Orion Investor Presentation

Updated on 2 February 2016



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.



Contents

- 4 Orion in brief
- 17 Strategy and financial objectives
- 23 Key financials
- 30 R&D long term opportunities units
- 57 Business units

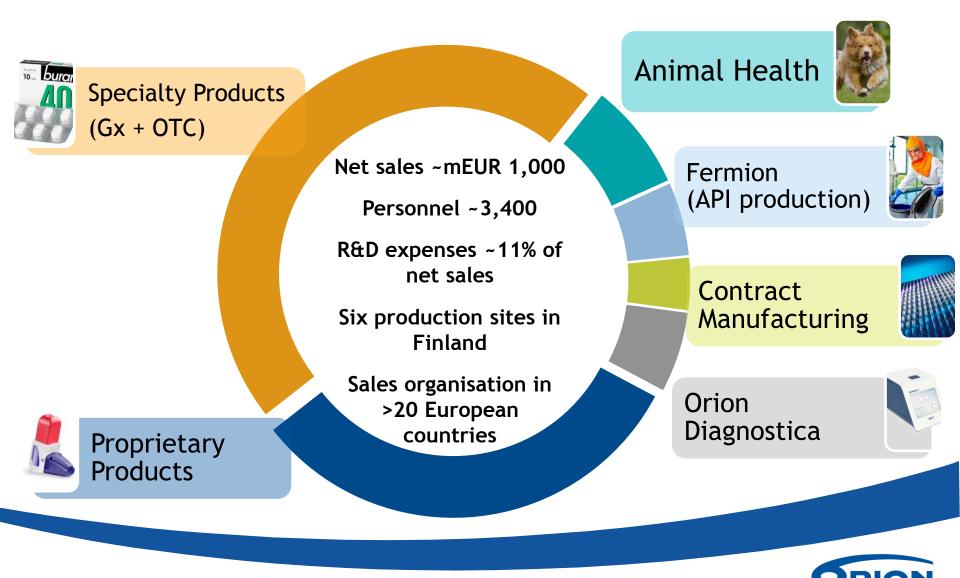








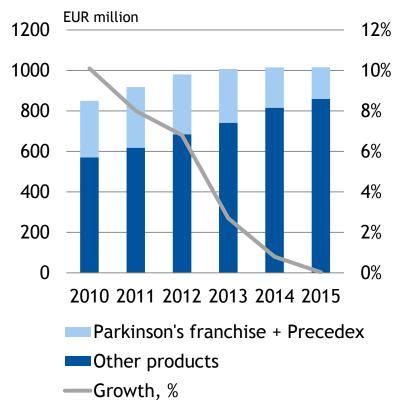
Orion today - building well-being since 1917



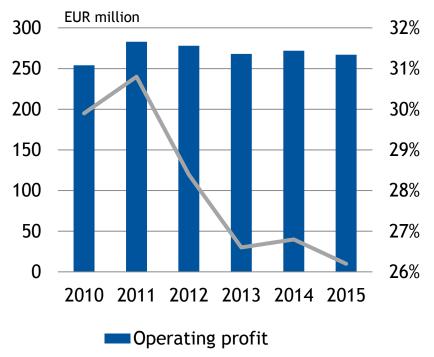
Building well-being

Steady development despite patent expiries

Net sales



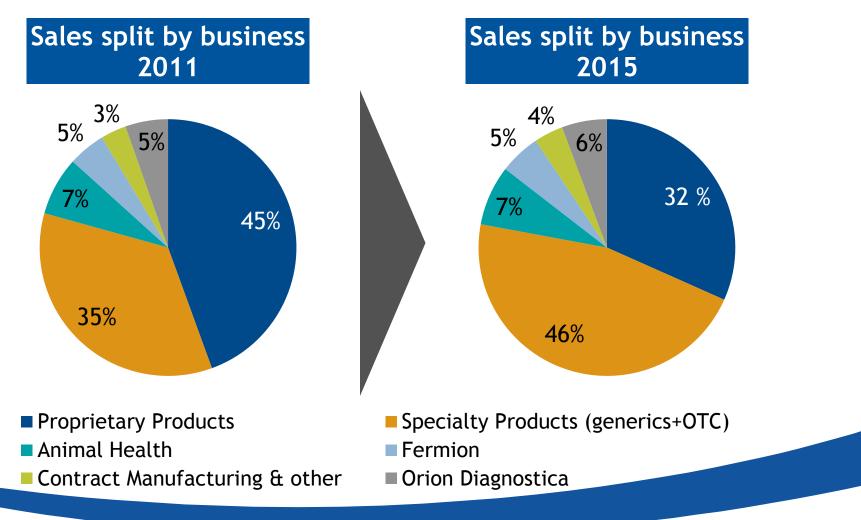
Operating profit



—Operating profit margin

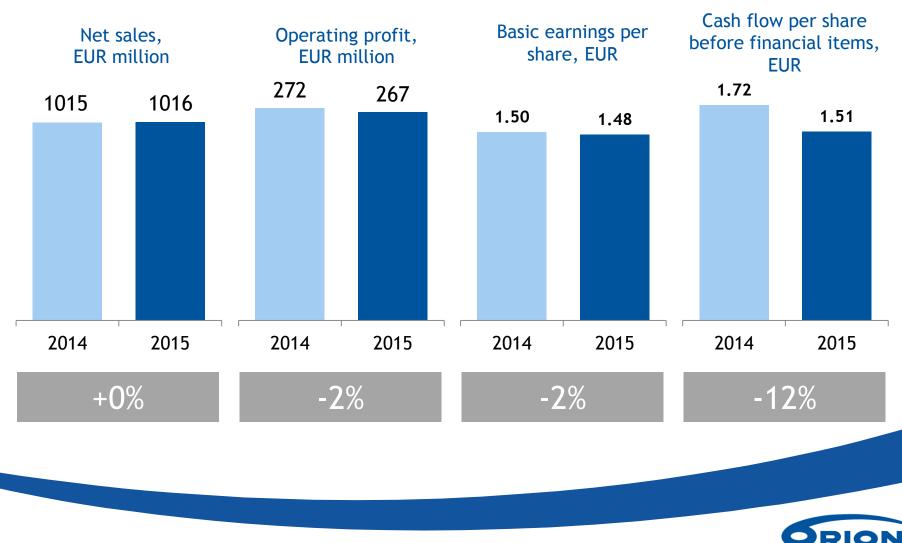


Product mix is changing





Key figures for 2015

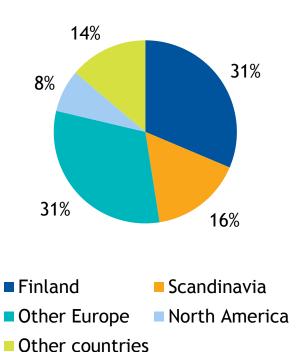


Building well-being

Breakdown of net sales

Net sales, EUR million	2015	Change vs. 2014
Pharmaceuticals	961	-0%
Proprietary Products	323	-14%
Specialty Products	471	+10%
Animal Health	77	+10%
Fermion	53	-8%
Contract manufacturing & other	37	+9%
Orion Diagnostica	58	+3%
Group items	-3	+1%
Group total	1,016	+0%

