

# First nine months 2022 FINANCIAL RESULTS

4 NOVEMBER 2022



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## 9M 2022 financial results - highlights



Operating revenue growth of 24% to €575.5 Mn and EBITDA growth of 25% to €173.9 Mn in 9M 2022.



Sales of the heparin franchise increased by 11% to €200.6 Mn in 9M 2022.



Sales of Neparvis<sup>®</sup> increased by 4% to €28.8 Mn in 9M 2022.



CMO sales increased by 49% to €267.9 Mn in 9M 2022.



For 2023, ROVI expects its operating revenue to show low-double-digit negative growth on 2022, although a positive growth of between 5% and 10% is expected in comparison with the 2021 figure.

# Milestones achieved – Glicopepton Biotech and first position in the Sustainalytics ESG ranking



## Glicopepton Biotech founded to produce compounds of high technological value

ROVI announced that it presented Glycopepton Biotech, S.L., a joint venture with Càrniques Celrà, S.L. and Grupo Empresarial Costa, S.L. that involves the creation of one of the first national structures for self-sufficiency in heparins.

The project involves the construction of a facility at the Industrial Logistics Platform of Fraga (Huesca), which will produce compounds of high biological value that derive from the intestinal mucosa of pigs. It will involve a joint investment of approximately 40 million euros over the next four years and is expected to create around 30 direct skilled jobs. The project will be subject to obtaining the applicable administrative and regulatory permits and authorisations.



## ROVI obtained an “ESG Risk Rating 2022” of 17.3, the first position in the sub-industry “pharmaceuticals”

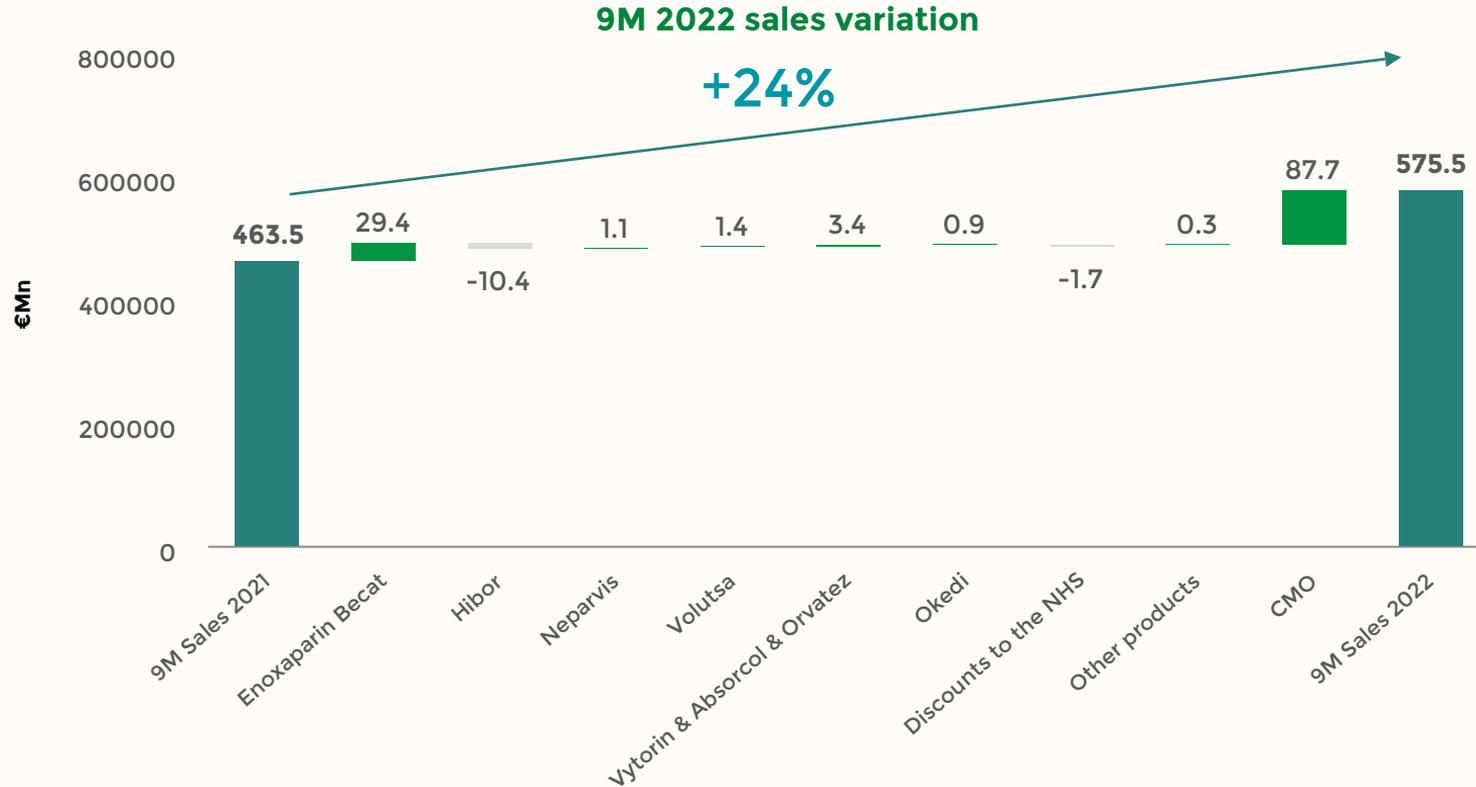
ROVI’s ESG aspects have been evaluated by Sustainalytics, having obtained an “ESG Risk Rating 2021” of 17.3, which places the company at low risk (between 10 and 20). This rating improves by 1.1 points the one achieved in the previous year (18.4).

