### Company presentation for investors

2014 Q1-Q3



### 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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## Advances in pharmaceutical development projects

- Net sales and operating profit include significant milestone payments received from collaboration partners that were higher than in previous year
- Good growth in Specialty Products sales
- First generic competitors to Precedex entered US markets
- Recruiting of patients for ODM-201 Phase III clinical trial started (ARAMIS)
- Out of two COMT inhibitors, ODM-104 was selected for further development
- Phase I clinical trial of new FGFR+VEGFR inhibitor (ODM-203) for treatment of cancers started









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### Net sales originate mainly in Europe Breakdown of EUR 760 million net sales in Q1-Q3/2014

Key figures by business divisions	Q1-Q3/ 2014	Change %
Net sales of Pharmaceuticals, EUR million	721	+4%
Proprietary Products	285	-0%
Specialty Products	310	+11%
Animal Health	50	-5%
Fermion	46	-1%
Contract manufacturing & other	29	-5%
Pharmaceuticals operating profit, EUR million	219	+7%
Net sales of Diagnostics business, EUR million	42	-4%
Operating profit of Diagnostics business, EUR million	4.9	+25%

Sales split by market area





# Best-selling pharmaceuticals Q1-Q3/2014

	Net sales,	EUR milli	ion				2013
Stalevo®, Comtess® & Comtan® (Parkinson's disease)	-17%					130	207
Simdax® (acute decompensated heart failure)	+5%				35		46
Precedex® (intensive care sedative)	-39%			25			59
<i>dexdor</i> ® (intensive care sedative)	+37%			25			25
Easyhaler® product family (asthma, COPD)	+18%			25			29
Generic entacapone products (Parkinson's disease)	+187%		20				10
Burana® (inflammatory pain)	-2%		17				23
Dexdomitor®, Domitor®, Domosedan® and Antisedan® (animal sedatives)	-12%		16				25
Marevan® (anticoagulant)	+7%	13					16
Divina® (menopausal symptoms)	-3%	10					15
Total	44% of ph	armaceu	iticals ne	t sales		314	

Products based on Orion's inventions in blue

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## Product mix is changing





## Outlook for 2014 (unchanged)

Net sales	Net sales will be at similar level to 2013 (net sales in 2013 were EUR 1,007 million)
Operating profit	Operating profit will be at similar level to 2013 (operating profit in 2013 was EUR 268 million)
Group's capital expenditure	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





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## Balancing mid-term – building long-term





## 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**







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



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# Key clinical pharmaceutical development projects

Project	Indication	PHASE			Registration
Bufomix Easyhaler <sup>®</sup> (budesonide-formoterol) <sup>1)</sup>	Asthma, COPD		II	Ш	
Easyhaler <sup>®</sup> salmeterol-fluticasone	Asthma, COPD		Ш	Ш	
ODM-201 (androgen receptor inhibitor) <sup>2)</sup>	Prostate cancer		Ш	Ш	
Levosimendan <sup>3)</sup>	Low Cardiac Output Syndrome	I	Ш	Ш	
ORM-12741 (alpha-2c adrenoceptor antagonist) $^{4)}$	Alzheimer's disease		lla		
Dexmedetomidine <sup>5)</sup> (intranasal)	Treatment of pain		llb		
ODM-104 (more effective COMT inhibitor)	Parkinson's disease				
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumors				
<sup>1)</sup> Aim is to obtain marketing authorisation for prod	luct in at least some European		= Phas	e comp	leted

<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 ongoing

17 Investor Presentation 2014 Q1-Q3 More info at: <u>http://www.orion.fi/en/rd/orion-rd/pipeline/</u>

# Research projects 2013 (16)

HIT Finding	Active-To-Hit	Hit-To-Lead	Lead Optimization		
0 0				•	•
Oncology A		0 0 0		•	
Oncology B					
Oncology C				• •	
Oncology D					
CNS A					
CNS B					•
CNS C				•	•
CNS D	•				•
CNS E				0 0 0	•
CNS F	0	•		0 0 0	•
CNS G		0 0 0		0 0 0	•
CNS H		0 0 0	6 0 6 0 6 0 6 0 6 0 6 0	0 0 0	•
CNS I		0 0 0	• • • • • • • • • • • • • • • • • • •	0 0 0	•
CNS J		0 0 0		•	•
CNS H Super g	generic			•	•
	(Biologic) for new indic	cation			•
Snapshot of O	rion's preclinical pipeli ts Day on 20 November	ne presented at Orior	<b>Precandidate</b> า	Candidate	СТА
9 Jayraatar Dra	antation 2014 01 02				<b>D</b> RIC

