Orion Investor Presentation

Updated on 28 July 2015



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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Orion in brief

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Orion today - building well-being since 1917



Building well-being

5 Investor Presentation (updated on 28 July 2015)

Solid growth and good profitability



Geographical sales split in 2014



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Building well-being

Sales split in 2014 and development vs. 2013



Building well-being

7 Investor Presentation (updated on 28 July 2015)

Product mix is changing for the time being



8 Investor Presentation (updated on 28 July 2015)

Building well-being

Best-selling pharmaceuticals 2014



Products based on Orion's inventions in blue font



Balancing mid-term – building long-term





Two share classes, broad shareholder base

By number of shares on 30 Jun

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

By number of votes on 30 Jun



- 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. 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 2006–30 Jun 2015



Building well-being

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From conglomerate to pharmaceuticals and diagnostics company



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Building well-being

Orion's strategy and financial objectives



Orion's strategy - Mission to build well-being







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.
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







300 35% 250 30% Operating 200 25% profit, EUR million 150 20% Operating 100 15% profit, % of net 10% 50 sales 5% 0 20142015 •Operating 2010 2011 201203 profit target >20%

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 2015 (updated on 9 July 2015)

Net sales	Net sales are estimated to be at similar level to 2014 (net sales were EUR 1,015 million in 2014).
Operating profit	Operating profit is estimated to exceed EUR 260 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 R&D – long term opportunities



Orion's R&D strategy

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	 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 PoC
- Risk and reward sharing
- Partner has commercial capabilities especially in USA
- Potential for income before commercial sales in form of milestones



Key clinical pharmaceutical development projects 1/2

Project	Indication	PHASE		Ξ	Registration
Bufomix Easyhaler [®] (budesonide-formoterol) ¹⁾	Asthma, COPD		Ш	Ш	
Easyhaler [®] salmeterol-fluticasone	Asthma, COPD		Ш	Ш	
ODM-201 (androgen receptor inhibitor) ²⁾	Prostate cancer	I	Ш	Ш	
Levosimendan ³⁾	Low Cardiac Output Syndrome	I	Ш	Ш	
ORM-12741 (alpha-2c adrenoceptor antagonist) ⁴⁾	Alzheimer's disease		lla		
Dexmedetomidine (intranasal) ⁵⁾	Treatment of pain		llb		
ODM-109 (oral levosimendan)	ALS		Ш		
¹⁾ Aim is to obtain marketing authorisation for product in at least some European				se con	npleted

countries not included in decentralised marketing authorisation application process. ²⁾ In collaboration with Bayer ³⁾ Partner: Tenax Therapeutics, Inc.

⁴⁾ In collaboration with Janssen Pharmaceuticals ⁵⁾ Partner: Recro Pharma, Inc.

= Phase ongoing

= New phase initiated

More info at: <u>http://www.orion.fi/en/rd/orion-rd/pipeline/</u>



Key clinical pharmaceutical development projects 2/2

Project	Indication		PHASE	Registration
ODM-104 (more effective COMT inhibitor)	Parkinson's disease			
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	I		
ODM-108 (negative allosteric modulator of TRPA1 ion channel)	Neuropathic pain	I		
			= Phase con	npleted
			= Phase ong	joing

More info at: <u>http://www.orion.fi/en/rd/orion-rd/pipeline/</u>



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



ARN-509



ODM-201 general structure

	AR	Antagonism IC50 (nM)				Proliferation
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

ODM-203 (targeted FGFR+VEGFR inhibitor)

Solid tumours

ClinicalTrials.gov identifier: NCT02264418

31 Investor Presentation (updated on 28 July 2015) <u>http://www.orion.fi/en/rd/orion-rd/pipeline/</u>

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) Alzhe

Alzheimer's disease

l IIa

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







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

ODM-104 (more effective COMT inhibitor)

Parkinson's disease

- 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: First/Best-in-class GABA B PAM molecule for the treatment of Essential tremor