ROVI attains the first position out of 458 companies in the sub-industry “pharmaceuticals” and 22th out of a total of 970 companies in the “pharmaceutical industry”, which includes biotech, pharmaceutical and laboratory equipment companies.

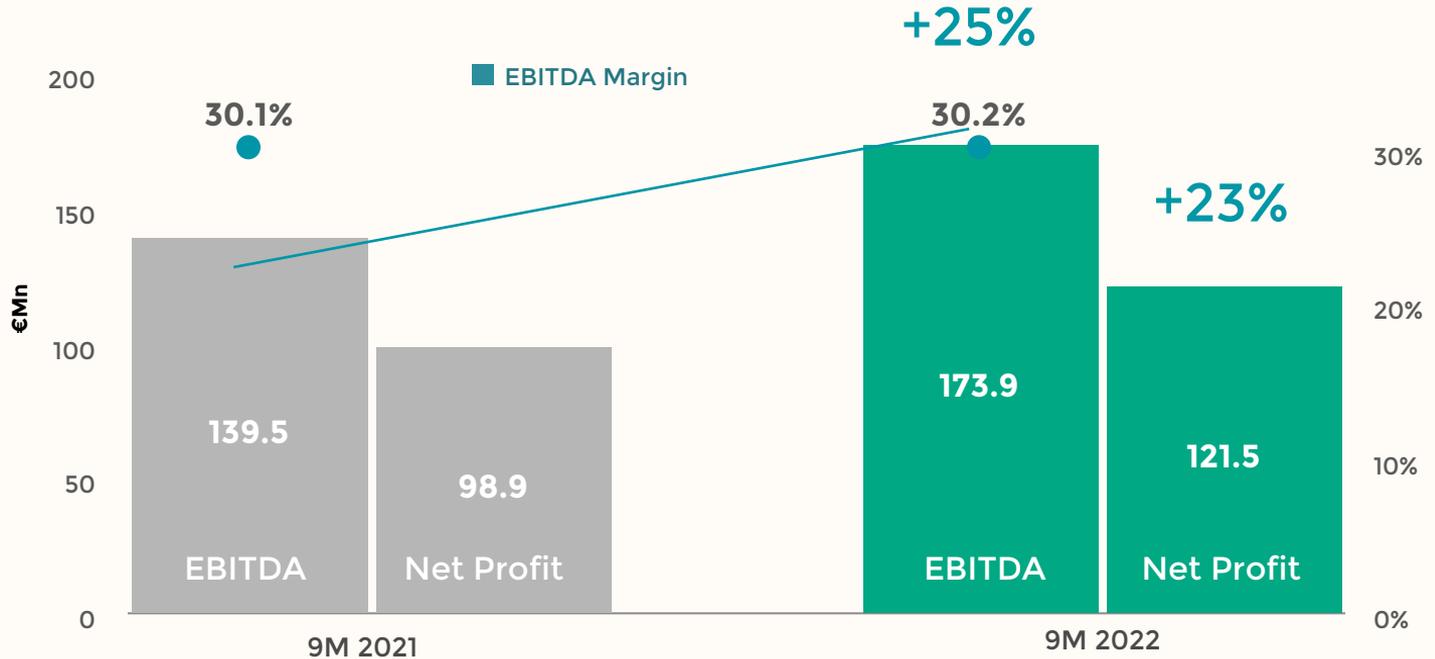
# OPERATING RESULTS



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



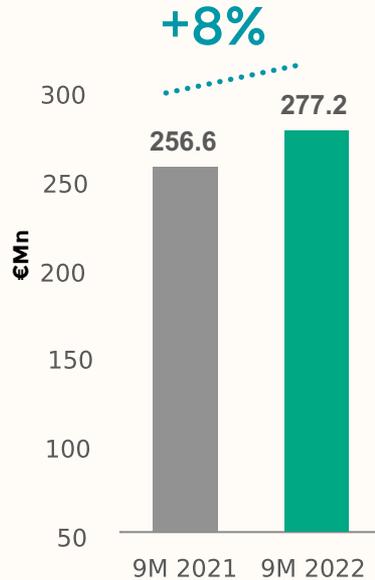
## ...with high profitability



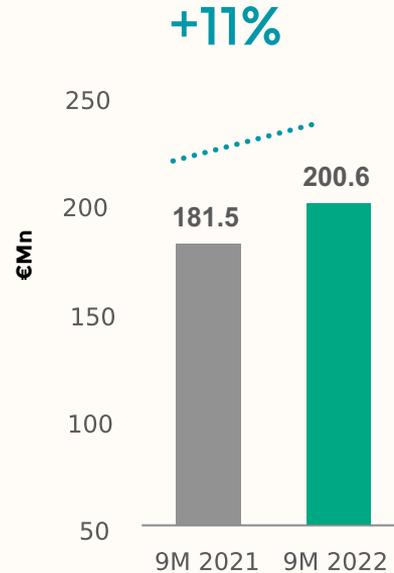
- EBITDA increased to €173.9 Mn in 9M 2022, a rise of 25% compared to 9M 2021.
- Net profit increased by 23%, from €98.9 Mn in 9M 2021 to €121.5 Mn in 9M 2022.

