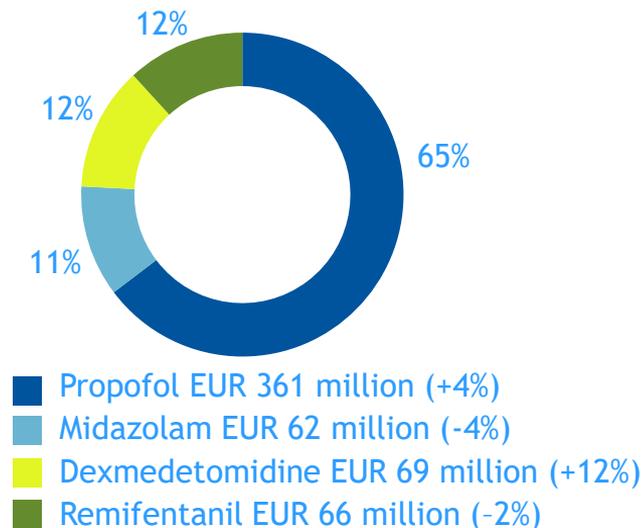
*) Market shares of volumes in November 2018

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

Sales, EUR million



Total value of the European sedatives market: EUR 558 million (+3%)



Source: IQVIA, MAT 9/2018



Specialty Products



Specialty Products

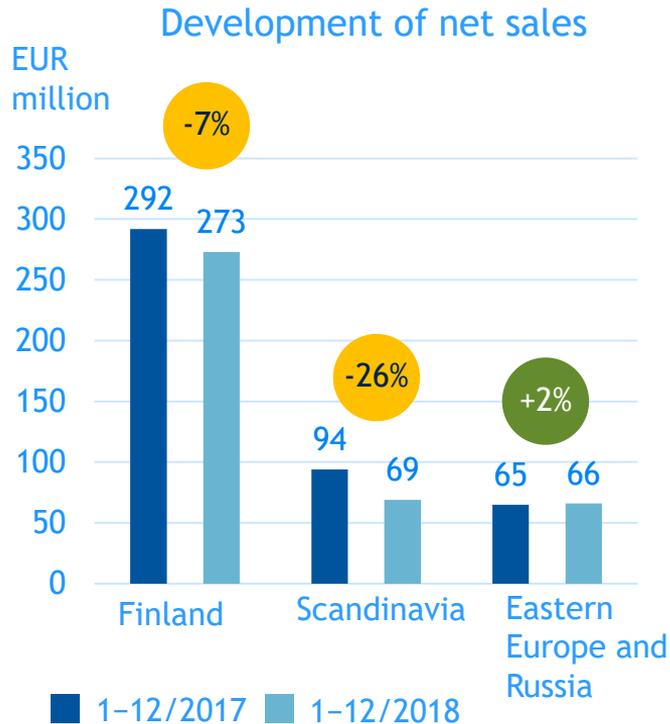
- Net sales decreased in Finland and Scandinavia, and grew in Eastern Europe and Russia.

- 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.

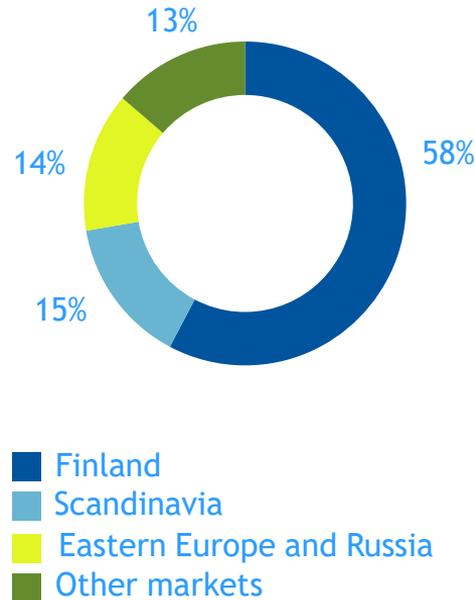


- Net sales of biosimilars decreased from record year 2017.
 - The decrease was due to tightened competition, declined price level and the situation of tendering competitions.
 - Orion won the national tender in Norway in late 2018, deliveries to start in Q1/2019.
-
- In Finland, sales of Amgevita (adalimumab),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

