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All the figures in this presentation have been rounded, which is why the total sums of individual figures may differ from the total sums shown.



### Content

- 1) Orion in brief
- 2) Highlights of 2020
- 3) Research & Development
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- 6) Financial calendar



# **Orion in brief**



### Key messages



Orion develops, manufactures and markets human and animal pharmaceuticals and APIs. Products marketed in >100 countries.

 Balanced business model: Both
 proprietary drugs and generics.



# Orion at a glance (2020 figures)



Sales by market area



Finland
Scandinavia
Other Europe
North America
ROW

# Financial development between 2008 and 2020





#### Operating profit



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### **Orion's businesses**





In-house developed drugs and other drugs with valid product protection for global markets. Own sales network in Europe.

Generic prescription drugs, OTC and non-medicinal products, biosimilars. Finland 56% Scandinavia 16% Eastern Europe 14% ROW 14%

# **Aptus**° Animal Health

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Own animal drugs for global markets. Other drugs and well-being products. Own sales network in the Nordics and Eastern Europe.



Active pharmaceutical ingredients (APIs) for own proprietary products. CMO & CDMO services for other pharma companies.





2016 2017 2018 2019 2020 46%



2016 2017 2018 2019 2020 8%



2016 2017 2018 2019 2020

7%

= share of Group net sales in 2020

### Outlook for 2021



### Net sales

Orion estimates that in 2021 net sales will be **slightly lower** than in 2020 (net sales in 2020 were EUR 1,078 million).

### Operating profit

Operating profit is estimated to be **lower or clearly lower** than in 2020 (in 2020 operating profit was EUR 280 million).

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### Key assumptions behind the outlook



### Net sales

- + Nubeqa®
- Other growing products
- Milestones
- dexdor®
- **Simdax**®
- Animal Health
- -/? Specialty Products

### Operating profit

### + Nubeqa®

- No more depreciation expenses from Parkinson's franchise
- Milestones
- dexdor®
- Simdax®
- Normalisation of cost level (without Parkinson's depreciation)
- -/? Specialty Products

Orion's strategic growth target and financial objectives

Strategic growth target: Net sales EUR 1.5 billion in 2025

### Financial objectives:

**Growing net sales more rapidly than growth of the pharma 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.

### Key elements of Orion's growth



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2025 Growth target: New Proprietary Products and R&D pipeline as growth drivers - all units target for organic growth THREATS/CHALLENGES **OPPORTUNITIES** SIMDAX Darolutamide\* Stalevo Generic ARASENS & ARANOTE N U B E O A **COMTan**<sup>®</sup> competition (darolutamide) <sup>300 mg</sup> tablets dexdo Easyhaler® tiotropium\* Comtess<sup>-</sup> Animal Health R&D\* Failures in R&D programmes In-licensing and product acquisitions Pricing pressure **Proprietary** Specialty Animal R&D Expiry of a major distribution agreement (Animal Health) Products **Products** Health Expansion to new geographical market areas

\*) requires successful clinical trials

Key clinical deve	lopment pipeline	Phase completed Phase ongoing			
Project/compound	Indication	Phase I Phase II Phase III Registration			
ARASENS / darolutamide <sup>1</sup>	Prostate cancer (mHSPC)	Phase I Phase II Phase III			
ARANOTE / darolutamide <sup>1</sup>	Prostate cancer (mHSPC)	Phase I Phase II Phase III			
ODM-208	Prostate cancer (CRPC)	Phase I Phase II			
ODM-209	Prostate cancer (CRPC), breast cancer	Phase I			
Easyhaler® tiotropium	COPD	Bioequivalence study			
New dry-powder inhaler / indacaterol-glycopyrronium	COPD	Bioequivalence study			
Oncology       Respiratory <sup>1)</sup> In collaboration with Bayer       Updates vs. Q3 2020:         • New project: ARANOTE phase III study         • ODM-208 moved to phase II         • New project: New dry-powder inhaler / indacaterol-glycopyrronium         • ODM-203 (partnering negotiations ongoing) and ODM-207 removed from key clinical development pipeline					



# Orion had ~72,000 shareholders on 31 December 2020

### By number of shares



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

Private corporations

- Public sector
- Non-profit institutions

Financial and insurance corporations

### By number of votes



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### Largest shareholders by votes and shares on 31 December 2020