ODM-106



ODM-106 shows efficacy and safety in Essential tremor

ODM-106 (GABA-B receptor positive allosteric modulator) Essential tremor

- Alleviates tremor in essential tremor animal model (harmaline -induced tremor)
- No signs of development of tolerance after repeated doses
- No sedative or other CNS side-effects in preclinical models
- Well tolerated in the preclinical safety studies
- Efficacy also shown in parkinsonian tremor, levodopa-induced dyskinesia and pain models
- Phase I FIMPAM trial ongoing ClinicalTrials.gov identifier: NCT02393950



Building well-being

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

ODM-108



ODM-108 shows efficacy and safety in Neuropathic pain



Building well-being

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

ODM-109



LEVALS study - levosimendan in ALS patients

ODM-109 (oral levosimendan)

ALS

1 11

- The first phase II study aims to demonstrate beneficial effects on respiratory function
- 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 development in US by Tenax Therapeutics

Levosimendan	Low Cardiac Output I II III
Development of levosimendan for Low Cardiac Output 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 early 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: <u>www.leopards-trial.org</u>
*) <u>www.tenaxthera.com</u>	

DION

Building well-being





Dexmedetomidine development for acute postoperative pain by Recro Pharma

Dexmedetomidine (intranasal)

Treatment of pain

llb

- 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

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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



Sales, EUR million

Easyhaler Products = Orion invented inhaler + generic APIs





dexdor[®] intensive care sedative

European sedative market MAT3/2015* Total market value EUR 509 million (+3%)



- Propofol EUR 338 million (+1%)
- Midazolam EUR 76 million (-3%)
- Dexmedetomidine EUR 30 million (+37%)
- Remifentanil EUR 64 million (+9%)

*Source: IMS Health sales statistics MAT3/2015



Product protection situation of key products

Key patents or data protection expire

Molecule	Product	Indication	Europe	USA	Japan
Entacapone	Stalevo [®] , Comtess [®] and Comtan [®]	Parkinson's disease	November 2012 October 2013 ¹⁾	October 2013	January 2015 ²⁾
Levosimendan	Simdax®	Acute decompensated heart failure	September 2015	Not marketed	Not marketed
Dexmedetomidine	Precedex® dexdor®	Intensive care sedative	July 2013 September 2021 ³⁾	January 2014 4)	June 2012
 ¹⁾ Stalevo data pro ²⁾ Data protection (3) ³⁾ Dexdor data prot ⁴⁾ Six months paed 	of Comtan expired	recedex in the United Stat	es expired		



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





Key financials

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Key figures by quarter











Key figures for 2011–02/2015

Orion's key figures	2011	2012	2013	2014	Q1-Q2/2015	Q1-Q2/2014	Change %
Net sales, EUR million	917.9	980.4	1,006.9	1,015.3	514.9	521.7	-1.3%
Operating profit, EUR million	282.9	278.3	267.7	272.4	157.1	153.4	+2.4%
Profit before taxes, EUR million	282.0	276.6	264.0	267.8	155.6	151.2	+2.9%
R&D expenses, EUR million	87.5	105.8	101.9	106.2	52.9	56.9	-6.9%
Equity ratio, %	64.2%	61.0%	53.6%	52.3%	49.5%	51.3%	
Gearing, %	-6.9%	-1.7%	8.4%	-4.7%	13.1%	18.9%	
ROCE (before taxes), %	49.4%	45.9%	38.5%	36.6%	45.3%	42.1%	
Return on equity, %	43.3%	41.0%	40.3%	41.1%	50.6%	49.3%	
Basic earnings per share, EUR	1.49	1.47	1.46	1.50	0.88	0.86	+2.2%
Cash flow per share before financial items, EUR	1.10	1.23	1.02	1.72	0.67	0.93	-27.6%
Dividend per share, EUR	1.30	1.30	1.25	1.30			
Capital repayment per share, EUR	0.12						



