

#### Orion Interim Report Q1/2013

23 April 2013

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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.



#### 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



### Net sales and operating profit

Group key figures	Q1/2013	Q1/2012*	Change %	2012*
Net sales, EUR million	249	247	+1%	980
Operating profit, EUR million	74	79	-6%	278
Basic earnings per share, EUR	0.39	0.42	-6%	1.47
Cash flow per share before financial items, EUR	0.07	0.27	-74%	1.23

- Net sales similar to comparative period
  - Pharmaceuticals business's net sales excluding Parkinson's drugs (Stalevo<sup>®</sup>, Comtess<sup>®</sup> and Comtan<sup>®</sup>) up by 3%
- Operating profit
  - Margin lower due to higher proportion of sales from products with lower margins
  - Research expenses higher



#### Breakdown of net sales

#### By business divisions



#### By market area





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### Pharmaceuticals business

Key figures for Pharmaceuticals business	Q1/2013	Q1/2012*	Change %	2012*
Net sales of Pharmaceuticals, EUR million	234	233	+1%	929
Proprietary Products	100	99	+1%	404
Specialty Products	96	90	+6%	367
Animal Health	15	18	-19%	69
Fermion	13	16	-16%	48
Contract manufacturing and other	10	9	+10%	41
Pharmaceuticals operating profit, EUR million	74	79	-6%	287

- Net sales of Parkinson's drugs down by 5%, and accounted for 26% of segment's net sales
- Net sales excluding Parkinson's drugs up by 3%
- Orion further strengthened its position as market leader in Finland





# 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® 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® (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)	AH	4.9	6.4	-23.1%	23
8. Fareston® (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	y Products			

AH = Animal Health



### Orion clear market leader in Finland

#### Finnish human pharmaceuticals market in Q1/2013

Wholesale EUR 497 million (+1%)

#### Orion in Finnish human pharmaceuticals market

- Sales growth 7%
- Orion clear market leader
  - Market share 12%
- Orion especially strong in self-care products and substitutable prescription drugs

# Finland's biggest pharmaceutical companies in Q1/2013





Source: Finnish Pharmaceutical Data Q1/2013

# Sales of Parkinson's drugs growing in Japan

#### Overall markets for Parkinson's drugs January—December 2012

- United States <sup>3)</sup> USD 771 million (+8%)
- Five largest European markets <sup>1) 3)</sup> EUR 963 million (+1%)
- Japan <sup>2)</sup> EUR 593 million (+13%)

Sales of Orion's Stalevo, Comtess & Comtan Parkinson's drugs January—December 2012

- United States <sup>3)</sup> USD 134 million (-30%)
- Five largest European markets <sup>1) 3)</sup> EUR 157 million (+1%)
- Japan <sup>2)</sup> EUR 67 million (+21%)

Market shares of Orion's branded Parkinson's drugs	2012	2011
Finland <sup>2)</sup>	24%	24%
Sweden <sup>2)</sup>	14%	14%
Norway <sup>2)</sup>	15%	15%
Denmark <sup>2)</sup>	<b>19</b> %	1 <b>9</b> %
Germany <sup>3)</sup>	16%	15%
UK <sup>3)</sup>	15%	15%
United States <sup>3) 4)</sup>	17%	26%
Japan <sup>2)4)</sup>	11%	11%

<sup>1)</sup> Germany, UK, France, Spain and Italy

<sup>2)</sup> including sales to hospitals and retail distributors

- <sup>3)</sup> sales to retail distributors only
- <sup>4)</sup> Novartis sales area



Source: IMS Health sales statistics for January–December 2012

### Precedex and *dexdor*<sup>®</sup> growing strongly

Markets for intensive care sedative Precedex January–December 2012

- Total USD 270 million (+31%)
- United States USD 213 million (+32%)

