



# Company presentation for investors

Q1 2015

# Forward-looking statements

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.

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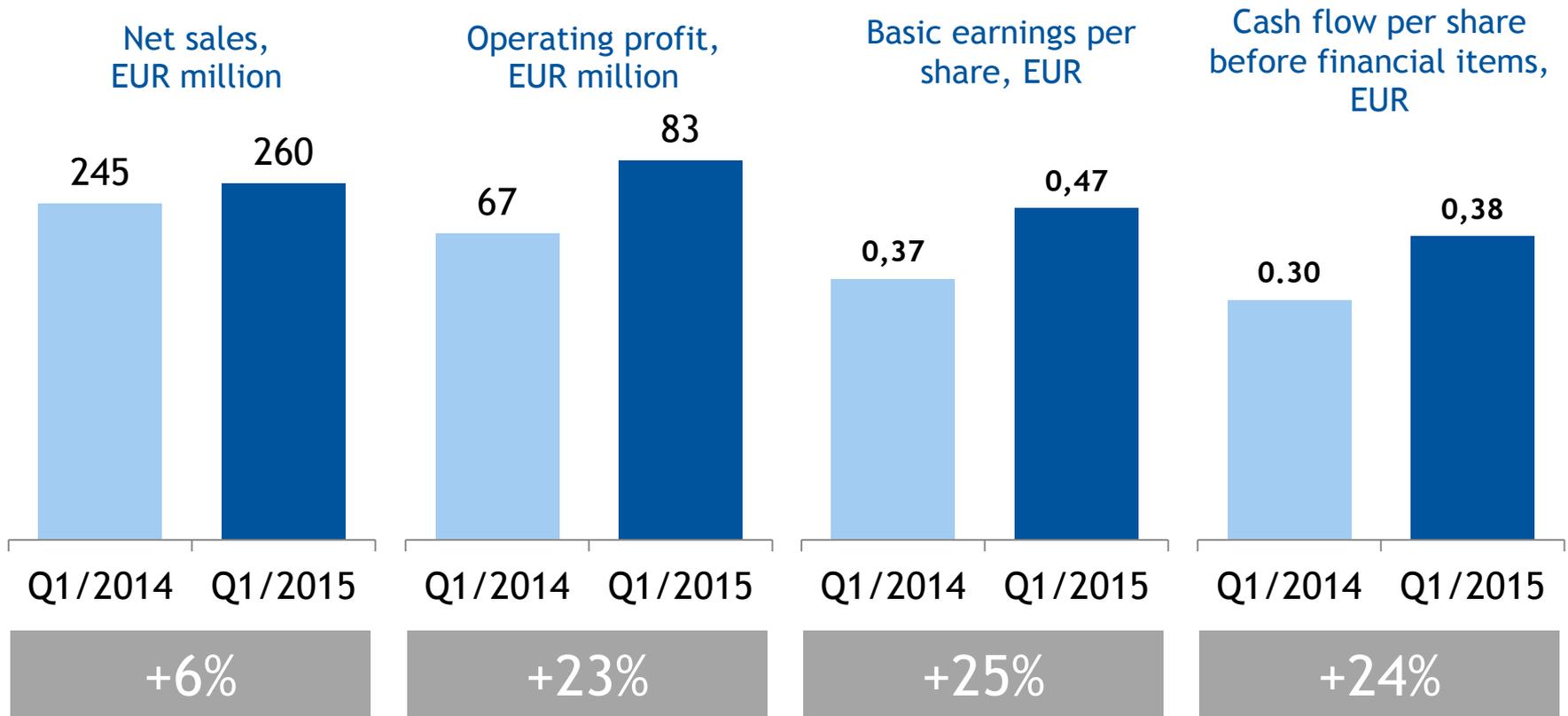


# Year started strongly

- Net sales were slightly higher and operating profit clearly higher than in comparative period
- Generic competition to Stalevo started to extend in Europe, but Proprietary Products sales as a whole remained steady due to strong growth in sales of the Easyhaler product family and Dexdor
- Sales grew well in the other business divisions
- Clinical development pipeline strengthened by two new projects
- Outlook estimate for 2015 was updated after the review period



# Key figures



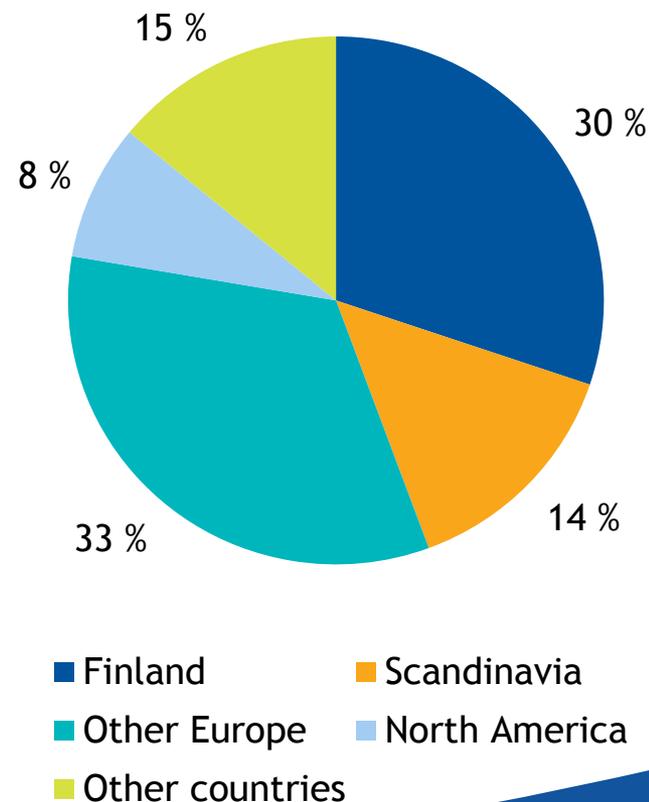
**R&D expenses, EUR 25 million (-5%)**

# Net sales originate mainly in Europe

## Breakdown of EUR 260 million net sales in Q1 2015

Key figures by business divisions	Q1_2015	Change %
<b>Net sales of Pharmaceuticals, EUR million</b>	<b>244</b>	<b>+7%</b>
Proprietary Products	89	+1%
Specialty Products	109	+6%
Animal Health	22	+40%
Fermion	15	-1%
Contract manufacturing & other	10	+16%
<b>Pharmaceuticals operating profit, EUR million</b>	<b>81</b>	<b>+22%</b>
<b>Net sales of Diagnostics business, EUR million</b>	<b>16</b>	<b>-1%</b>
<b>Operating profit of Diagnostics business, EUR million</b>	<b>4.0</b>	<b>+55%</b>

Sales split by market area



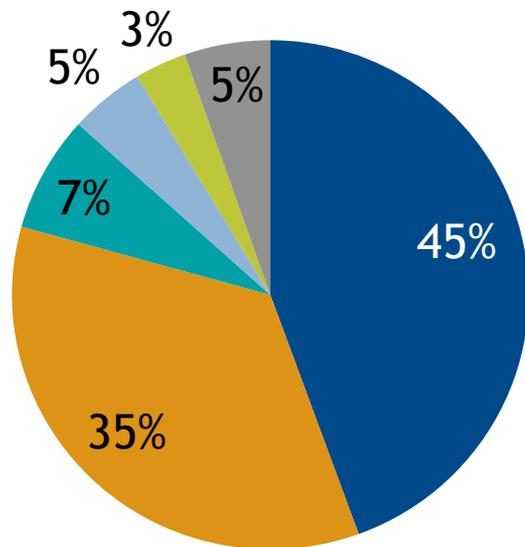
# Best-selling pharmaceuticals Q1/2015

	Net sales, EUR million		2014
Stalevo®, Comtess® & Comtan® (Parkinson's disease)	42	-10%	169
Simdax® (acute decompensated heart failure)	13	+19%	47
Easyhaler® product family (asthma, COPD)	12	+59%	35
dexdor® (intensive care sedative)	11	+40%	35
Dexdomitor®, Domitor®, Domosedan® & Antisedan® (animal sedatives)	7	+42%	25
Generic entacapone products (Parkinson's disease)	6	-9%	26
Burana® (inflammatory pain)	6	+1%	23
Marevan® (anticoagulant)	5	+3%	17
Precedex® (intensive care sedative)	5	-49%	30
Divina® range (menopausal symptoms)	4	+24%	15
<b>Total</b>	45% of pharmaceuticals net sales		110

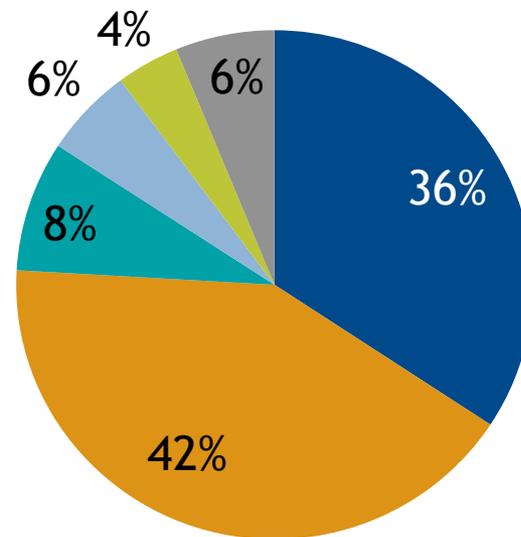
Products based on Orion's inventions in blue font

