## Orion Investor presentation

Updated on 18 July 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.

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.

Content

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# **Orion in brief**



#### Orion today - year 2017 in figures



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, that was completed on 30 April 2018, Orion Diagnostica business is reported as discontinued operation. All figures in this presentation are for continuing operations, if not otherwise stated.

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32%

## Steady development despite patent expiries

Net sales



Parkinson franchise + Precedex
 Other products

Growth, %

#### Operating profit



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## Orion's product mix has changed



Contract manufacturing & other

Net sales, EUR million

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#### **Our businesses**



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#### **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 pharmaceutical ingredients (APIs)



**Contract Manufacturing** Production for other pharmaceutical companies

# 

#### 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	trategic developmen	t projects			

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## Orion had ~74,000 shareholders on June 30, 2018

By number of shares



- Households (Finnish retail)
- Non-Finnish holders and nominee-registered
- Private corporations

44 %

- 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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#### Clinical trials are progressing



- ODM-201/darolutamide for prostate cancer in collaboration with Bayer:
  - ARAMIS progresses on schedule. The Phase III trial to be completed in September.
  - Patient recruitment has been finalized for ARASENS trial. The Phase III trial is expected to be completed in 2022.

- ODM-109/orally administered levosimendan for ALS:
  - First patients recruited for the REFALS trial.
  - Orion conducts the Phase III trial on its own.
- ODM-104 for Parkinson's disease:
  - The primary endpoint of the Phase II trial reached.
  - The results are being analysed.
    Orion is looking for a possible partner.

## **Orion's key pharmaceutical development projects**

Project	Indication		Phase		Registration
Easyhaler® salmeterol-fluticasone	Asthma, COPD	Bioequivalence study		Registration	
Easyhaler® tiotropium	COPD	Bioequivalence study			
Darolutamide (ODM-201) <sup>1)</sup>	Prostate cancer (nmCRPC)	I.	Ш	Ш	
Darolutamide (ODM-201) <sup>1)</sup>	Prostate cancer (mHSPC)	I	II	Ш	
ODM-109 (oral levosimendan)	ALS	I	II	Ш	
ODM-104 (more effective COMT inhibitor)	Parkinson's disease	I	II		
ODM-203 (FGFR+VEGFR inhibitor)	Solid tumours	I.	Ш	-	
ODM-207 (BET protein inhibitor)	Cancer	- E			
ODM-208 (CYP11A1 inhibitor)	Prostate cancer (CRPC)	l I			
1) In collaboration with Payor					

<sup>1)</sup> In collaboration with Bayer

More information on R&D projects: https://www.orion.fi/en/rd/orion-rd/pipeline/

- = Completed
  - = Ongoing
  - = Status changed



# 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 finalized, estimated completion of the trial in 2022.

# ODM-109: Oral levosimendan for ALS

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- First patients recruited in July for the Phase III clinical trial (REFALS).
- By enhancing respiratory muscle function in ALS patients, orally administered levosimendan can help maintain breathing capacity and benefit overall functioning of ALS patients.
- Orion is investing approximately EUR 60 million over three years in the trial.

- The aim is to apply for marketing authorisation in the US and Europe.
- Levosimendan has been granted an Orphan Drug Designation in the US and in the EU.
- It is a molecule originally developed by Orion for the treatment of acute decompensated heart failure. Simdax has been in the market for this indication since 2000.

#### **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

More information about the study: www.clinicaltrials.gov, Indentifier: NCT03505021

#### ALS (Amyotrophic lateral sclerosis) as a rare disease



# 1-2/<br/>100,000~16,800~12,500~450-500IncidencePatients<br/>in the US in 2017Patients<br/>in EuropePatients<br/>in Finland



## 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 1-6/2018



#### Continuing to build the future

Profitability was good, profit margin for continuing operations exceeded financial target. Strong cash flow. Net sales and operating profit for continuing operations fell behind from the exceptionally strong comparison period.

Clinical trials are proceeding. Three Phase III clinical trials are ongoing, the first estimated to be completed in September.



Sales of Proprietary Products were at level with comparative period. Challenging operating environment, tougher price competition and lower sales of biosimilars resulted in decrease in Specialty Products' sales.



The outlook remains unchanged. The sale of Orion Diagnostica was closed on 30 April 2018.



