



# 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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# Results 2014 Q1-Q2 & Outlook



# Payments from partners increased net sales and operating profit

- Net sales increased slightly and operating profit increased
- Orion began global partnership with Bayer for developing and commercialising compound ODM-201
- Net sales and operating profit include payments received from Bayer (EUR 23 million) and Takeda (EUR 6 million)
- Stalevo granted marketing authorisation in Japan in beginning of July
- Generic competition to Stalevo that has begun in Germany has not yet materially affected Orion's sales



# Key figures for 2014 Q1-Q2

	Q1-Q2/2014	Q1-Q2/2013	Change %	2013
Net sales, EUR million	521.7	497.4	+4.9%	1 006.9
Operating profit, EUR million	153.4	135.2	+13.4%	267.7
% of net sales	29.4%	27.2%		26.6%
R&D expenses, EUR million	56.9	50.9	+11.6%	101.9
% of net sales	10.9%	10.2%		10.1%
Basic earnings per share, EUR	0.86	0.72	+19.3%	1.46
Cash flow per share before financial items, EUR	0.93	0.27	+247.9%	1.02



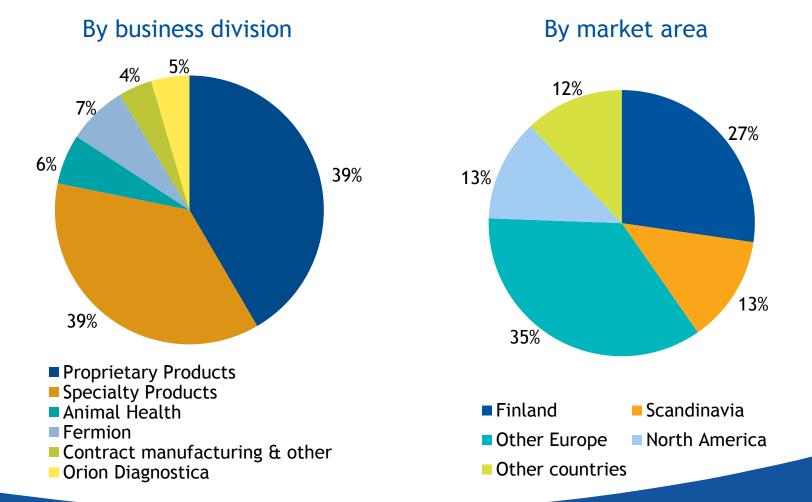
# Key figures by business areas

Key figures for Pharmaceuticals business	Q1-Q2/2014	Q1-Q2/2013	Change %	2013
Net sales of Pharmaceuticals, EUR million	494.3	469.2	+5.4%	953.0
Proprietary Products	203.6	193.1	+5.5%	390.4
Specialty Products	203.7	187.7	+8.5%	384.9
Animal Health	32.0	34.5	-7.2%	70.8
Fermion	34.8	34.3	+1.5%	63.5
Contract manufacturing and other <sup>1)</sup>	20.2	19.6	+2.8%	43.3
Pharmaceuticals operating profit, EUR million	155.0	138.3	+12.1%	272.9
Key figures for Diagnostics business				
Net sales, EUR million	29.1	29.9	-2.6%	57.1
Operating profit, EUR million	2.9	1.9	+58.6%	4.6

<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.



# Net sales originate mainly in Europe Breakdown of EUR 522 million net sales in Q1-Q2/2014





# Best-selling pharmaceuticals

Orion's best-selling pharmaceuticals, EUR million	Business Division	Q1-Q2/2014	Q1-Q2/2013	Change %	2013
1. Stalevo®, Comtess® & Comtan® (Parkinson's disease)	PP	93	111	-16%	207
2. Simdax® (acute decompensated heart failure)	PP	23	23	+1%	46
3. dexdor® (intensive care sedative)	PP	17	12	+38%	25
4. Easyhaler® product family (asthma, COPD)	PP	16	14	+22%	29
5. Precedex® (intensive care sedative)	PP	16	23	-29%	59
6. Generic entacapone products (Parkinson's disease)	SpP	14	5	+180%	10
7. Burana® (inflammatory pain)	SpP	11	11	-2%	23
8. Dexdomitor®, Domitor®, Domosedan® and Antisedan® (animal sedatives)	АН	9	11	-18%	25
9. Marevan® (anticoagulant)	SpP	9	8	+4%	16
10. Trexan® (rheumatoid arthritis, cancer)	SpP	7	6	+26%	11
Total		215	223	-4%	452
Share of Pharmaceuticals net sales		43%	47%		47%

Products based on Orion's inventions in blue

PP = Proprietary Products SpP = Specialty Products AH = Animal Health



# Outlook for 2014 (updated on 2 June 2014)

- Net sales will be at similar level to 2013 (net sales in 2013 were EUR 1,007 million)
- Operating profit will be at similar level to 2013 (operating profit in 2013 was EUR 268 million)
  - Was earlier: Operating profit will be slightly lower than in 2013 (operating profit in 2013 was EUR 268 million)
- Group's capital expenditure will be about EUR 60 million excluding substantial corporate or product acquisitions (Group's capital expenditure in 2013 was EUR 78 million)

