## Orion Investor presentation

Updated on 30 April 2018



#### Disclaimer



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.

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#### Content

- 1) Orion in brief
- 2) Research & development
- 3) Highlights of 1–3/2018
- 4) Outlook and financials
- 5) Business divisions



ORION



# **Orion in brief**



# Orion today - year 2017 in figures (adjusted)



On 21 April 2018, Orion signed an agreement on the sale of all shares in Orion Diagnostica Oy (i.e. the Orion Diagnostica business division). Following the transaction, Orion Diagnostica business is reported as discontinued operation. The figures for 2017 are adjusted, and do not include Orion Diagnostica.

## Steady development despite patent expiries

#### Net sales



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#### **Operating profit**

2018

## Orion's product mix has changed



Net sales, EUR million



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#### **Our businesses**





#### **Proprietary Products**

In-house developed drugs and other drugs with valid product protection



Specialty Products Generic prescription drugs, OTC and non-medicinal products, biosimilars



# Animal Health

Medicine and well-being products for animals



Fermion Active pharma

Active pharmaceutical ingredients (APIs)



**Contract Manufacturing** Production for other pharmaceutical companies

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# ORION

### Orion's strategy - Mission to build well-being

Ageing population	Advancements in science					
Cost burden in healthcare	Launching innovative and cost-effective pharmaceuticals and treatment methods for <b>patients</b>		Working together for our <b>customers</b>		Succeeding together!	
Increased personal responsibility for health	Continuously improving our performance in <b>sustainability</b>	<b>Growing</b> faster than the market		Quality and safety	Productivity and flexibility	
	Strong development of <b>profitability</b> is a target		Partnerships	Competitive product portfolio		Future R&D
Megatrend	s S	trategic targets			Top Supply Chain	
Focus areas	s S	strategic developmen	t projects			

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## Orion had ~69,000 shareholders on March 31, 2018

#### By number of shares



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

#### By number of votes



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# **Research and development**



#### Focus areas of Orion's R&D

#### Proprietary Products



- CNS
- Oncology
- Respiratory (Easyhaler® product family)

#### Animal Health



Orion utilises the R&D of proprietary products to develop new medicines for animals.

#### Fermion

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- APIs to Orion's proprietary products
- Generic APIs
- Contract development for pharmaceutical companies

## Together we can achieve more in R&D

Research			Early development		Late stage development		
Target identification and validation	Hit to Lead generation	Lead optimisation	Candidate selection, preclinical	Phase I	Phase II	Phase III	
8–24 mo.	12–24 mo.	18–36 mo.	development 12–24 mo.	12–14 mo.	12–36 mo.	18–48 mo.	
Collaboration with partners				Со	llaboration with	partners	





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## Key clinical pharmaceutical development projects

Project	Indication	F	PHAS	E	Re	gistration
Easyhaler® salmeterol-fluticasone	Asthma, COPD	Bioe	Bioequivalence study		F	Registration
Easyhaler® tiotropium	COPD	Bioe	Bioequivalence study			
Darolutamide (ODM-201) <sup>1)</sup>	Prostate cancer (nmCRPC)	1.1	Ш	Ш		
Darolutamide (ODM-201) <sup>1)</sup>	Prostate cancer (mHSPC)	1.1	Ш	Ш		
ODM-109 (oral levosimendan)	ALS	1.1	Ш	III		
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	1.1	Ш			
ODM-203 (targeted FGFR+VEGFR inhibitor)	Solid tumours	1.1	Ш			
ODM-207 (BET protein inhibitor)	Cancer	1				
ODM-208 (CYP11A1 inhibitor)	Prostate cancer (CRPC)	1				
<sup>1)</sup> In collaboration with Bayer			=Pha	se com	oleted	
				ise ongo	-	
More information on R&D projects: https://www.orion.fi/en/rd/orion-rd/pipeline/			=Stat	us chan	ged	
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Investor Presentation © Orion Corporation			2018		14	Building well-being

# Darolutamide: An androgen receptor targeted therapy for prostate cancer





Darolutamide (ODM-201) is an androgen receptor antagonist that

- Binds to the androgen receptor with high affinity
- Prevents efficiently androgen receptor signaling
- Low blood-brain barrier (BBB) penetration, potentially resulting in less side-effects in central nervous system.

