### Company presentation for investors

Q1/2013



### 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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### Results & Outlook Q1/2013



### First quarter as anticipated

- Net sales similar to comparative period of previous year
- Operating profit slightly lower than in previous year as expected
- In March Orion submitted a marketing authorisation application for a budesonide-formoterol combined formulation in the Easyhaler<sup>®</sup> product family in Europe
- After the review period Orion Diagnostica commenced negotiations to streamline company operations and improve profitability



# Key figures for Q1/2013 and FY 2012

	Q1/13	Q1/12*	Change %	2012*	2011	Change %
Net sales, EUR million	249.4	247.4	+0.8%	980.4	917.9	+6.8%
Operating profit, EUR million	74.1	78.6	-5.7%	278.3	282.9	-1.6%
% of net sales	<b>29.7</b> %	31.8%		28.4%	30.8%	
R&D expenses, EUR million	24.6	23.1	+6.7%	105.8	87.5	+20.9%
% of net sales	9.9%	9.3%		10.8%	<b>9.</b> 5%	
Basic earnings per share, EUR	0.39	0.42	-6.1%	1.47	1.49	-1.3%
Coch flow por chore hofers						
Cash flow per share before	0.07	0.07		4 9 9	4 40	42 40/
financial items, EUR	0.07	0.27	-73.5%	1.23	1.10	+12.1%



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\* Amended IAS 19 Employee Benefits standard has been applied retrospectively, so 2012 comparative period data are restated accordingly.

# Key figures by business areas

Key figures for Pharmaceuticals business	Q1/13	Q1/12*	Change %	2012*	2011	Change %
Net sales of Pharmaceuticals, EUR million	234.2	232.5	+0.7%	928.9	870.6	+6.7%
Proprietary Products	100.3	99.0	+1.4%	403.7	408.9	-1.3%
Specialty Products	95.7	90.2	+6.1%	367.2	320.8	+14.4%
Animal Health	14.8	18.2	-19.0%	69.2	67.8	+2.0%
Fermion	13.4	16.0	-16.4%	48.4	43.3	+11.7%
Contract manufacturing and other <sup>1)</sup>	10.1	9.2	+9.9%	40.5	29.7	+36.1%
Pharmaceuticals operating profit, EUR million	73.9	78.8	-6.3%	286.5	287.6	-0.4%
Key figures for Diagnostics business						
Net sales, EUR million	15.9	15.5	+2.3%	54.1	49.5	+9.3%
Operating profit, EUR million	2.3	2.5	-8.1%	2.3	4.9	-51.9%

<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.



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\* Amended IAS 19 Employee Benefits standard has been applied retrospectively, so 2012 comparative period data are restated accordingly.

### Net sales originate mainly in Europe Breakdown of EUR 249 million net sales in Q1/2013



By market area





# Best-selling pharmaceuticals

Orion's best-selling pharmaceuticals, EUR million	Business Division	Q1/2013	Q1/2012	Change %	2012
1. Stalevo <sup>®</sup> , Comtess <sup>®</sup> and Comtan <sup>®</sup> (Parkinson's disease)	PP	60.3	63.2	-4.7%	250
2. Precedex <sup>®</sup> (intensive care sedative)	PP	12.0	10.3	+16.3%	45
3. Simdax <sup>®</sup> (acute decompensated heart failure)	PP	10.8	10.4	+4.4%	44
4. Easyhaler <sup>®</sup> product family (asthma, COPD)	PP	6.2	7.0	-11.2%	27
5. Burana® (inflammatory pain)	SpP	5.8	5.8	+0.4%	23
6. dexdor <sup>®</sup> (intensive care sedative)	PP	5.7	2.2	+156.2%	13
7. Dexdomitor <sup>®</sup> , Domitor <sup>®</sup> , Domosedan <sup>®</sup> and Antisedan <sup>®</sup> (animal sedatives)	АН	4.9	6.4	-23.1%	23
8. Fareston <sup>®</sup> (breast cancer)	SpP	4.7	3.5	+35.5%	12
9. Marevan® (anticoagulant)	SpP	4.0	4.4	-7.4%	16
10. Divina® range (menopausal symptoms)	SpP	3.5	3.8	<b>-9.6</b> %	16
Total		117.8	116.9	+0.8%	468
Share of Pharmaceuticals net sales		50%	50%		50 %
= Products based on Orion's inventions	PP = Proprieta SpP = Specialt	•			