# Product mix is changing

Sales split by business  
2011



Sales split by business  
Q1/2015



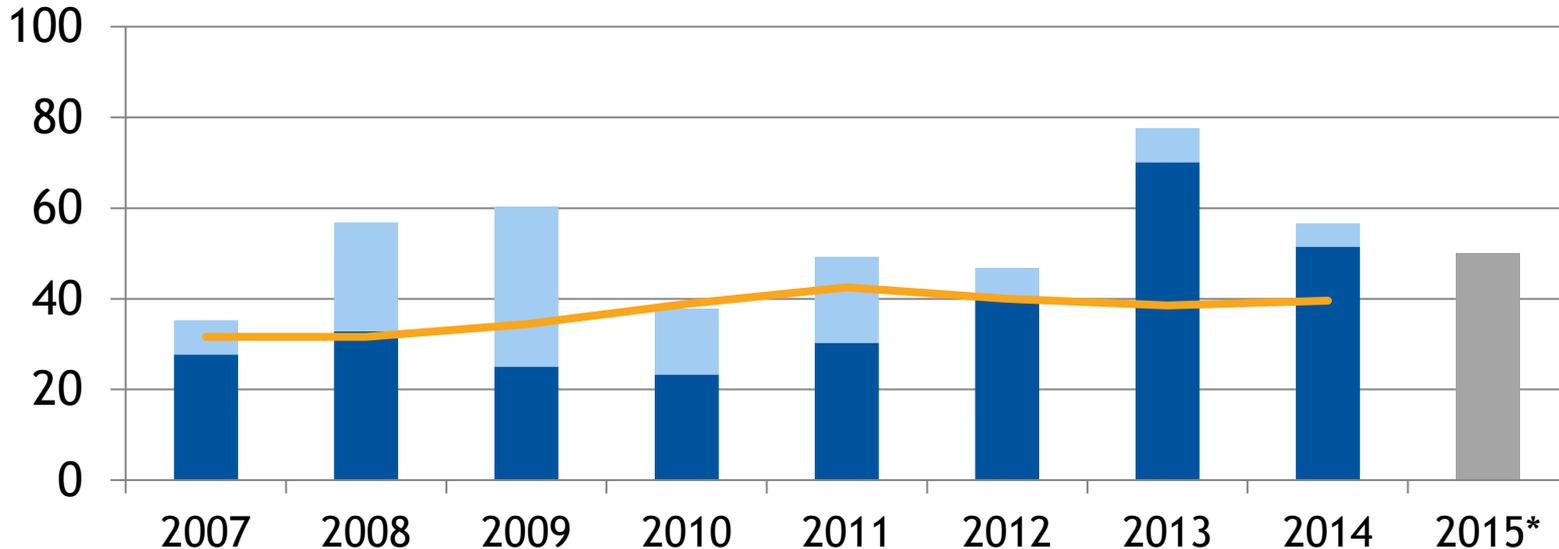
- Proprietary Products
- Animal Health
- Contract Manufacturing & other

- Specialty Products (generics+OTC)
- Fermion
- Orion Diagnostica

# Capex normalising after investment program

## Orion Capex

EUR million



Intangible assets

Property, plant and equipment

Depreciation, amortisation and impairment

\*) Estimate for 2015

# Outlook for 2015 (updated on 24 April 2015)

<b>Net sales</b>	Net sales will be slightly lower than in 2014 (net sales were EUR 1,015 million in 2014).
<b>Operating profit</b>	Operating profit is estimated to exceed EUR 230 million.
<b>Group's capital expenditure</b>	The Group's capital expenditure will be about EUR 50 million excluding substantial corporate or product acquisitions (The Group's capital expenditure was EUR 57 million in 2014).



# Orion's strategy and financial targets

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



# Orion's financial objectives

## **Increasing net sales.**

Achievement of this objective requires continuous investment in development of the product portfolio.

## **Maintaining profitability at a good level.**

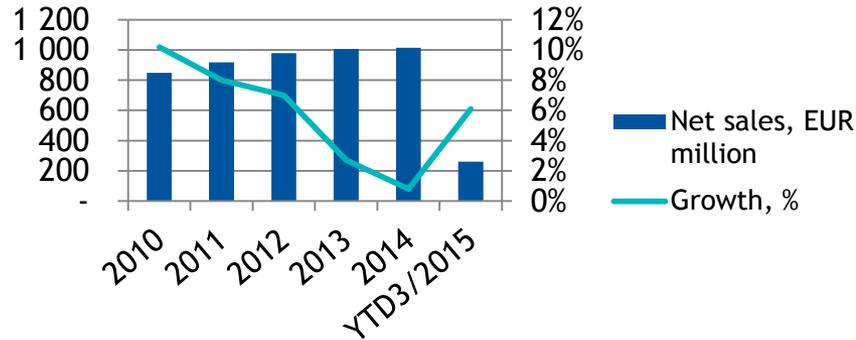
The aim is operating profit that exceeds 20% of net sales.

## **Keeping the equity ratio at least 50%.**

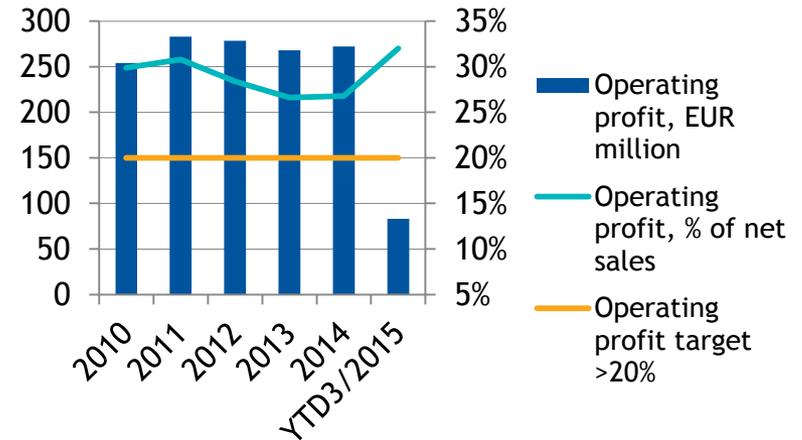
**Distributing an annual dividend that in the next few years will be at least EUR 1.20 per share, and increasing the dividend in the long term.**

# Orion's financial objectives

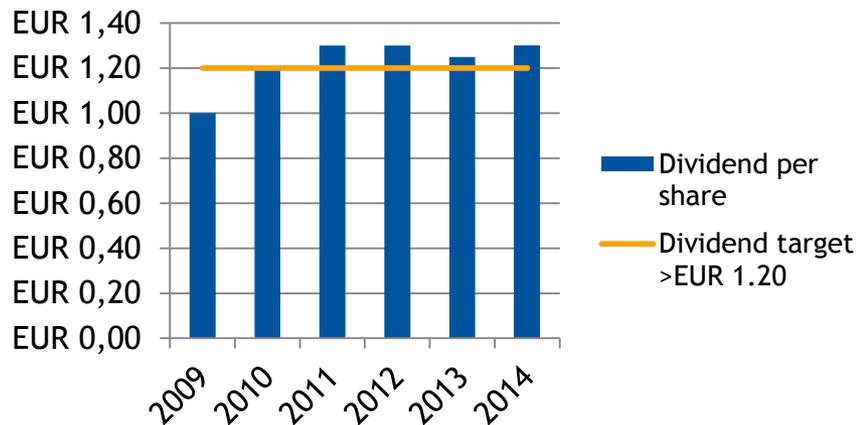
## Net sales



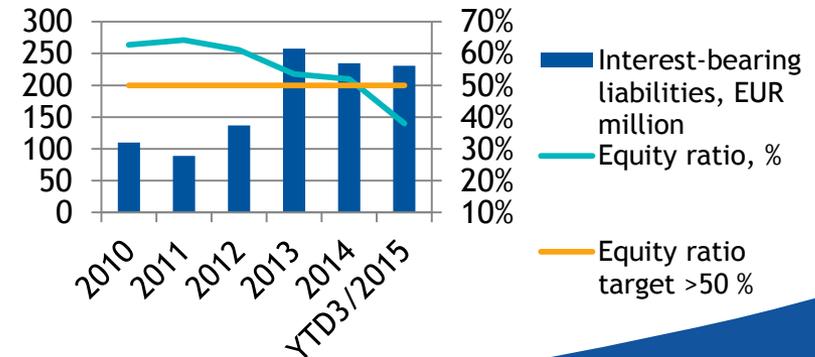
## Operating profit



## Dividend



## Equity ratio and interest-bearing liabilities



# Balancing mid-term – building long-term

Generic competition for Parkinson's franchise and Precedex.

Timing of milestone payments.

Global pricing pressure, especially on new products.

Long-term growth opportunities from R&D pipeline. Milestone payments.

Generic drugs and self-care products.

Easyhaler<sup>®</sup> combinations and *dexdor*<sup>®</sup> for European markets.

Operational flexibility and efficiency.



# Orion R&D - long term opportunities

# Orion's R&D strategy

## Increased productivity

R&D operational model renewed in 2009

## Focused therapy areas

Focus on three core therapy areas + generics

- Central nervous system diseases
- Oncology and critical care
- Easyhaler pulmonary drugs

## Shared risks and rewards

Emphasis on collaboration and partnerships

- Clinical studies are performed globally, Orion's focus on Europe
- Partnerships are usually sought for clinical phase III at the latest
- Partners are important in marketing authorisation cases in countries outside Europe
- Orion holds the rights for further develop and market the candidate compounds

## Focus on strengths

In-house R&D covers mainly late-stage research and early-stage development phases