Income Statement 2011–02/2015

Formation of profits, EUR million	2011	2012	2013	2014	Q1-Q2/2015	Q1-Q2/2014	Change %
Net sales	917.9	980.4	1,006.9	1,015.3	514.9	521.7	-1.3%
Cost of goods sold	-305.1	-350.8	-393.5	-401.7	-185.9	-195.3	-4.8%
Gross profit	612.8	629.6	613.4	613.6	329.0	326.4	+0.8%
Other operating income and expenses	3.0	6.3	5.6	1.7	-0.3	0.7	
Sales and marketing expenses	-204.8	-206.1	-204.9	-193.4	-94.8	-95.5	-0.7%
R&D expenses	-87.5	-105.8	-101.9	-106.2	-52.9	-56.9	-6.9%
Administrative expenses	-40.6	-45.7	-44.5	-43.3	-23.9	-21.3	+12.1%
Operating profit	282.9	278.3	267.7	272.4	157.1	153.4	+2.4%
Profit before taxes	282.0	276.6	264.0	267.8	155.6	151.2	+2.9%
Profit for the period	209.5	206.9	206.2	211.3	123.4	120.7	+2.3%



Capex normalising after investment program



Building well-being

65 Investor Presentation (updated on 28 July 2015)

Financial position

EUR million	6/15	6/14	Change%	EUR million	6/15	6/14	Change%
Non-current assets total	350.5	360.5	-2.8%				
Inventories	199.4	196.2	+1.6%	Equity total	461.0	464.1	-0.7%
Trade receivables	178.8	175.1	+2.1%	Interest-bearing non- current liabilities	204.3	227.4	-10.1%
Other receivables	46.1	46.3	-0.4%	Non-current liabilities total	272.9	260.8	+4.6%
Cash & cash equivalents & money market investments	169.4	164.9	+2.7%	Current liabilities total	210.3	218.0	-3.5%
Current assets total	593.7	582.4	+1.9%	Liabilities total	483.2	478.8	+0.9%
Assets total	944.1	943.0	+0.1%	Equity and liabilities total	944.1	943.0	+0.1%



Development of Net working capital





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



Q1-Q2/2015 Highlights

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Year continued strongly

- Net sales nearly the same level as in comparative period and operating profit slightly higher
- Specialty Products net sales up 10%
- Early-phase research portfolio developed well
- European Commission granted marketing authorisation for Orion's Animal Health division's new proprietary drug Sileo[®]
- Outlook estimate for 2015 updated after the review period





Key figures



Breakdown of mEUR 515 net sales in Q1-Q2/2015

Key figures by business divisions	Q1-Q2/ 2015	Q1-Q2/2014	Change %
Net sales of Pharmaceuticals, EUR million	486	494	-1.6%
Proprietary Products	172	204	-15.8%
Specialty Products	223	204	+9.7%
Animal Health	44	32	+36.5%
Fermion	29	35	-17.6%
Contract manufacturing & other	19	20	-5.2%
Pharmaceuticals operating profit, EUR million	157	155	+1.4%
Net sales of Diagnostics business, EUR million	30	29	+3.5%
Operating profit of Diagnostics business, EUR million	5.6	3.2	+77.2%



Breakdown of mEUR 515 net sales in Q1-Q2/2015



By market area





Building well-being

Best-selling pharmaceuticals Q1–Q2/2015

	Net sa	ales, EUF	R mill	lion			2014
Stalevo [®] , Comtess [®] & Comtan [®] (Parkinson's disease)	-13%					80	169
Simdax [®] (acute decompensated heart failure)	+14%			26	6		47
Easyhaler [®] product family (asthma, COPD)	+53%			25			35
dexdor [®] (intensive care sedative)	+33%			22			35
Dexdomitor [®] , Domitor [®] , Domosedan [®] & Antisedan [®] (animal sedatives)	+79%		16				25
Generic entacapone products (Parkinson's disease)	-14%	12					26
Burana [®] (inflammatory pain)	+0%	11					23
Marevan [®] (anticoagulant)	+23%	10					17
Remsima [®] (rheumatoid arthritis, inflammatory bowel disease)	+391%	8					6
Precedex [®] (intensive care sedative)	-50%	8					30
Total	45%	of pharr	nace	uticals ne	et sales	220	
Products based on Orion's inventions in blue font	_						



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Orion Investor Relations