#### Key figures 1-6/2018 (continuing operations)



#### Development of net sales and operating profit (continuing operations)

Net sales, EUR million



#### Operating profit, EUR million (excl. the sale of Orion Diagnostica)



(1) Product sales without change in margins
 (2) Change in margins of product sales (1) & (2) Exchange rates generated about EUR 9 million of the overall EUR 12 million decline in product sales gross profit



# The profit impact of the sale of Orion Diagnostica closed on 30 April 2018

Capital gain

+128 MEUR

Pension gain

+5 MEUR

Administrative costs of the transaction





## Geographical breakdown and development of net sales

1-6/2018

North America

Other markets

6%

30%





Other Europe America markets

#### ■ 1-6/2017 ■ 1-6/2018

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#### Net sales by business division



1-6/2018 2%

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## Best-selling pharmaceuticals 1-6/2018

		Indication	Net sales (EUR million)	Change vs 1-6/2017
1.	Stalevo Comtess COMTan	Parkinson's disease	60	+ 4%
2.		Asthma, COPD	44	+18%
3.	dexdor	Intensive care sedative	34	+1%
4.	SIMDAX Tevosimendan	Acute heart failure	29	-1%
5.	Biosimilars <b>SRemsima</b> Riteria Infliximab Rituximab	Rheumatoid arthritis, inflammatory bowel diseases, lymphoma	15	-47%
6.		Animal sedatives	14	-17%
7.	Precedex" (dexmedetomidne HCI hjector)	Intensive care sedative	11	-15%
8	burana	Inflammatory pain	11	-3%
9.	Divina series Divina	Menopausal symptoms	9	+7%
10.	Marevan <sup>®</sup>	Anticoagulant	8	-13%

= Products of Proprietary Products business division





**Proprietary Products** 



#### **Proprietary Products**

#### Easyhaler

- Continued growth driven by the budesonide-formoterol Easyhaler.
- Preparing for the launch of the salmeterol-fluticasone Easyhaler.

#### Dexdor

• Sales continued to grow in most of the countries, despite generic competition expanding in Europe.



#### Simdax

• Sales revived after the Q1 downswing to the level with comparison period.

#### Parkinson's drugs

 Sales increased due to timing of deliveries. In the long term, sales are expected to continue to decrease.



# Increase in sales of Parkinson's drugs was due to timing of deliveries



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

#### Orion's own sales

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Sales of Orion's branded Parkinson's drugs by market area (MAT3/2018)



Source: IQVIA

# Easyhaler product family is growing



- The product family sales grew by 18%, driven by budesonide-formoterol Easyhaler, which grew by 26%.
- Budesonide-formoterol Easyhaler is sold in all key European markets.
  - Orion's market share of the product varies: in Sweden 38%, in Germany 6%.
- In March, Orion received positive conclusions for the salmeterol-fluticasone Easyhaler under the decentralised EU marketing authorisation procedure. National approval procedures started in 23 countries. The first national marketing authorisations have now been granted. Launch preparations are underway.
- Development of the seventh product, tiotropium, is ongoing.

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

Sales, EUR million



Total value of the European sedatives market: EUR 548 million (+3%) 12% 12% 64% 11% Propofol EUR 352 million (+1%) Midazolam EUR 63 million (-6%) Dexmedetomidine EUR 67 million (+26%) Remifentanil EUR 66 million (+4%)

Source: IQVIA, MAT3/2018

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**Specialty Products** 


#### **Specialty Products**



# • Sales grew in Eastern Europe and Russia.

- In Finland, sales declined due to tightening price competition.
- In Scandinavia, sales decline was mainly due to the lower sales of the biosimilar Remsima.



 Sales of biosimilars decreased due to the situation of tendering competitions, tightening competition and declined price level.

 Biosilar offering to expand with a third product (Celltrion's trastuzumab).

# Specialty Products: challenging operating environment and tightening price competition showed as a decrease in sales



Net sales by market area 1-6/2018



Net sales by product 1-6/2018

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# Orion's sales declined in Finland due to changing operating environment

Human pharmaceuticals sales in Finland in 1-6/2018

Total sales of medicinal and non-medicinal products in Finland

**1,329** EUR million (1,215)

Market development

+9%



Orion's sales

155 EUR million (169)

Orion's development

-8%

Tightening price competition reduced Orion's net sales in 2017 by EUR 15 million. The effect is expected to be as large in 2018.

# Orion remains strong in home market Finland



**EUR** million



Human pharmaceuticals in total **Orion's market** share 12% (14%)

Self-care products in pharmacy channel

Orion's market share

23%

(24%)

Prescription drugs Orion's market share 9% (12%) Reference priced prescription

share 26%

Orion's market

drugs

# Fermion's new production plant operational in Hanko - nearly 100% of production is exported



#### 6,000 EUR > 30 200-> ~ 20 million $m^2$ 300 t

Expansion investment 2016-2018

Production facility and equipment for the production of APIs

Enables capacity increase Number of APIs manufactured at Hanko

- Special expertise in demanding production of active pharmaceutical ingredients (APIs), e.g. extremely potent substances.
- The aim is to captively manufacture the APIs for Orion's in-house developed proprietary drugs, such as darolutamide.
- Modernised, advanced technology at Hanko strengthens Fermion's global competitive position, meets increasingly strict regulatory requirements and provides the means to meet growing demand.
- The Hanko facility manufactures azathioprine and entacapone, among others, in which Fermion is the leading manufacturer globally.