### Darolutamide: Two trials in phase III proceeding



- Patients with non-metastatic, castrationresistant prostate cancer at high risk for developing metastatic disease
- Endpoints:
  - Primary: Darolutamide over placebo in metastasis-free survival
  - Secondary: Overall survival, time to first symptomatic skeletal event, time to first initiation of cytotoxic chemotherapy, time to pain progression, and to characterize the safety and tolerability of darolutamide
- Recruitment finalized, the trial proceeding as planned with estimated completion in September 2018.



- Patients with metastatic, hormone-sensitive prostate cancer
- Treatment: Darolutamide with androgen deprivation therapy (hormonal therapy) and six cycles of docetaxel (chemotherapy)
- Endpoints:
  - Primary: Darolutamide over placebo in overall survival
  - Secondary: Time to castration resistance, time to antineoplastic therapy, time to first symptomatic skeletal event, time to initiation of opioids, time to pain progression, and to characterize the safety and tolerability of darolutamide
- Recruitment proceeding well, estimated completion of the trial in 2022.

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#### **ODM-109: Oral levosimendan for ALS**



- ALS (Amyotrophic lateral sclerosis) is a fast progressing and fatal neurodegenerative disease:
  - Leads to diaphragm and skeletal muscle weakness and eventually paralysis and death typically due to respiratory failure.
  - An orphan disease with incidence of 1-2 /100,000 (MS disease: 2.5/100,000)
- Levosimendan is developed for symptomatic treatment for muscle weakness, the main symptom of ALS:
  - Levosimendan has shown positive effect on diaphgram muscle function in experimental studies in animals and in humans.
  - Positive signal from a small phase II study in ALS patients.

### **ODM-109: REFALS phase III trial**



Costs of the trial: ~ EUR 60 million approximately over three years

- = SVC% (slow vital capacity) measure of breathing capacity compared to normal subjects
- = ALSFRS-R (ALS functional rating scale) overall assessment of ALS symptoms



## ODM-208: Pan-steroid hormone synthesis inhibitor (CYP11A1 inhibitor) for castration-resistant prostate cancer

- Steroid hormones stimulate the growth of hormonally regulated cancers, such as most prostate and breast cancers.
- Hormonal treatments are highly effective, but drug resistance will often eventually emerge and cancer will start growing again.
- Preclinical studies have shown that ODM-208 inhibits the synthesis of steroids hormones. It has potential efficacy also for those cancers that have become resistant to the standard hormonal treatments.
- The steroid hormones that are needed and do not promote cancer growth are replaced with additional medication.



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# Orion highlights 1-3/2018



## A good start for the year

• Strong cash flow and good profitability,

28% operating profit margin exceeded financial objectives.

- Net sales and profit affected by tightening generic and price competition, smaller milestone payments and exchange rate changes. Comparative period was exceptionally strong.
- Easyhaler product family and Dexdor grew.
- Positive conclusions received for the salmeterol-flucatisone Easyhaler under the decentralised EU marketing authorisation procedure.
- Two new clinical trials:
  - CYP11A1 inhibitor for prostate cancer (ODM-208) Phase I
  - Oral levosimendan (ODM-109) Phase III
- Alzheimer's research project (ORM-12741) discontinued.
- Orion to sell Orion Diagnostica to an investment fund managed by Axcel Management A/S. Orion Diagnostica business is reported as a discontinued operation.



The Q1 2018 slides only covers continuing operations without Orion Diagnostica.

#### Development of net sales and operating profit



#### Operating profit, EUR million



1) Product sales without change in margins 2) Change in margin of product sales 1-2) Exchange rates generate about EUR 5 million of the overall decline (MEUR 12) in gross profit.

### Geographical breakdown of net sales

1-3/2018



Finland
Scandinavia
Other Europe
North America
Other markets

Orion's own sales network



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#### Net sales by business division

Net sales, EUR million	1-3/ 2018	1-3/ 2017	Change
Specialty Products	118	122	-3%
Proprietary Products	93	98	-6%
Animal Health	20	19	+5%
Fermion	12	16	-20%
Contract manufacturing & other	4	11	-59%



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2018



# Pharmaceuticals business



# Best-selling pharmaceuticals 1-3/2018

	Product	Indication	Net sales (EUR million)	Change vs 1-3/2017
1.	<b>Stalevo</b> <u>Comt</u> ess <u>COMTan</u>	Parkinson's disease	28	-8%
2.	🗱 Easyhaler®	Asthma, COPD	22	+20%
3.	dexdor	Intensive care sedative	18	+5%
4.	SIMDAX Jevosimendon	Acute heart failure	14	-7%
5.	Biosimilars	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	11	-4%
6.		Animal sedatives	8	+13%
7.	burana <sup>®</sup>	Inflammatory pain	6	+2%
8.	Precedex® (dexmedetomidine HCI Injection)	Intensive care sedative	5	-24%
9.	Marevan°	Anticoagulant	4	+8%
10.	Divina series	Menopausal symptoms	4	+13%
	Products of Proprietory Products business divi			

