FIRST NINE MONTHS 2021

## **FINANCIAL RESULTS**



NOVEMBER 2021

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## 9M 2021 financial results - highlights



Operating revenue growth of 53% to €463.5Mn and EBITDA growth of 100% to €139.5Mn in 9M 2021.



Sales of the heparin franchise increased by 15% to €181.5Mn in 9M 2021.



Sales of Neparvis<sup>®</sup> increased by 28% to €27.7Mn in 9M 2021.



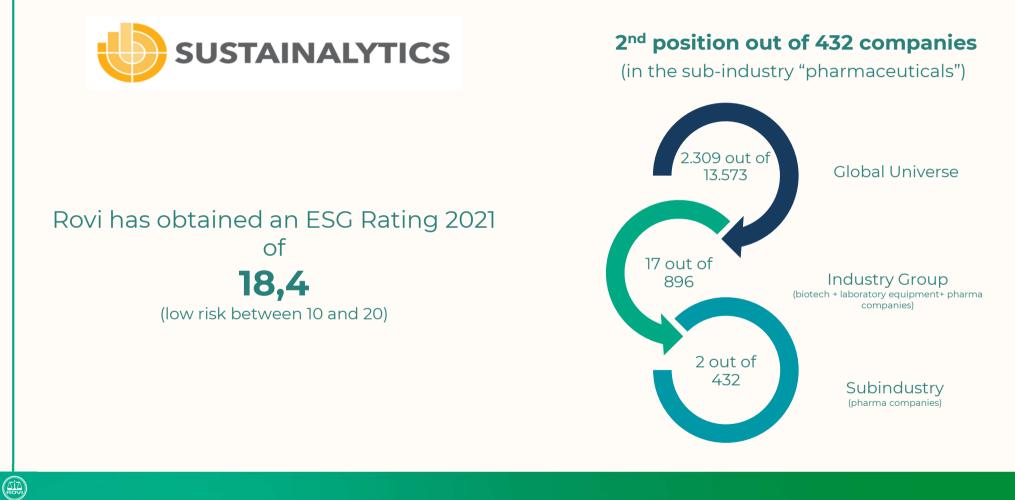
CMO sales increased by 187% to €180.2Mn in 9M 2021.



For 2021, ROVI is upgrading again its 2021 operating revenue guidance from the range between 35% and 40% to the 40% and 45% range.



## Milestone achieved – ESG Risk Rating 2021



#### **ROVI Share Buyback Program**

#### **Purpose and scope**

To redeem own shares of ROVI (share capital reduction) while, at the same time, increasing the remuneration of ROVI's shareholders by raising earnings per share.

#### **Duration**

From today, 3 November 2021, for a **twelve-month** period.

Maximum monetary amount

Up to **125,000,000 euros**.

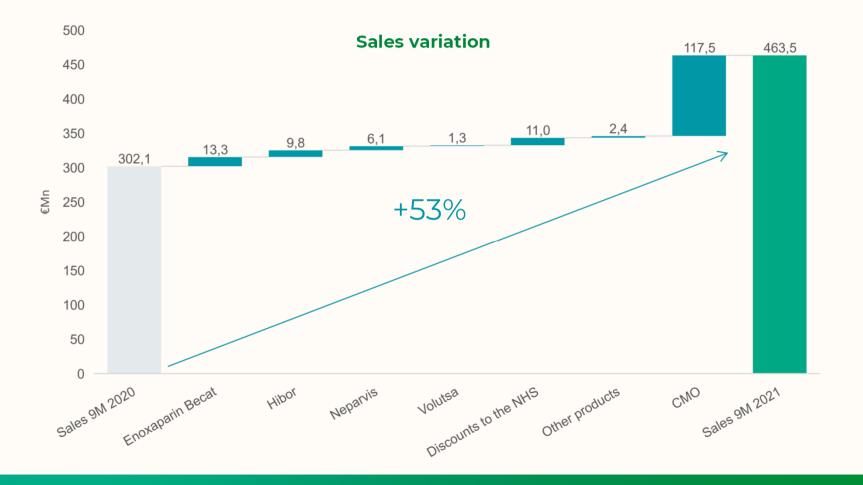
#### Maximum number of shares to be acquired

