#### Company presentation for investors

FY 2014



#### 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 forwardlooking 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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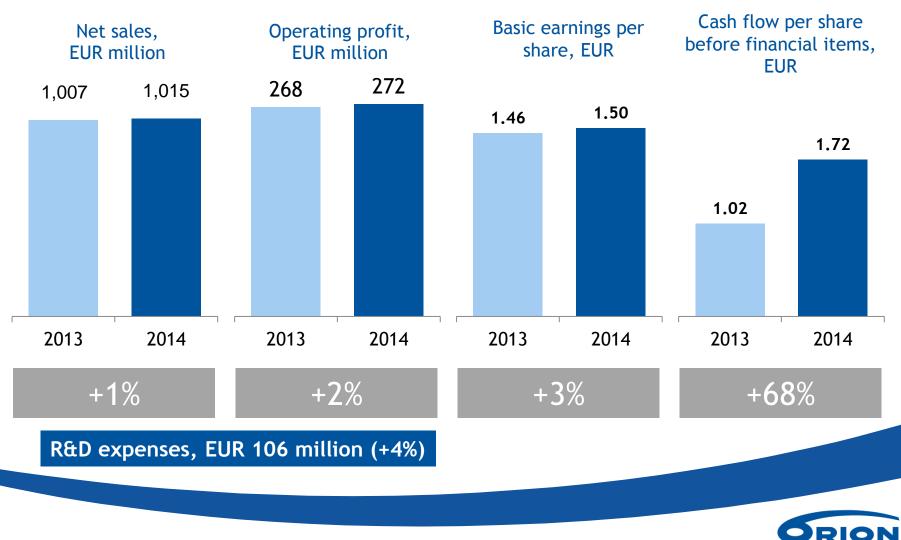
# Good year in pharmaceutical development and commercialisation projects

- Marketing authorisations for Bufomix Easyhaler in Europe and Stalevo in Japan
- Worldwide collaboration with Bayer on ODM-201 development and commercialisation
- Early phase clinical development pipeline boosted
- Specialty Products sales grew well
- Commencement of generic competition to Precedex in USA and to Stalevo in Germany
- Net sales and operating profit include EUR 39 million of milestone payments
- Board's proposal for dividend per share is EUR 1.30







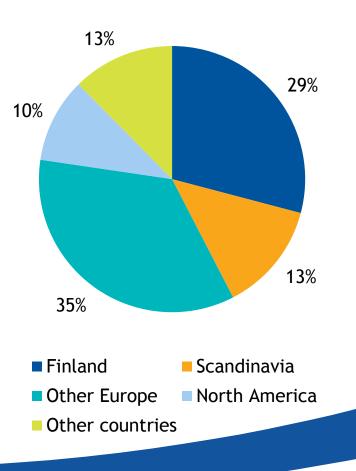


**Building well-being** 

#### Net sales originate mainly in Europe Breakdown of EUR 1,015 million net sales in 2014

Key figures by business divisions	2014	Change %
Net sales of Pharmaceuticals, EUR million	962	+1%
Proprietary Products	373	-4%
Specialty Products	427	+11%
Animal Health	70	-1%
Fermion	57	-10%
Contract manufacturing & other	34	-21%
Pharmaceuticals operating profit, EUR million	276	+1%
Net sales of Diagnostics business, EUR million	56	-1%
Operating profit of Diagnostics business, EUR million	6.4	+38%