- i.e. discovery, preclinical phase and clinical phases I and II

## Diversification

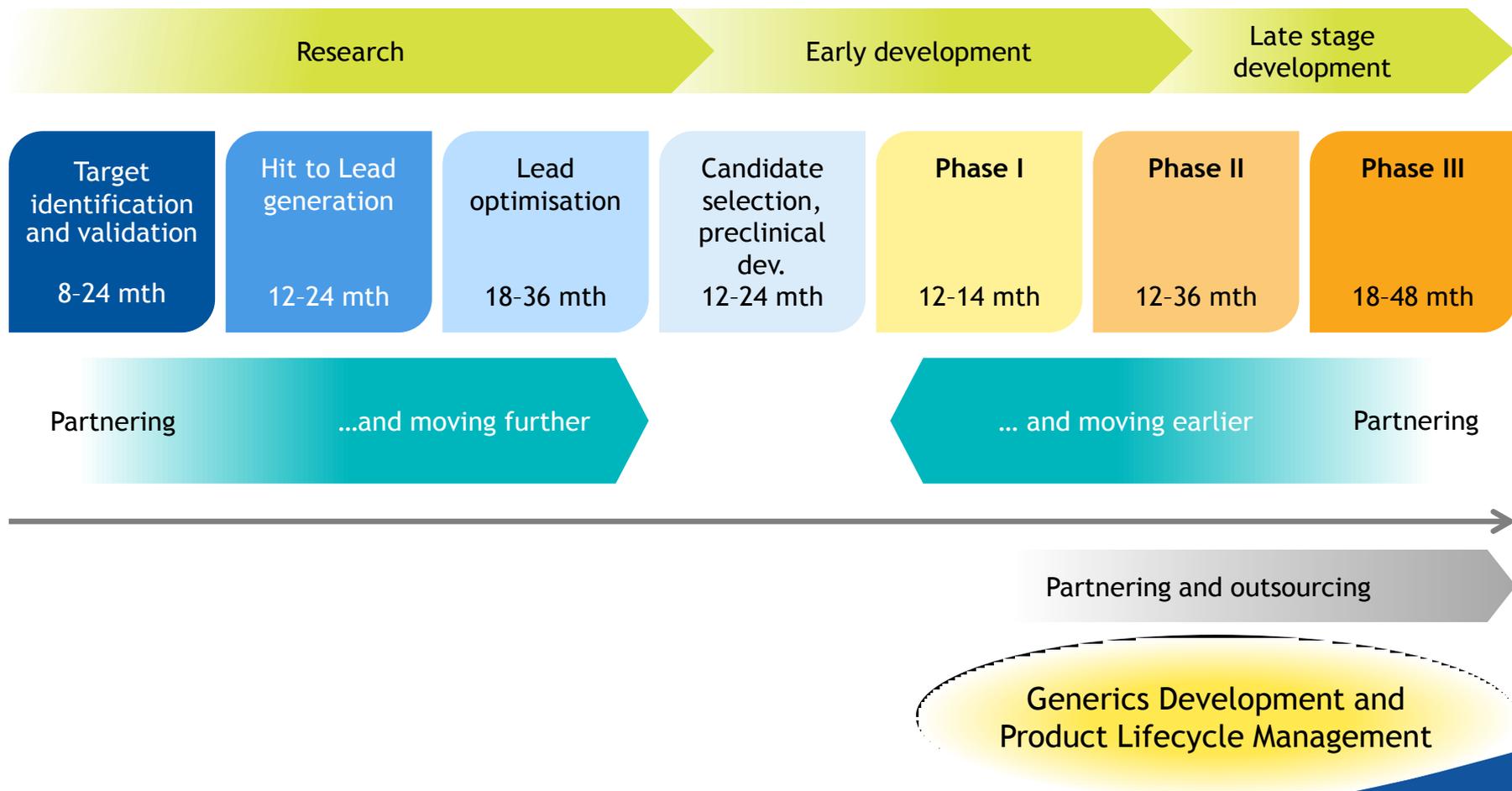
Constant strive to

- Increase the overall number of programmes
- Balance the risks of individual projects
- Acquire new early research molecules
- Improve the life-cycle management of own innovative treatments

## M&As

Active in-licensing of drug candidates or products

# Collaborative networks across the R&D value chain



# Key clinical pharmaceutical development projects 1/2

Project	Indication	PHASE			Registration
Bufomix Easyhaler® (budesonide-formoterol) <sup>1)</sup>	Asthma, COPD	I	II	III	
Easyhaler® salmeterol-fluticasone	Asthma, COPD	I	II	III	
ODM-201 (androgen receptor inhibitor) <sup>2)</sup>	Prostate cancer	I	II	III	
Levosimendan <sup>3)</sup>	Low Cardiac Output Syndrome	I	II	III	
ORM-12741 (alpha-2c adrenoceptor antagonist) <sup>4)</sup>	Alzheimer's disease	I	IIa		
Dexmedetomidine (intranasal) <sup>5)</sup>	Treatment of pain	I	IIb		
ODM-109 (oral levosimendan)	ALS	I	II		

<sup>1)</sup> Aim is to obtain marketing authorisation for product in at least some European countries not included in decentralised marketing authorisation application process.

<sup>2)</sup> In collaboration with Bayer <sup>3)</sup> Partner: Tenax Therapeutics, Inc.

<sup>4)</sup> In collaboration with Janssen Pharmaceuticals <sup>5)</sup> Partner: Recro Pharma, Inc.

	= Phase completed
	= Phase ongoing
	= New project

More info at: <http://www.orion.fi/en/rd/orion-rd/pipeline/>

# Key clinical pharmaceutical development projects 2/2

Project	Indication	PHASE			Registration
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	I			
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumours	I			
ODM-204 (CYP17 enzyme and androgen receptor inhibitor)	Prostate cancer	I			
ODM-106 (GABA-B receptor positive allosteric modulator)	Essential tremor	I			
ODM-108 (negative allosteric modulator of TRPA1 ion channel)	Neuropathic pain	I			

 = Phase completed

 = Phase ongoing

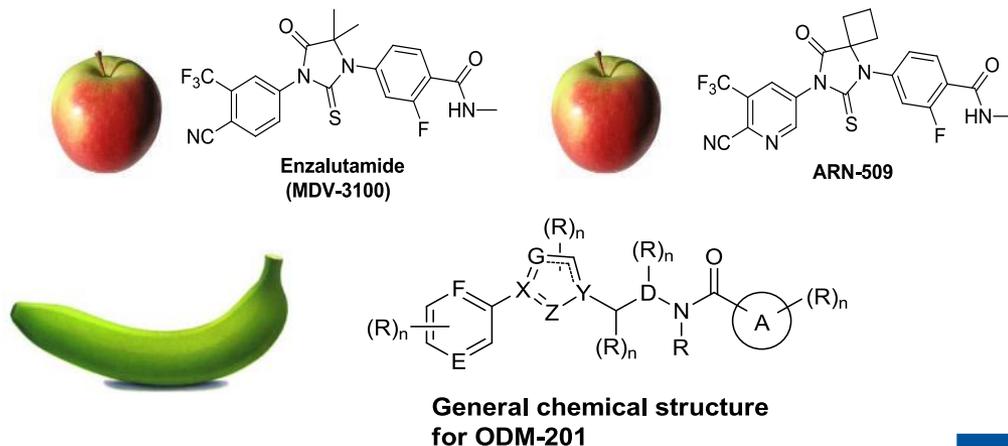
 = New project

More info at: <http://www.orion.fi/en/rd/orion-rd/pipeline/>

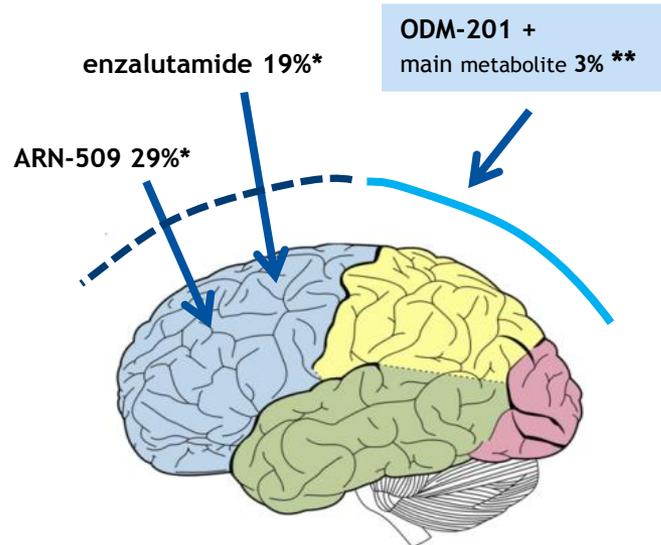
# ODM-201: Partnership with Bayer - Financial terms

- Orion and Bayer will jointly develop ODM-201, with Bayer contributing a major share of the costs of future development
- Bayer will commercialize ODM-201 globally and Orion has the option to co-promote ODM-201 in Europe
- Orion is eligible to receive milestone payments from Bayer upon achievement of certain development, tech transfer and commercialization milestones
- Orion will receive substantial royalties on future sales
- Orion will be responsible for manufacturing of the product

# ODM-201 has a unique profile



- No brain entry
- No CYP inhibition or induction expected with therapeutic doses
- M0 prostate cancer market: no approved therapies



Compound	AR affinity Ki (nM)	Antagonism WT AR IC50 (nM)	Proliferation VCaP IC50 (nM)
enzalutamide	78	155	400
ARN-509	53	168	300
ODM-201	9	65	500
ORM-15341 (main metabolite)	8	25	600

\*Refs. Clegg et al, Cancer Research 2012; Forster et al, Prostate 2011  
 \*\* Rat autoradiography (QWBA confirms brain/plasma ratio of 14C-ODM-201 related radioactivity was 0.04-0.06, indicating negligible penetration to the brain  
 Source: ECC2013 poster E17-2119

# ODM-201: Phase 3 study ongoing

- Phase 3 study in non-metastatic castration resistant prostate cancer (nm-CRPC) patients who are at high risk for developing metastatic disease
- Primary endpoint
  - ODM-201 over placebo in metastasis-free survival (MFS)
- Secondary endpoints
  - Overall survival, time to first symptomatic skeletal event (SSE), time to first initiation of cytotoxic chemotherapy, time to pain progression, and to characterize the safety and tolerability of ODM-201.