**1,682,000** shares of the Company, representing approximately 3% of the Company's share capital

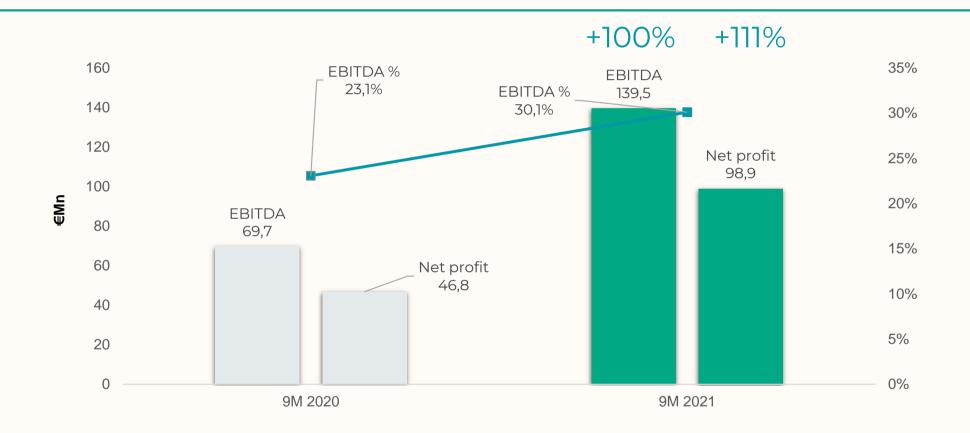
## **OPERATING RESULTS**



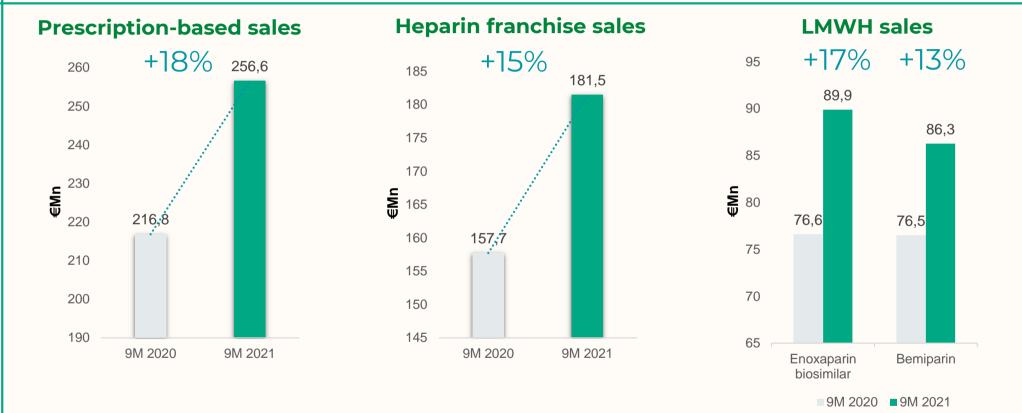
## Growth driven by CMO and specialty pharma businesses...



## ...with high profitability



EBITDA increased to €139.5Mn in 9M 2021, a rise of 100% compared to the same period of the last year. Net profit increased by 111%, from €46.8Mn in 9M 2020 to €98.9Mn in 9M 2021.

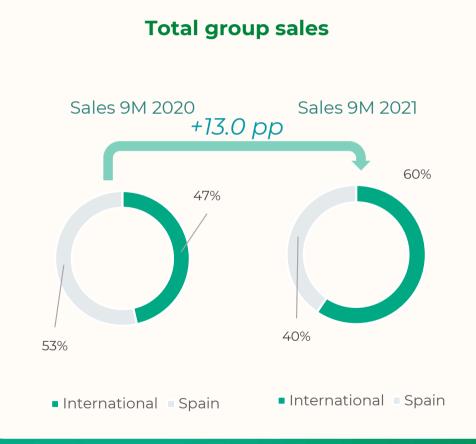


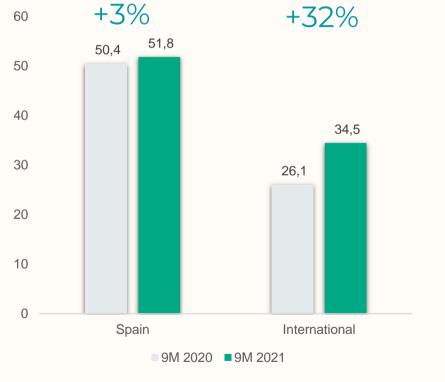
#### Heparins, leading the specialty pharmaceutical business

Sales of prescription-based pharmaceutical products increased by 18% to €256.6Mn in 9M 2021. Sales of the heparin franchise increased by 15% to €181.5Mn in 9M 2021. Heparin sales represented 39% of operating revenue in 9M 2021 compared to 52% in 9M 2020.