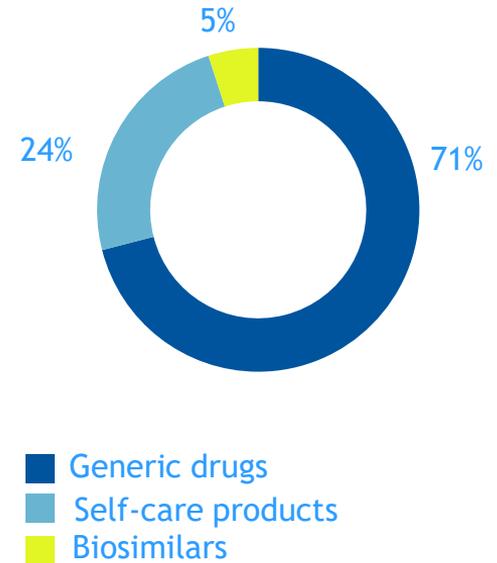
Specialty Products: tightened price competition and lower sales of biosimilars showed as a decrease in net sales



Net sales by region 1-12/2018



Net sales by product 1-12/2018



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 (1-12/2018)

490

MEUR (528)

Market development

-7%



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

126

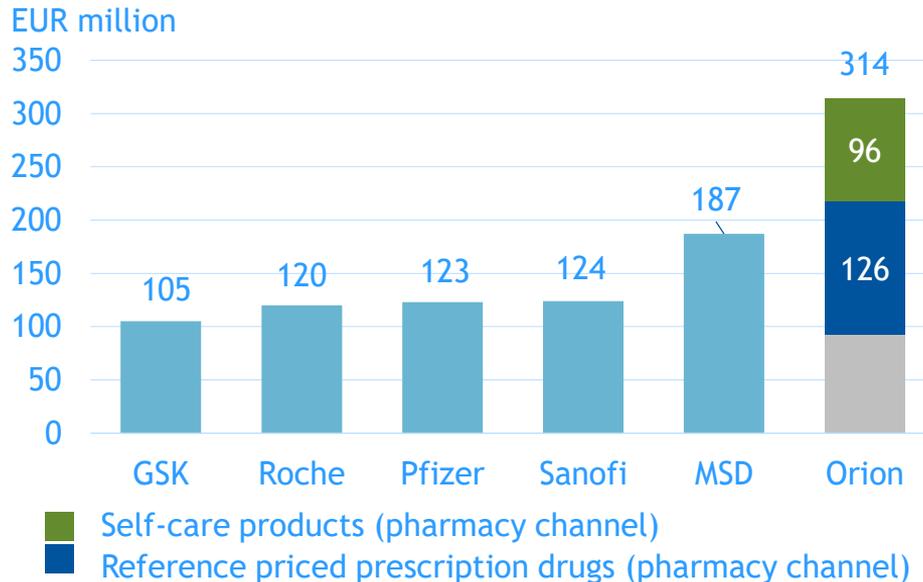
MEUR (139)

Orion's development

-9%

Orion is Finland's most significant provider of pharmaceuticals

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%

(13%)



Research and development

Orion's key clinical drug development projects

Project	Indication	Phase			Registration
Easyhaler® tiotropium	COPD	Bioequivalence study			
Darolutamide ¹⁾	Prostate cancer (nmCRPC)	I	II	III	
Darolutamide ¹⁾	Prostate cancer (mHSPC)	I	II	III	
ODM-109 (oral levosimendan)	ALS	I	II	III	
ODM-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			

¹⁾ In collaboration with Bayer

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

	= Completed
	= Ongoing
	= 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.



ODM-109: Oral levosimendan for ALS

- First patients recruited in July 2018 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): Phase III clinical trial REFALS recruiting

450 patients

- Levosimendan
1-2mg/day
(300 patients)
- Placebo
(150 patients)

~ 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

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.

Material themes of Orion's sustainability

- Patient safety
- Ensuring reliable supply of medications
- Manufacturing medications in an environmentally sustainable way: efficient use of materials, energy efficiency, wastewater management

Customer complaints
(Pharmaceuticals)

56

Ppm (64)

Audits undertaken
by Orion

238

(314)

Energy savings

1,074

MWh (3,725)

Energy savings
target set for 2025
achieved

40%

(31%)

Injury rate

5.5

LTIF 1 (6.3)

Digital projects to improve patients' well-being

- **Daisy:**
Optimising Parkinson's patient's quality ON-time (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.



Outlook

Investments in growth EUR 30 million in 2019

- 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.



Orion calendar

Financial Statements 2018	By week 10
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

Capital Markets Day
in Helsinki on 22/5/2019



Building well-being