#	Shareholder	% of votes	Number of votes	# :	Shareholder	% of shares	Number of shares
1	Erkki Etola and companies	6.21	50,200,000	1	Ilmarinen Mutual Pension Insurance Company	2.65	3,735,128
2	Maa- ja vesitekniikan tuki r.y. and companies	5.15	41,667,200	2	Erkki Etola and companies	1.91	2,700,000
3	Ilmarinen Mutual Pension Insurance Company	4.58	37,051,609	3	Maa- ja vesitekniikan tuki r.y. and companies	1.48	2,083,360
4	Ylppö Jukka Arvo	3.11	25,140,449	4	Elo Mutual Pension Insurance Company	1.28	1,800,655
5	Into Ylppö and commanding votes	1.97	15,952,688	5	The Social Insurance Institution of Finland, KELA	1.18	1,658,368
6	Aho Group Oy and commanding votes	1.80	14,584,798	6	Ylppö Jukka Arvo	1.02	1,444,865
7	Saastamoisen säätiö (foundation)	1.62	13,099,920	7 '	Varma Mutual Pension Insurance Company	0.77	1,079,397
8	Orion Pension Fund	1.37	11,064,792	8	Into Ylppö and commanding votes	0.73	1,028,340
9	Eija Ronkainen and companies	1.33	10,748,639	9	The State Pension Fund	0.66	925,000
10	Ingman Finance Oy Ab	1.10	8,900,000	10	Aho Group Oy and commanding votes	0.52	731,917
11	Elo Mutual Pension Insurance Company	0.91	7,363,855	11 (	Orion Pension Fund	0.51	724,840
12	Leikola Erkki	0.70	5,638,000	12	Orion Oyj	0.48	671,082
13	Salonen Seppo Tapani	0.67	5,443,740	13	Saastamoisen säätiö (foundation)	0.46	654,996
14	Westerlund Riikka Maritza	0.60	4,882,700	14	Eija Ronkainen and companies	0.41	574,139
15	Kavetvuo Matti Ilmari	0.52	4,170,000	15	Ingman Finance Oy Ab	0.32	445,000
16	Kytilä Miika Elias Anton	0.45	3,662,200	16	Nordea Pro Finland Fund	0.31	430,377
17	Salonen Ilkka Mikael	0.45	3,610,620	17 3	Schweizer Nationalbank	0.30	422,562
18	Lenko Hanna Liisa	0.42	3,358,000	18	Orion Research Foundation	0.29	415,510
19	Kytilä Juha	0.39	3,126,500	19	The estate of Jouko Brade and companies	0.29	410,000
20	Orion Research Foundation	0.36	2,942,434	20	Salonen Seppo Tapani	0.25	355,287
	20 largest shareholders, total	33.72	272,598,144		20 largest shareholders, total	15.79	22,290,823
	Other shareholders	66.28	535,869,201		Other shareholders	84.21	118,843,455
	Total		808,467,345		Total		141,134,278

### Orion B share performance January 2016 - December 2020



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# Highlights in January-December 2020



# Strong performance amid the challenges posed by the COVID-19 pandemic



COVID-19	<ul> <li>Orion was able to secure the continuity of production.</li> <li>No disruptions in the availability of products or raw materials.</li> <li>Securing the health and safety of employees and patients in on-going clinical trials was a priority.</li> </ul>
Net sales & operating profit	<ul> <li>COVID-19 clearly increased the demand of some products but the development of net sales was good in many areas also without the COVID-19 impact.</li> <li>Due to the impacts of the pandemic, the operating profit was roughly about EUR 40 million higher than was estimated in the beginning of 2020.</li> <li>Dividend proposal EUR 1.50 per share.</li> </ul>
R&D	<ul> <li>REFALS trial (ODM-109) did not meet the pre-specified endpoints.</li> <li>New leader, structure and strategy for the R&amp;D organisation.</li> <li>Progression in clinical development pipeline and new projects.</li> </ul>

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### Key figures 1-12/2020

Net sales **1,078** 

MEUR (1,051) +3% Operating profit **280**MEUR (253)
+11%

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Operating profit margin 26%

(24%)

ofit Cash flow per share before financial items

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**1.85** EUR (1.68)

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+10%



## Development of net sales in 1-12/2020 vs. 1-12/2019



\* Nubeqa® product sales & royalty \*\* Proprietary Products and Specialty Products \*\*\* Animal Health, Fermion and Contract Manufacturing \*\*\*\* Without Nubeqa® royalties