Sales split by market area





Best-selling pharmaceuticals 2015

Product	Indication	Net sales 2015 EUR million	Change vs. 2014
Stalevo Comtess COMTan	Parkinson's disease	138	-1 9 %
Easyhaler ®	Asthma, COPD	51	+45%
SIMDAX levosimendan	Acute decompensated heart failure	51	+9%
dexdor	Intensive care sedative	45	+26%
© Remsima™ Infliximab	Rheumatoid arthritis, inflammatory bowel diseases	28	+404%
DEXDOMITOR DOMITOR DOMOSEDAN & ANTISEDAN	Animal sedatives	27	+10%
Generic entacapone products	Parkinson's disease	25	-2%
burana	Inflammatory pain	23	-2%
Marevan [®]	Anticoagulant	19	+11%
Precedex* (dexmedetomidine HCI Injection)	Intensive care sedative	18	-40%

Key clinical pharmaceutical development projects 1/2

Project	Indication		PHASE		Registration
Easyhaler [®] budesonide-formoterol ¹⁾	Asthma, COPD	1	Ш	Ш	Registration
Easyhaler [®] salmeterol-fluticasone	Asthma, COPD	1	Ш	Ш	
ODM-201 (androgen receptor inhibitor) ²⁾	Prostate cancer (nm-CRPC)	I	Ш	Ш	
Levosimendan ³⁾	Low Cardiac Output Syndrome	Т	Ш	III	
ORM-12741 (alpha-2c adrenoceptor antagonist) ⁴⁾	Alzheimer's disease	1	lla		
Dexmedetomidine (intranasal) ⁵⁾	Treatment of pain	1	llb		
ODM-109 (oral levosimendan)	ALS	1	Ш		
¹⁾ Aim is to obtain marketing authorisation for product in		= Phase completed			
countries not included in decentralised marketing author ²⁾ In collaboration with Bayer ³⁾ Partner: Tenax Therapeutic		= Phase ongoing			
⁴⁾ In collaboration with Janssen Pharmaceuticals ⁵⁾ Partner			= Sta	tus ch	anged

More info about R&D projects at: http://www.orion.fi/en/rd/orion-rd/pipeline/



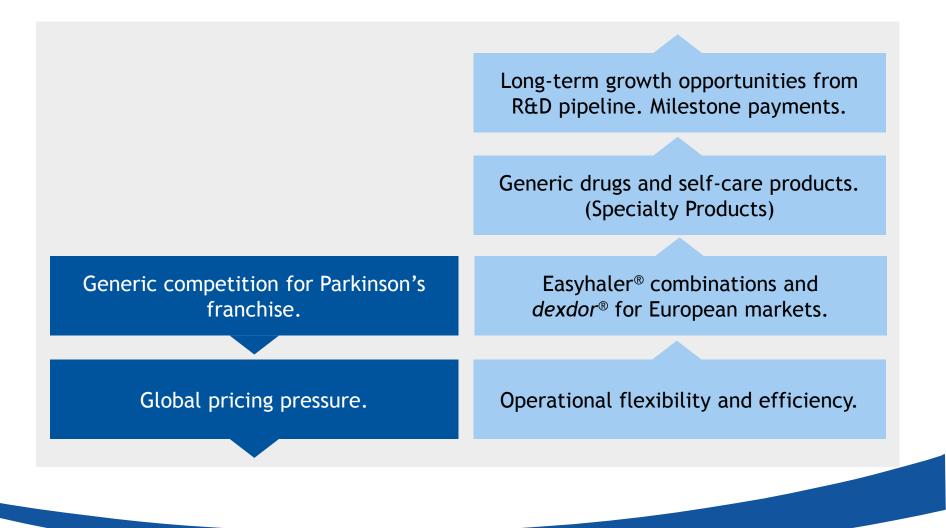
Key clinical pharmaceutical development projects 2/2

Project	Indication		PHASE	Registration
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-108 (negative allosteric modulator of TRPA1 ion channel)	Neuropathic pain	I		
			= Phase cor	npleted
			= Phase ong	going

More info about R&D projects at: <u>http://www.orion.fi/en/rd/orion-rd/pipeline/</u>