## Well positioned to drive long-term leadership in Low Molecular Weight Heparins (LMWH)

Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 15% to €176.2Mn in 9M 2021





#### **Bemiparin sales**

#### Strong growth potential of Enoxaparin Biosimilar Becat®

#### Well-Established Network to Minimize Time-to-Market in 26 Marketed in countries Germany, UK, in Europe in 28 countries Italy, Spain, and 24 in Portugal and the Rest of Poland the World **Enoxaparin Biosimilar Becat® Sales Ramp-up** +17%40 33,3 35 29,6 29,4 28 27,2 27,2 30 24.8 25 20 19.8 16,5 20 16.4 13.5 15 1,5...4,1...4,8... 10 5 €Mn () 032018 022018 042017 012021 2202 012018

#### in 7 European countries... 50-70% Market Share ... of the reference product ...the largest enoxaparin ...which account for c.75% market market with €1.3bn sales<sup>2</sup> of the European market <sup>3</sup> ROVI launched enoxaparin in Canada, Malasya, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia and Bahamas in 9M 2021 🛛 😫 🚺 🕘 💼 🛟 🔁 Continue international expansion in other markets with €0.7br strong growth potential through out-licensing agreements Market Sales² Already Signed Out-Licensed Agreements: 107 Countries

**Commercial Strategy** 

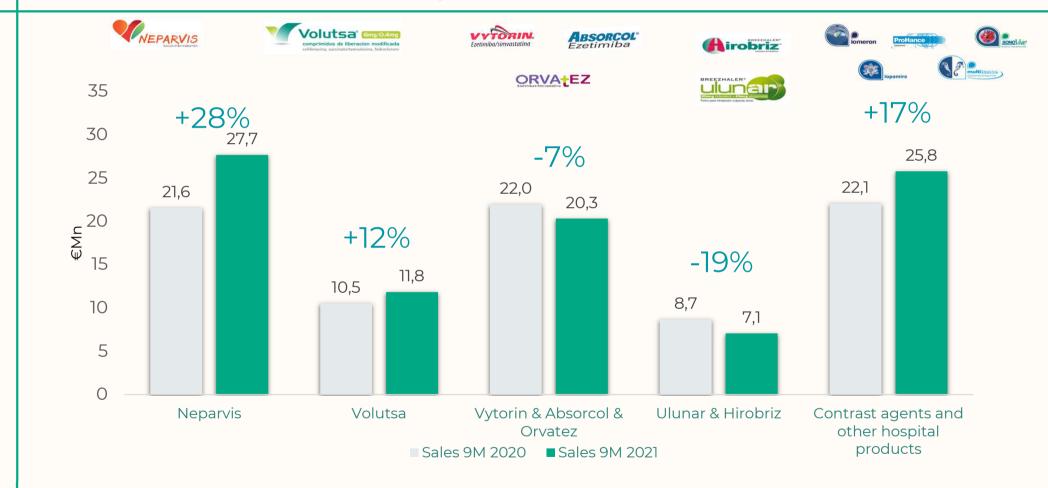
ROVI will directly market

enoxaparin biosimilar Becat®

Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales 3. QuintilesIMS, 2015. were negligible. IOVIA MIDAS 01 2020 In the long-term, biosimilars

tend to reach a...

# Neparvis® and Volutsa® leading the growth of the specialty pharma business



#### Value added CMO services

#### **CMO strategy**

ROVI and Moderna will strengthen their collaboration:

- For the manufacture of the active substance of the COVID-19 Vaccine Moderna.
- In the fill-finish of the COVID-19 Vaccine Moderna by increasing its fill-finish capacity.

#### Packaging Excellence Centre in our Alcalá de Henares plant

2 new blister high speed lines. State-of-the art 7 packaging lines fully dedicated to injectables. installations Total 14 packaging lines.