# Development of operating profit in 1-12/2020 vs. 1-12/2019 9 -14 280 25 -7 253 1.72/2019 Product sales\* Product sales\* Product sales\* Product nix\* Exchange rates\*\* Nilestones & royalties Other income Fixed cost 1.12/2020

\* Product & service sales without sales margin and product mix change and exchange rate effect \*\*\* Exchange rate effect on gross margin \*\* Product sales margin and product mix change but without exchange rate effect



## All units showed growth



OPIO 1 - 12/20207% 8% 39% 46% Proprietary Products Specialty Products Animal Health Fermion & CM



# **TOP 10 products in 1-12/2020**

			EUR million	vs. 1-12/2019
1.	Easyhaler® product portfolio	115	+10%	
2.	Stalevo®, Comtess®, Comtar	99	+1%	
3.	Simdax®	62	-8%	
4.	dexdor®	55	-3%	
5.	Dexdomitor®, Domitor®, Domosedan®, Antisedan®		35	-4%
6.	Burana®	23	-6%	
7.	Divina® series	21	+8%	
8.	Remsima®, Ritemvia®, Amgevita® (biosimilars)		18	-53%
9.	Trexan®		17	+46%
10.	Nubeqa®	17	+609%	
	Proprietary Products	Specialty Products	Animal Healt	h



**Proprietary Products** 



### Nubeqa® and Easyhaler® product portfolio growth drivers



### ■ 1-12/2020 ■ 1-12/2019

Proprietary Products sales split 1-12/2020



#### Easyhaler® product portfolio sales +10% 1-12/2020 Budesonide-formoterol Easyhaler® MEUR 72 (62) +15% 40 1-12/2020 Other Easyhaler® products MEUR 43 (42) +2% 30 Sales, MEUR 10 0 Q3 Q2 Q3 Q4 Q2 Q3 Q4 **Q2 Q4** Q1 Q2 Q3 Q4 Q1 Q1 Q1 **Q2** Q3 **Q1** 04 2016 2018 2019 2020 2017 ■ Other Budesonide-formoterol Easyhaler®

### Parkinson's franchise sales at similar level to 2019 strong variation within the year



# Dexdor® and Simdax® - impact of generic competition starting to show



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**Specialty Products** 



# Strong generic prescription sales in Scandinavia mitigated the decline due to biosimilars





# Strong year for Gx prescription drugs even without COVID-19 impact - biosimilars declined as anticipated



### Sales split 1-12/2020



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### Specialty Products' sales change vs. 2019





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### In Finland, market for reference priced prescription drugs levelled off after demand spike in March

The market for reference priced prescription drugs in Finland\* (1–12/2020)

MEUR 449 (452)

Market development



The sales of Orion's reference priced prescription drugs in Finland

MEUR **110** (108)

Orion's development

\* The reference-priced prescription drugs group metric counts in products that were reference-priced prescription drugs at the time the statistics were compiled. For this reason, sales figure in the comparative period may deviate from previously published data.

### Orion is strong in home market Finland

Human pharma market in Finland 1–12/2020 Medicinal and non-medicinal products in hospital and pharmacy channels: EUR 2,903 million



Reference priced prescription drugs Orion market share in pharmacy

25%

(24%)\*

\* The reference-priced prescription drugs group metric counts in products that were reference-priced prescription drugs at the time the statistics were compiled. For this reason, the market share figure in the comparative period may deviate from previously published data.

### Self-care products

Orion market share in pharmacy



#### Human pharmaceuticals total

Orion market share in hospital & pharmacy

(11%)
# Key business targets in 2021



# Orion's responsibility and COVID-19



## **ORION'S RESPONSIBILITY PROGRAM**

Ensuring patient safety and reliable supply of medications

Responsibility for employees, the environment and the ethics and transparency of operations



- Ensuring reliable supply of medications is the most important task for Orion at the moment
  - Product inventories at a good level
  - Ensuring the availability of raw and starting materials and externally sourced ready-made products
  - Readiness to prioritise production and increase capacity if necessary
  - Ensuring the safety of patients in clinical trials

- Taking care of the health and safety of employees is essential
  - Specific measures taken in critical production and quality control to ensure the continuation of production
  - Masks for work-related travelling and commuting
  - Reducing non-essential contacts
  - Remote audits at production sites