# Outlook



# Outlook for 2018



Net sales	Due to generic and price competition Orion estimates that in 2018 the net sales excluding Orion Diagnostica will be <b>at the same level or slightly lower</b> 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 <b>estimated to be lower</b> than in 2017 (operating profit excluding Orion Diagnostica and capital gains was EUR 284 million in 2017).
	As estimated earlier, Orion has recognised a EUR 128 million capital gain in other operating income from the sale of Orion Diagnostica. Due to the uncertainty relating to the variable component included in the transaction, the capital gain does not include any part of the variable component.



# **Financials**



#### **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.



€

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**



#### Operating profit



#### Dividend



Net sales, EUR million
Growth, %

Operating profit, EUR million
 Operating profit margin
 Operating profit target >25%

Dividend per share, EUR
 Dividend target
 \*) 2016: includes extra dividend EUR 0.20

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# Key figures by quarter



#### Net sales, EUR million





#### Operating profit, EUR million



# Cash flow per share before financial items\*, EUR



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#### **Key figures**

Orion's key figures	2013	2014	2015	2016	ADJ.2017	H1/2018	Change vs. H1/2017
Net sales, EUR million	1,006.9	1,015.3	1,015.6	1,073.5	1,033.6	493.3	-6.2%
Operating profit, EUR million	267.7	272.4	266.6	314.6	284.1	139.5	-12.1%
Profit before taxes, EUR million	264.0	267.8	262.3	310.9	277,7	137.3	-11.2%
R&D expenses, EUR million	101.9	106.2	108.1	118.2	99.1	51.7	+4.9%
Equity ratio, %	53.6%	52.3%	57.4%	60.8%	64.6%	67.1%	
Gearing, %	8.4%	-4.7%	<b>-9.6</b> %	-12.4%	-1 <b>.9</b> %	-7.7%	
ROCE (before taxes), %	38.5%	36.6%	35.7%	40.9%	36.2%	65.4%	
Return on equity, %	40.3%	41.1%	37.5%	40.3%	34.2%	70.3%	
Basic earnings per share, EUR	1.46	1.50	1.48	1.77	1.61	1.73	+91.4%
Cash flow per share before financial items, EUR	1.02	1.72	1.51	1.62	1.09	1.75	+334.3%
Dividend per share, EUR	1.25	1.30	1.30	1.55*	1.45		

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

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2018

#### **Income statement**

Formation of profits, EUR million	2013	2014	2015	2016	ADJ. 2017	H1/2018	Change vs. H1/2017
Net sales	1,006.9	1,015.3	1,015.6	1,073.5	1,033.6	493.3	-6.2%
Cost of goods sold	-393.5	-401.7	-405.8	-421.7	-417.6	-187.5	-6.5%
Gross profit	613.4	613.6	609.8	651.8	616.0	305.8	-6.1%
Other operating income and expenses	5.6	1.7	1.5	24.3	4.9	3.7	+112.6%
Sales and marketing expenses	-204.9	-193.4	-190.4	-194.7	-188.9	-96.5	+0.8%
R&D expenses	-101.9	-106.2	-108.1	-118.2	-99.1	-51.7	+4.9%
Administrative expenses	-44.5	-43.3	-46.2	-48.7	-48.8	-21.8	-7.6%
Operating profit	267.7	272.4	266.6	314.6	284.1	139.5	-12.1%
Profit before taxes	264.0	267.8	262.3	310.9	277.7	137.3	-11.2%
Profit for the period for continuing operations					219.1	109.3	-10.4%
Profit for the period for discontinued operations					6.9	133.4	
Profit for the period	206.2	211.3	208.2	249.0	226.0	242.8	+91.6%

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**Financial position** 



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

#### Orion Capex, EUR million







Intangible assets

 Depreciation, amortisation and impairment

#### Development of net working capital



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



-----Net Working Capital

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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 വ 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 January 2016 - June 2018

Index 31.12.2015=100



Orion B 73.57 Orion B total return 82.95 Europe/Pharmaceutical 87.06 OMXH 125.08

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# **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, Simdax
- Possible milestones from development pipeline projects
- New products from R&D pipeline
- ✓ Generic competition

#### Net sales



# Proprietary human pharmaceuticals developed by Orion



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



Vs. 2016

-2%

Vs. 2016

+10%

58

2018

### 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



Responsibility



# Patient safety, ethical operations and responsible supply chain are the cornerstones of Orion's corporate responsibility

#### In 2017:

- 31% of the energy savings target set for 2025 was achieved.
- New water collection systems were introduced in production to minimise pharmaceutical residue emissions.
- We worked to improve occupational safety and safety culture.
- Openness: Orion disclosed its financial collaboration with healthcare professionals.
  - In Finland, 90% (83%) gave their consent to publishing their speaker fees



Read more in the Sustainability Report 2017: www.orion.fi/en/Orion-group/Sustainability



#### **Orion calendar**

#### 2018

Interim Report 1–9/2018

24.10.2018

#### 2019

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Financial Statements Release 2018 Annual General Meeting Interim Report 1–3/2019 Half-Year Financial Report 1–6/2019 Interim Report 1–9/2019 6.2.2019 26.3.2019 25.4.2019 17.7.2019 23.10.2019



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