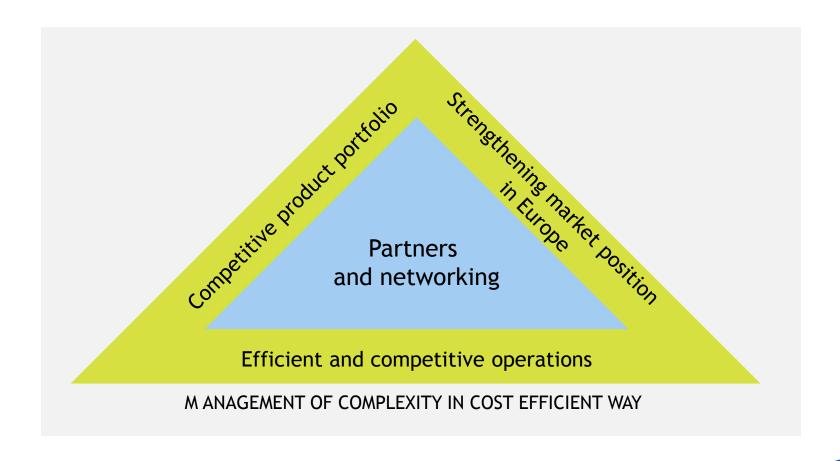




# Orion's strategy and financial targets



# Profitable growth and increased shareholder value whilst keeping business risks under control





## Balancing mid-term - building long-term

Upside potential from pipeline progress

Parkinson's franchise post patent Precedex royalty stream post patent Enlargened portfolio in the Nordics
Continued growth in Eastern Europe and Russia
Contract Manufacturing

Pricing pressure especially on new introductions

Easyhaler combinations dexdor® for European markets

Operational flexibility and efficiency



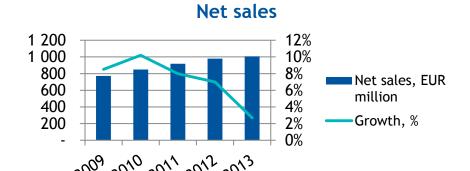
# Orion's financial objectives

#### Orion's financial objectives are:

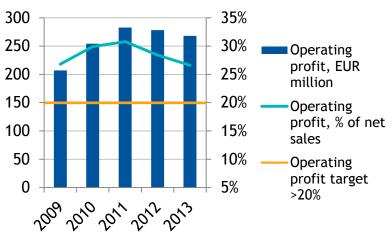
- Ensuring financial stability
- Profitable growth

#### The objectives are achieved through:

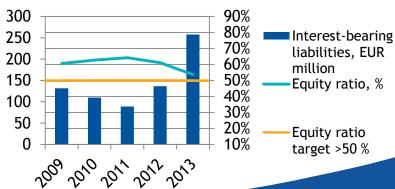
- Increasing net sales. Achievement of this objective requires continuous investment in development of the product portfolio.
- Maintaining profitability at a good level, the aim being operating profit that exceeds 20% of net sales.
- Keeping the equity ratio at least 50%.



#### **Operating profit**



# Equity ratio and interest-bearing liabilities







Orion R&D long term opportunities

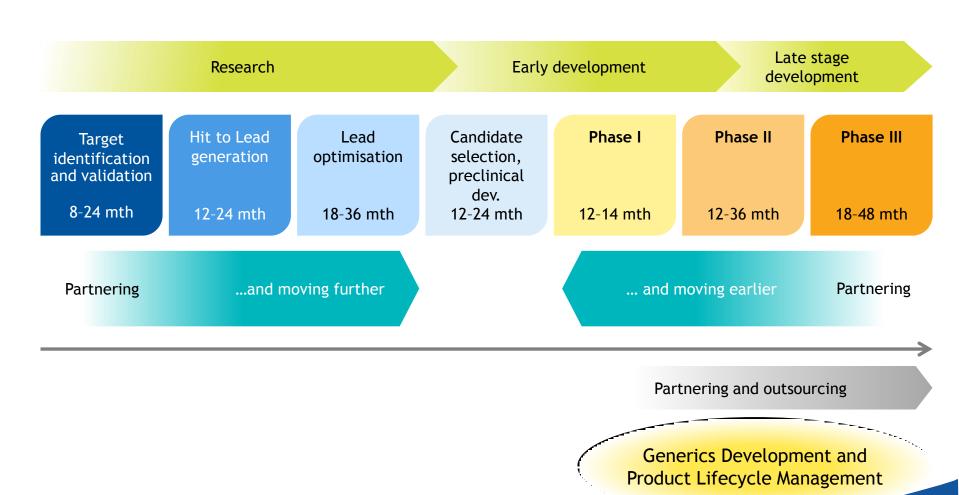


# Orion's R&D strategy

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	<ul> <li>Emphasis on collaboration and partnerships</li> <li>Clinical studies are performed globally, Orion's focus on Europe</li> <li>Partnerships are usually sought for clinical phase III at the latest</li> <li>Partners are important in marketing authorisation cases in countries outside Europe</li> <li>Orion holds the rights for further develop and market the candidate compounds</li> </ul>
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	<ul> <li>Constant strive to</li> <li>Increase the overall number of programmes</li> <li>Balance the risks of individual projects</li> <li>Acquire new early research molecules</li> <li>Improve the life-cycle management of own innovative treatments</li> </ul>
M&As	Active in in-licensing of drug candidates or products