# **Research and development**



## Focus areas of Orion's R&D



## **Proprietary products**

- Neurological disorders (including rare diseases)
- Oncology
- Respiratory (dry-powder inhaler platforms)



## Animal Health

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



## Fermion

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



# Together we can achieve more in R&D



Key clinical deve	lopment pipeline	Phase completed Phase ongoing
Project/compound	Indication	Phase I Phase II Phase III Registration
ARASENS / darolutamide <sup>1</sup>	Prostate cancer (mHSPC)	Phase I Phase II Phase III
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Easyhaler® tiotropium	COPD	Bioequivalence study
New dry-powder inhaler / indacaterol-glycopyrronium	COPD	Bioequivalence study
Oncology Respirator <sup>1)</sup> In collaboration with Bayer	<ul> <li>New project: ARANO</li> <li>ODM-208 moved to p</li> <li>New project: New d</li> </ul>	hase II ry-powder inhaler / indacaterol-glycopyrronium negotiations ongoing) and ODM-207 removed from key clinical





ARASENS trial aims to expand the indication of darolutamide to metastatic hormone-sensitive prostate cancer (mHSPC)



**Secondary endpoints:** 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 characterise the safety and tolerability of darolutamide.

## **ARANOTE trial**



## Treatment

Darolutamide + ADT

## Primary endpoint Radiological progressionfree survival (rPFS)

Patient enrollment about to start ~555 patients expected

Estimated completion in 2024e

## Financial impacts of darolutamide and regulatory update



- **Bayer** has the right to commercialise darolutamide globally.
- **Orion** will co-promote in several European countries. Orion will manufacture the product.
- Milestone payments upon first commercial sales:
  - EUR 45 million in the US Q3/2019
  - EUR 20 million in the EU Q2/2020
  - EUR 8 million in Japan Q2/2020
- Tiered royalties on product sales
  - Will be approximately 20%, including product sales to Bayer.
- Potential one-off payments if certain sales targets are met.

- Darolutamide has been approved for the treatment of nmCRPC eg. in
  - USA July 2019
  - Japan January 2020
  - EU March 2020
- Filings (nmCRPC) underway or planned in other regions

## Global prostate cancer estimates (2018)



## CYP11A1 inhibitors (ODM-208 & ODM-209)



ODM-208 & ODM-209 prevent the synthesis of ALL steroid hormones

> *Glucocorticoids and mineralocorticoids* need to be replaced during therapy

# Potential indications

## Prostate Cancer

Breast Cancer

Endometrial cancer of the uterus Adrenocortical carcinoma Some hormone-producing benign tumours

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# Orion investigates CYP11A1 inhibitors in two first-in-human Phase I-II trials

## The CYPIDES trial (ODM-208)

- Advanced prostate cancer that progressed during one or more novel hormonal therapy and chemotherapy
- Proceeded to clinical phase II

## The STESIDES trial (ODM-209)

- Advanced prostate cancer that progressed during one or more novel hormonal therapy and chemotherapy
- Advanced breast cancer that progressed during two or more systemic treatments
- Patient enrollment started in April 2019

- 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** and **ODM-209** inhibit the synthesis of steroid hormones. They have 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.



# Sustainability is built into Orion's mission



### Orion's Sustainability Agenda and indicators 2020 Patient safety and ensuring **Responsibility for** reliable supply of medications the environment Business ethics and **Responsibility for Orionees** transparency (Su) **Energy savings** Customer Greenhouse gas Code of Conduct Injury rate target set for complaints GxP\* audits emissions training, no. of 2025 by Orion (pharmaceuticals) (scope 1&2) participants achieved 3 41() 18,611 53% 3.6 141 76 (238)tCO2e (20,123) Ppm (76) (51%) LTIF 1 (6.6) (n/a)





# **Appendices**



## Track record vs. financial objectives



Orion Diagnostica Oy was divested in 2018 and is not included in the Net sales and Operating profit figures from 2017 onwards.