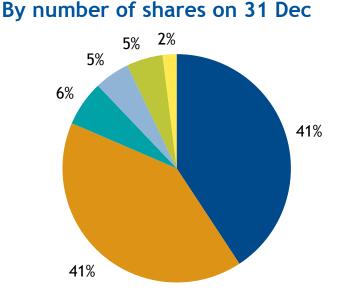


Balancing mid-term - building long-term



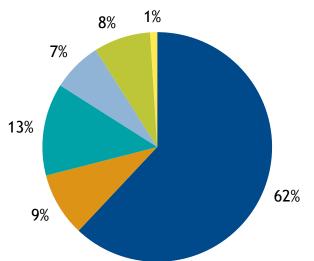


Two share classes, broad shareholder base



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

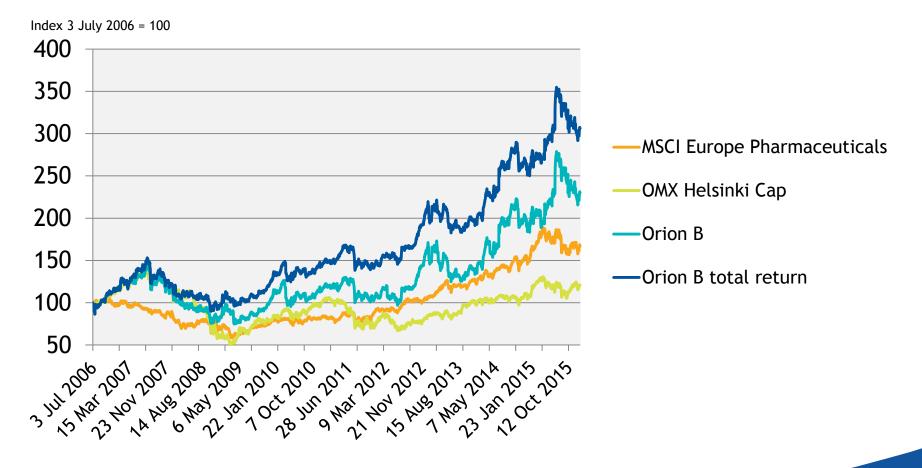
By number of votes on 31 Dec



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

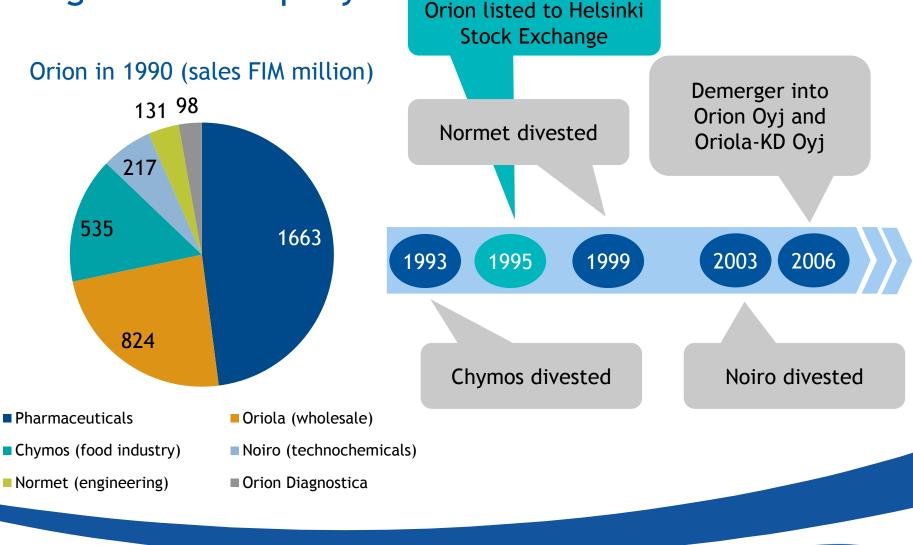
Altogether 141.3 million shares and ca. 50,000 shareholders. Both share classes, A and B, are listed on NASDAQ OMX Helsinki since 1 July 2006. A share (ORNAV) has 20 votes/share and B share (ORNBV) has 1 vote/share in the AGM, but they have equal rights to assets and dividends.

Orion B share performance 3 July 2006–31 Dec 2015





From conglomerate to pharmaceuticals and diagnostics company



Building well-being



Orion's strategy and financial objectives



		Ori	on's st	rategy	_	
Ageing population	Advancements in science			•••	well-be	eing
Cost burden in healthcare	Launching innovative and cost-effective pharmaceuticals and treatment methods for patients		Working together for our customers		Succeeding Together!	
Increased personal responsibility for health	Continuously improving our performance in sustainability	Growing faster than the market		Quality and safety	Productivity and flexibility	Strengthening our position in Europe
	Strong development of profitability is a target		Partnerships	Competitive product portfolio		Development of SpP's commercialization process
Megatre	nds	Str	ategic targets		Top Supply Chain	The best R&D
Strategic	c focus areas	Str	ategic developme	nt projects		

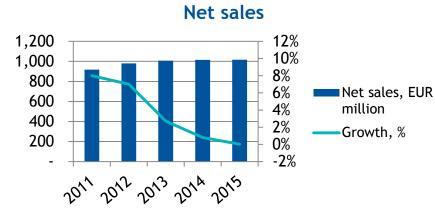
18 Investor Presentation (updated on 2 Feb 2016)

Orion's financial objectives

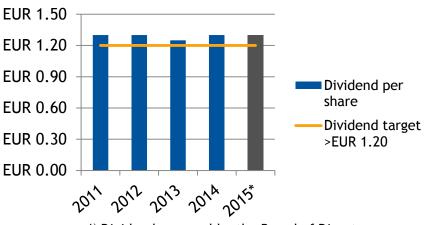
71	Increasing net sales. Achievement of this objective requires continuous investment in development of the product portfolio.
>	Maintaining profitability at a good level. The aim is operating profit that exceeds 20% of net sales.
2	Keeping the equity ratio at least 50%.
€	Distributing an annual dividend that in the next few years will be at least EUR 1.20 per share, and increasing the dividend in the long term.



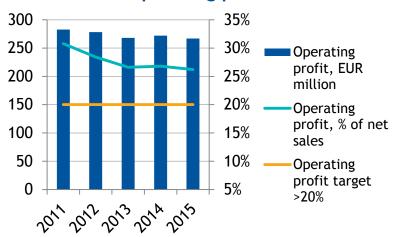
Orion's financial objectives



Dividend

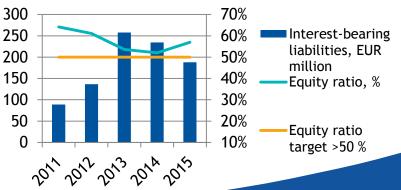


*) Dividend proposal by the Board of Directors



Operating profit

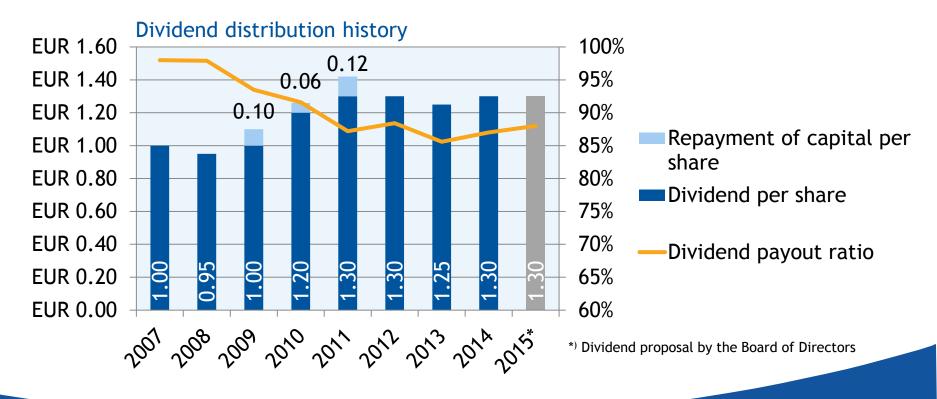
Equity ratio and interest-bearing liabilities





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.





Outlook for 2016

Net sales	Net sales are estimated to be at similar level to 2015 (net sales were EUR 1,016 million in 2015).
Operating profit	Operating profit estimated to exceed EUR 240 million.