Sales split by market area





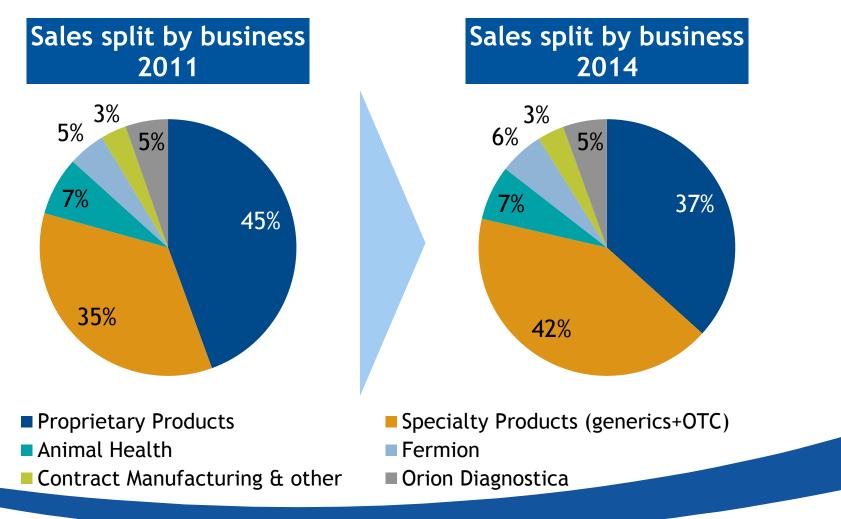
## Best-selling pharmaceuticals 2014

	Net sales, EUR n	nillion				2013
Stalevo <sup>®</sup> , Comtess <sup>®</sup> & Comtan <sup>®</sup> (Parkinson's disease)	-18%				169	207
Simdax <sup>®</sup> (acute decompensated heart failure)	+2%				47	46
Easyhaler <sup>®</sup> product family (asthma, COPD)	+22%			35		29
<i>dexdor</i> ® (intensive care sedative)	+39%			35		25
Precedex <sup>®</sup> (intensive care sedative)	-50%		30			59
Generic entacapone products (Parkinson's disease)	+151%		26			10
Dexdomitor <sup>®</sup> , Domitor <sup>®</sup> , Domosedan <sup>®</sup> and Antisedan <sup>®</sup> (animal sedatives)	-1%		25			25
Burana® (inflammatory pain)	-0%	23				23
Marevan® (anticoagulant)	+7%	17				16
Divina® range (menopausal symptoms)	-1%	15				15
Total	44% of pharma	ceuticals net	sales		422	

Products based on Orion's inventions in blue font

**ORION** Building well-being

#### Product mix is changing





## Outlook for 2015

Net sales	Net sales will be slightly lower than in 2014 (net sales were EUR 1,015 million in 2014).
Operating profit	Operating profit is estimated to exceed EUR 200 million.
Group's capital expenditure	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

Ageing population	Advancements in science					
Cost burden in healthcare	Launching innovative and cost-effective pharmaceuticals and treatment methods for patients		Working together for our <b>Customers</b>	Ó	Succeeding Together!	
Increased personal responsibility for health	Continuously improving our performance in sustainability	<b>Growing</b> faster than the market		Quality and safety	Productivity and flexibility	Strengthening our position in Europe
	Strong development of <b>profitability</b> is a target		Partnerships	Competitive product portfolio		Management of net working capital
Megatr	ends	Strate	egic targets		Top Supply Chain	The best R&D
Focus a	areas	Strate	egic developme	ent projects		



#### Orion's financial objectives

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

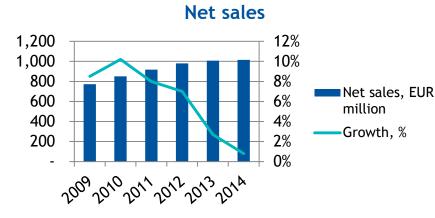
Maintaining profitability at a good level. The aim is operating profit that exceeds 20% of net sales.

Keeping the equity ratio at least 50%.

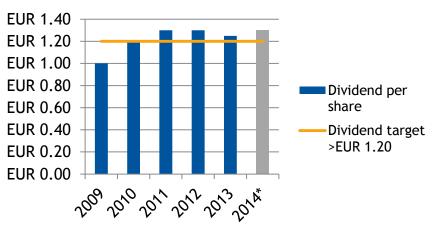
Distributing an annual dividend that in the next few years will be at least EUR 1.20 per share, and increasing the dividend in the long term.