#### New capacities for our plants

Madrid	1 new state of the art syringe filling line. Total 4 filling lines. 1 new automatic syringe inspection machine. Total 3 lines.
San Sebastián de los Reyes	1 high speed syringe filling line. 3 new state of the art vials filling lines. Total 4 lines. 2 new automatic vials inspection machine. Total 4 lines. 1 new automatic vials packaging machine.
Granada	1 new line supporting production phases of the active. substance of the MRNA vaccine.

#### Sales 9M 2021 180,2 €Mn +187% 62,7 Sales 9M 2020 150 175 200 $\bigcirc$ 25 50 75 100 125

CMO sales increased by 187% to €180.2Mn in 9M 2021 as a result of:

- The booking of the income related to the production of the COVID-19 vaccine;
- The booking of the income related to the activities to prepare the plant for the COVID-19 vaccine production under the agreement with Moderna; and
- The redirection of our toll manufacturing activities strategy towards highvalue-added products.

ROVI expects the toll manufacturing business to increase by between 2 and 2.5 times, including production of the COVID-19 vaccine.

13

#### **CMO** evolution

#### ISM<sup>®</sup> Platform opens up new avenues of growth for ROVI

#### **Overview**

- Internally-developed and patented innovative drug-release technology, ISM®<sup>1</sup>, which allows for the sustained release of compounds administered by injection
- Based on two separate syringes respectively containing (a) the drug and polymer (solid state) and (b) the solvent (liquid state)
- Potential wide applicability of ISM® technology to new chronic therapeutic areas, including psychiatry and oncology
- 505(b)(2) path of approval for candidates leveraging ISM® technology

Product	Potential Indication	Current Situation	Key Milestones
DORIA® Risperidone, monthly	Schizophrenia	Phase III	In approval process in Europe and in USA
Letrozole ISM® Long acting Letrozole	Breast Cancer	Phase I	Phase I started in November 2017
Risperidone, quarterly	Schizophrenia	Non-Clinical	
Concentrated on improving posology for already approved compounds, which benefits risk / reward profile			
Multiple FDA / GMP approved facilities to support the platform			

#### Key Company Highlights of ISM<sup>®</sup> Platform

1 Predictability	Pop PK <sup>2</sup> model & simulations already validated for DORIA® in Phase I & II Clinical Program	Expected high success rate in Phase III
2 Usability	Improved stability	No cold chain needed
3 Flexibility	Selecting the most convenient posology depending on clinical needs	From 1 to 6- month administration
4 Improved Clinical Management	Long-acting injection (1-6 months) plasma therapeutic levels from day 1	Rapid onset & sustained clinical effect
5 Vertical Integration	Technological barriers (e.g. power filling) Strong IP Manufacturing capabilities	Protected technology Fully integrated manufacturing plants

## Outlook 2022



2022 operating revenue growth rate

Mid-single-digit

#### The key Growth levers in 2022

Specialty Pharma	СМО	
Bemiparin	Spare capacity in the manufacturing	
Biosimilar of Enoxaparin	plants	
Launches such as Neparvis® and Volutsa®	New customers to be acquired	
Existing portfolio of specialty pharmaceuticals	Agreement with Moderna	

Given the uncertainties associated to the development of the Covid-19 pandemic, it is not yet possible to make a precise assessment of the impact that the pandemic will have on 2022.

15

## FINANCIAL RESULTS

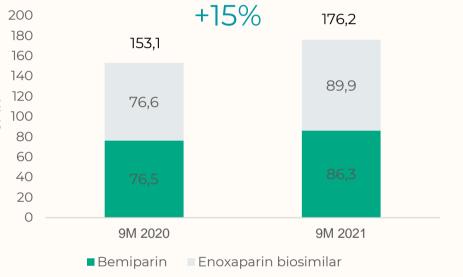


### Good revenue level with resilient sales growth

#### **Operating revenue**



LMWH sales



**Operating revenue** increased by 53% to €463.5Mn, achieved on:

- 187% increase in CMO; and
- 18% growth in prescription-based products.
- Contrast agents and other hospital products increased by 17%.

Sales of **LMWH** increased by 15% to €176.2Mn in 9M 2021.

• Enoxaparin biosimilar sales increased by 17% to €89.9Mn and Bemiparin sales increased by 13% to €86.3Mn.