AH = Animal Health



### Outlook for 2013

- Net sales will be at similar level to 2012 (net sales in 2012 were EUR 980 million)
- Operating profit will be slightly lower than in 2012 (operating profit in 2012 was EUR 278 million\*)
- Group's capital expenditure will be about EUR 80 million excluding substantial corporate or product acquisitions (Group's capital expenditure in 2012 was EUR 47 million)



\* Amended IAS 19 Employee Benefits standard has been applied retroactively, so 2012 comparative period data are restated accordingly.

Orion's strategy and financial targets



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





# Balancing mid-term – building long-term



**Building well-being** 

# 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	<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 in-licensing of drug candidates or products



# Collaborative networks across the R&D value chain



# Number of pre-clinical research projects has tripled since 2006





# Key clinical pharmaceutical development projects

		Clir	nical pha	ases	
Project	Indication	I	П	Ш	Registration
Easyhaler® budesonide-formoterol	Asthma, COPD				
Easyhaler® salmeterol-fluticasone	Asthma, COPD				
Stalevo® for Japanese market <sup>1)</sup>	Parkinson's disease				
ODM-101 (more effective levodopa product)	Parkinson's disease				
ORM-12741 (alpha-2c adrenoceptor antagonist)	Alzheimer's disease		lla		
ODM-201 <sup>2)</sup> (androgen receptor antagonist)	Advanced prostate cancer				
ODM-103 (COMT-inhibitor)	Parkinson's disease				
Androgen receptor antagonist and alpha-2c adrenoceptor antagonist	Molecule ready for transfer to clinical phase trials if required				
<sup>1)</sup> Conducted by partner Novartis			= Phas	e compl	eted
<sup>2)</sup> Jointly with Endo Pharmaceuticals			= Phas	e ongoir	ng



### ORM-12741, alpha-2c adrenoceptor antagonist

- Background: ORM-12741 is a highly potent and selective alpha-2c adrenoceptor (AR) antagonist that has demonstrated efficacy in rodent models
- Indication: Cognitive and behavioral symptoms in patients with Alzheimer's disease
- Promising results from phase II safety, tolerability and efficacy study presented at AAN Annual Meeting 2013
  - Press release: <u>http://www.orion.fi/en/News-and-media/Press-</u> releases2/Archive/2013/2/
  - Study poster: <u>http://www.orion.fi/en/Research-and-</u> <u>developement/Congress-publications/</u>
- Next step: Negotiations to find a suitable partner for next development phase are ongoing



### ODM-201, androgen receptor antagonist

- A novel antiandrogen intended for patients with progressive metastatic castration-resistant prostate cancer mCRPC
- Joint collaboration with Endo Pharmaceuticals
  - more about the collaboration at <a href="https://www.orion.fi/orion-and-endo">www.orion.fi/orion-and-endo</a>
- Phase I/II study results published at Esmo in September 2012 and at ASCO GU in February 2013
  - Unlike other antiandrogens does not enter the brain
  - Showed good tolerability and high anti-tumor activity
  - Read the ARADES trial study posters and abstract at: <u>www.orion.fi/congress-publications</u>
- Phase II study ongoing with 100+ patients