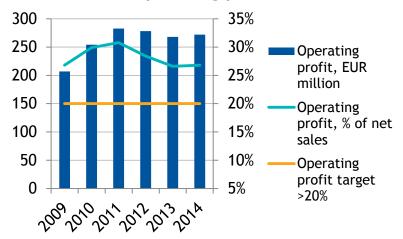
### Orion's financial objectives



#### Dividend

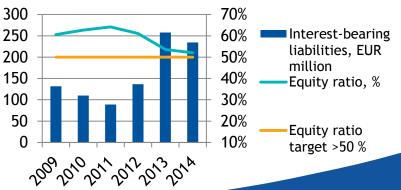


\*) Dividend proposal by the Board of Directors



#### **Operating profit**

Equity ratio and interest-bearing liabilities





#### Balancing mid-term - building long-term

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

Generic competition for Parkinson's franchise and Precedex.

Timing of milestone payments.

Generic drugs and self-care products.

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

Global pricing pressure, especially on new products.

#### Operational flexibility and efficiency.



Orion R&D long term opportunities

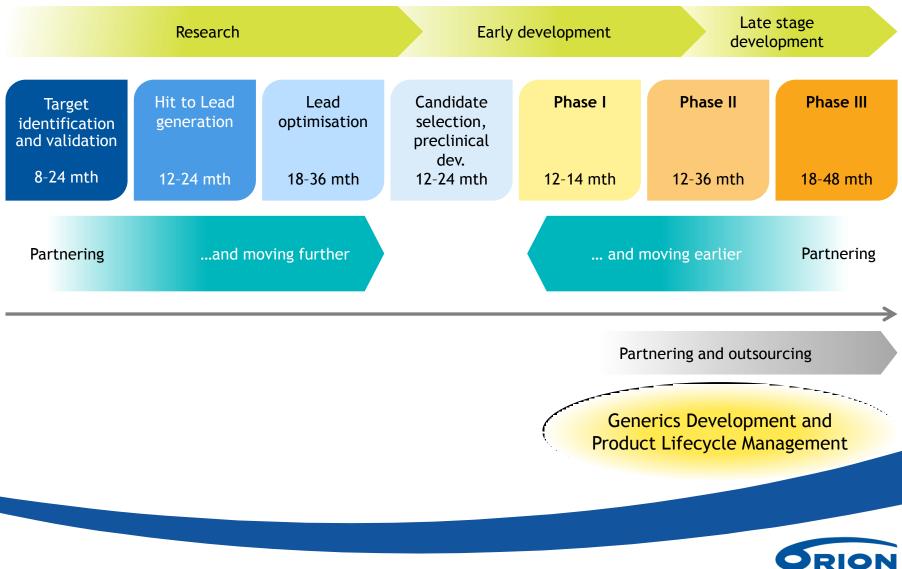


## Orion's R&D strategy

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	<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	<ul> <li>In-house R&amp;D covers mainly late-stage research and early-stage development phases</li> <li>i.e. discovery, preclinical phase and clinical phases I and II</li> </ul>
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-licensing of drug candidates or products



## Collaborative networks across the R&D value chain



**Building well-being** 

# Key clinical pharmaceutical development projects

Project	Indication		PHASE		Registration
Bufomix Easyhaler <sup>®</sup> (budesonide-formoterol) <sup>1)</sup>	Asthma, COPD		Ш	Ш	
Easyhaler <sup>®</sup> salmeterol-fluticasone	Asthma, COPD	I.	Ш	Ш	
ODM-201 (androgen receptor inhibitor) <sup>2)</sup>	Prostate cancer	I	Ш	Ш	
Levosimendan <sup>3)</sup>	Low Cardiac Output Syndrome	I	Ш	III	
ORM-12741 (alpha-2c adrenoceptor antagonist) <sup>4)</sup>	Alzheimer's disease		lla		
Dexmedetomidine (intranasal) <sup>5)</sup>	Treatment of pain		llb		
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				
<sup>1)</sup> Aim is to obtain marketing authorisation for product in at	•		= Pha	se con	npleted
countries not included in decentralised marketing authorisation application process.			= Pha	se ong	oing

<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.



