

# First quarter 2023 FINANCIAL RESULTS

10 MAY 2023



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This Presentation also includes certain alternative performance measures ("APMs") that have not been prepared under IFRS-EU and have not been reviewed or audited by the Company's auditors nor by any independent expert. Moreover, the way the Group defines and calculates these measures may differ to the way similar measures are calculated by other companies. Accordingly, they may not be comparable.

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## 2023 first quarter financial results - highlights



Operating revenue decreased by 2% to €201.6 Mn in the first post-pandemic quarter.



Positive evolution of Okedi® (Risperidone ISM®), which doubled its sales to 2.2 million euros in Q1 2023 vs Q4 2022.



CMO sales increased by 2% to €97.3 Mn in Q1 2023.



Sales of the heparin franchise decreased by 19% to €61.2 Mn in Q1 2023 mainly due to fewer orders from partners.



Good performance of Neparvis® and Volutsa®, whose sales increased by 22% and 16% in Q1 2023, rising to €11.3 Mn and €5.0 Mn, respectively.



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

# Milestones achieved – Clinical development of a new formulation of letrozole and evaluation process for Risvan® in US



## Clinical development of a new three-monthly formulation of letrozole (hereinafter, Letrozole LEBE) rather than the initially planned annual formulation of Letrozole ISM®

ROVI has decided to commence the clinical development of a new three-monthly formulation of letrozole (hereinafter, Letrozole LEBE), rather than the initially planned annual formulation of Letrozole ISM®. The objective of this new development is to reach bioequivalence in the plasma levels of letrozole in comparison with the daily administration of oral doses of Femara® 2.5 mg.

With this new clinical programme for Letrozole LEBE, ROVI estimates it could reduce the research times in comparison to those for an annual formulation of the product, thus making it likely that the three-monthly formulation could be marketed several years earlier and, furthermore, the investment necessary to attain the objectives of this project could also be reduced.



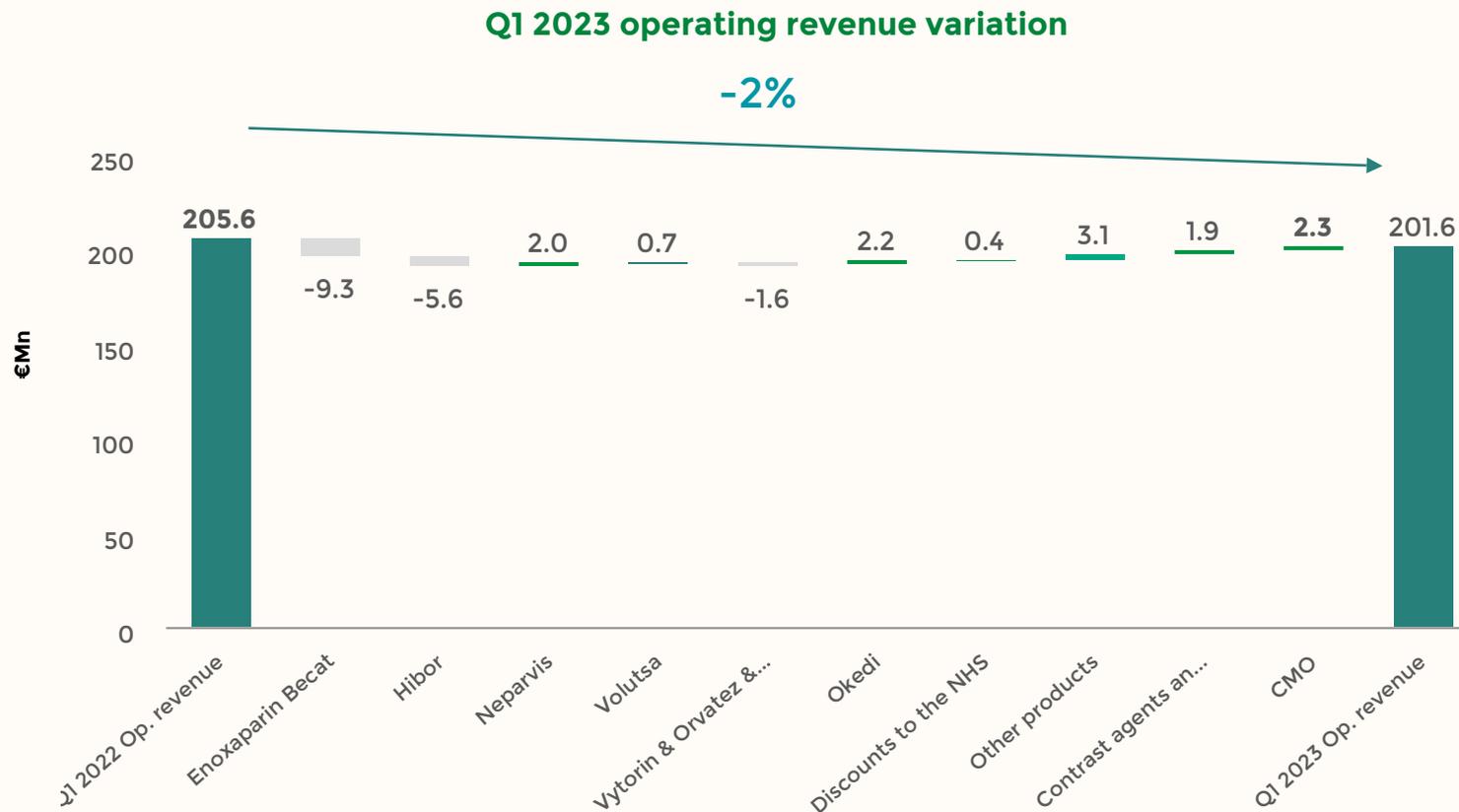
## Evaluation process to obtain marketing authorisation for Risvan® in the US