# ORM-12741 - collaboration with Janssen

- Licence agreement announced on 19 December 2013 (includes ORM-12741 and other compounds)
- Orion received USD 31 million upfront payment which will mainly be used against additional Phase IIa study costs
- Orion is eligible to receive milestone payments from Janssen upon successful completion of certain development and commercialization events, as well as royalties on future sales
- Orion has exclusive commercialization rights in Europe
- Janssen has worldwide exclusive license to develop ORM-12741 and an exclusive right to commercialize it outside Europe
- Orion and Janssen will co-fund the development after an additional Phase IIa study is completed successfully by Orion

# ORM-12741, first Phase 2a Study in AD

- Objective
  - To evaluate safety and efficacy of ORM-12741 in treatment of cognitive and behavioral symptoms of Alzheimer's disease
- Design and Methodology
  - Randomised, double-blind, placebo-controlled, parallel-group Phase 2a study in 100 patients
  - Patients with moderately severe Alzheimer's disease (MMSE 12 - 21)
  - Behavioural and psychological symptoms present (NPI  $\geq$  15)
  - All on stable dose of donepezil, rivastigmine or galantamine for at least 3 months
  - 2 dose levels of ORM-12741 and placebo for 12 weeks as an add-on therapy
- Main Endpoints
  - A battery of computerized neurocognitive tests (CDR System)
    - Pre-specified primary emphasis on composite scores for Quality of Episodic Memory, Quality of Working Memory, Speed of Memory and Power of Attention
  - Neuropsychiatric inventory (NPI)
  - Safety: AEs, vital signs, safety lab, ECG

# ORM-12741 first Phase 2a Study – Conclusions

- Clear positive effects on memory measures on active treatment groups as compared to placebo
  - Clear and statistically significant positive treatment effect on Quality of Episodic Memory (\*p=0.03)
  - Clear and statistically significant positive treatment effect on Quality of Memory (\*p=0.013)
- Clear and statistically significant positive treatment effect on Neuropsychiatric Inventory (NPI) Caregiver Distress score (\*p=0.034)
- Trend for positive treatment effect in Neuropsychiatric Inventory (NPI) total score for the low dose group (\*p=0.12)
- ORM-12741 was generally well tolerated

\*Main treatment effect (used doses: 30-60mg and 100-200 mg)

# ORM-12741 — Next Steps

- A new formulation study followed by
- An additional Phase 2a in AD patients focusing on
  - Confirmation of the first Phase 2a results - especially on NPI
  - Dosing
- Development options for Phase 3

## Cognition

- ✓ Pros': Several compound shown to work, clear study designs, endpoints & regulatory path
- ✓ Cons': Old generic drugs on market, new competitors in pipeline, lower price expectation than for the latter

## Neuropsychiatric symptoms

- ✓ Pros': Huge unmet need, less competition, high value
- ✓ Cons': Endpoints & regulatory path less clear - need clarification before Phase 3

# ODM-104 and ODM-106

**ODM-104** is a new molecule that enhance the therapeutic effects of levodopa used to treat Parkinson's disease by blocking the COMT enzyme. The pre-clinical study results indicated that ODM-104 is more effective than the COMT inhibitor entacapone, which is already in the markets.

**ODM-106** is an investigational GABA-B positive allosteric modulator (PAM) that enhances the effect of the naturally occurring agonist GABA, but has a low side-effect potential in preclinical studies due to low efficacy and potency as a GABA-B agonist. Preclinical studies indicate that ODM-106 has the potential to alleviate essential tremor (ET), parkinsonian tremor and levodopa-induced dyskinesia in patients with Parkinson's disease, without causing sedation.

# ODM-108 and ODM-109

**ODM-108** is a novel, highly potent, selective and reversible negative allosteric modulator of Transient Receptor Potential A1 (TRPA1) ion channel and is very effective in several, repeated dosing, preclinical models of neuropathic or inflammatory pain. The TRPA1 ion channel is considered to be a prioritised target for the treatment of pain and a number of companies are active in this field. ODM-108 did not demonstrate sedation when tested at preclinically effective doses and is optimised for good absorption.

**ODM-109** is orally administered levosimendan, a troponin C selective calcium sensitizer enhancing cardiac and skeletal muscle function. Available studies indicate that ODM-109 has the potential to support diaphragm and thus respiratory function as well as strength and endurance of other skeletal muscles in patients with amyotrophic lateral sclerosis (ALS).

# ODM-203 and ODM-204

**ODM-203** is an investigational targeted Fibroblast Growth Factor Receptor (FGFR) + Vascular Endothelial Growth Factor Receptor (VEGFR) inhibitor that is designed to block growth of FGFR signaling dependent tumours. ODM-203 is unique as it is a selective and equally potent inhibitor against both the FGFR and VEGFR family kinases. In accordance ODM-203 shows strong antitumour activity in both FGFR and VEGFR dependent nonclinical tumour models.

**ODM-204** is a unique, investigational dual inhibitor of CYP17 enzyme and androgen receptor (AR) designed to block the growth of castration-resistant prostate cancer (CRPC). Similar to enzalutamide, ODM-204 binds to AR with high affinity and inhibits receptor function by blocking the activity as well as the nuclear translocation of AR. In addition, similar to abiraterone, ODM-204 inhibits CYP17 enzyme required for testosterone synthesis in males. Both CYP17 and AR are key mechanisms in the growth of CRPC.



# Proprietary Products and Specialty Products update

# Product protection situation of key products

## Key patents or data protection expire

Molecule	Product	Indication	Key patents or data protection expire		
			Europe	USA	Japan
Entacapone	Stalevo <sup>®</sup> , Comtess <sup>®</sup> and Comtan <sup>®</sup>	Parkinson's disease	November 2012 October 2013 <sup>1)</sup>	October 2013	January 2015 <sup>2)</sup>
Levosimendan	Simdax <sup>®</sup>	Acute decompensated heart failure	September 2015	Not marketed	Not marketed
Dexmedetomidine	Precedex <sup>®</sup> <i>dexdor</i> <sup>®</sup>	Intensive care sedative	July 2013 September 2021 <sup>3)</sup>	January 2014 <sup>4)</sup>	June 2012

<sup>1)</sup> Stalevo data protection expired

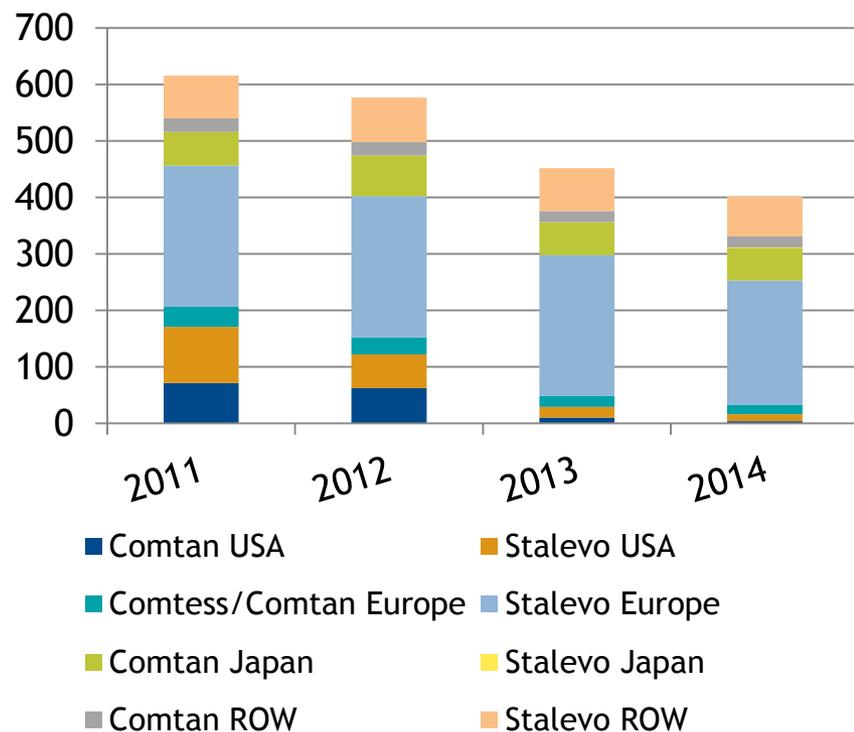
<sup>2)</sup> Data protection of Comtan expired;

<sup>3)</sup> *dexdor*<sup>®</sup> data protection expires

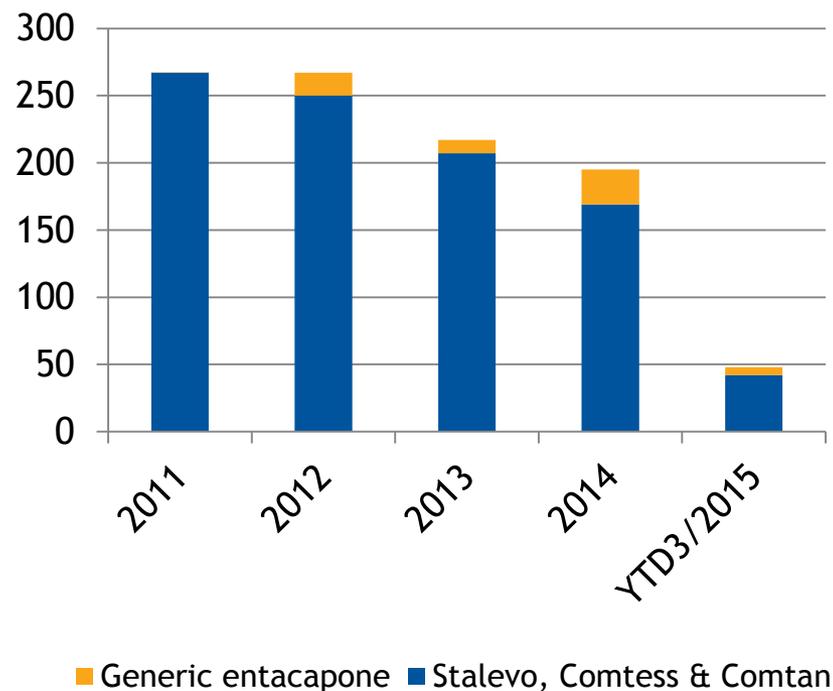
<sup>4)</sup> Six months paediatric exclusivity granted for Precedex in the United States expired

# Turning points of Parkinson's franchise

Annual in-market sales, EUR million\*



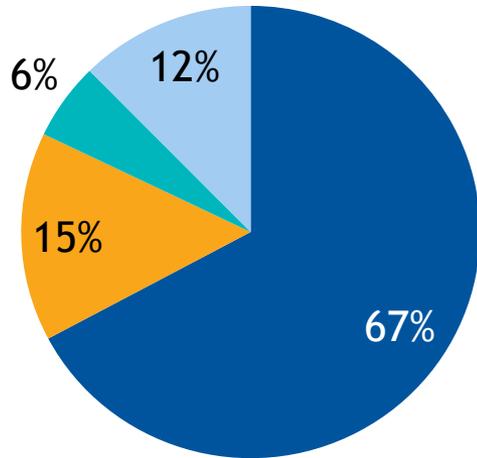
Orion sales, EUR million



	USA	EUROPE	JAPAN
STALEVO	First generics in April 2012	First generics in Q2/2014	
COMTESS/COMTAN	First generics in October 2012	First generics in Q4/2012	Data protection ended in January 2015