# Research projects 2013 (16)

HIT Finding	Active-To-Hit	Hit-To-Lead	Lead Optimization		
0 0		· :		0 0	
Oncology A		- 		•	
Oncology B					
Oncology C				•	
Oncology D					> •
CNS A					
CNS B	٥	0	• •		
CNS C	•			0 0 0	•
CNS D					•
CNS E					•
CNS F	0			0 0 0	•
CNS G		0 0	0 0 0 0 0	0 0 0	•
CNS H		0 0 0		0 0 0	•
CNS I		0 0 0		0 0 0	•
CNS J		0 0 0		0 0 0	•
CNS H Super g	eneric			•	•
	Biologic) for new indic	ation			•
Snapshot of Or	ion's preclinical pipelir	ne presented at Orion	Precandidate	Candidate	СТА
Capital Market	s Day on 20 November	2013.			
					SPIC
	EV2044				

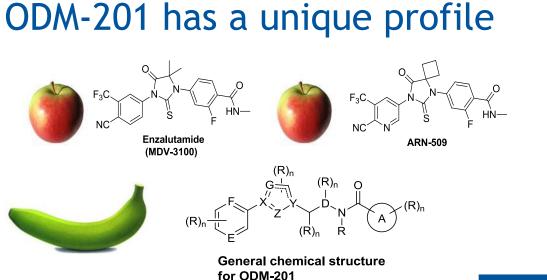
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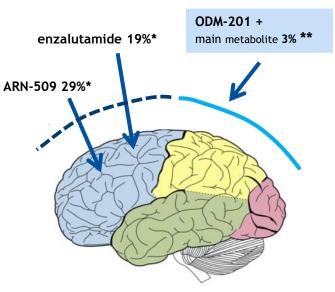
**Building well-being** 

# 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







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

\*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 Source: ECC2013 poster E17-2119



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

#### 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 levodopainduced dyskinesia in patients with Parkinson's disease, without causing sedation.



#### 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 castrationresistant 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

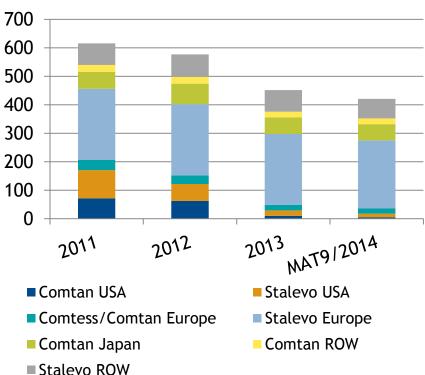
Molecule	Product	Indication	Europe	USA	Japan
Entacapone	Stalevo <sup>®</sup> , Comtess <sup>®</sup> and Comtan <sup>®</sup>	Parkinson's disease	November 2012 October 2013 <sup>1)</sup>	October 2013	January 2015 <sup>2)</sup>
Levosimendan	Simdax®	Acute decompensated heart failure	September 2015	Not marketed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

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

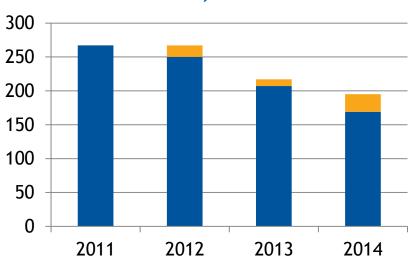
<sup>4)</sup> Six months paediatric exclusivity granted for Precedex in the United States expired