## Collaborative networks across the R&D value chain





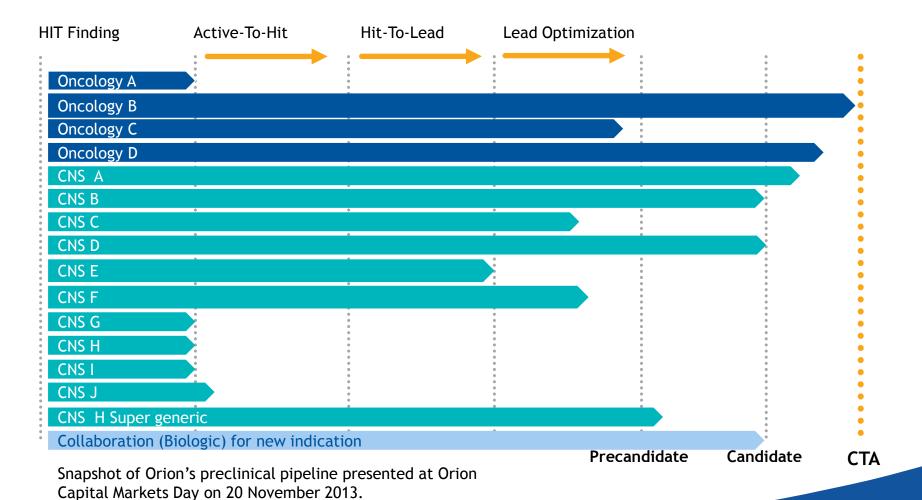
# Key clinical pharmaceutical development projects

Project	Indication	PHASE		Registration	
Stalevo® for Japanese markets 1)	Parkinson's disease	1	Ш	Ш	Registration
Bufomix Easyhaler® (budesonide-formoterol) 5)	Asthma, COPD	-1	Ш	Ш	
Easyhaler® salmeterol-fluticasone	Asthma, COPD	1	Ш	Ш	
ODM-201 (androgen receptor inhibitor) 6)	Prostate cancer	-1	Ш	Ш	
Levosimendan <sup>3)</sup>	Low Cardiac Output Syndrome	-1	П	Ш	
ORM-12741 (alpha-2c adrenoceptor antagonist) <sup>2)</sup>	Alzheimer's disease	1	lla		
Dexmedetomidine 4) (intranasal)	Treatment of pain	1	IIb		
ODM-103 (more effective COMT inhibitor)	Parkinson's disease	-1			
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	-1			
1) Partner: Novartis, 2) In collaboration with Janssen Pharmaceuticals			= Phas	e compl	leted
<sup>3)</sup> Partner: Tenax Therapeutics, Inc. <sup>4)</sup> Partner: Rec	ro Pharma, Inc.		= Phas	e ongoii	ng

<sup>&</sup>lt;sup>5)</sup> Aim is to obtain marketing authorisation for product in at least some European countries not included in decentralised marketing authorisation application process. <sup>6)</sup> In collaboration with Bayer



# Research projects 2013 (16)







ORM-12741, alpha-2c adrenoceptor antagonist



#### 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 pts
- Patients with moderately severe Alzheimer's disease (MMSE 12 21)
- Behavioural and psychological symptoms present (NPI ≥ 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



<sup>\*</sup>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 prize 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-201 a new generation androgen receptor (AR) inhibitor for prostate cancer



## 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
- Orion received EUR 50 million upfront payment of which EUR 23 million was included in Q2 profit and EUR 27 million is estimated to be used for development costs of ODM-201