# dexdor<sup>®</sup> intensive care sedative

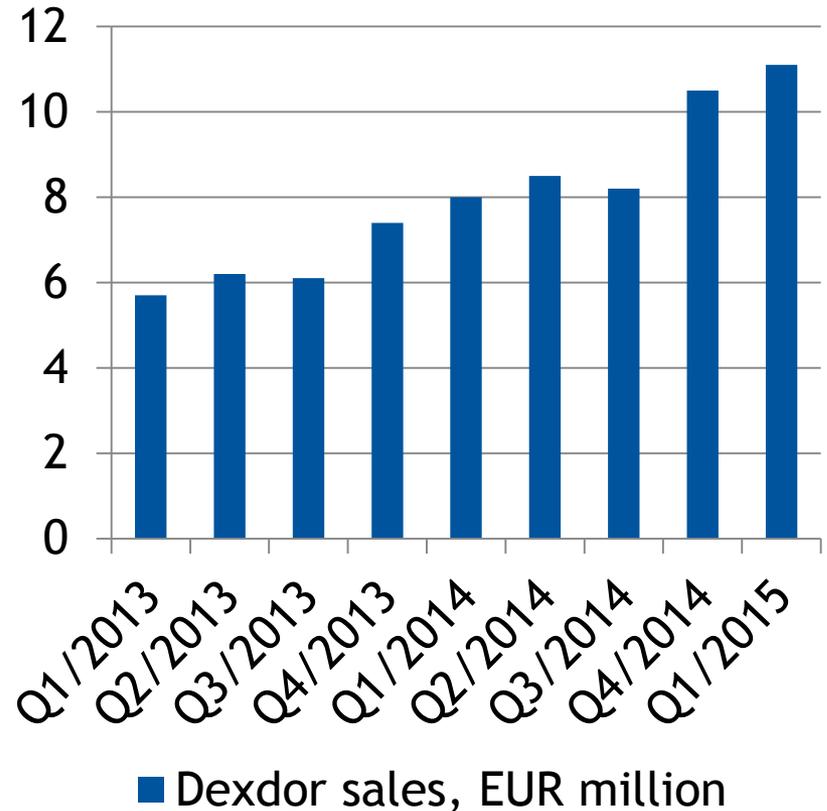
European sedative market MAT12/2014\*  
Total market value EUR 509 million (+3%)



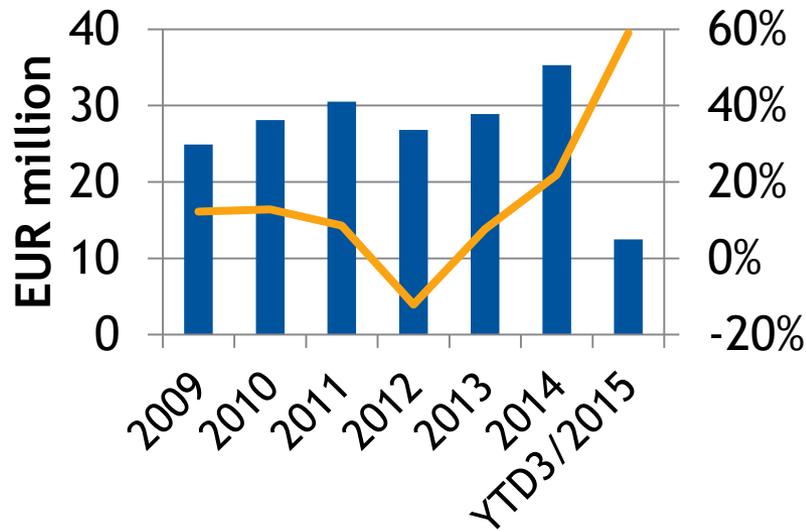
- Propofol EUR 342 million (+3%)
- Midazolam EUR 76 million (-3%)
- Dexmedetomidine EUR 28 million (+28%)
- Remifentanyl EUR 63 million (+4%)

\*Source: IMS Health sales statistics MAT12/2014

## Dexdor sales



# Easyhaler® for asthma and COPD



■ Sales — Growth %

- Easyhaler® is authorised in 30 countries and coverage expanding, excl. USA and Japan
- Rights to Easyhaler® products repatriated in various European countries in 2012

1993 Buventol  
Easyhaler®  
(salbutamol)



1994 Beclomet  
Easyhaler®  
(beclomethasone)



2002 Budesonide  
Easyhaler®  
(budesonide)



2004 Formoterol  
Easyhaler®  
(formoterol)



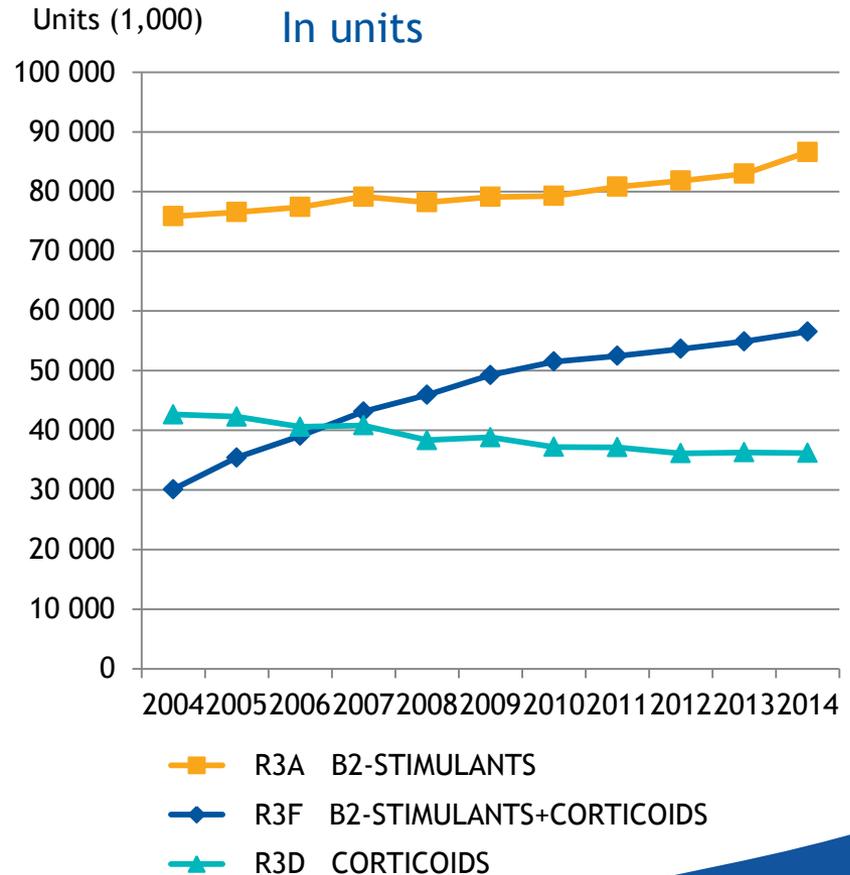
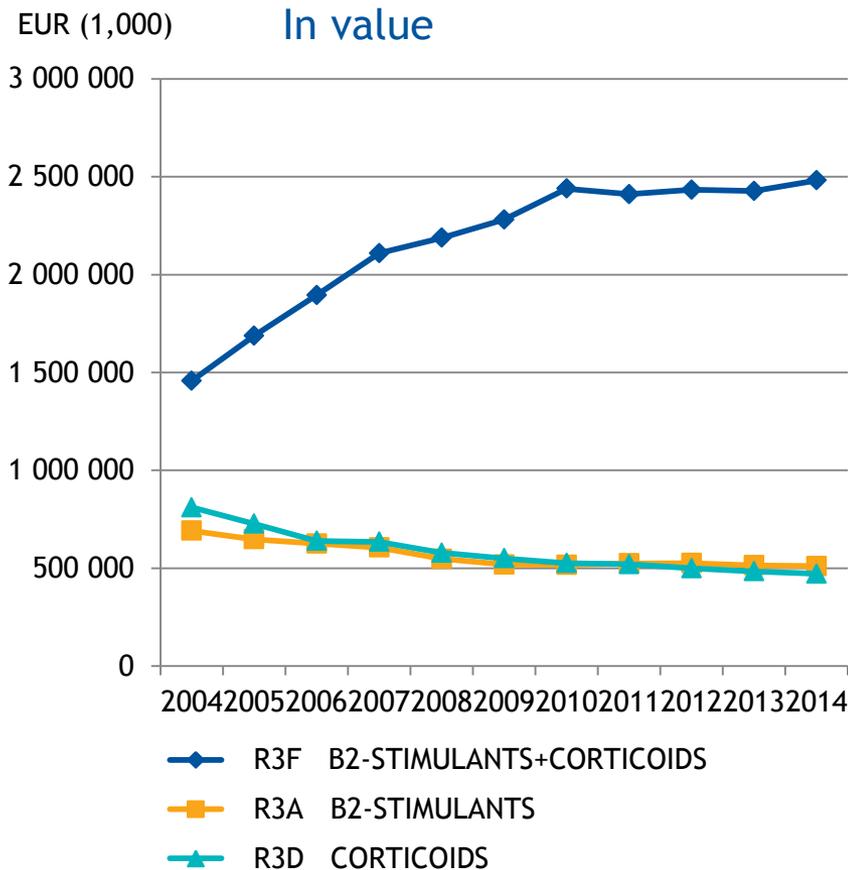
2014 Bufomix  
Easyhaler®  
(budesonide-  
formoterol)