## Turning points of Parkinson's franchise



#### Annual in-market sales, EUR million\*



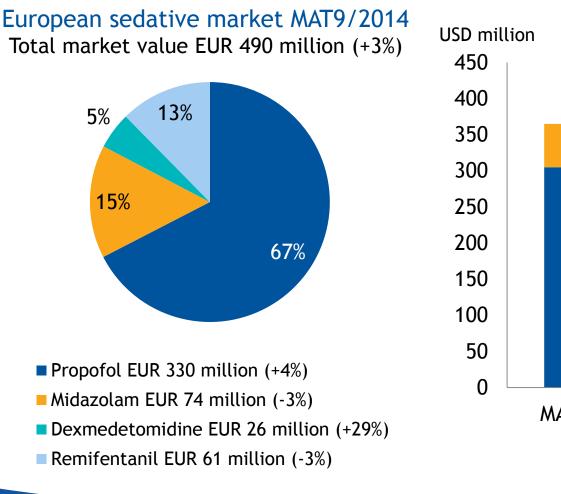
Orion sales, EUR million

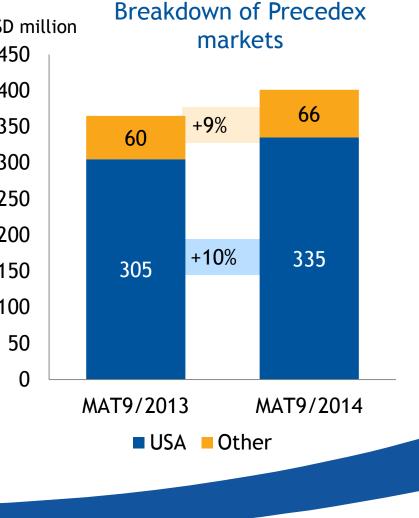
■ Generic entacapone ■ Stalevo, Comtess & Comtan

	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

\*Source: IMS Health MAT9/2014

#### Precedex® and *dexdor*® intensive care sedatives

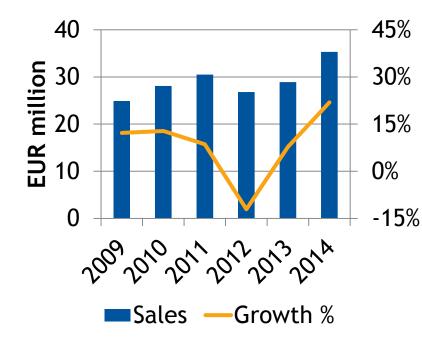




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Source: IMS Health MAT9/2014

## 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

(budesonide-

Easyhaler®

formoterol)