# Heparins, leading the specialty pharmaceutical business

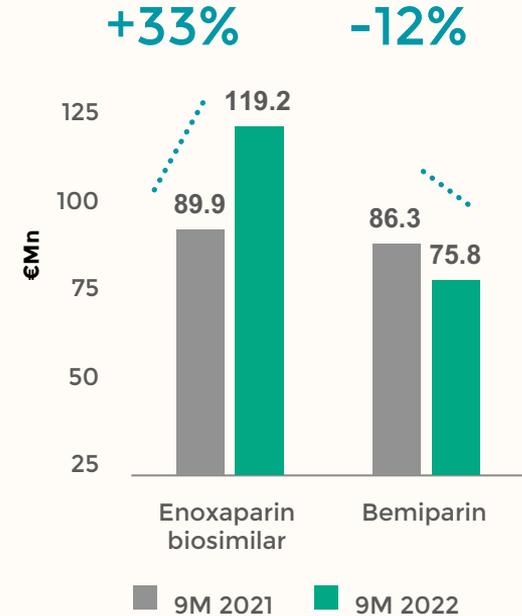
## Prescription-based sales



## Heparin franchise sales



## LMWH sales

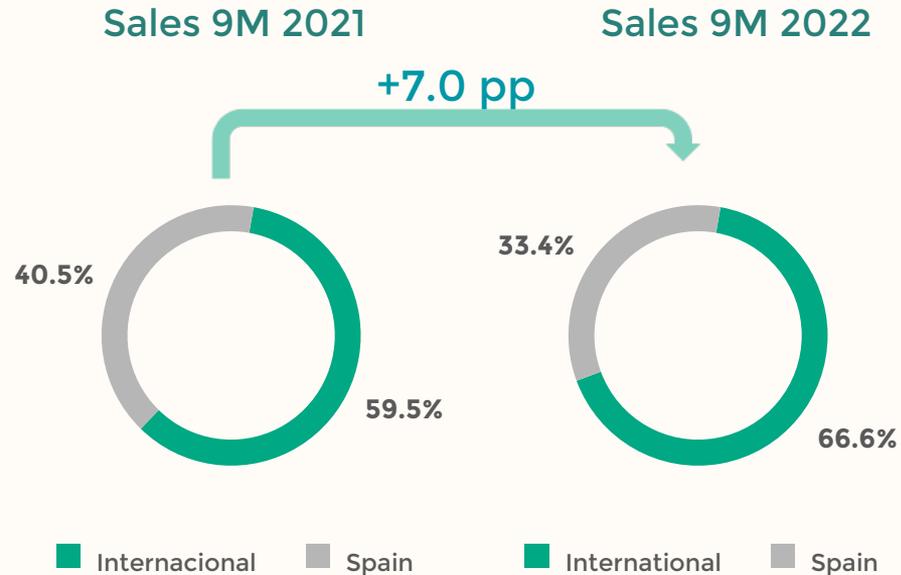


- Sales of prescription-based pharmaceutical products increased by 8% to €277.2 Mn in 9M 2022.
- Sales of the heparin franchise increased by 11% to €200.6 Mn in 9M 2022.
- Heparin sales represented 35% of operating revenue in 9M 2022 compared to 39% in 9M 2021.

## Successful internationalization plan

- Well positioned to drive long-term leadership in Low Molecular Weight Heparins (LMWH)
- Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 11% to €195.1 Mn in 9M 2022

### Total group sales

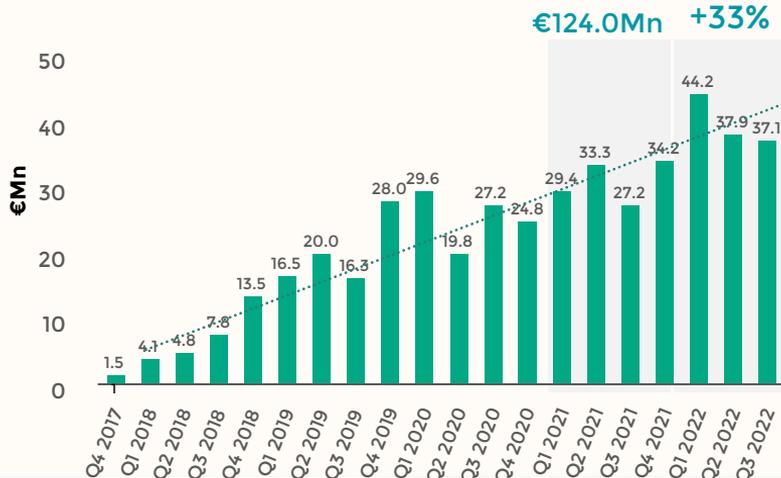


# Strong growth potential of Enoxaparin Biosimilar Becat®

## Well-Established Network to Minimize Time-to-Market

- Direct marketed in Germany, UK, Italy, Spain, Portugal and Poland
- Approved in 26 countries in Europe and 31 in the Rest of the World
- Launched in 38 countries

## Enoxaparin Biosimilar Becat® Sales Ramp-up



## Commercial Strategy

ROVI will directly market enoxaparin biosimilar Becat® in 7 European countries...

...the largest enoxaparin market with €1.3bn sales<sup>2</sup>

...which account for c.75% of the European market<sup>3</sup>

In the long-term, biosimilars tend to reach a...