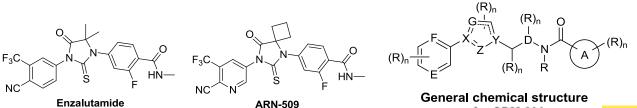


## ODM-201: Next steps

- 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.
- Phase 3 study ongoing



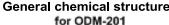
# ODM-201 has a unique profile













ARN-509 29%*	

enzalutamide 19%\*

ODM-201 +

main metabolite 3% \*\*

*Refs. Clegg et al,	Cancer	Research	2012;	Forster	at	al,
Prostate 2011						

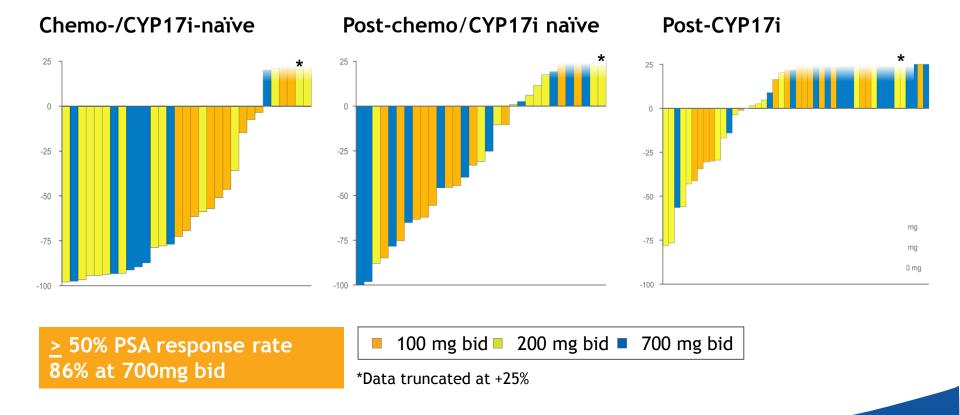
\*\* Rat autoradiography (QWBA confirms brain/plasma ratio of 14C-ODM-201 related radioactivity was 0.04-0.06, indicating negligible penetration to the brain

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

- No brain entry
- No CYP inhibition or induction expected with therapeutic doses



# In ARADES I/II study 12 wk PSA response was most pronounced in Chemo-/CYP17i naive patients





# Most common (>10%) adverse events in ARADES study by grade

Follow-up until week 12	N of patients (%) (N=124)				
	Grade 1-2	Grade 3	Grade 4		
Fatigue / Asthenia	30 (24%)	1 (1%)	-		
Back pain	17 (14%)	1 (1%)	-		
Constipation	16 (13%)	-	-		
Nausea	13 (10%)	1 (1%)	-		
Pain	13 (10%)	1 (1%)	-		
Decreased appetite	12 (10%)	-	-		

- No clear evidence that any observed toxicity is drug related
- No related seizures one case of convulsion was reported 27 days after stopping treatment
- Safety profile after longer treatment period remains similar





ODM-103 and ODM-104 for Parkinson's disease



#### ODM-103 and -104 for Parkinson's disease

#### ODM-103, more effective COMT-inhibitor

#### Pre-clinical study

Pre-clinical study results indicated that ODM-103 is more effective than entacapone

Phase I Safety study ongoing in Europe since summer 2012

#### ODM-104, more effective COMT-inhibitor

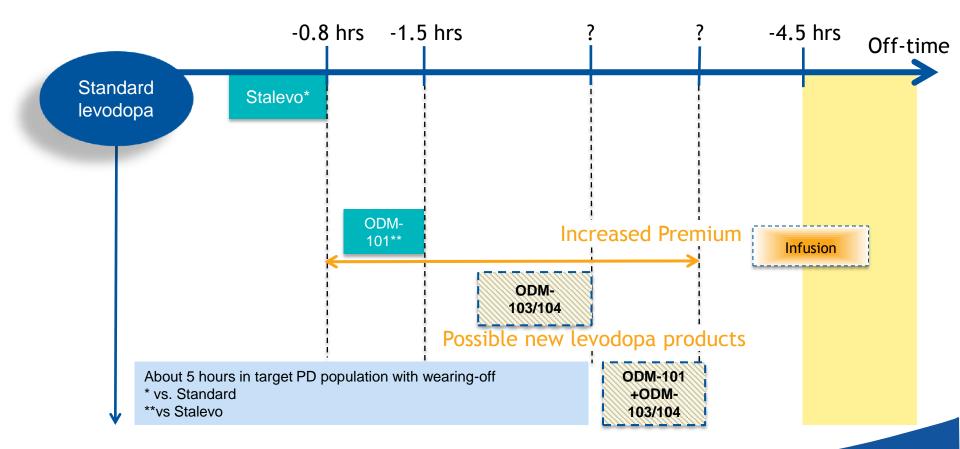
#### Pre-clinical study

Pre-clinical study results indicated that ODM-104 is more effective than entacapone

Phase I Safety study ongoing in Europe since summer 2013



Target is to develop the best possible peroral levodopa product to increase premium for market access - improved efficacy / reduced OFF-time