# Gross margin mainly impacted by the increase in the LMWH raw material cost of goods sold

#### 57.6% 58.1% 60% 250 50% +52% 200 40% €Mn 150 30% 100 20% 175,4 50 10% 0 0% 9M 2020 9M 2021 Gross profit -Gross margin

#### **Gross profit and Gross margin**

#### **Gross margin impacts**

**Gross profit** increased by 52% to €266.8Mn in 9M 2021, the **gross margin** showing a decrease of 0.5 pp from 58.1% in 9M 2020 to 57.6% in 9M 2021, mainly due to the increase in the LMWH raw material cost of goods sold in 9M 2021 compared to 9M 2020.

ROVI expects LMWH raw material prices to continue to decline in 2021 as a result of the increase in the pig population in China.

Nevertheless, despite the potential decrease in LMWH raw material prices, the impact on the gross margin will continue to be negative because of the long LMWH manufacturing process, in which the raw material currently being used, stocked for several months, was purchased at higher prices.

#### Cost control along with commitment to R&D

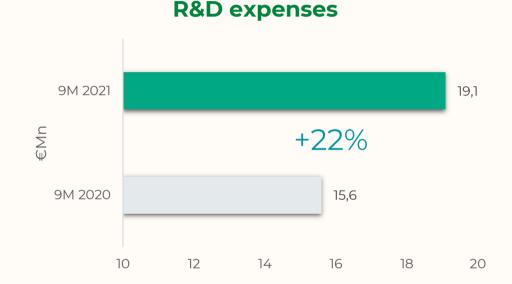
#### +20%35% 23.4% 29.8% 100 30% 80 25% €Mn 20% 60 15% 90.1 40 10% 20 5% 0% 9M 2020 9M 2021 SG&A ——SG&A/Operating revenue

SG&A expenses

SG&A increased 20% to €108.3Mn in 9M 2021 mainly as a result of:

- An increase in expenses related to the manufacture of the Moderna vaccine; and
- An increase in expenses due to the preparation of the Risperidone ISM® launch in Europe.

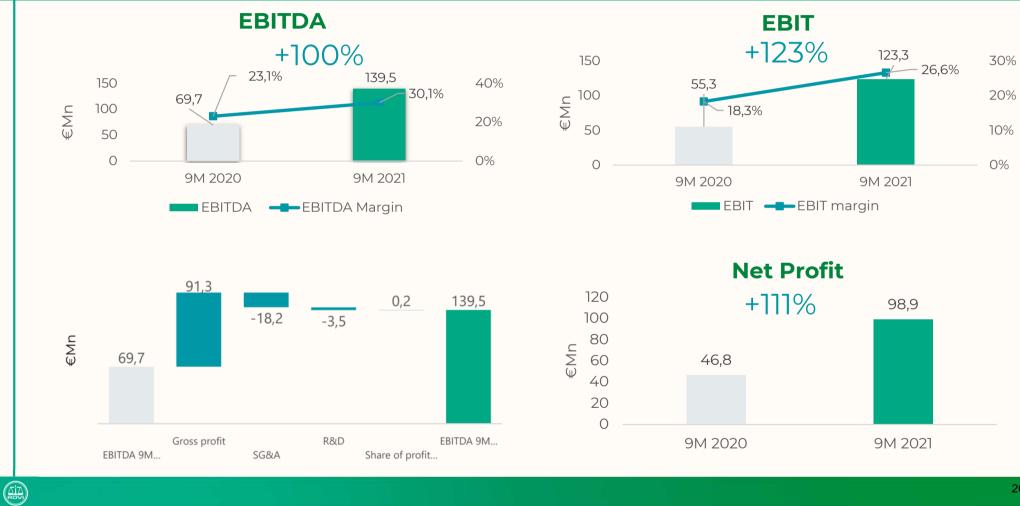
Excluding expenses related to COVID-19, SG&A would have increased by 23% to €106.9Mn in 9M 2021 compared to €87.0Mn in 9M 2020.