# ODM-101 and ODM-103 for Parkinson's disease

### ODM-101, more effective levodopa product

Phase II Proof of Concept study

- Over 100 patients in Europe
- Key results indicate that ODM-101 is more efficacious than Stalevo
- ODM-101 reduced time periods during the day when patients do not have adequate treatment response
- Press releases: <u>http://www.orion.fi/ODM-</u> <u>101-PII-press-release</u>

 <u>http://www.orion.fi/en/News-and-</u> media/Press-releases2/Archive/2013/3/

#### Next step

• Search for a suitable collaboration approach for the next development phase is ongoing

#### 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



Proprietary Products and Specialty Products update



# Turning points of Parkinsons's franchise



**Comtan in-market sales** EUR 22 million in 2011, EUR 23 million in 2012 **Stalevo in-market sales** EUR 71 million in 2011, EUR 78 million in 2012

Source: IMS Health 2012



# Rx value shares in USA after generic launches



**Building well-being** 

Total Rx value in USA - all entacapone products

# Precedex has captured a significant market share in the USA

### Sedation market in USA in 2003

Total market value USD 594 million in 2003



Source: IMS Health 2012

#### Sedation market in USA in MAT9/2012 Total market value USD 459 million in 2011





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### dexdor® has growth potential in Europe



### Precedex® and *dexdor*® in brief

- API is dexmedetomidine which is a sedative agent originated by Orion's R&D
- Precedex available in more than 30 countries
  - In USA since 2000
  - In Japan since 2004
  - In-market sales USD 270 million in 2012 (+31% YoY)
- dexdor® received European marketing authorisation on 16<sup>th</sup> September 2011
  - Launches ongoing
  - Available in 15+ countries
  - Estimated peak sales potential EUR 100 million a year



# Global coverage with well-known Easyhaler device

- Easyhaler® is authorised in 30 countries and coverage expanding, excl. USA and Japan
- Targeting the pulmonologists and general practitioners
- Favorable results from budesonide/formoterol combination development study. Marketing authorisation application submitted in Europe in Q1/2013.
- Fluticasone/salmeterol combination in clinical development (pharmacokinetics)
- Indication in both combinations is asthma (adults and children) and COPD (chronic obstructive pulmonary disease)
- Rights to Easyhaler products repatriated in various European countries





### 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 2012

By geographic area						
Eastern Europ	be 34					
Scandinavia	45					
Finland	18					
Other	19					

**By product type** Rx 109 OTC/SeCa 7









# Key figures by quarter\*











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\* Amended IAS 19 Employee Benefits standard has been applied retrospectively, so 2012 comparative period data are restated accordingly.

# Key figures for 2009–Q1/2013

Orion's key figures	2009	2010	2011	2012*	Q1/2013	Q1/2012*	Change %
Net sales, EUR million	771.5	849.9	917.9	980.4	249.4	247.4	+0.8%
Operating profit, EUR million	207.0	254.2	282.9	278.3	74.1	78.6	-5.7%
Profit before taxes, EUR million	203.7	252.6	282.0	276.6	73.8	78.7	-6.2%
R&D expenses, EUR million	95.2	85.5	87.5	105.8	24.6	23.1	+6.7%
Equity ratio, %	60.6%	62.7%	63.6%*	61.0%	41.2%	38.8%	
Gearing, %	-8.9%	-12.2%	-7.2%*	-1.7%	-4.6%	-21.2%	
ROCE (before taxes), %	37.4%	45.0%	50.5%*	46.8%	50.4%	59.7%	
Return on equity, %	35.3%	40.7%	44.5%*	42.0%	49.8%	58.0%	
Basic earnings per share, EUR	1.07	1.31	1.49	1.47	0.39	0.42	-6.1%
Cash flow per share before financial items, EUR	1.03	1.26	1.10	1.23	0.07	0.27	-73.5%
Dividend per share, EUR	1.00	1.20	1.30	1.30			
Capital repayment per share, EUR	0.10	0.06	0.12				

\* Amended IAS 19 Employee Benefits standard has been applied retrospectively, so 2011-2012 comparative period data are restated accordingly. R