2002 Buventol Easyhaler® (budesonide)

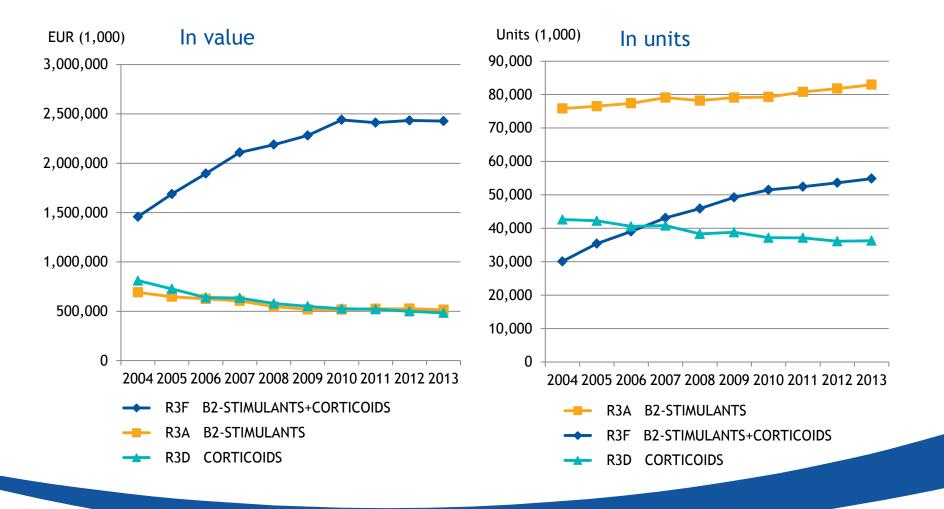


2010→ Development of fluticasonesalmeterol





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

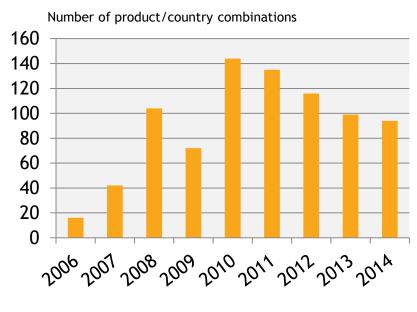




Source: IMS Health 2013

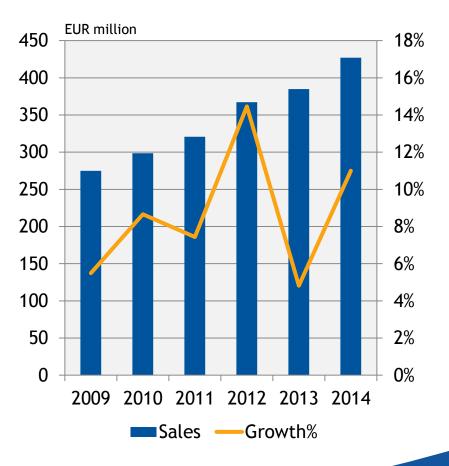
## Launches are basis for future growth in SpP

#### Specialty Products launches



#### SpP launches in 2014

By geographic	area
Eastern Europe	26
Scandinavia	35
Finland	27
Other	6

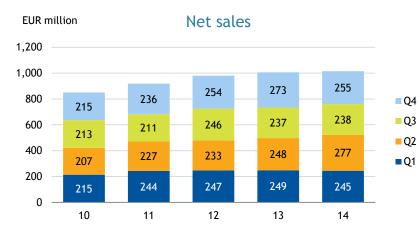


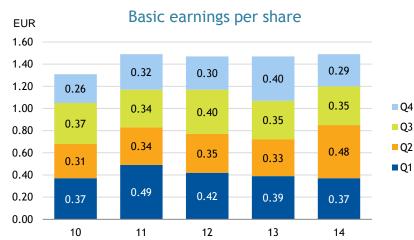


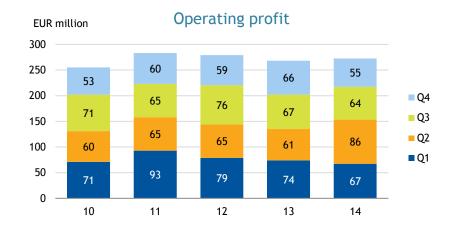


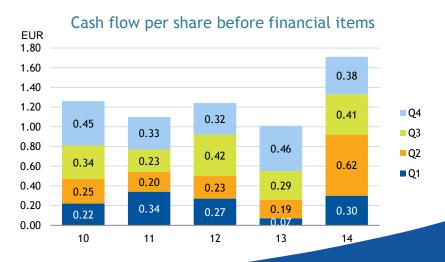


## Key figures by quarter











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### Key figures for 2010–2014

Orion's key figures	2010	2011	2012	2013	2014	Change %
Net sales, EUR million	849.9	917.9	980.4	1,006.9	1,015.3	+0.8%
Operating profit, EUR million	254.2	282.9	278.3	267.7	272.4	+1.8%
Profit before taxes, EUR million	252.6	282.0	276.6	264.0	267.8	+1.4%
R&D expenses, EUR million	85.5	87.5	105.8	101.9	106.2	+4.2%
Equity ratio, %	62.7%	64.2%	61.0%	53.6%	52.3%	
Gearing, %	-12.2%	- <b>6.9</b> %	-1.7%	8.4%	-4.7%	
ROCE (before taxes), %	45.0%	<b>49.</b> 4%	45.9%	38.5%	36.6%	
Return on equity, %	40.7%	43.3%	41.0%	40.3%	41.1%	
Basic earnings per share, EUR	1.31	1.49	1.47	1.46	1.50	+2.7%
Cash flow per share before financial items, EUR	1.26	1.10	1.23	1.02	1.72	+68.4%
Dividend per share, EUR	1.20	1.30	1.30	1.25	1.30*	
Capital repayment per share, EUR	0.06	0.12				