50-70% Market Share<sup>4</sup>

...of the reference product market

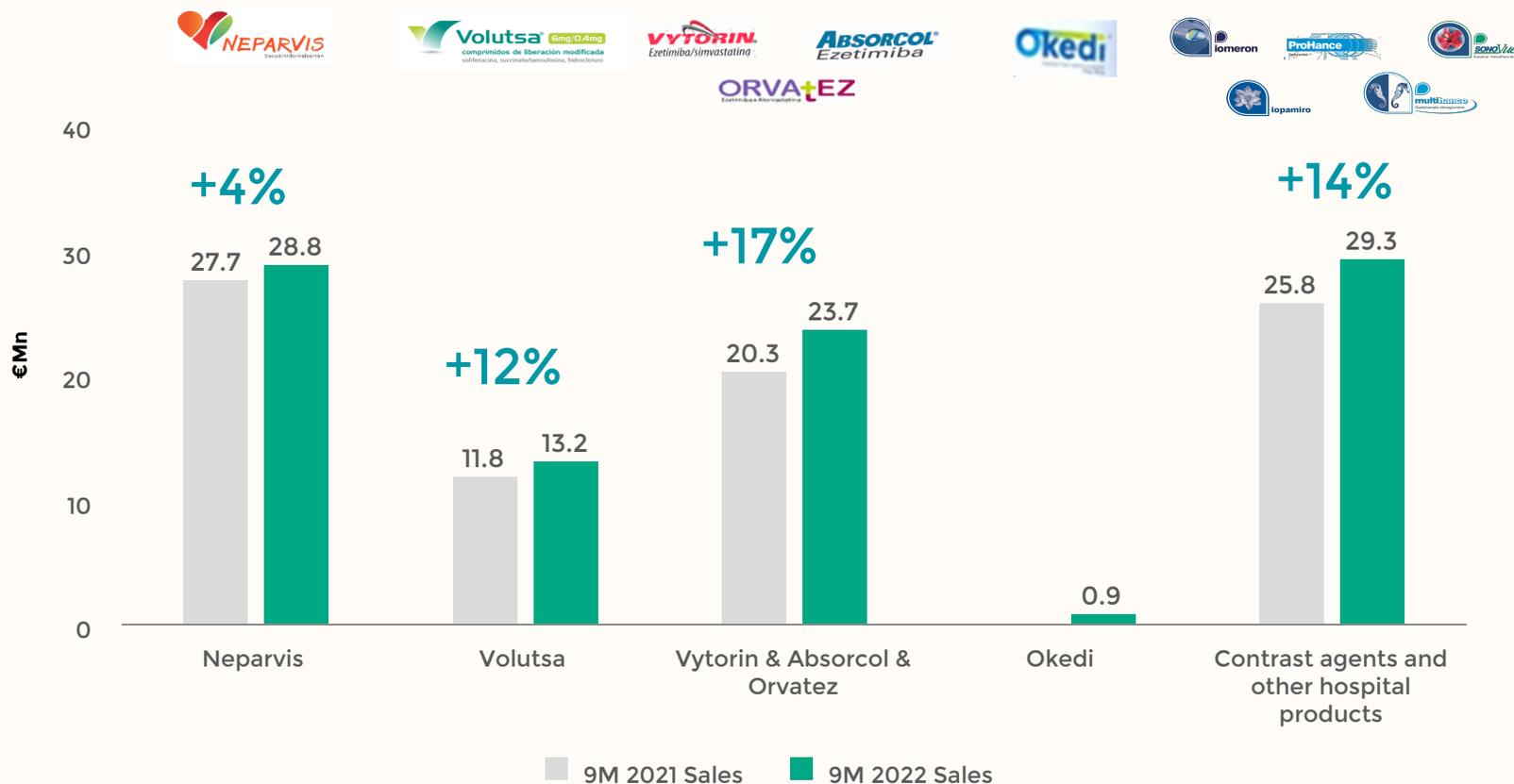
ROVI launched its enoxaparin biosimilar in 5 countries in 9M 2022: Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo.

Continue international expansion in other markets with strong growth potential through out-licensing agreements

€0.7bn Q1 2020 MAT Market Sales<sup>7</sup>

1. Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible.  
 2. IQVIA MIDAS Q1 2020  
 3. QuintilesIMS, 2015.  
 4. Technavio 2016 biosimilars report.

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



# Value added CMO services

## CMO strategy

### ROVI and Moderna will expand long-term collaboration:

- This new agreement, which has a term of ten years, includes a series of investments expected to allow the manufacturing capacity to increase across ROVI's facilities in Madrid, Spain.
- In addition to producing Moderna's COVID-19 vaccine, ROVI's platform could also be utilized to service future Moderna mRNA vaccine candidates.

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

#### State-of-the art installations

2 new blister high speed lines.  
7 packaging lines fully dedicated to injectables.  
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.

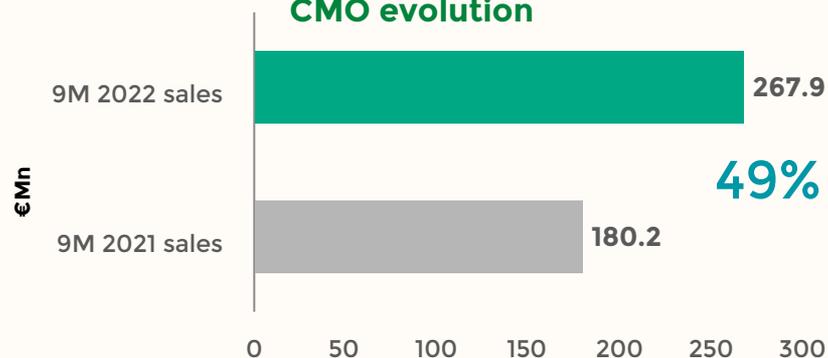
#### San Sebastián de los Reyes

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.

## CMO evolution



CMO sales increased by 49% to €267.9 Mn in 9M 2022 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 reorientation of our contract manufacturing activities strategy towards high-value-added products.