2010→  
Development of  
fluticasone-  
salmeterol

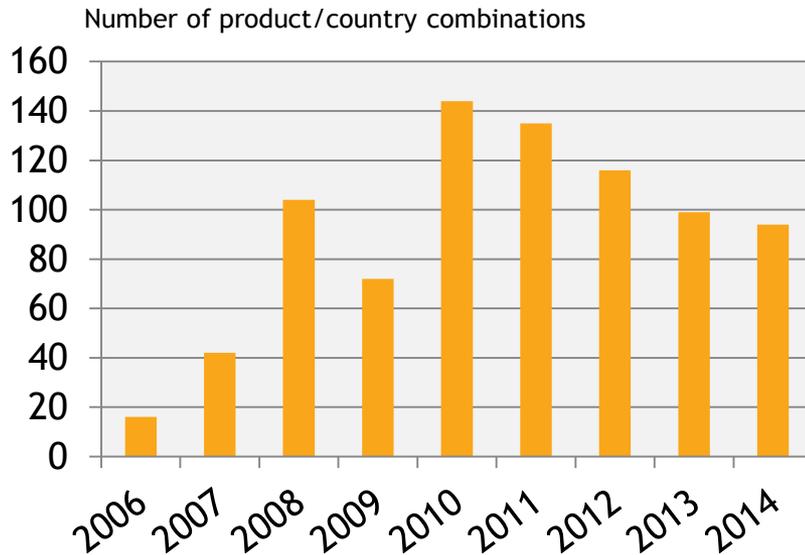


# Retail sales of inhaled respiratory drugs market in Top 5 Europe



# Launches are basis for future growth in SpP

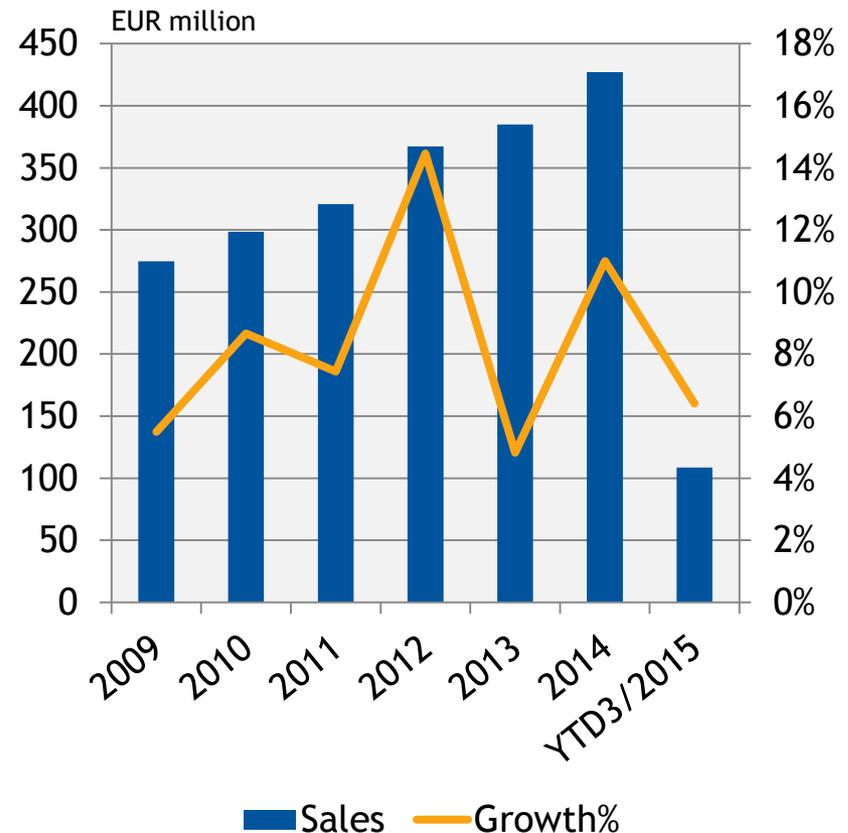
## Specialty Products launches



### SpP launches in 2014

#### By geographic area

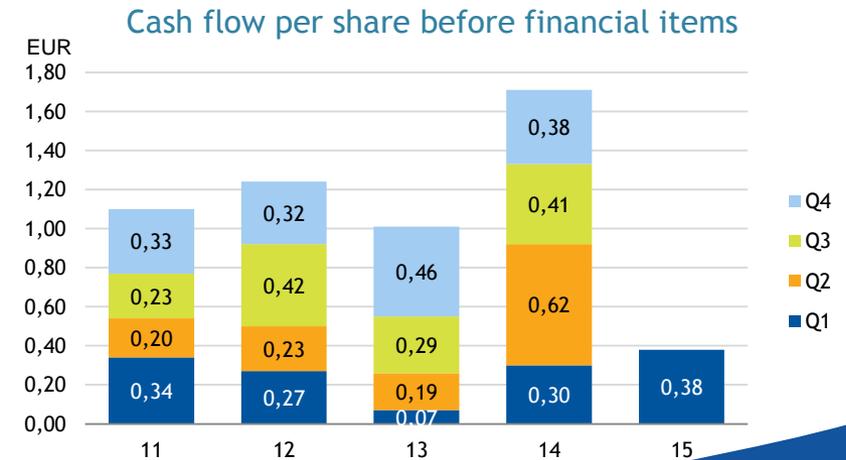
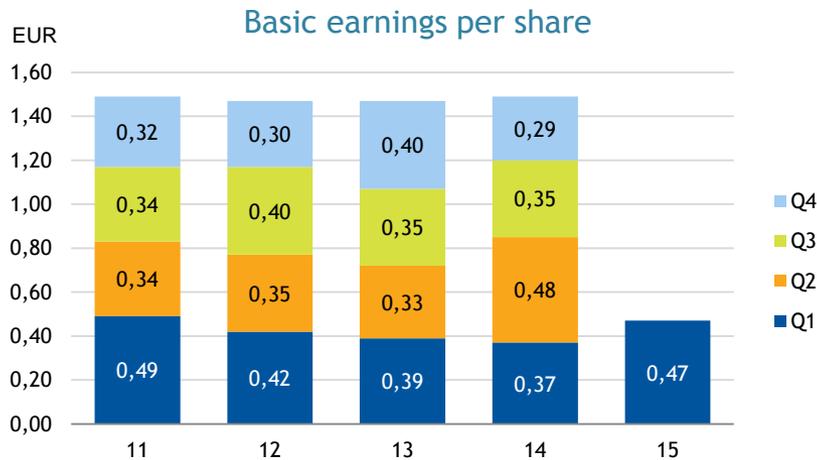
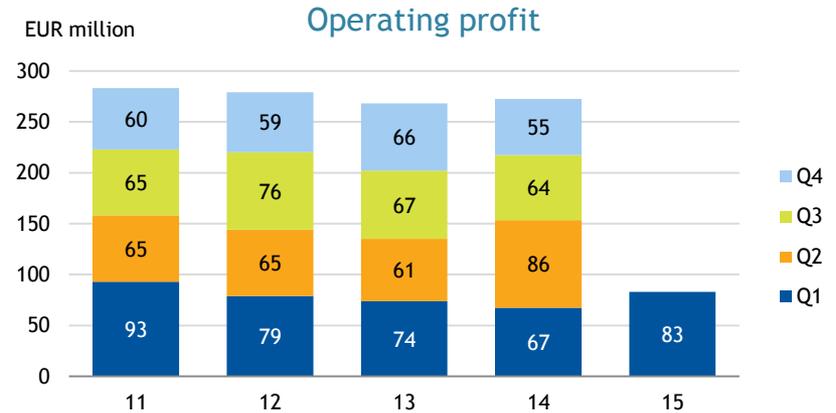
Eastern Europe	26
Scandinavia	35
Finland	27
Other	6





# Key financials

# Key figures by quarter



# Key figures for 2011–Q1/2015

Orion's key figures	2011	2012	2013	2014	Q1/2015	Q1/2014	Change %
Net sales, EUR million	917.9	980.4	1,006.9	1,015.3	259.9	245.0	+6.1%
Operating profit, EUR million	282.9	278.3	267.7	272.4	83.1	67.4	+23.3%
Profit before taxes, EUR million	282.0	276.6	264.0	267.8	82.7	66.5	+24.4%
R&D expenses, EUR million	87.5	105.8	101.9	106.2	25.1	26.3	-4.6%
Equity ratio, %	64.2%	61.0%	53.6%	52.3%	38.1%	38.9%	
Gearing, %	-6.9%	-1.7%	8.4%	-4.7%	-20.3%	-0.1%	
ROCE (before taxes), %	49.4%	45.9%	38.5%	36.6%	50.4%	38.9%	
Return on equity, %	43.3%	41.0%	40.3%	41.1%	57.4%	46.5%	
Basic earnings per share, EUR	1.49	1.47	1.46	1.50	0.47	0.37	+24.8%
Cash flow per share before financial items, EUR	1.10	1.23	1.02	1.72	0.38	0.30	+24.3%
Dividend per share, EUR	1.30	1.30	1.25	1.30			
Capital repayment per share, EUR	0.12						

# Income Statement 2011–Q1/2015

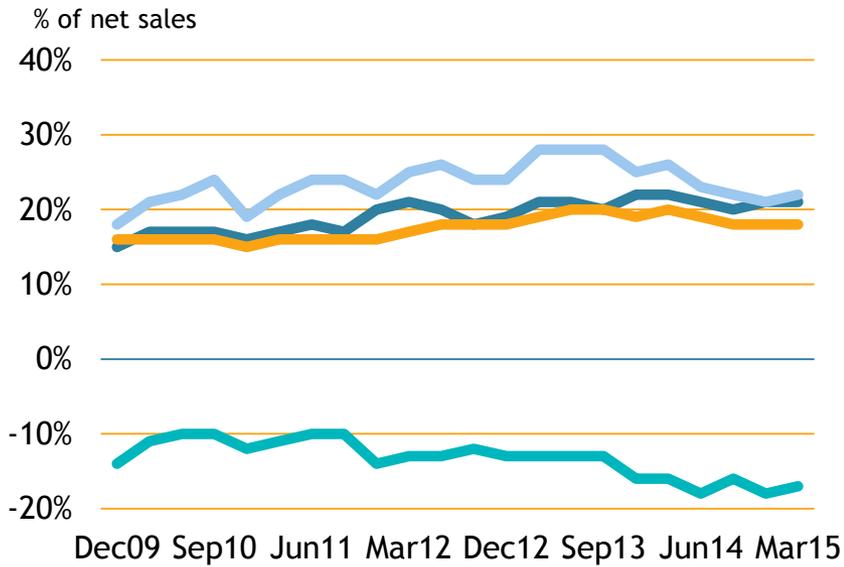
Formation of profits, EUR million	2011	2012	2013	2014	Q1/2015	Q1/2014	Change %
Net sales	917.9	980.4	1,006.9	1,015.3	259.9	245.0	+6.1%
Cost of goods sold	-305.1	-350.8	-393.5	-401.7	-91.4	-95.8	-4.6%
Gross profit	612.8	629.6	613.4	613.6	168.5	149.2	+13.0%
Other operating income and expenses	3.0	6.3	5.6	1.7	-2.2	0.2	
Sales and marketing expenses	-204.8	-206.1	-204.9	-193.4	-46.6	-46.3	+0.6%
R&D expenses	-87.5	-105.8	-101.9	-106.2	-25.1	-26.3	-4.6%
Administrative expenses	-40.6	-45.7	-44.5	-43.3	-11.5	-9.4	+23.2%
Operating profit	282.9	278.3	267.7	272.4	83.1	67.4	+23.3%
Profit before taxes	282.0	276.6	264.0	267.8	82.7	66.5	+24.4%
Profit for the period	209.5	206.9	206.2	211.3	65.7	52.6	+24.9%