\*) Dividend proposal by the Board of Directors



### Income Statement 2010–2014

Formation of profits, EUR million	2010	2011	2012	2013	2014	Change %
Net sales	849.9	917.9	980.4	1,006.9	1,015.3	+0.8%
Cost of goods sold	-283.2	-305.1	-350.8	-393.5	-401.7	+2.1%
Gross profit	566.8	612.8	629.6	613.4	613.6	
Other operating income and expenses	1.2	3.0	6.3	5.6	1.7	-68.8%
Sales and marketing expenses	-188.9	-204.8	-206.1	-204.9	-193.4	-5.6%
R&D expenses	-85.5	-87.5	-105.8	-101.9	-106.2	+4.2%
Administrative expenses	-39.3	-40.6	-45.7	-44.5	-43.3	-2.7%
Operating profit	254.2	282.9	278.3	267.7	272.4	+1.8%
Profit before taxes	252.6	282.0	276.6	264.0	267.8	+1.4%
Profit for the period	184.7	209.5	206.9	206.2	211.3	+2.5%

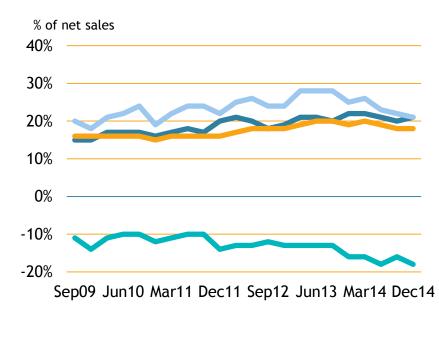


### Financial position

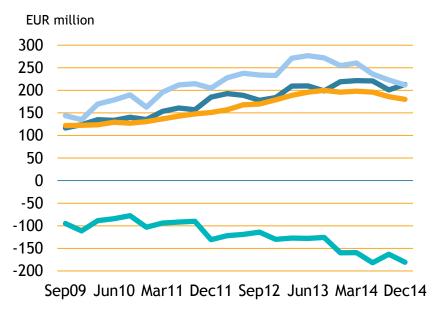
EUR million	12/14	12/13	Change%	EUR million	12/14	12/13	Change%
Non-current assets total	349.1	349.2					
Inventories	178.7	195.5	-8.6%	Equity total	514.9	513.9	+0.2%
Trade receivables	174.0	169.9	+2.4%	Interest-bearing non- current liabilities	210.0	233.3	-10.0%
Other receivables	41.2	49.7	-17.1%	Non-current liabilities total	271.8	267.6	+1.6%
Cash & cash equivalents & money market investments	258.5	214.7	+20.4%	Current liabilities total	196.5	165.3	+18.8%
Current assets total	652.4	629.8	+3.6%	Liabilities total		465.1	
	032.4	027.0	+3.0%	Equity and liabilities	486.5	403.1	-0.3%
Assets total	1,001.5	979.0	+2.3%	total	1,001.5	979.0	+2.3%