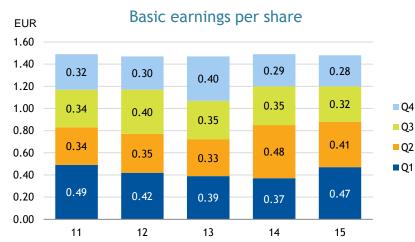


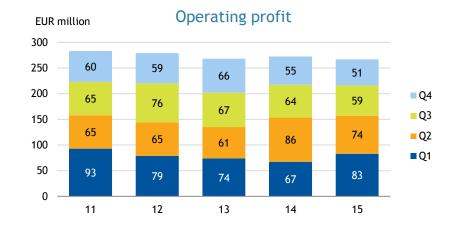


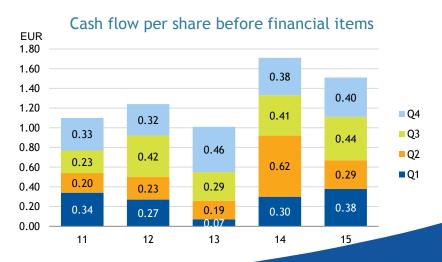


Key figures by quarter











24 Investor Presentation (updated on 2 Feb 2016)

Key figures for 2011–2015

Orion's key figures	2011	2012	2013	2014	2015	Change %
Net sales, EUR million	917.9	980.4	1,006.9	1,015.3	1015.6	
Operating profit, EUR million	282.9	278.3	267.7	272.4	266.6	-2.2%
Profit before taxes, EUR million	282.0	276.6	264.0	267.8	262.3	-2.1%
R&D expenses, EUR million	87.5	105.8	101.9	106.2	-108.1	+1.8%
Equity ratio, %	64.2%	61.0%	53.6%	52.3%	57.4%	
Gearing, %	- 6.9 %	-1.7%	8.4%	-4.7%	-9.6%	
ROCE (before taxes), %	49.4%	45.9%	38.5%	36.6%	35.7%	
Return on equity, %	43.3%	41.0%	40.3%	41.1%	37.5%	
Basic earnings per share, EUR	1.49	1.47	1.46	1.50	1.48	-1.6%
Cash flow per share before financial items, EUR	1.10	1.23	1.02	1.72	1.52	-12.1%
Dividend per share, EUR	1.30	1.30	1.25	1.30	1.30 ^{*)}	
Capital repayment per share, EUR	0.12					

*) Proposal by the Board of Directors

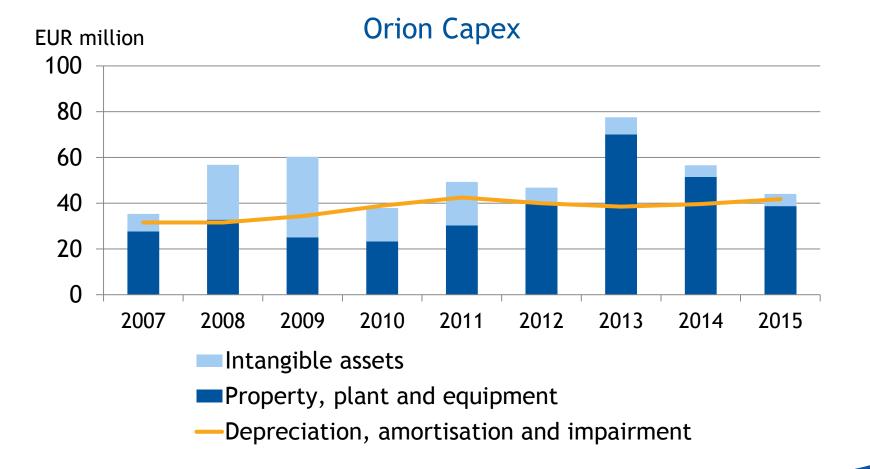


Income Statement 2011–2015

Formation of profits, EUR million	2011	2012	2013	2014	2015	Change %
Net sales	917.9	980.4	1,006.9	1,015.3	1015.6	- 5
Cost of goods sold	-305.1	-350.8	-393.5	-401.7	-405.8	+1.0%
Gross profit	612.8	629.6	613.4	613.6	609.8	-0.6%
Other operating income and expenses	3.0	6.3	5.6	1.7	1.5	-14.2%
Sales and marketing expenses	-204.8	-206.1	-204.9	-193.4	-190.4	-1.5%
R&D expenses	-87.5	-105.8	-101.9	-106.2	-108.1	+1.8%
Administrative expenses	-40.6	-45.7	-44.5	-43.3	-46.2	+6.7%
Operating profit	282.9	278.3	267.7	272.4	266.6	-2.2%
Profit before taxes	282.0	276.6	264.0	267.8	262.3	-2.1%
Profit for the period	209.5	206.9	206.2	211.3	208.2	-1.5%



Capex normalising after investment program



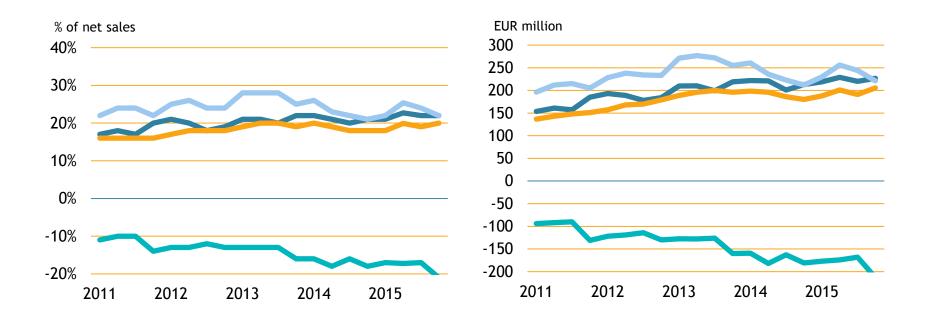


Financial position

EUR million	12/15	12/14	Change%	EUR million	12/15	12/14	Change%
Non-current assets total	373.3	349.1	+6.9%				
Inventories	205.7	178.7	+15.1%	Equity total	594.9	514.9	+15.5%
Trade receivables	192.1	174.0	+10.4%	Interest-bearing non- current liabilities	177.9	210.0	-15.3%
Other receivables	31.2	41.2	-24.2%	Non-current liabilities total	219.2	271.8	-19.4%
Cash & cash equivalents & money market investments	245.2	185.5	+32.2%	Current liabilities total	233.3	214.7	+8.7%
Current assets total	674.1	652.4	+3.3%	Liabilities total	452.5	486.5	-7.0%
Assets total	1,047.4	1,001.5	+4.6%	Equity and liabilities total	1,047.4	1,001.5	+4.6%