# Key figures by quarter



## Net sales, EUR million





## Operating profit, EUR million



Cash flow per share before financial items, EUR million



# Key figures

Orion's key figures	2016	2017	2018	2019	2020	Change vs. 2019		
Net sales, EUR million	1,073.5	1,033.6	977.5	1,051.0	1,078.1	+2.6%		
EBITDA	355,2	323,6	293.9	308.9	336.5	+9.0%		
Operating profit, EUR million	314.6	284.1	252.8	252.8	280.1	+10.8%		
Profit before taxes, EUR million	310.9	277.7	248.4	250.8	278.3	+10.9%		
R&D expenses, EUR million	118.2	99.1	104.0	119.3	123.2	+3.3%		
Equity ratio, %	60.8%	64.6%	68.8%	76.7%	66.7%			
Gearing, %	-12.4%	-1.9%	-17.1%	-17.8%	-25.4%			
ROCE (before taxes), %	40.9%	36.2%	44.3%	<b>29.9</b> %	34.8%			
Return on equity, %	40.3%	34.2%	45.5%	25.8%	<b>29.</b> 1%			
Basic earnings per share, EUR	1.77	1.56	1.40	1.43	1.56	+9.8%		
Interest bearing net debt	-79.4	-12.7	-132.1	-139.1	-185.8	+33.6%		
Cash flow per share before financial items, EUR	1.62	1.09	2.32	1.68	1.85	+9.6%		
Dividend per share, EUR	1.55	1.45	1.50	1.50	1.50*			
* Proposal by the Board of Directors		<sup>=</sup> includes both continuing and discontinued (Orion Diagnostica) operations						

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## **Income statement**

Formation of profits, EUR million	2016	2017	2018	2019	2020	Change vs. 2019
Net sales	1,073.5	1,033.6	977.5	1,051.0	1 078.1	+2.6%
Cost of goods sold	-421.7	-417.6	-387.9	-417.6	-427.0	+2.3%
Gross profit	651.8	616.0	589.6	633.4	651.0	+2.8%
Other operating income and expenses	24.3	4.9	5.5	2.2	5.4	+148.8%
Sales and marketing expenses	-194.7	-188.9	-195.3	-215.7	-204.3	-5.3%
R&D expenses	-118.2	-99.1	104.0	-119.3	-123.2	+3.3%
Administrative expenses	-48.7	-48.8	-43.0	-47.8	-48.9	+2.3%
Operating profit	314.6	284.1	252.8	252.8	280.1	+10.8%
Profit before taxes	310.9	277.7	248.4	250.8	278.3	+10.9%
Profit for the period for continuing operations		219.1	197.3	200.4	219.9	+9.7%
Profit for the period for discontinued operations		7.0	132.9			
Profit for the period	249.0	226.0	330.3	200.4	219.9	+9.7%

All 2016 figures in the table include both continuing and discontinued (Orion Diagnostica) operations.

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## **Royalties and milestones**

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## **Development of Proprietary Products net sales**





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**Financial position** 



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## **Development of capital expenditure**

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## Orion capex, EUR million



## Development of net working capital



**EUR** million 400 300 200 100 0 -100 -200 -300 Mar14 Jun14 Sep14 Dec14 Mar15 Jun15 Sep15 Sep15 Jun18 Sep18 Dec18 Jun19 Sep19 Dec19 Mar20 Jun 20 Sep20 Dec20 σ Jun1 Sep1 Mar1 Jun1 Sep1 Dec Mar Mar Dec Mar

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

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

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# Dividend distribution policy and dividend history

• 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.

#### 1,75 110% 0.20 0.12 105% 1,50 0.06 100% ).10 1,25 95% 90% 1,00 **85**% 50 0,75 80% 75% 0,50 70% 0,25 **65**% 0,00 60% Sol 000 2010 2011 2012 2013 2014 2015 2015 ŝ

## EUR Dividend distribution history



100th anniversary dividend
Repayment of capital per share
Dividend per share
Dividend payout ratio

\* Change in dividend payout ratio is due to higher EPS (EUR 2.35) which is explained by the divestment of Orion Diagnostica \*\* Proposal by the Board of Directors

# Easyhaler® - diverse treatment options for asthma and COPD by utilising the same inhaler technology

- Easyhaler® is a dry-powder inhaler developed in-house
- Orion has developed Easyhaler®-adapted dry powder formulations of several well-known generic active substances:
  - salbutamol, beclometasone, budesonide, formoterol, salmeterol and fluticasone
- Key benefits:
  - Dosing accuracy and consistent deposition
  - Easy to teach, learn and use
  - A wide range of products



## **Upcoming events**

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Annual General Meeting Interim Report 1-3/2021 Capital Markets Day 2021 Half-Year Financial Report Interim Report 1-9/2021 25/3/2021 27/4/2021 26/5/2021 19/7/2021 20/10/2021





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