= Products of Proprietary Products business division



#### **Proprietary Products**

- As expected, sales of Stalevo, Comtess and Comtan continued to decline.
- The Easyhaler product family continued to grow. Positive conclusions received for the salmeterol-flucatisone formulation under the decentralised EU marketing authorisation procedure.
- Dexdor sales continued to grow in most European markets despite the commencement of generic competition in Germany.
- Simdax sales declined. The basic patent has expired, but this is not estimated to materially impact Simdax sales in 2018.



# As expected, sales of Parkinson's drugs continued to decline



- Deliveries of Parkinson's drugs (Stalevo, Comtess/Comtan) to key partners
- Orion's own sales

#### Sales of Orion's branded Parkinson's drugs by market area MAT12/2017



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# Easyhaler product family is growing



Others Budesonide-formoterol Easyhaler

- The product family sales grew by 20%, driven by budesonide-formoterol Easyhaler, which grew by 36%.
- Budesonide-formoterol Easyhaler is now launched in all key European markets:
  - Menarini launched the product in France in Q1/2018.
  - First marketing authorisation applications submitted outside Europe (APAC, MENA).
  - Orion's market share varies: Sweden 37%, Germany 6%.
- Salmeterol-flucatisone Easyhaler received positive conclusions under the decentralised EU marketing authorisation procedure. National approval procedures have started in 23 countries.
- Development of the seventh product, tiotropium, is underway.

### Dexdor intensive care sedative sales continued to grow in most European markets

Sales, EUR million Q2 Q3 Q4 Q1  Total value of the European sedatives market MAT12/2017: EUR 542 million (+4%)



#### \*Source: IQVIA MAT12/2017

## **Specialty Products**

Net sales in key markets, EUR million	1-3/18	vs 1-3/17
Finland	68	-6%
Scandinavia	21	+6%
Eastern Europe and Russia	15	+11%

- The net sales of Specialty Products declined by 3%.
- Sales grew in Scandinavia and in Eastern Europe and Russia. In Finland, sales declined due to tightening price competition.
- Biosimilar sales declined by 4%. Ritemvia sales have commenced. The situation of tendering competitions, tougher competition and lower price level contributed to lower Remsima sales.



# Orion is a significant player in the Nordic generic drugs market

- Orion's market position in 2017: Finland #1, Sweden #2, Denmark #2, Norway #3
- Biosimilars drive market growth in Scandinavia:
  - The market of generic and self-care products grew by 9% in 2017, Orion's growth 8%.
  - When taking biosimilars into account, Orion grew faster than the market: Market growth was 21%, Orion's growth 34%.
- In the Finnish pharmaceuticals market, the sales of reference priced drugs declined by 9% in 2017.

#### Generic and self-care product sales 2017

Orion vs market trend, (figure in brackets includes also biosimilars)



Source: IQVIA 2017

#### Orion remains strong in home market Finland

Human pharmaceuticals market in Finland 1-3/2018

- Total sales of medicinal and nonmedicinal products EUR 652 million
- Orion's market share 12%
- Overall market growth +11%, Orion's sales declined 6% due to changing operating environment:
  - Tightening price competition reduced Orion's net sales in 2017 by EUR 15 million. The effect is expected to be as large in 2018.







#### **Discontinued operation: Diagnostics business**



## Orion has sold Orion Diagnostica to an investment fund managed by Axcel Management A/S

- Signed on 21 April 2018, closing on April 30 2018
- Fixed purchase price ~EUR 163 million
- In addition, possible variable component of max. EUR 60 million, based on ROI at exit
- Orion estimates to recognise a capital gain of about EUR 128 million in other operating income for 2018 (does not include any part of the variable component).
- The capital gain will strengthen Orion's equity position and maintain the ability to achieve dividend distribution objective.

"The sale allows Orion to further focus on growth of Pharmaceuticals business."