Proprietary
Products and
Specialty Products
update



# Product protection situation of key products

Key patents or data protection expire

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

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

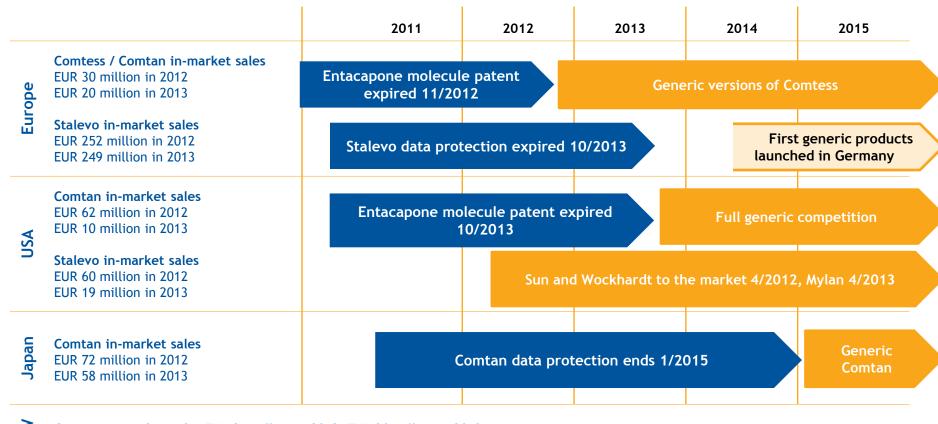


<sup>&</sup>lt;sup>2)</sup> Data protection of Comtan expires;

<sup>3)</sup> Dexdor data protection expires

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

## Turning points of Parkinsons's franchise



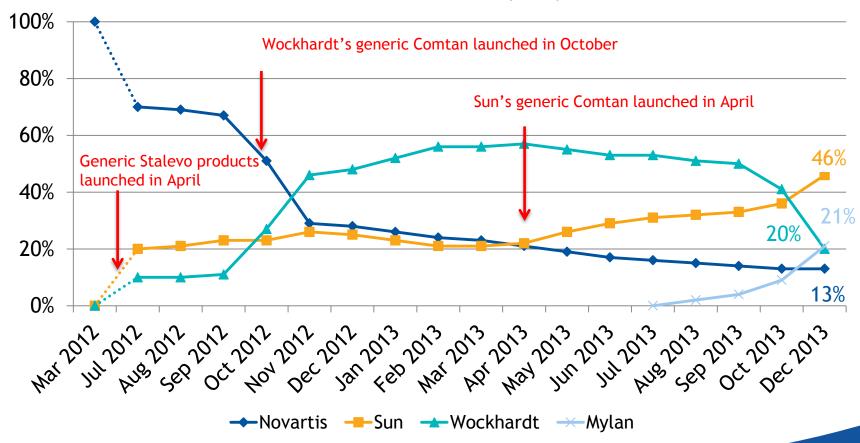
Comtan in-market sales EUR 24 million in 2012, EUR 20 million in 2013 Stalevo in-market sales EUR 79 million in 2012, EUR 76 million in 2013

Source: IMS Health 2013



## Rx value shares in USA after generic launches

Total Rx value in USA - all entacapone products

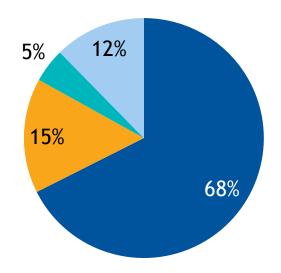




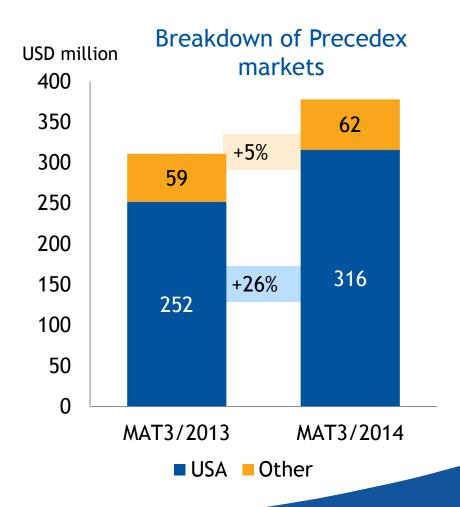
## Precedex® and dexdor® intensive care sedatives

## European sedative market MAT3/2014

Total market value EUR 479 million (+1.4%)

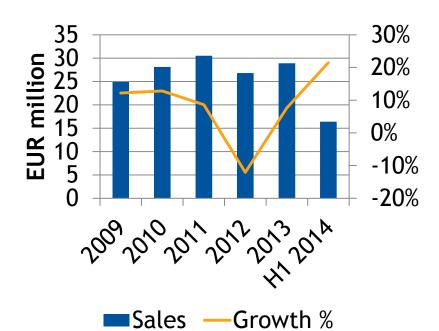


- Propofol EUR 323 million (+4%)
- Midazolam EUR 74 million (-5%)
- Dexmedetomidine EUR 22 million (+46%)
- Remifentanil EUR 59 million (-13%)





## Easyhaler® for asthma and COPD



- 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)