Development of Net working capital



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



Orion R&D long term opportunities

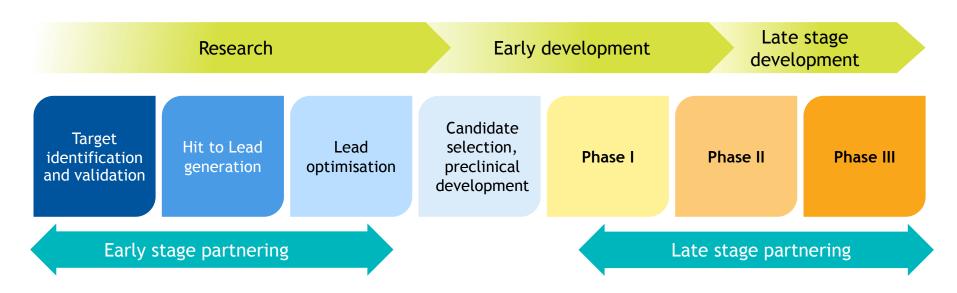


Orion's R&D strategy

Focused therapy areas	Focus on three core therapy areas • Central nervous system diseases • Oncology and critical care • Easyhaler pulmonary drugs
Shared risks and rewards	 Emphasis on collaboration and partnerships Clinical studies are performed globally, Orion's focus on Europe Partnerships are usually sought for clinical phase III at the latest Partners are important in marketing authorisation cases in countries outside Europe Orion holds the rights for further develop and market the candidate compounds
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	Constant strive to Increase the overall number of programmes Balance the risks of individual projects Acquire new early research molecules Improve the life-cycle management of own innovative treatments



Collaborative networks across the R&D value chain



KEY CHARACTERISTICS OF LATE STAGE PARTNERING

- Late stage partnering typically after Proof of Concept
- Risk and reward sharing
- Partner has commercial capabilities especially in USA
- Potential for income before commercial sales in form of milestones



A novel second generation androgen receptor (AR) inhibitor for the treatment of castration resistant prostate cancer

ODM-201

In collaboration with Bayer

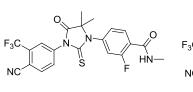


ODM-201: Partnership with Bayer - Financial terms

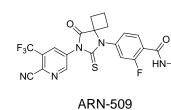
- Orion and Bayer will jointly develop ODM-201, with Bayer contributing a major share of the costs of future development
- Bayer will commercialize ODM-201 globally and Orion has the option to co-promote ODM-201 in Europe
- Orion is eligible to receive milestone payments from Bayer upon achievement of certain development, tech transfer and commercialization milestones
- Orion will receive substantial royalties on future sales
- Orion will be responsible for manufacturing of the product

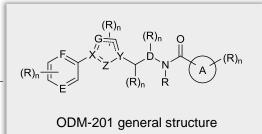


ODM-201 has a unique profile

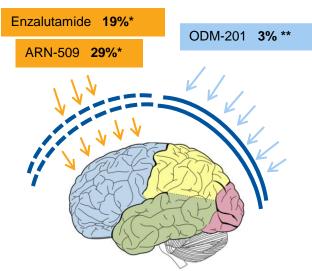


Enzalutamide





	AR						
Compound	affinity Ki (nM)	WT AR	AR (F876L)	AR (T877A)	AR (W741L)	VCaP IC50 (nM)	
Bicalutamide	12	150	218	957	Agonist		
Enzalutamide	86	155	Agonist	296	>10000	400	
ARN-509	68	168	Agonist	1130	>10000	300	
ODM-201	9	65	66	1782	1500	500	



*Refs. Clegg et al, 2012; Forster at al, 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)

- ODM-201 blocks the function of androgen receptor in both biochemical and cell assays with equal or better potency compared to enzalutamide and ARN-509
- Low likelihood for brain entry demonstrated in preclinical models



ODM-201 Phase III study ongoing in non-metastatic castration resistant prostate cancer (nmCRPC)

ODM-201 (androgen receptor inhibitor)²⁾

Prostate cancer



- nmCRPC patients who are at high risk for developing metastatic disease are included (n=1500)
- 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.
- Operational responsibility transferred from Orion to Bayer in December 2014
- The study is proceeding as planned with estimated completion in 2018



ClinicalTrials.gov identifier: NCT02200614



A unique and selective dual FGFR+VEGFR inhibitor for FGFR-dependent tumors

ODM-203

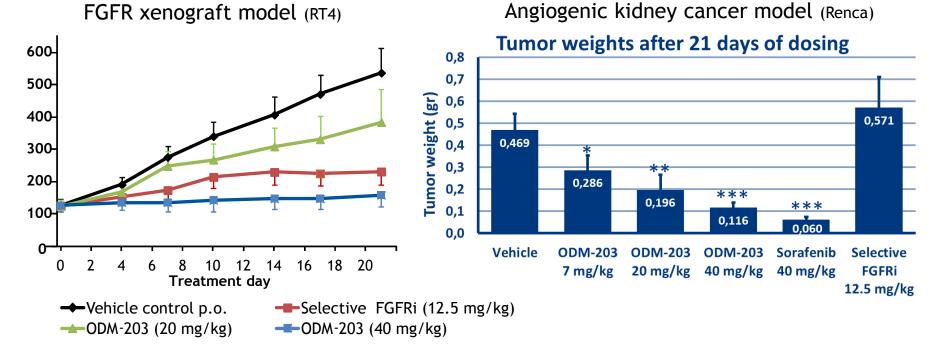


Angiogenic indications with altered FGFR signalling

Tumor type	Genomic alterations of FGFRs and FGFs
Breast (luminal)	$\sim 35\%$ (FGFR1 amp, FGFR2 amp, FGFR4 amp, FGFs)
NSCLC-SCC	~20% (FGFR1 amp, FGFR2 amp)
Bladder (invasive)	~15% (FGFR3 fusions, FGFR1 amp, FGFs)
Prostate	~14% (FGFR1 amp, FGFR2&3 fusions)
Colorectal	~10% (FGFR1 amp, FGFR3 mut)
Endometrial	~10% (FGFR2 mut)
Gastric	~ 7 % (FGFR2 amp)
Renal	~ 6 % (FGFR4 amp)



ODM-203 has strong in vivo antitumor activity



- Superior activity in angiogenic tumor models
- Strong antitumor activity in several FGFR dependent models
 - No effect in a FGFR and VEGFR independent xenograft model