# **Outlook and financials**


### Outlook for 2018 (updated on 21 April 2018)

Net sales	Due to generic and price competition Orion estimates that in 2018 the net sales excluding Orion Diagnostica will be at the same level or slightly lower than in 2017 (net sales were EUR 1,034 million excluding Orion Diagnostica in 2017).
Operating profit	Orion continues persistent actions to generate growth. Due to the estimated sales development and these actions the operating profit excluding Orion Diagnostica and material capital gains is estimated to be lower than in 2017 (operating profit excluding Orion Diagnostica and capital gains was EUR 284 million in 2017). Orion estimates to recognise EUR 128 million capital gain in other operating income from the sale of Orion Diagnostica at the closing of the transaction. Due to the uncertainty relating to the variable component included in the transaction, the estimated capital gain does not include any part of the variable component.

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#### **Orion's financial objectives**



Growing net sales more rapidly than growth of the pharmaceuticals market. Achievement of this objective requires continuous investment in development of the product portfolio.



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Keeping the equity ratio at least 50%.



Maintaining profitability at a good level. The aim is operating profit that exceeds 25% of net sales. Distributing an annual dividend that in the next few years will be at least EUR 1.30 per share, and increasing the dividend in the long term.

#### **Financial objectives**



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### Key figures by quarter



#### Basic earnings per share, EUR



#### Operating profit, EUR million



# Cash flow per share before financial items, EUR



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#### **Key figures**



\*) 2016: dividend includes extra dividend of EUR 0.20

Orion signed on 21 April 2018 an agreement on the sale of Orion Diagnostica. Following the transaction, Orion Diagnostica business is reported as discontinued operation. The figures for 2017 given on this table include continuing and discontinued operations, depending on the item.

#### **Income statement**



Orion signed on 21 April 2018 an agreement on the sale of Orion Diagnostica. Following the transaction, Orion Diagnostica business is reported as discontinued operation. Consolidated statement of financial position includes both continuing and discontinued operations. **Financial position** 



Consolidated statement of financial position includes both continuing and discontinued operations.

#### **Development of capital expenditure**

Orion Capex, EUR million





Property, plant and equipment

Intangible assets

 Depreciation, amortisation and impairment

Consolidated statement of financial position includes both continuing and discontinued operations.

#### Development of net working capital



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



Consolidated statement of financial position includes both continuing and discontinued operations.

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#### **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.

#### 1.75 100% 0.06 0.12 1.50 95% 90% 1.25 0.10 85% 1.00 0.75 80% 0.50 75% .95 8 8 20 80 22 80 ഹ 45 LO 0.25 70% $\overline{\mathbf{O}}$ 0.00 65% 2007 2008 2009 2014 2015 2016 2017 201 201 2013 2016: includes extra dividend EUR 0.20

#### EUR Dividend distribution history



Repayment of capital per share
Dividend per share
Dividend payout ratio

### Orion B share performance, 1/2016-3/2018



Index 31.12.2015=100





## **Business units**



#### **Proprietary Products**

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

Key drivers for business

- ▲ Easyhaler, Dexdor, & Simdax
- Possible milestones from development pipeline projects
- New products from R&D pipeline
- ✓ Generic competition

#### Net sales



### Proprietary human pharmaceuticals developed by Orion



Product	Indication	Year	Easyhaler®	Year	Indication
dexdor	Sedative for ICU use	2011	Bufomix Easyhaler®	2014	
<b>Stalevo</b>	Parkinson's disease	2003	Formoterol Easyhaler®	2004	
SIMDAX <sup>®</sup> levosimendan	Acute decompensated heart failure	2000	Budesonid Easyhaler®	2002	Asthma and COPD
Precedex <sup>®</sup> (dexmedetomidine HCI Injection)	Sedative for ICU use	1999	Beclomet Easyhaler®	1994	
<u>Comt</u> ess <u>COMTan</u>	Parkinson's disease	1998	Buventol Easyhaler®	1993	
FARESTON.	Breast cancer	1988			

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





Vs. 2016

-2%

Vs. 2016

+10%

### Specialty Products – portfolio of hundreds of different product







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### **Animal Health**



In-house developed proprietary products

DOMOSEDAN®

DOMOSEDAN GEL

Sileo

- 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
- New product to be launched: Clevor ropinirole eye drop

### Fermion has an important strategic role



#### **EUR** million



\*) Excluding supply to Orion



APIs for Orion's proprietary products



Generic APIs for Orion and other pharmaceutical companies



Contract development and manufacturing

#### Contract manufacturing & other

EUR million







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Orion has special capacity e.g. in hormonal products



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