# Financial position

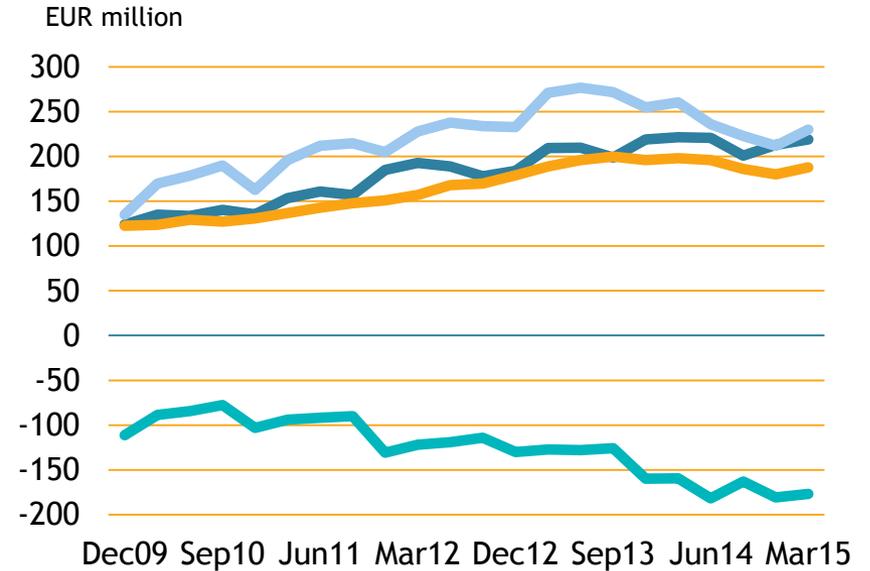
EUR million	3/15	3/14	Change%
<b>Non-current assets total</b>	<b>348.5</b>	354.0	-1.5%
Inventories	186.4	198.0	-5.8%
Trade receivables	171.5	168.3	+1.9%
Other receivables	51.7	52.4	-1.4%
Cash & cash equivalents & money market investments	312.2	254.3	+22.8%
<b>Current assets total</b>	<b>721.8</b>	673.0	+7.3%
<b>Assets total</b>	<b>1,070.3</b>	1,026.9	+4.2%

EUR million	3/15	3/14	Change%
<b>Equity total</b>	<b>401.8</b>	392.09	+2.5%
Interest-bearing non-current liabilities	206.1	229.3	-10.1%
<b>Non-current liabilities total</b>	<b>271.9</b>	261.4	+4.0%
<b>Current liabilities total</b>	<b>396.6</b>	373.5	+6.2%
<b>Liabilities total</b>	<b>668.5</b>	634.9	+5.3%
<b>Equity and liabilities total</b>	<b>1,070.3</b>	1,026.9	+4.2%

# Development of Net working capital



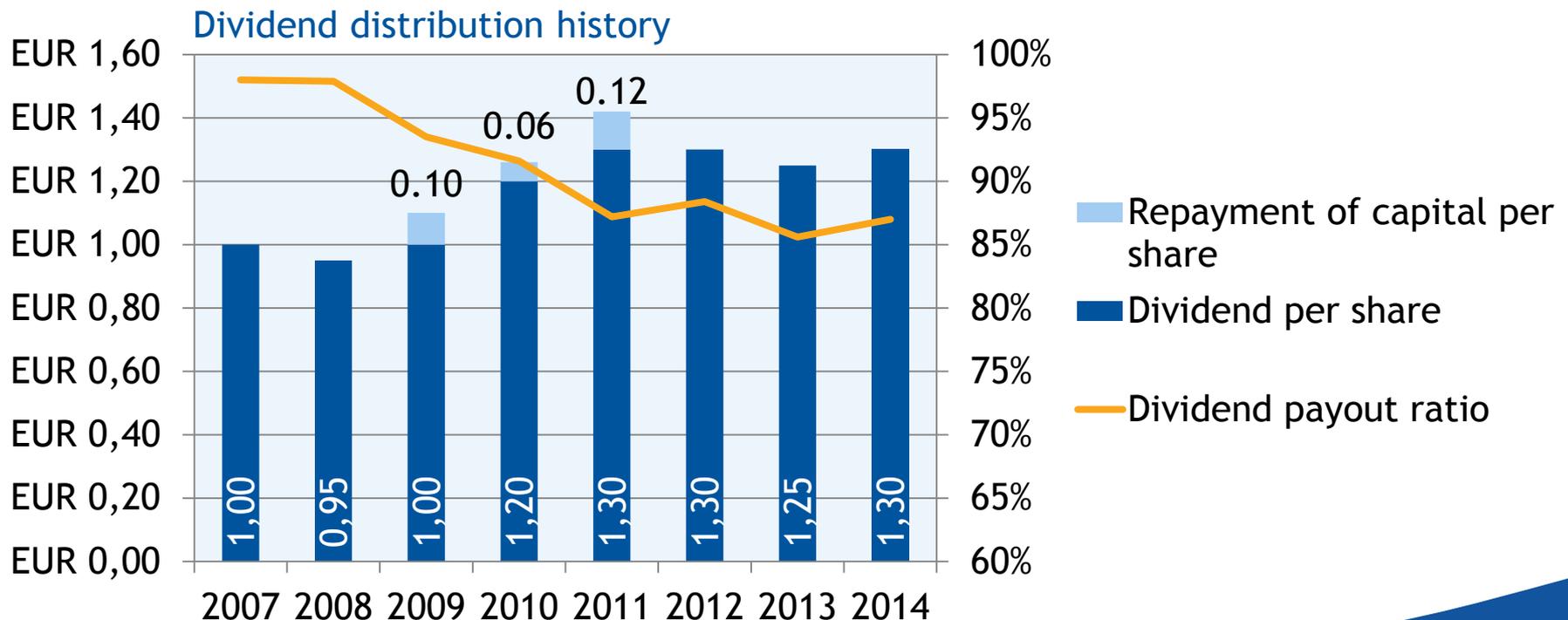
- Receivables
- Inventories
- Short-term non-interest bearing liabilities
- Net Working Capital



- Receivables
- Inventories
- Short-term non-interest bearing liabilities
- 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.

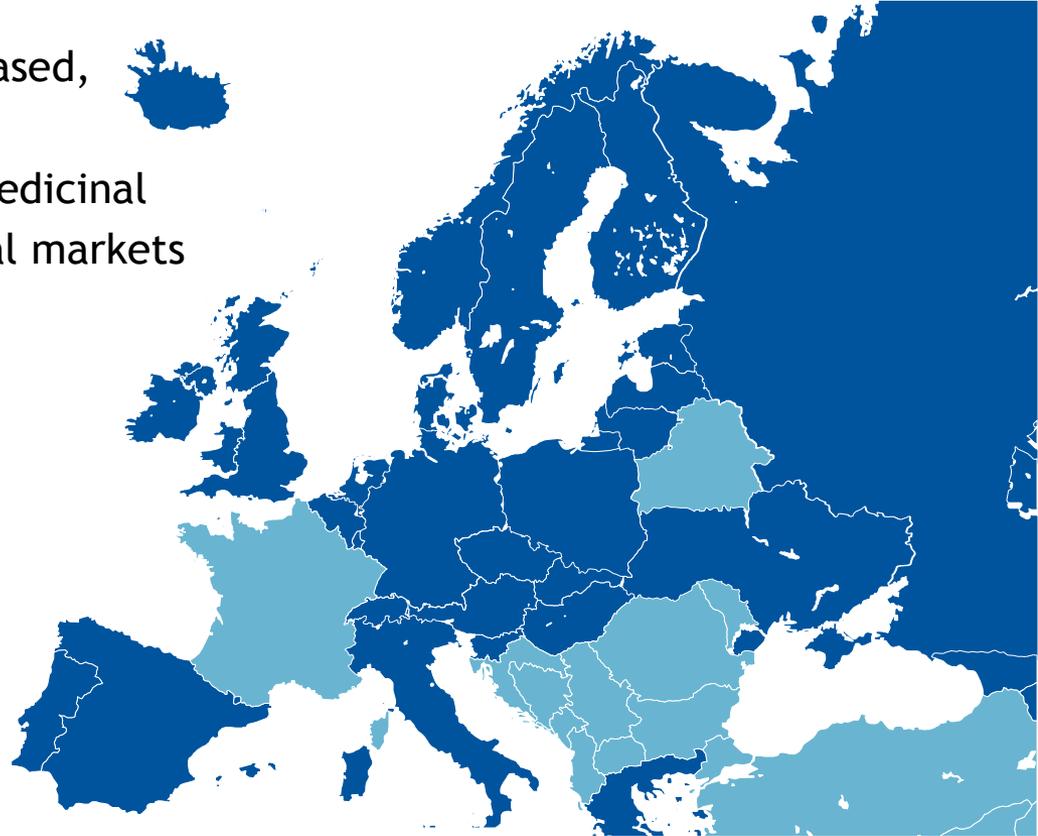




# General info

# Building well-being since 1917

Orion is an innovative, European, R&D-based, pharmaceutical and diagnostic company with a special emphasis on developing medicinal treatments and diagnostic tests for global markets



## Orion in brief

2014

Net sales	EUR 1 015 million
Operating profit	EUR 272 million
R&D expenses	EUR 106 million
No. of personnel (at end of)	3,450
in Finland	2,769
in other countries	681

# Business units



## Proprietary Products

- Patented prescription drugs
- CTAs: CNS, oncology & critical care, Easyhaler pulmonary drugs
- Net sales in 2014 EUR 373 million



## Fermion

- Active pharmaceutical ingredients (API's) for Orion and other companies
- Net sales in 2014 EUR 57 million (excluding supplies for own use)



## Specialty Products

- Generic prescription drugs
- Self-care products
- Net sales in 2014 EUR 427 million



## Contract Manufacturing & Other<sup>1)</sup>

- Pharmaceutical manufacturing for other companies
- Net sales in 2014 EUR 34 million



## Animal Health

- Veterinary medicines and care products for pets and production animals
- Net sales in 2014 EUR 70 million



## Orion Diagnostica

- Diagnostic test systems for point-of-care testing in healthcare and hygiene testing for industry
- Net sales in 2014 EUR 56 million

<sup>1)</sup> Contract manufacturing and other is included in the Pharmaceuticals business segment but is not a separate business division. It is part of the Group's Supply Chain organisation.