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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







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, 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 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



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



	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 ends in January 2015

\*Source: IMS Health MAT6/2014

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





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## 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 2013

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





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# Key figures by quarter











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# Key figures for 2010–Q3/2014

Orion's key figures	2010	2011	2012	2013	Q1-Q3/2014	Q1–Q3/2013	Change %
Net sales, EUR million	849.9	917.9	980.4	1,006.9	760.0	734.3	+3.5%
Operating profit, EUR million	254.2	282.9	278.3	267.7	217.2	201.8	+7.6%
Profit before taxes, EUR million	252.6	282.0	276.6	264.0	214.0	199.6	+7.2%
R&D expenses, EUR million	85.5	87.5	105.8	101.9	77.9	72.2	+8.0%
Equity ratio, %	62.7%	64.2%	61.0%	53.6%	55.3%	51.5%	
Gearing, %	-12.2%	- <b>6.9</b> %	-1.7%	8.4%	5.7%	20.5%	
ROCE (before taxes), %	45.0%	49.4%	<b>45.9</b> %	38.5%	38.7%	39.4%	
Return on equity, %	40.7%	43.3%	41.0%	40.3%	44.1%	40.7%	
Basic earnings per share, EUR	1.31	1.49	1.47	1.46	1.21	1.07	+13.6%
Cash flow per share before financial items, EUR	1.26	1.10	1.23	1.02	1.34	0.56	+138.6%
Dividend per share, EUR	1.20	1.30	1.30	1.25			
Capital repayment per share, EUR	0.06	0.12					



## Income Statement 2010–Q3/2014

Formation of profits, EUR million	2010	2011	2012	2013	Q1–Q3/2014	Q1—Q3/2013	Change %
Net sales	849.9	917.9	980.4	1,006.9	760.0	734.3	+3.5%
Cost of goods sold	-283.2	-305.1	-350.8	-393.5	-295.5	-286.9	+3.0%
Gross profit	566.8	612.8	629.6	613.4	464.5	447.4	+3.8%
Other operating income and expenses	1.2	3.0	6.3	5.6	-0.3	3.4	-109.4%
Sales and marketing expenses	-188.9	-204.8	-206.1	-204.9	-137.9	-144.7	-4.7%
R&D expenses	-85.5	-87.5	-105.8	-101.9	-77.9	-72.2	+8.0%
Administrative expenses	-39.3	-40.6	-45.7	-44.5	-31.2	-32.1	-2.8%
Operating profit	254.2	282.9	278.3	267.7	217.2	201.8	+7.6%
Profit before taxes	252.6	282.0	276.6	264.0	214.0	199.6	+7.2%
Profit for the period	184.7	209.5	206.9	206.2	170.4	150.5	+13.2%



## Financial position

EUR million	9/14	9/13	Change%	EUR million	9/14	9/13	Change%
Non-current assets total	362.7	352.7	+2.8%				
Inventories	185.2	199.6	-7.2%	Equity total	515.6	477.4	+8.0%
Trade receivables	164.1	157.9	+3.9%	Interest-bearing non- current liabilities	217.5	240.8	-9.7%
Other receivables	37.9	43.7	-13.4%	Non-current liabilities total	251.3	284.0	-11.5%
Cash & cash equivalents & money market investments				Current liabilities total			
Current assets total	213.6	172.8	+23.6%	Liabilities total	196.5	165.3	+18.8%
	600.7	574.1	+4.6%	Equity and liabilities	447.8	449.3	-0.3%
Assets total	963.4	926.8	+4.0%	total	963.4	926.8	+4.0%



# Development of Net working capital







Short-term non-interest bearing liabilities

Receivables

Inventories



# **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.



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## 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		



Orion's own sales organisation's areas

Sales areas of partners



## **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
   Not sales in 2012 EUP 42 million
- Net sales in 2013 EUR 43 million



### Animal Health

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

• 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



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

### By number of votes on 30 Sep



- 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. 52,400 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– 30 Sep 2014





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