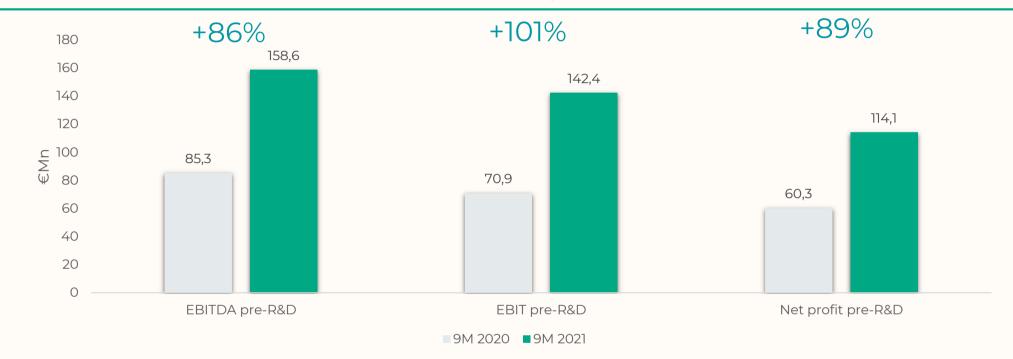
**R&D expenses** increased 22% to €19.1Mn in 9M 2021. These expenses are related to:

- The repetition of the bioavailability study comparing multiple doses of Risperidone ISM® with oral risperidone, in response to the major observation of the Committee for Medicinal Products for Human Use (CHMP);
- Letrozole-ISM<sup>®</sup> Phase I trial; and
- Development of a new formulation of Risperidone-ISM® for a 3-monthly injection.

## **EBITDA, EBIT & Net Profit analysis**



#### PRE-R&D analysis

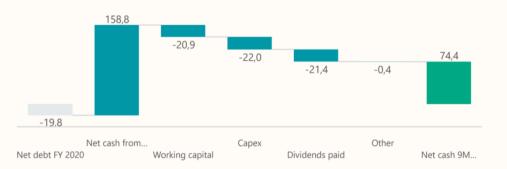


EBITDA "pre-R&D" increased by 86%, from €85.3Mn in 9M 2020 to €158.6Mn in 9M 2021.
EBIT "pre-R&D" increased by 101%, from €70.9Mn in 9M 2020 to €142.4Mn in 9M 2021.
Net profit "pre R&D" increased by 89%, from €60.3Mn in 9M 2020 to €114.1Mn in 9M 2021.

#### **Capital expenditure and Free Cash Flow**

#### 30 22,0 25 \*\*\*\*\* 16,9 20 €Mn 15 10 5 0 9M 2020 9M 2021 New vial filling line and operations expansion 11% Maintenance Capex 34% Escúzar plant 39% ISM industrialisation 16%

#### **CAPEX Evolution**



**FCF** evolution

Cash Flow from operating activities increased to €137.9Mn in 9M 2021 mainly due to:

- Increase of €70.1Mn in profit before income tax;
- Increase of €2.1Mn in the "inventories" line in 9M 2021 (mainly as a result of lower heparin stock levels) compared to a decrease of €79.4Mn in 9M 2020;
- Booking of €21.5Mn under the "Proceeds from toll manufacturing services" caption in 9M 2021 compared to the €18.1Mn euros recognized in 9M 2020; and
- Increase of €10.7Mn in the "trade and other payables" item in 9M2021 compared to a decrease of €5.3Mn in 9M 2020.

ROVI invested €22.0Mn in 9M 2021 and the 3 main investments projects are:

- ISM Industralization
- Escúzar plant
- New Moderna vaccine lines

## **Debt analysis**

#### Debt breakdown by source (%) **Debt maturities** 50 45.6 Total debt 45 €71.9Mn 40 22% 35 30 25 Financial liabilities for leases 20 Debt with public administration 15 10,0 9,9 10 Bank borrowings 4,9 1,5 5 0 2022 2024 2021 2023 2025 and beyond

#### Debt with public administration represented 15% of total debt, with 0% interest rate.

Net cash of €74.4Mn as of 30 September 2021 vs €56.1Mn as of 30 June 2021 and €19.8Mn net debt as of 31 December 2020.

ROVI General Shareholders Meeting, on 17 June 2021, approved the payment of a gross **dividend** of 0.3812 euros per share on 2020 earnings; it means an increase of 118% compared to the dividend on 2019 earnings (€0.1751/share) and represents a 35% pay out (vs 25% pay out last year). This dividend was paid on 7 July 2021.

## News-flow 2021-2022

	Specialty pharma	Sales of biosimilar of Enoxaparin
		Additional new products to be launched in 2022
		Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar outside Europe
	СМО	New contracts to be announced Evolution of Moderna's vaccine manufacturing
	ISM® technology platform	Marketing authorization for Doria <sup>®</sup> in Europe and USA
		Discussions with FDA initiated to review Letrozole ISM <sup>®</sup> phase I results as well as the next steps for continuing the clinical development

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