2004 Formoterol Easyhaler® (formoterol)



1994 Beclomet Easyhaler® (beclomethasone)



2014 Bufomix Easyhaler® (budesonideformoterol)



2002 Buventol Easyhaler® (budesonide)

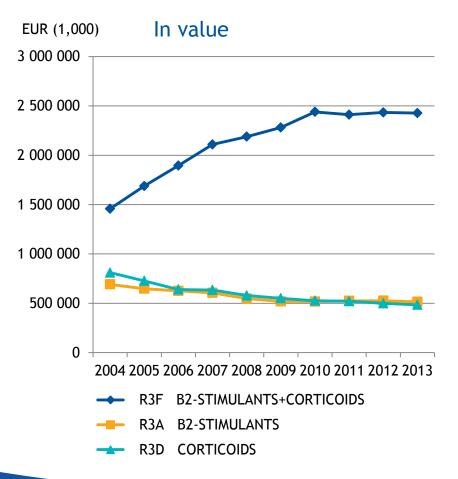


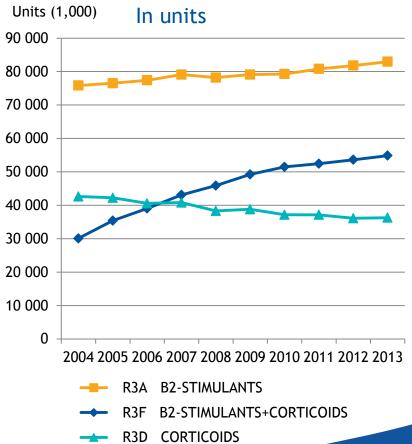
2010→
Development of fluticasonesalmeterol





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



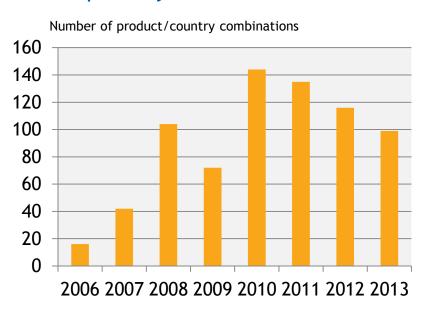


Source: IMS Health 2013



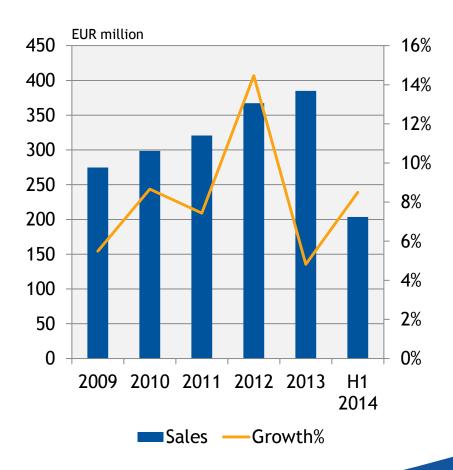
## Launches are basis for future growth in SpP

## **Specialty Products launches**



#### SpP launches in 2013

By geographic area
Eastern Europe 27
Scandinavia 37
Finland 26
Other 9



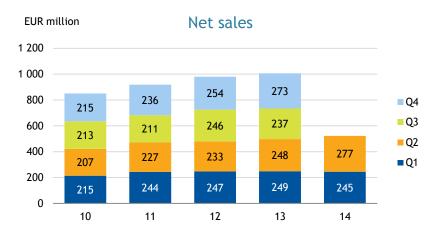


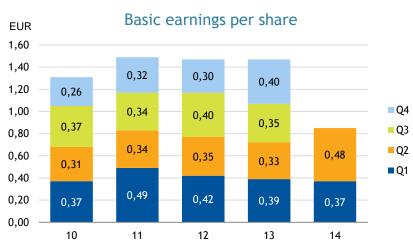


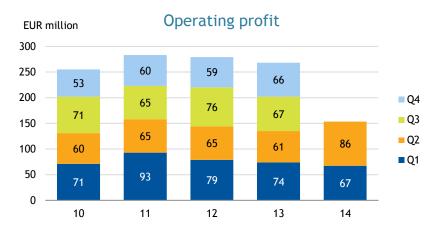
# Key financials

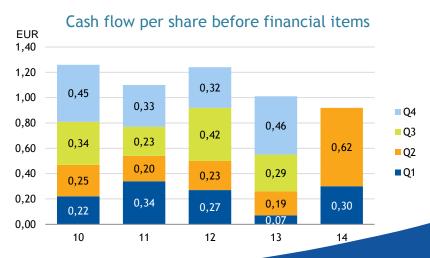


# Key figures by quarter











# Key figures for 2010—Q2/2014

Orion's key figures	2010	2011	2012	2013	Q1-Q2/2014	Q1-Q2/2013	Change %
Net sales, EUR million	849.9	917.9	980.4	1,006.9	521.7	497.4	+4.9%
Operating profit, EUR million	254.2	282.9	278.3	267.7	153.4	135.2	+13.4%
Profit before taxes, EUR million	252.6	282.0	276.6	264.0	151.2	134.3	+12.6%
R&D expenses, EUR million	85.5	87.5	105.8	101.9	56.9	50.9	+11.6%
Equity ratio, %	62.7%	64.2%	61.0%	53.6%	51.3%	48.1%	
Gearing, %	-12.2%	-6.9%	-1.7%	8.4%	18.9%	32.7%	
ROCE (before taxes), %	45.0%	49.4%	45.9%	38.5%	42.1%	41.0%	
Return on equity, %	40.7%	43.3%	41.0%	40.3%	49.3%	43.3%	
Basic earnings per share, EUR	1.31	1.49	1.47	1.46	0.86	0.72	+19.3%
Cash flow per share before financial items, EUR	1.26	1.10	1.23	1.02	0.93	0.27	+247.9%
Dividend per share, EUR	1.20	1.30	1.30	1.25			
Capital repayment per share, EUR	0.06	0.12					