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### Income Statement 2009–Q1/2013

Formation of profits, EUR million	2009	2010	2011	2012*	Q1/2013	Q1/2012*	Change %
Net sales	771.5	849.9	917.9	980.4	249.4	247.4	+0.8%
Cost of goods sold	-265.2	-283.2	-305.1	-350.8	-91.8	-86.8	+5.8%
Gross profit	506.3	566.8	612.8	629.6	157.6	160.6	-1.9%
Other operating income and expenses	6.0	1.2	3.0	6.3	0.3	1.5	-78.3%
Sales and marketing expenses	-160.0	-188.9	-204.8	-206.1	-48.5	-49.3	-1.5%
R&D expenses	-95.2	-85.5	-87.5	-105.8	-24.6	-23.1	+6.7%
Administrative expenses	-50.2	-39.3	-40.6	-45.7	-10.6	-11.2	-5.0%
Operating profit	207.0	254.2	282.9	278.3	74.1	78.6	-5.7%
Profit before taxes	203.7	252.6	282.0	276.6	73.8	78.7	-6.2%
Profit for the period	151.4	184.7	209.5	206.9	55.6	59.1	-6.0%



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### Financial position

EUR million	3/13	3/12	Change%	EUR million	3/13	3/12	Change%
Non-current assets total	334.2	292.9	+14.1%				
Inventories	189.2	156.9	+20.6%	Equity total	382.4	341.1	+12.1%
Trade receivables	164.4	165.1	-0.4%	Interest-bearing non-current liabilities	103.4	134.0	-22.8%
Other receivables	48.2	29.3	+64.6%	Non-current liabilities total	147.0	171.1	-14.1%
Cash and cash equivalents	192.7	235.9	-18.3%	Current liabilities total	399.4	367.8	+8.6%
Current assets total	594.5	587.2	+1.3%	Liabilities total	546.4	539.0	+1.4%
Assets total	928.7	880.1	+5.5%	Equity and liabilities total	928.7	880.1	+5.5%



### Development of Net working capital



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



Short-term non-interest beargin liabilities

Inventories

Net Working Capital



### **Dividend distribution**

### 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

#### EUR 1,60 160% 1,40 140% 1,20 120% 1,00 100% 0,80 80% 0,60 60% 0,40 40% 0,20 20% 0,00 0% 2008 2009 2010 2011 2012 Dividend per share Cash flow per share

### Dividend distribution history

Repayment of capital — Dividend payout ratio

Overall payout ratio







### Building well-being is Orion's Mission

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	2012
Net sales	EUR 980 million
Operating profit	EUR 278 million
R&D expenses	EUR 106 million
No. of personnel (at end of)	3,486
in Finland	2,783
in other countries	703

Orion's own sales organisation's areas

Sales areas of partners



### **Business divisions**



### **Proprietary Products**

Patented prescription drugs
CTAs: CNS, oncology & critical care, Easyhaler pulmonary drugs
Net sales in 2012 EUR 404 million



### Fermion

Active pharmaceutical ingredients (API's) for Orion and other companies
Net sales in 2012 EUR 48 million (excluding supplies for own use)



### **Specialty Products**

Generic prescription drugs
Self-care products
Net sales in 2012 EUR 367 million



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

 Pharmaceutical manufacturing for other companies
 Not sales in 2012 EUP 41 million

### Animal Health

 Veterinary medicines and care products for pets and production animals
 Not color in 2012 FUP 60 million

• Net sales in 2012 EUR 69 million



### Orion Diagnostica

 Diagnostic test systems for point-ofcare testing in healthcare and hygiene testing for industry
 Net sales in 2012 EUR 54 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 Branded generics

Western and Central Europe Strong position with proprietary products

Southern Europe Progress with proprietary products in hospital markets





### Orion shares are broadly held



#### 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. 55,000 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– 15 April 2013





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