ROVI informed on the evaluation process to obtain marketing authorisation for Risvan® (Risperidone ISM®) in the United States and reported that the Food and Drug Administration (FDA) has notified the Company that the user fee goal date is 27 July 2023. ROVI is awaiting an FDA inspection of its plant before the user fee goal date.

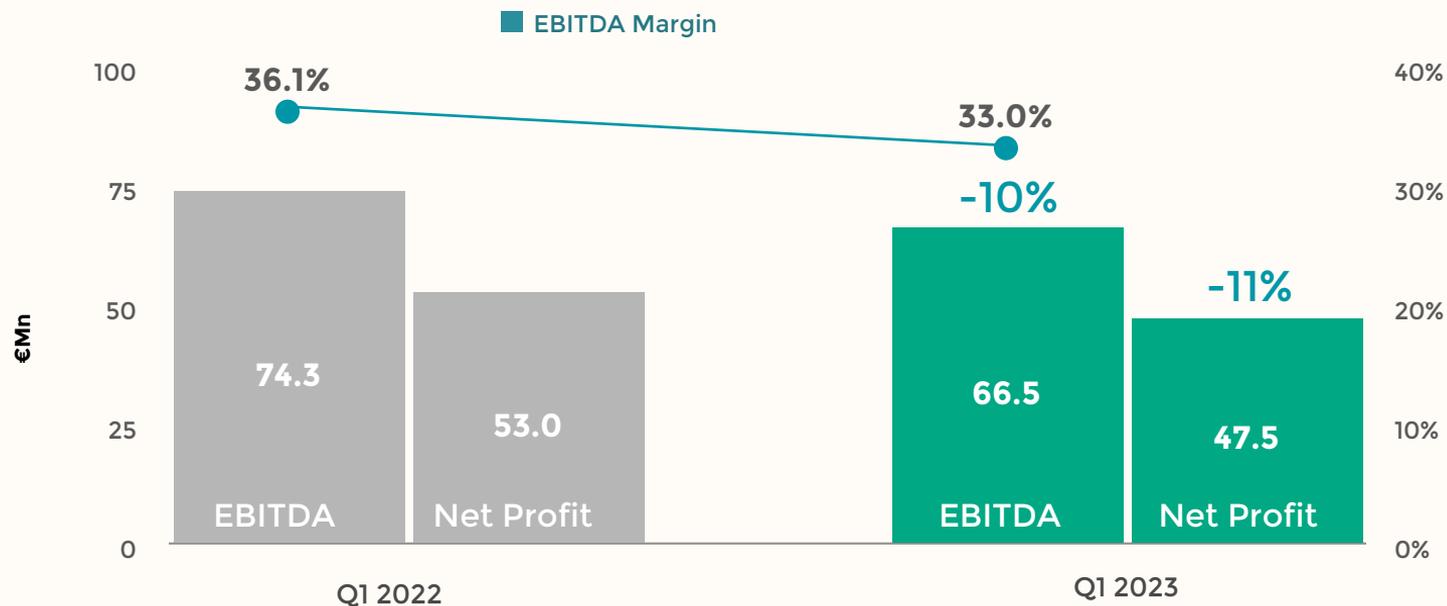
# OPERATING RESULTS



# CMO business, Okedi® and Neparvis®, main contributors to sales in the first post-pandemic quarter



## Evolution