# Income Statement 2010—Q2/2014

Formation of profits, EUR million	2010	2011	2012	2013	Q1-Q2/2014	Q1—Q2/2013	Change %
Net sales	849.9	917.9	980.4	1,006.9	521.7	497.4	+4.9%
Cost of goods sold	-283.2	-305.1	-350.8	-393.5	-195.3	-190.6	+2.4%
Gross profit	566.8	612.8	629.6	613.4	326.4	306.8	+6.4%
Other operating income and expenses	1.2	3.0	6.3	5.6	0.7	1.7	-61.8%
Sales and marketing expenses	-188.9	-204.8	-206.1	-204.9	-95.5	-99.7	-4.2%
R&D expenses	-85.5	-87.5	-105.8	-101.9	-56.9	-50.9	+11.6%
Administrative expenses	-39.3	-40.6	-45.7	-44.5	-21.3	-22.7	-6.0%
Operating profit	254.2	282.9	278.3	267.7	153.4	135.2	+13.4%
Profit before taxes	252.6	282.0	276.6	264.0	151.2	134.3	+12.6%
Profit for the period	184.7	209.5	206.9	206.2	120.7	101.4	+18.9%

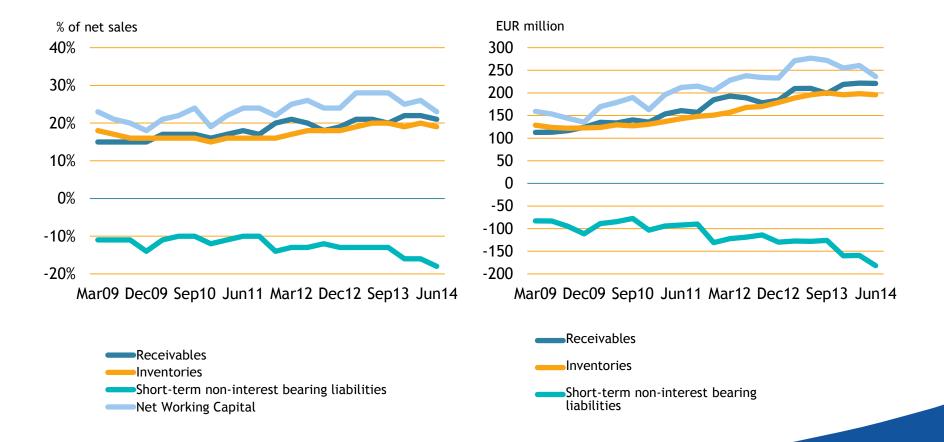


# Financial position

EUR million	6/14	6/13	Change%	EUR million	6/14	6/13	Change%
Non-current assets total	360.5	341.3	+5.7%				
Inventories	196.2	196.2		Equity total	464.1	427.4	+8.6%
Trade receivables	175.1	163.8	+6.9%	Interest-bearing non- current liabilities	227.4	250.5	-9.2%
Other receivables	46.3	47.9	-3.5%	Non-current liabilities total	260.8	295.1	-11.6%
Cash and cash equivalents	161.9	123.6	+31.0%	Current liabilities total	218.0	165.2	+32.0%
Current assets total	582.4	546.5	+6.6%	Liabilities total	478.8	460.3	+4.0%
Assets total	943.0	887.7	+6.2%	Equity and liabilities total	943.0	887.7	+6.2%