In February 2022, ROVI announced it expected the **CMO business** for the full year 2022 to **increase between 30% and 40%**. With the visibility that the Company has at this moment, ROVI expects to achieve the **higher end of this range**.

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

## Overview

- Internally-developed and patented innovative drug-release technology, ISM<sup>®</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<sup>®</sup> technology to new chronic therapeutic areas, including psychiatry and oncology
- 505(b)(2) path of approval for candidates leveraging ISM<sup>®</sup> technology

Product	Potential Indication	Current Situation	Key Milestones
Risperidone-ISM <sup>®</sup> , monthly	Schizophrenia	Phase III	<ul style="list-style-type: none"> <li>Approved in Europe</li> <li>In approval process in USA</li> </ul>
Letrozole ISM <sup>®</sup> 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	<b>Predictability</b>	Pop PK <sup>2</sup> model & simulations already validated for Risperidone-ISM <sup>®</sup> in Phase I & II Clinical Program	Expected high success rate in Phase III
2	<b>Usability</b>	Improved stability	No cold chain needed
3	<b>Flexibility</b>	Selecting the most convenient posology depending on clinical needs	From 1 to 6-month administration
4	<b>Improved Clinical Management</b>	Long-acting injection (1-6 months) plasma therapeutic levels from day 1	Rapid onset & sustained clinical effect
5	<b>Vertical Integration</b>	Technological barriers (e.g. power filling) Strong IP Manufacturing capabilities	Protected technology Fully integrated manufacturing plants



# Outlook 2023



## 2023 operating revenue growth rate

**Low-double-digit negative growth vs 2022**  
**Positive growth of between 5% and 10% vs 2021**

## The key Growth levers in 2023

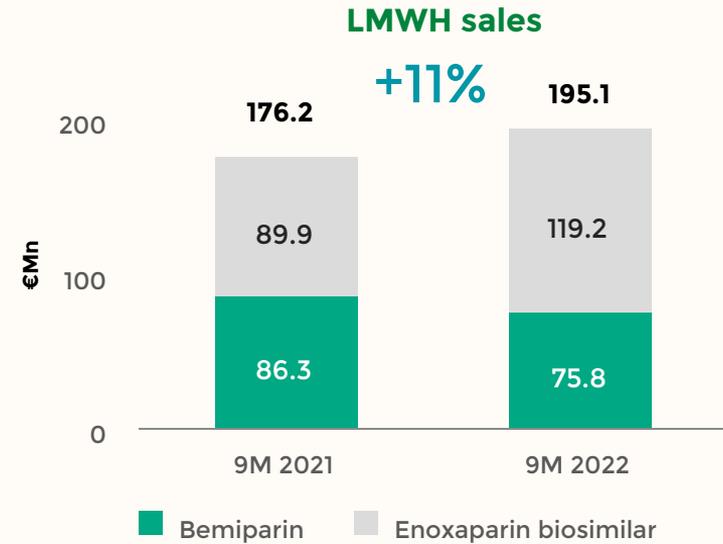
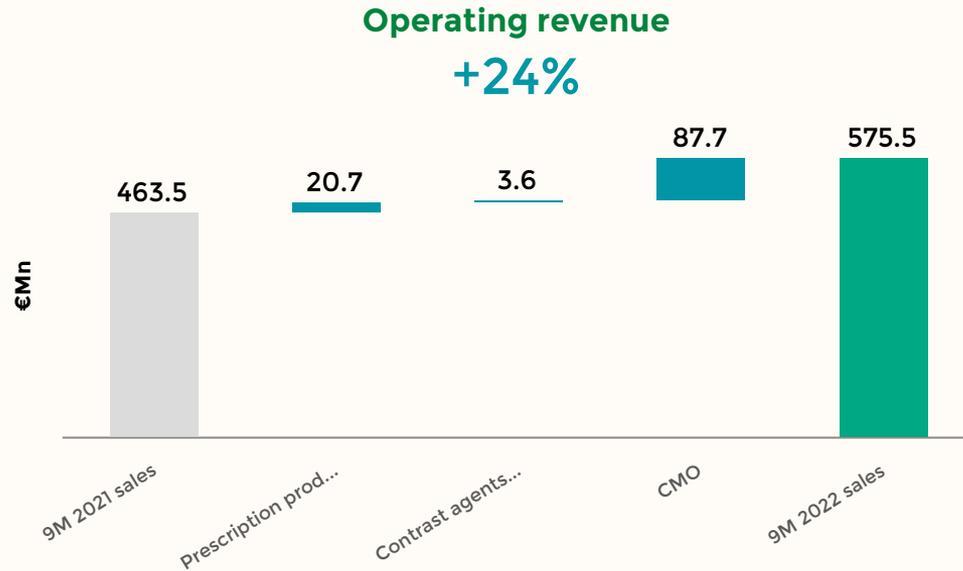
Specialty Pharma	CMO
Marketing of Okedi® in Europe	New customers to be acquired
LMWH franchise	Agreement with Moderna
License agreements (Neparvis® and Volutsa®)	Capacity increase
Existing portfolio of specialty pharmaceuticals	
New products distribution licenses	

Notwithstanding, in 2023 ROVI will face a new COVID-19 post-pandemic scenario in which the uncertainty related to the evolution of the disease is very high. It is not, therefore, possible to make a precise assessment of the impact that this new scenario could have on its CMO business.