Phase I KIDES trial ongoing

39

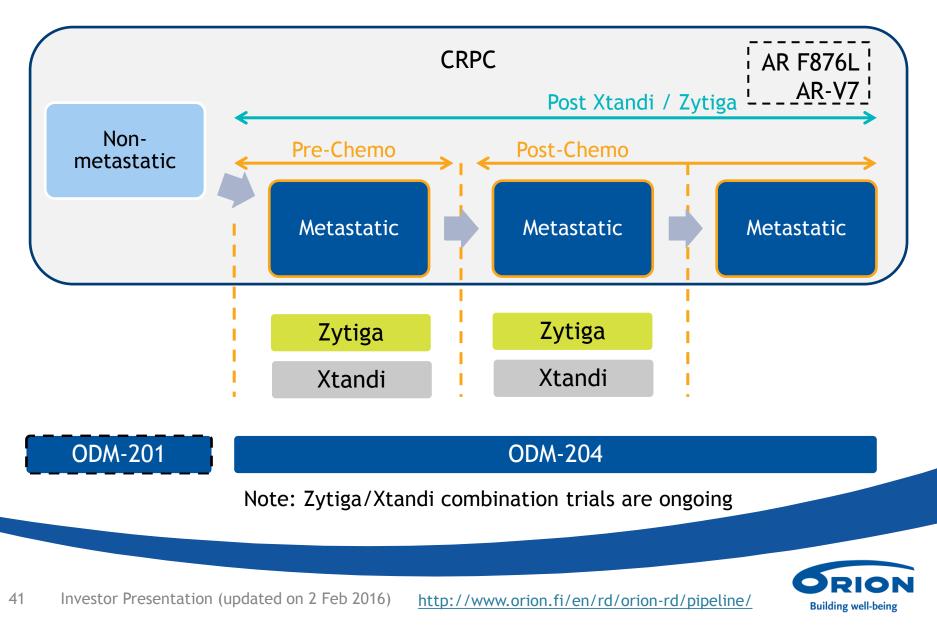
ODM-203 (targeted FGFR+VEGFR inhibitor)		Solid tumours	I	
ClinicalTrials.gov identifier: NCT02264418				
Investor Presentation (updated on 2 Feb 2016)	http://ww	w.orion.fi/en/rd/orion-	rd/pip	eline/

Target: Best-in-class treatment for metastatic Castration Resistant Prostate Cancer (mCRPC)

ODM-204



Positioning of ODM-204



ODM-204 - current status

ODM-204 (CYP17 enzyme and androgen receptor inhibitor)

Prostate cancer

Phase I/II DUALIDES trial ongoing

- Safety and Pharmacokinetics of ODM-204 in Patients With Metastatic Castration-Resistant Prostate Cancer (DUALIDES)
- Subgroups:

Number of subjects (approx.)	Chemotherapy	Second-generation AR inhibitor (e.g. enzalutamide)	CYP17A1i (e.g. abiraterone acetate)
15	Naive	Naive	Naive
15	Naive or pre-treated	Naive	Pre-treated
15	Naive or pre-treated	Pre-treated	Naive

ClinicalTrials.gov identifier: NCT02344017



ORM-12741 for Alzheimer's disease

In collaboration with Janssen



ORM-12741 - collaboration with Janssen

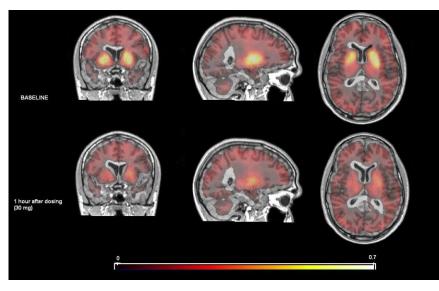
- Licence agreement announced on 19 December 2013 (includes ORM-12741 and other compounds)
- Orion received USD 31 million upfront payment which will mainly be used against additional Phase IIa study costs
- Orion is eligible to receive milestone payments from Janssen upon successful completion of certain 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

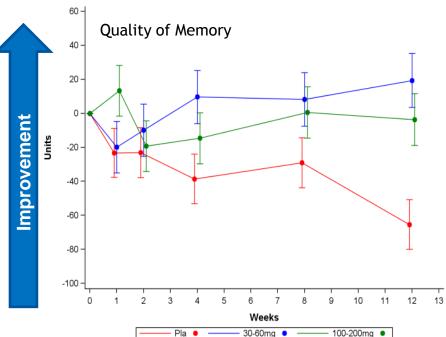


ORM-12741

- Highly potent and selective alpha-2C adrenoceptor antagonist
- Rodent models predict beneficial effects on cognition and neuropsychiatric symptoms (NPS)
- Phase 1 studies (healthy subjects)
 - Possible to administer orally
 - Well tolerated
 - Displacement of an alpha-2C PET tracer
- Phase 2a study in AD patients
 - Positive signals of efficacy in
 - Episodic and working memory
 - and
 - Neuropsychiatric symptoms

ClinicalTrials.gov identifier: NCT01324518





Phase 2 study on efficacy of ORM-12741 in AD

ORM-12741 (alpha-2c adrenoceptor antagonist) Alzheimer's disease

Improved formulation for the current Phase 2 study

- New formulation improving pharmacokinetic (PK) properties of ORM-12741 has been developed
- Phase 1 PK studies conducted to confirm qualities of the new formulation
- The improved formulation is used in the current Phase 2 study

Objectives

- To evaluate efficacy of ORM-12741 on agitation & aggression and other neuropsychiatric symptoms
- To evaluate efficacy of ORM-12741 on cognitive performance
- To evaluate safety

Design and methodology

- Randomised, double-blind, placebo-controlled, parallel-group, Phase 2 study
- Patients with mild to moderately severe Alzheimer's disease
- 2 dose levels of ORM-12741 and placebo

Sample size

100/group = ~300



lla

ſ ODM-104 τ.



New COMT-inhibitor ODM-104 for Parkinson's disease treatment

ODM-104 (more effective COMT inhibitor)

Parkinson's disease

Building well-being

- In phase I*, ODM-104 has been in well tolerated and superior to entacapone by improving COMT inhibition and levodopa pharmacokinetics in man
- Optimized carbidopa component further improves ODM-104 effect with double action on levodopa PK - levodopa exposure (AUC) increased over 30% when compared to entacapone
- Orion Pharma is currently developing a next generation PD product enabling the optimization of levodopa/carbidopa together with ODM-104
- Preparations for a phase II Proof-of-Concept study are ongoing. ODM-104 product will be compared with Stalevo® (levodopa/carbidopa/entacapone combination) in 66 PD patients with end-of-dose wearing-off symptoms