Sales of *dexdor*<sup>®</sup> intensive care sedative January–December 2012

• EUR 12 (1) million



**Building well-being** 

Source: IMS Health sales statistics for January–December 2012

# Key clinical pharmaceutical development projects

		Clinical phases			
Project	Indication	I	П	Ш	Registration
Easyhaler <sup>®</sup> budesonide-formoterol	Asthma, COPD				
Easyhaler <sup>®</sup> salmeterol-fluticasone	Asthma, COPD				
Stalevo <sup>®</sup> for Japanese markets <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 (more effective 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 <sup>2)</sup> Jointly with Endo Pharmaceuticals			= Phase completed = Phase ongoing		



### **Diagnostics** business

Key figures for Diagnostics business	Q1/2013	Q1/2012*	Change %	2012*
Net sales, EUR million	16	16	+2%	54.1
Operating profit, EUR million	2.3	2.5	-8%	2.3

- QuikRead<sup>®</sup> tests remained main product
  - Sales of more user-friendly prefilled QuikRead 101 system and QuikRead go<sup>®</sup>, a new generation testing instrument, developed well
- Profit affected mainly by expenditure on product development
- After the period Orion Diagnostica gave a negotiation proposal on streamlining operations and reducing the number of personnel in Finland by no more than 80



#### 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)



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#### **Orion Calendar**

- Interim Report January—June 2013
- Interim Report January—September 2013
- Capital Markets Day in Helsinki

30 July 2013

22 October 2013

20 November 2013







### 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%.



# Key figures by quarter\*











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# 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				



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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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# Main pharmaceutical development projects

- Expansion of *Easyhaler*<sup>®</sup> product family. Under development are *new budesonide-formoterol* and *fluticasone-salmeterol combined formulations* for treatment of asthma and COPD
  - Orion submitted the marketing authorisation application for the budesonide-formoterol formulation in Europe in March
- Orion and Novartis are developing Parkinson's drug *Stalevo®* for Japanese markets
  - Novartis initiated the necessary clinical bioavailability study in November 2012
- Development of androgen receptor antagonist (ODM-201) for treatment of advanced prostate cancer is in Phase II clinical trials undertaken jointly with Endo Pharmaceuticals. Negotiations to find a suitable partner for markets outside Europe and North America are ongoing
- Orion has completed Phase IIa clinical trials with an *alpha-2c adrenoceptor antagonist* (ORM-12741). The trials investigated the efficacy and safety of the drug candidate in treatment of cognitive and behavioural symptoms relating to Alzheimer's disease. The results were positive, and negotiations to find a suitable partner for the next development phase are ongoing
- Orion is developing a new more effective *levodopa product* (ODM-101) based on optimised new formulations and doses of known compounds. The results from Phase II clinical trials on efficacy were positive, and search for a suitable collaboration approach for the next development phase is ongoing
- Orion has Phase I clinical safety trials ongoing with a COMT inhibitor (ODM-103)
  - New molecule enhances the effects of levodopa used to treat Parkinson's disease
  - Pre-clinical study results indicated that new molecule is more effective than entacapone
- Orion has completed pre-clinical studies with another *androgen receptor antagonist molecule* and another *alpha-2c adrenoceptor antagonist molecule* 
  - Progress of these drug candidates into clinical trials will depend on the results of the ongoing androgen receptor antagonist and alpha-2c adrenoceptor antagonist clinical trials
- Pre-clinical studies include:
  - Prostate cancer, neuropathic pain, Parkinson's disease and Alzheimer's disease



### 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 <sup>2)</sup>	2015 <sup>3)</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>4)</sup>	January 2014 <sup>5)</sup>	June 2012

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

<sup>2)</sup> Entry of Wockhardt and Sun companies into markets in April 2012, Mylan in April 2013

<sup>3)</sup> Data protection expires; currently only Comtan available, project to develop Stalevo for Japanese markets ongoing

<sup>4)</sup> Dexdor data protection expires

<sup>5)</sup> Six months paediatric exclusivity granted for Precedex in the United States expires



### **Dividend distribution policy**

#### 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

Repayments of capital 2009–2011

2009: EUR 0.10 per share 2010: EUR 0.06 per share 2011: EUR 0.12 per share

#### Dividend distribution history