# FINANCIAL RESULTS



## Good revenue level with resilient sales growth



**Operating revenue** increased by **24%** to €575.5 Mn, achieved on:

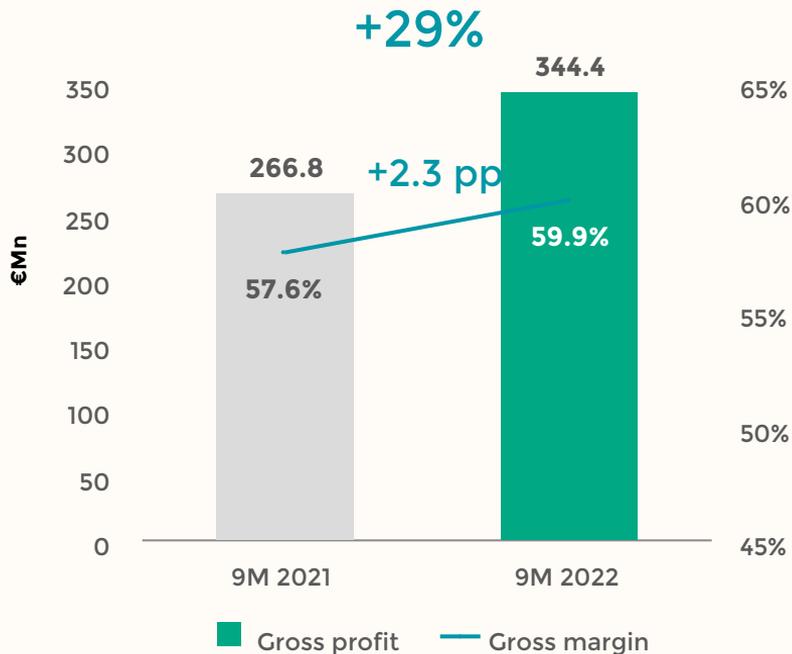
- **49%** increase in CMO; and
- **8%** growth in prescription-based products.
- Contrast agents and other hospital products increased by **14%**.

Sales of **LMWH** increased by **11%** to €195.1 Mn in 9M 2022.

- **Enoxaparin biosimilar** sales increased by **33%** to €119.2 Mn and **Bemiparin** sales decreased by **12%** to €75.8 Mn.

## Gross margin positively impacted by the CMO division

### Gross profit and Gross margin



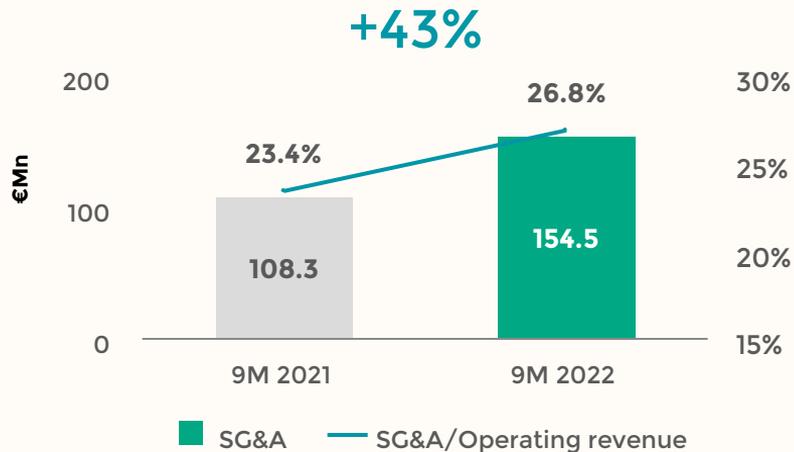
### Gross margin impacts

Gross profit increased by 29% to €344.4 Mn in 9M 2022, the gross margin showing an increase of 2.3 p.p. from 57.6% in 9M 2021 to 59.9% in 9M 2022, mainly because the increase in the CMO business contributed higher margins to Group sales.

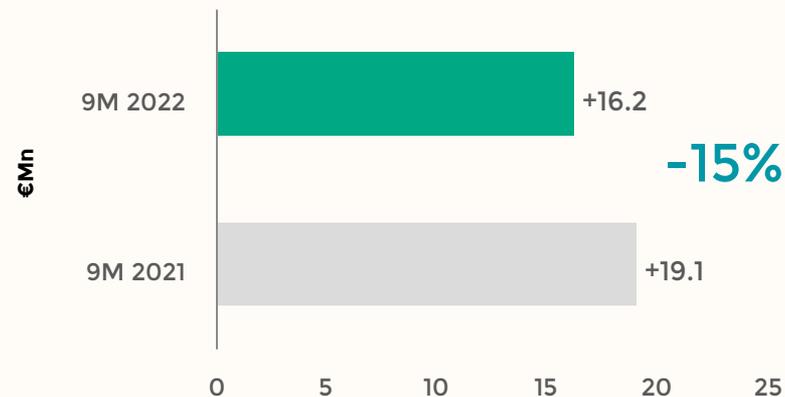
This positive impact on the gross margin offset the increase in the LMWH cost of goods sold in 9M 2022 compared to 9M 2021.