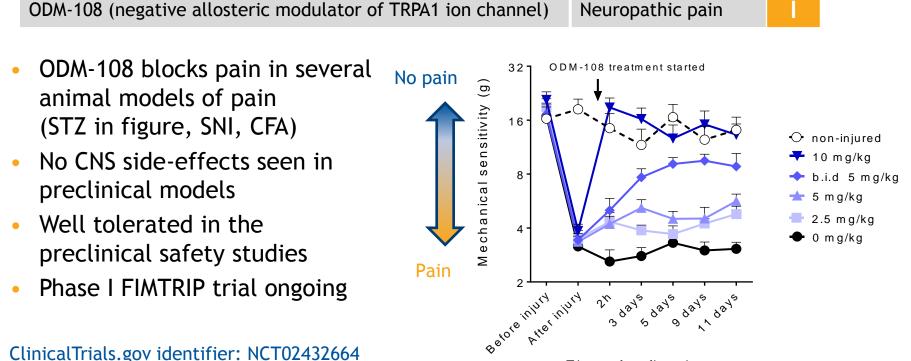
*) ClinicalTrials.gov identifier: NCT01840423

Target: Best-in-class TRPA1 antagonist molecule for the treatment of Neuropathic pain

ODM-108



ODM-108 shows efficacy and safety in Neuropathic pain



Time after first drug treatment



50 Investor Presentation (updated on 2 Feb 2016) <u>http://www.orion.fi/en/rd/orion-rd/pipeline/</u>

Target: Best symptomatic treatment for Amyotrophic Lateral Sclerosis (ALS)

ODM-109



LEVALS study - levosimendan in ALS patients

ODM-109	(oral levosimendan)	
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 The first phase II study aims to demonstrate beneficial effects on respiratory function

ALS

- Double-blind, cross-over design with 3 treatment periods
- Cross-over part of the study is followed by an open-label part for 6 months an opportunity to study long term effects
- The study will recruit approx. 50-60 patients in Europe

Levosimendan potentially delays the need for respiratory support and improves QoL in ALS patients by increasing skeletal muscle force

Regulatory considerations for ODM-109

- Possibility to seek parallel orphan designation in EU and US
- Several options for fast track designation



Levosimendan for Low Cardiac Output Syndrome

Partner Tenax Therapeutics



Levosimendan development in US by Tenax Therapeutics

Development of levosimendan for Low Cardiac Output	Syndrome
Syndrome (LCOS)	Possibility to include sepsis shock as an additional indication?
 Phase 3 LEVO-CTS trial to evaluate the efficacy of levosimendan in reducing morbidity/ mortality in cardiac surgery patients with reduced ejection fraction Data read out in 2016* Fast track status granted by FDA and protocol approved under SPA 	 Collaboration with Imperial College London for LeoPARDS trial Data read out in 2016* More information: www.leopards-trial.org

*) <u>www.tenaxthera.com</u> and <u>www.clinicaltrials.gov</u>



Dexmedetomidine for treatment of pain

Partner Recro Pharma



Dexmedetomidine development for acute postoperative pain by Recro Pharma

Dexmedetomidine (intranasal)

Treatment of pain



- Phase II trial to study the effect and safety of intranasal formulation of dexmedetomidine in adult patients undergoing bunionectomy surgery in US
- Possibility to avoid many of the side-effects associated with opioids
- Primary efficacy endpoint is summed pain intensity difference SPID48, over 48 hours starting on post op day 1.
- As a result of interim analyses in April, the total enrollment was reduced to 170 patients (was 200-250 pts)
- Phase IIb trial completed in July with positive results. Recro preparing to commence a Phase III clinical trial. *)

*) www.recropharma.com

ClinicalTrials.gov identifier: NCT02284243



Business units

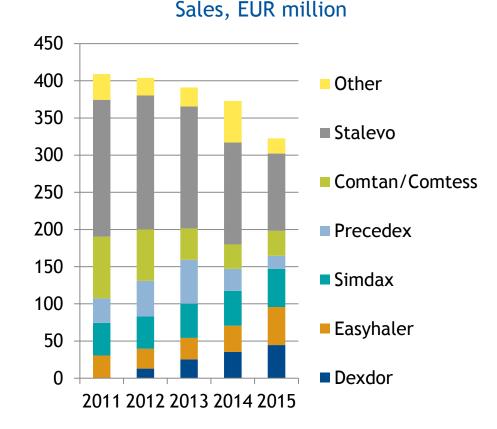


Proprietary products

- Mainly Orion in-house developed prescription drugs with valid product protect
- Global partner network in sales and R&D

Current main drivers

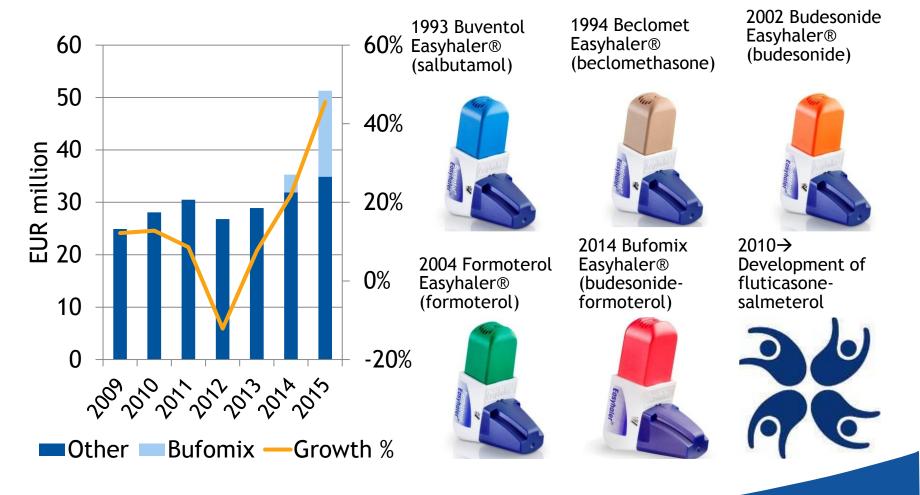
- Generic competition for Stalevo, Comtan/Comtess & Precedex
- Timing of milestones
- ▲ Dexdor, Easyhaler & Simdax
- Possible milestones from development pipeline projects



Building well-being

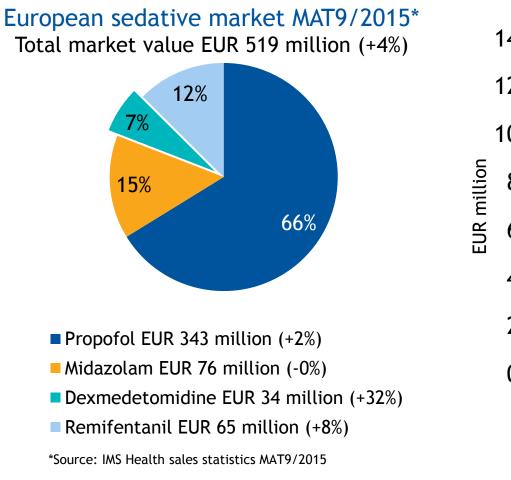
58 Investor Presentation (updated on 2 Feb 2016)