### Development of Net working capital



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

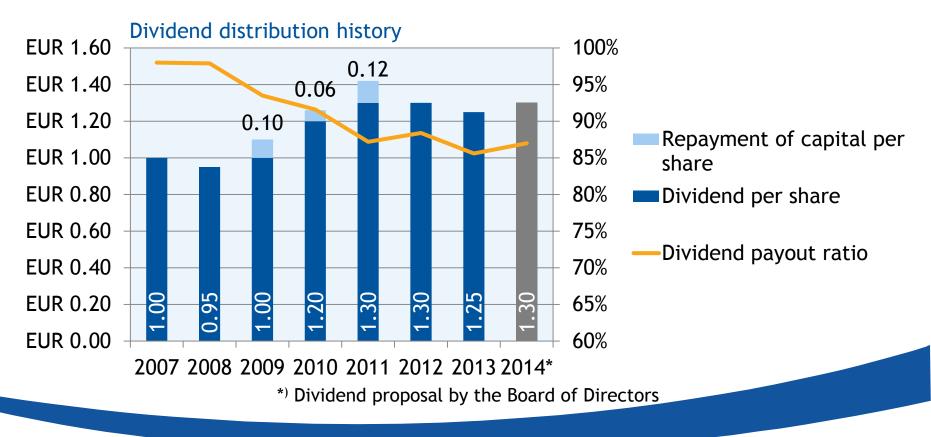


- Receivables
- Inventories
- Short-term non-interest bearing liabilities
- -----Net Working Capital



### **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.









### 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			



5

Sales areas of partners



### **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 Net sales in 2014 EUR 57 million



### **Specialty Products**

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



# Other<sup>1)</sup>



#### 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-ofcare 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

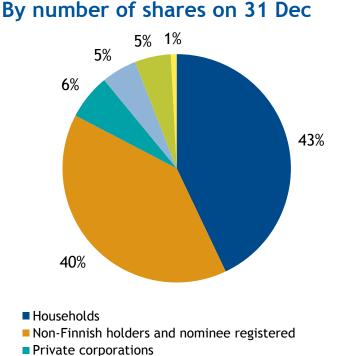
Western and Central Europe Strong position with proprietary products

Southern Europe Progress with proprietary products in hospital markets



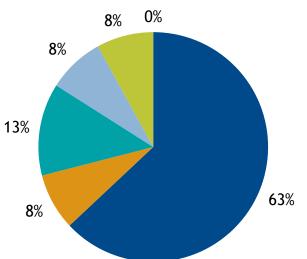


### Orion shares are broadly held



- Public sector
- Non-profit institutions
- Financial and insurance corporations

#### By number of votes on 31 Dec



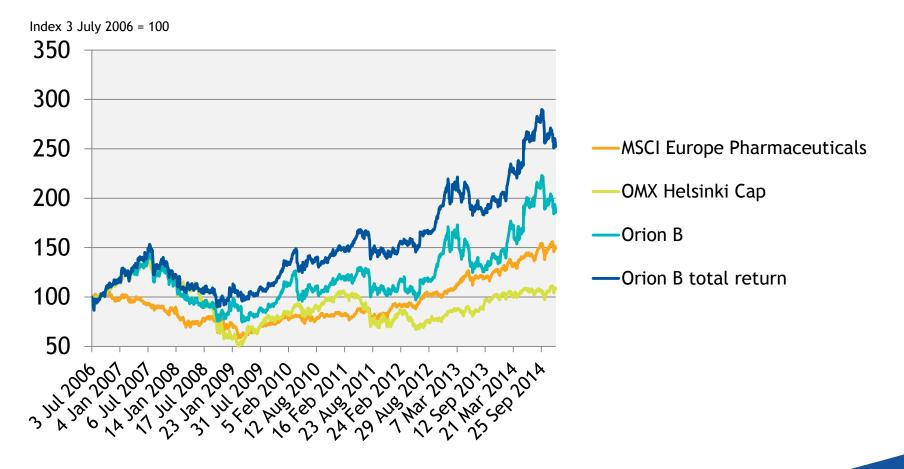
- Households
- Non-Finnish holders and nominee registered
- Private corporations
- Public sector
- Non-profit institutions
- Financial and insurance corporations

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.



Monthly updated info available at: <u>http://orion.fi/en/Orion-</u> group/investors/shareholders/ownership-structure/

### Orion B share performance 3 July 2006– 31 Dec 2014





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### Orion Investor Relations