## Cost control along with commitment to R&D

### SG&A expenses



### R&D expenses



**SG&A** increased 43% to €154.5 Mn in 9M 2022 mainly as a result of:

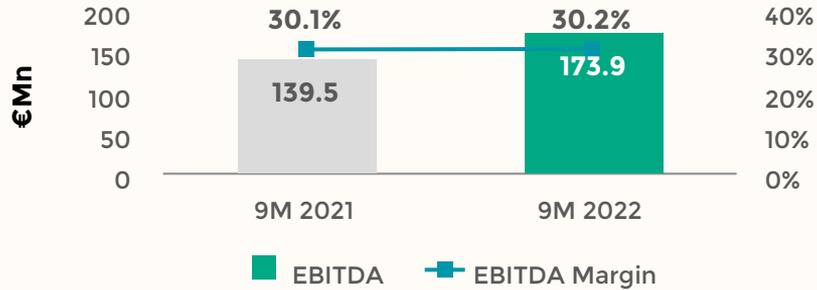
- An increase in expenses related to the manufacture of the Moderna vaccine;
- An increase of €5.8 Mn in the energy cost; and
- An increase in expenses due to the Okedi® launch in Europe.

**R&D expenses** decreased 15% to €16.2 Mn in 9M 2022. These expenses are related to:

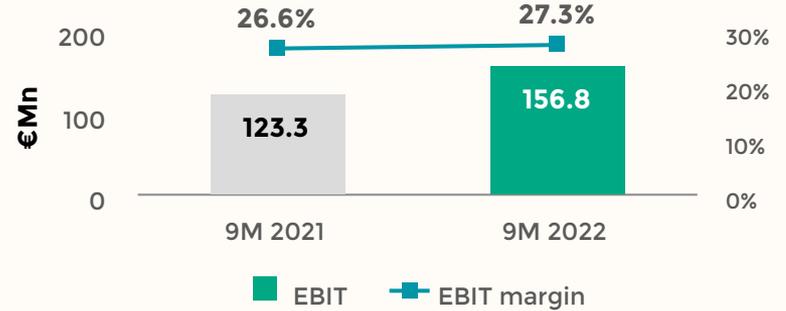
- Preparing the development of the next phase of Letrozole-ISM®; and
- Development of a new formulation of Risperidone-ISM® for a 3-monthly injection.

## EBITDA, EBIT & Net Profit analysis

### EBITDA +25%



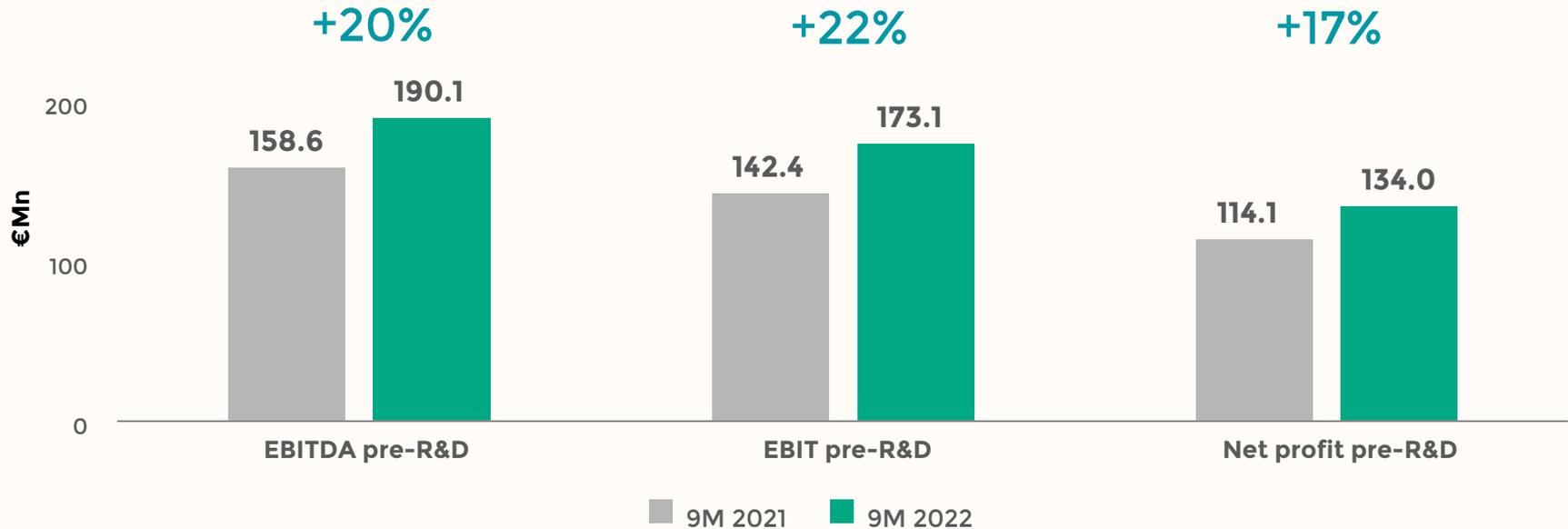
### EBIT +27%



### Net Profit



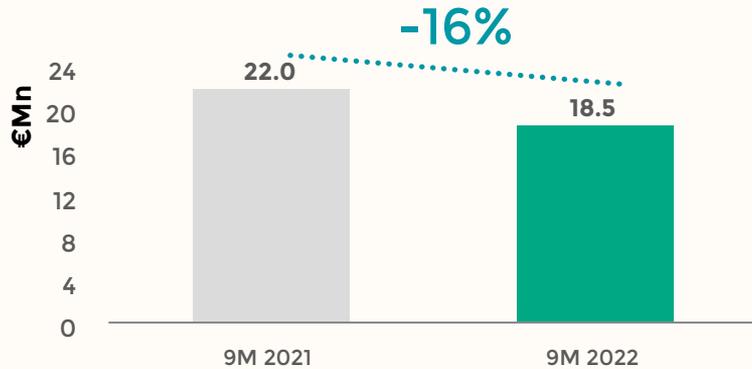
## PRE-R&D analysis



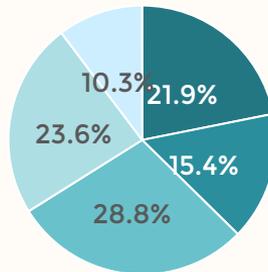
- **EBITDA “pre-R&D”** increased by 20%, from €158.6 Mn in 9M 2021 to €190.1 Mn in 9M 2022.
- **EBIT “pre-R&D”** increased by 22%, from €142.4 Mn in 9M 2021 to €173.1 Mn in 9M 2022.
- **Net profit “pre R&D”** increased by 17%, from €114.1 Mn in 9M 2021 to €134.0 Mn in 9M 2022.