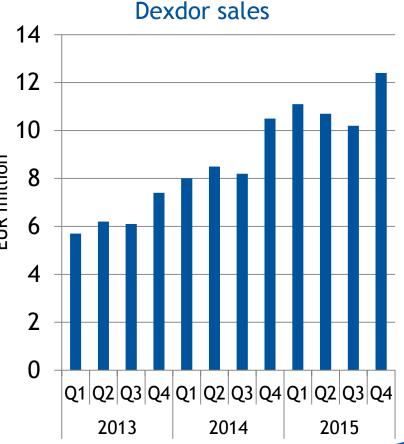
Easyhaler® for asthma and COPD Easyhaler products = Orion invented inhaler + generic APIs





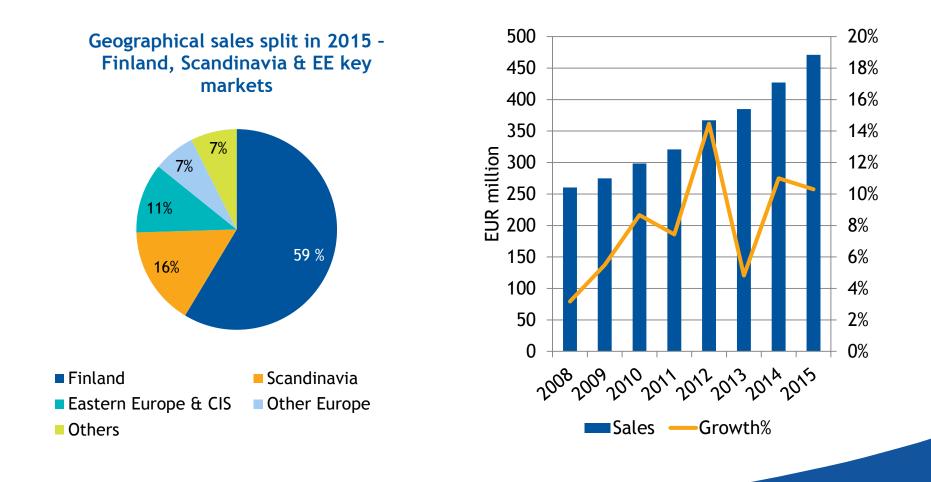
dexdor® intensive care sedative





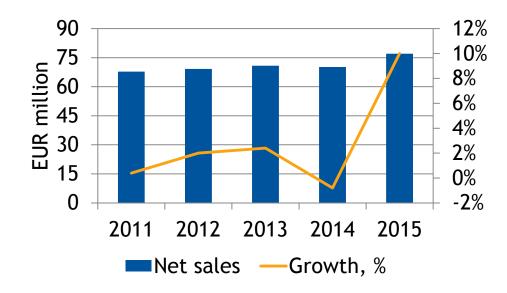


Steady sales growth for Specialty Products Orion Specialty Products = Gx + OTC including also non-medicinal products





Orion Pharma Animal Health



Product portfolio

- Medicinal and non-medicinal products for companion animals and livestock
- In-house developed proprietary products sold globally both through own sales network and through partners
- In-licensed products sold in own sales areas

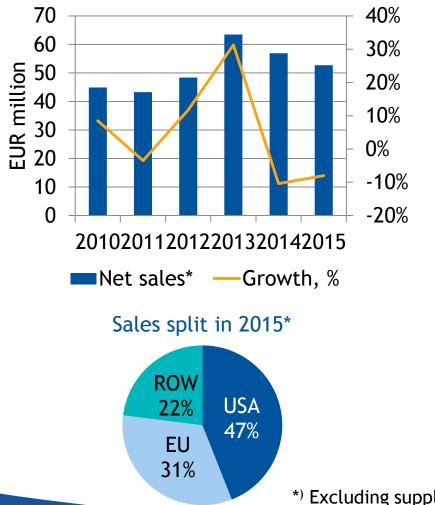


Orion Pharma Animal Health direct sales

Global sales coverage through partner network



Fermion has strategic importance



Fermion develops, manufactures and sells active pharmaceutical ingredients (APIs)

Business segments:

- NCEs for Orion's existing and new proprietary products
- Generics to Orion and other pharmaceutical companies worldwide
- Custom development and manufacturing for innovators with focus on high potency APIs

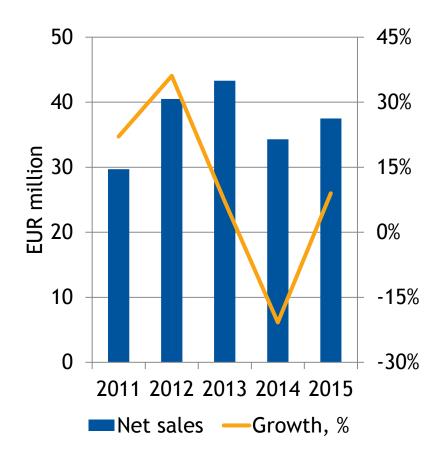
Main markets: USA, EU and Japan, ca. 100 customers

Ca. 35 products, both innovative and generic **APIs**

*) Excluding supply to Orion



Contract manufacturing & other



- Pharmaceutical manufacturing for other pharma companies
- Supply to global markets
- Orion has special know-how ie. in hormonal semi-solids and solutions

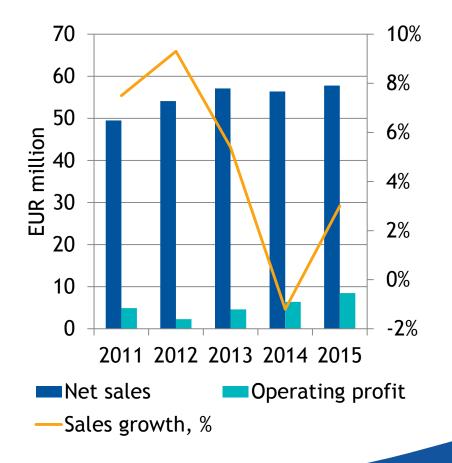
Read more

http://www.orion.fi/en/contractmanufacturing



Orion Diagnostica

- Diagnostic test systems for point-of-care testing in healthcare and hygiene testing for industry
- Main market areas: Europe (especially northern), China, USA, Japan
- Own sales units in 9 European countries, distributor network covering over 60 countries
- Focus in point-of-care IVD
- Key products: QuikRead® and GenRead® platforms





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