# Market position strengthened in Europe

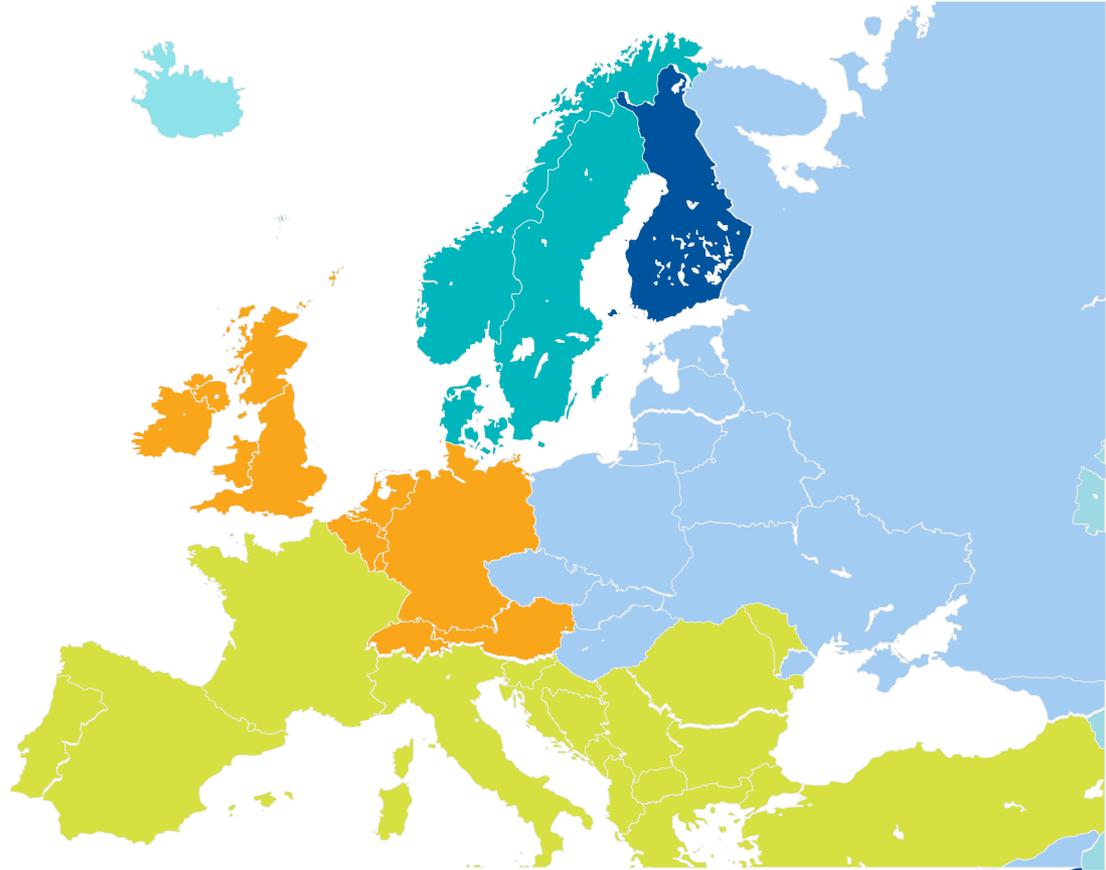
**Finland**  
Market leader

**Scandinavia**  
Strong domestic market position

**Eastern Europe**  
Generics

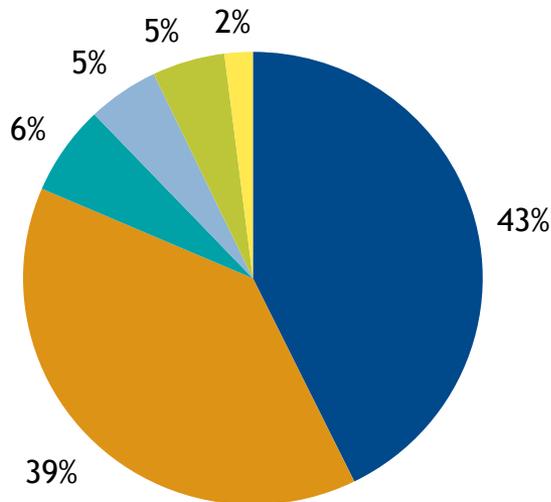
**Western and Central Europe**  
Strong position with proprietary products

**Southern Europe**  
Progress with proprietary products in  
hospital markets



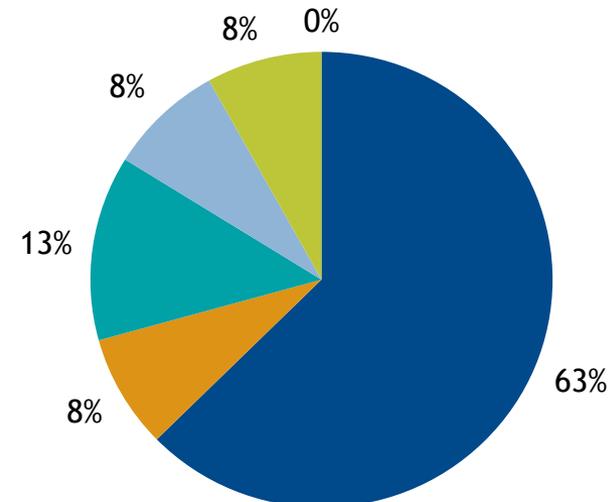
# Orion shares are broadly held

By number of shares on 31 Mar



- Households
- Non-Finnish holders and nominee registered
- Private corporations
- Public sector
- Non-profit institutions
- Financial and insurance corporations

By number of votes on 31 Mar



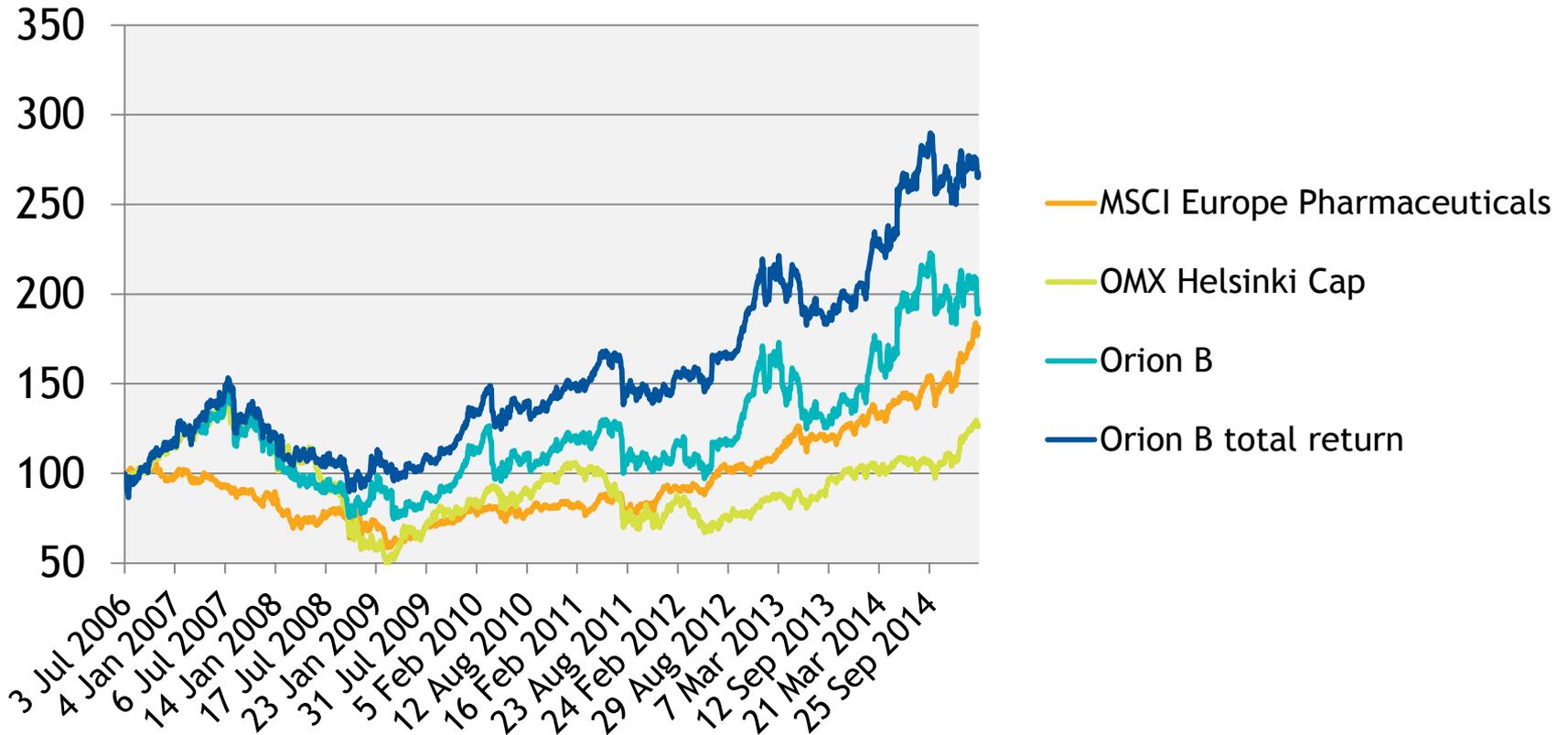
- Households
- Non-Finnish holders and nominee registered
- Private corporations
- Public sector
- Non-profit institutions
- Financial and insurance corporations

Altogether 141.3 million shares and ca. 52,000 shareholders. Both share classes, A and B, are listed on NASDAQ OMX Helsinki since 1 July 2006. A share (ORNAV) has 20 votes/share and B share (ORNBV) has 1 vote/share in the AGM, but they have equal rights to assets and dividends.

# Orion B share performance

3 July 2006— 31 Mar 2015

Index 3 July 2006 = 100



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