# Capital expenditure and Cash Flow

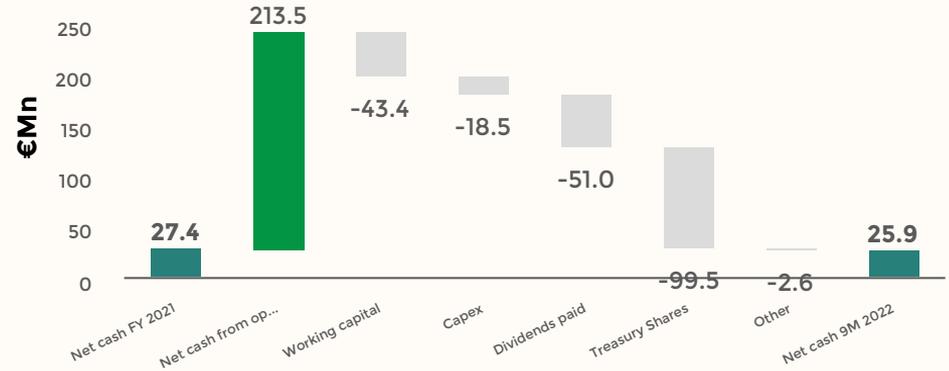
## CAPEX evolution



- Maintenance Capex
- ISM industrialisation
- Escúzar plant
- New filling lines and operations expansion
- Glicopeptón



## CF evolution



CF from operating activities increased to €170.0 Mn in 9M 2022 mainly due to:

- Increase of €33.6 Mn in profit before income tax;
- Booking of €55.3 Mn under the “Proceeds from toll manufacturing services” caption in 9M 2022 compared to the €21.5 Mn recognized in 9M 2021; and
- Increase of €2.6 Mn in the “trade and other receivables” item in 9M 2022 compared to a decrease of €33.6 Mn in 9M 2021.

ROVI invested €18.5 Mn in 9M 2022 and the 4 main investments projects are:

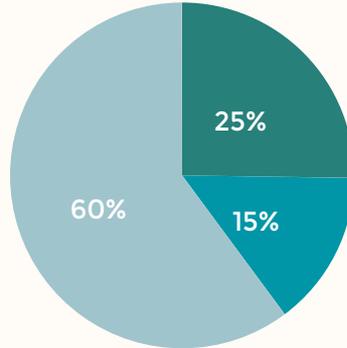
- ISM® Industrialization
- Escúzar plant
- New filling lines and operations expansion
- Glicopeptón

# Debt analysis

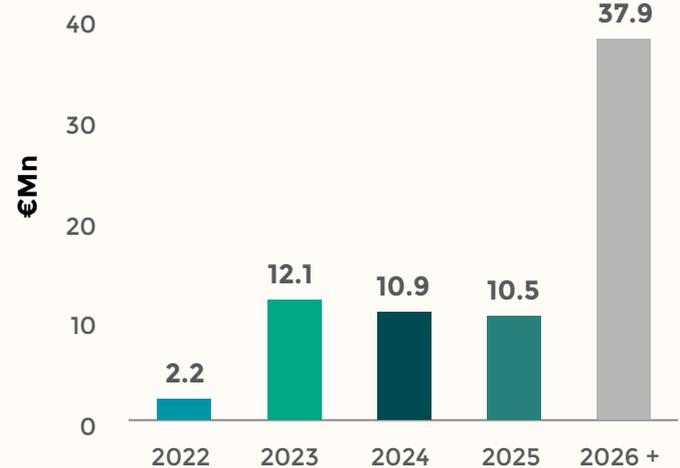
## Debt breakdown by source (%)

Total debt  
€73.6Mn

- Financial liabilities for leases
- Debt with public administration
- Bank borrowings



## Debt maturities



- **Debt with public administration represented 15% of total debt, with 0% interest rate.**
- **Net cash of €25.9Mn** as of 30 September 2022 vs €27.4Mn as of 31 December 2021.
- In July 2022, ROVI announced that the EIB had granted it a loan to support its investments in R&D&I. The loan is for €50 Mn with a repayment period of 10 years, has a three-year grace period, and may be drawn down over a term of two years.
- ROVI General Shareholders Meeting, on 14 June 2022, approved the payment of a gross dividend of €0.9556 per share on 2021 earnings; it means an increase of 151% and represents a 35% pay out. This dividend was paid on 7 July 2022.

## News-flow 2022-2023



Specialty pharma	Sales of biosimilar of Enoxaparin
	Additional new products to be launched in 2022-2023
	Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar outside Europe
CMO	New contracts in the toll manufacturing area Evolution of Moderna's vaccine manufacturing
ISM <sup>®</sup> technology platform	Launch and marketing of Okedi <sup>®</sup> in Europe Marketing authorization for Risperidone ISM <sup>®</sup> in 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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