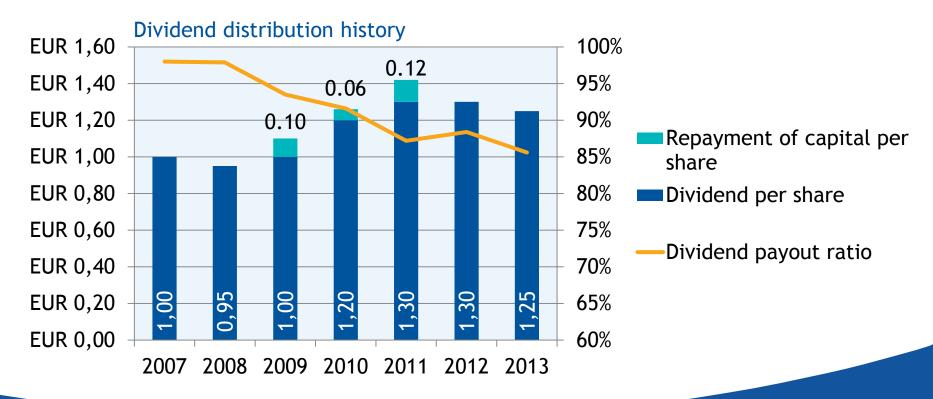
## Development of Net working capital





## 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.







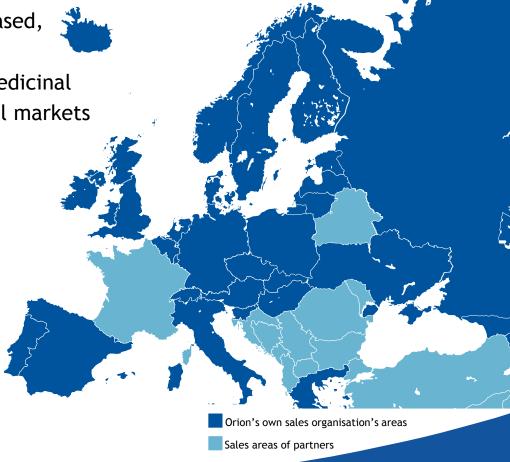
# General info



# 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	2013		
Net sales	EUR 1 007 million		
Operating profit	EUR 268 million		
R&D expenses	EUR 102 million		
No. of personnel (at end of)	3,519		
in Finland	2,816		
in other countries	703		





## **Business** units



## **Proprietary Products**

- Patented prescription drugs
- CTAs: CNS, oncology & critical care, Easyhaler pulmonary drugs
- Net sales in 2013 EUR 390 million



#### Fermion

- Active pharmaceutical ingredients (API's) for Orion and other companies
- Net sales in 2013 EUR 64 million (excluding supplies for own use)



## **Specialty Products**

- Generic prescription drugs
- Self-care products
- Net sales in 2013 EUR 385 million



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

- Pharmaceutical manufacturing for other companies
- Net sales in 2013 EUR 43 million



### **Animal Health**

- Veterinary medicines and care products for pets and production animals
- Net sales in 2013 EUR 71 million



## Orion Diagnostica

- Diagnostic test systems for point-ofcare testing in healthcare and hygiene testing for industry
- Net sales in 2013 EUR 57 million
- 1) 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** 

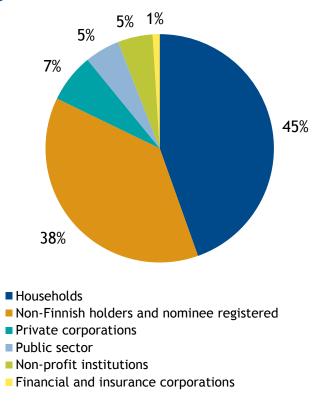
Progress with proprietary products in hospital markets



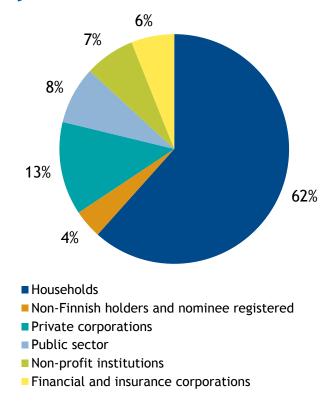


## Orion shares are broadly held

## By number of shares on 30 Jun



## By number of votes on 30 Jun

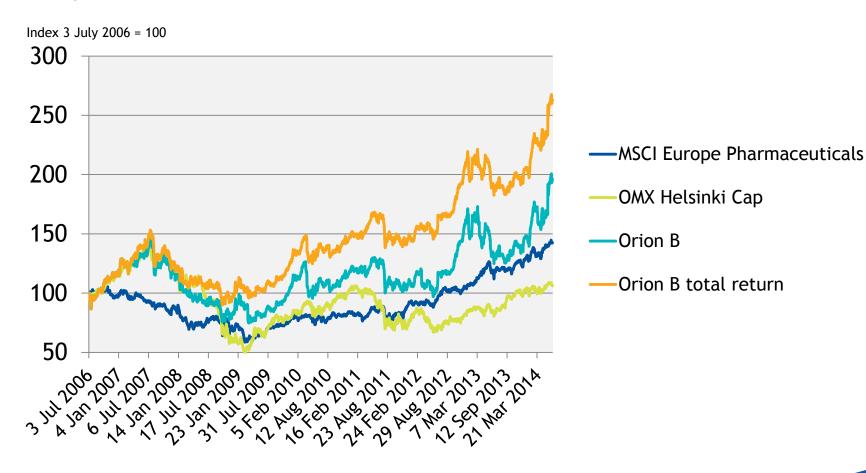


Altogether 141.3 million shares and ca. 54,000 shareholders. Both share classes, A and B, are listed on NASDAQ OMX Helsinki since 1 July 2006. A share (ORNAV) has 20 votes/share and B share (ORNBV) has 1 vote/share in the AGM, but they have equal rights to assets and dividends.



# Orion B share performance

3 July 2006— 30 Jun 2014







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# Orion Investor Relations