of EBITDA and net profit in the first post-pandemic quarter

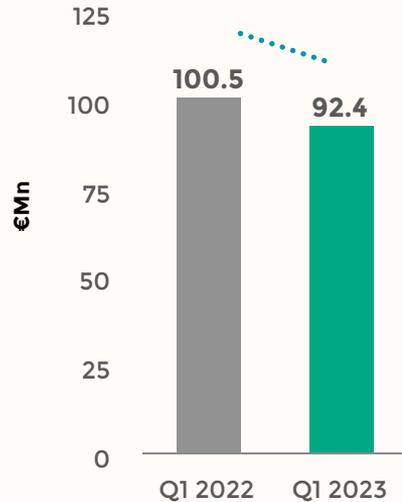


- EBITDA reached €66.5 Mn in Q1 2023, a decrease of 10% compared to Q1 2022.
- Net profit decreased by 11%, from €53.0 Mn in Q1 2022 to €47.5 Mn in Q1 2023.

# ROVI aspires to become a benchmark player in the LMWH field worldwide

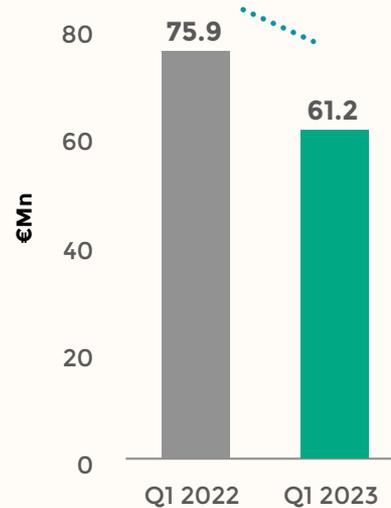
## Prescription-based sales

-8%



## Heparin franchise sales

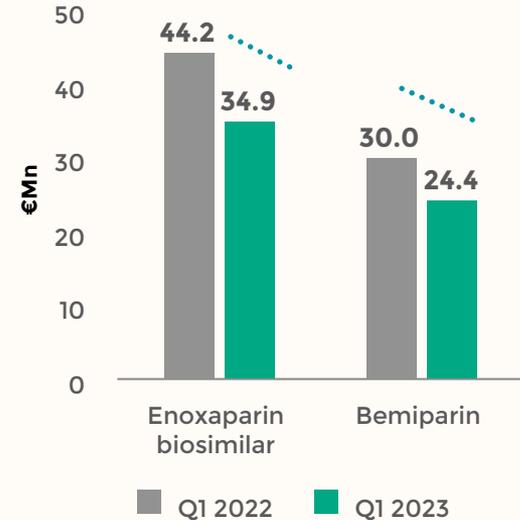
-19%



## LMWH sales

-21%

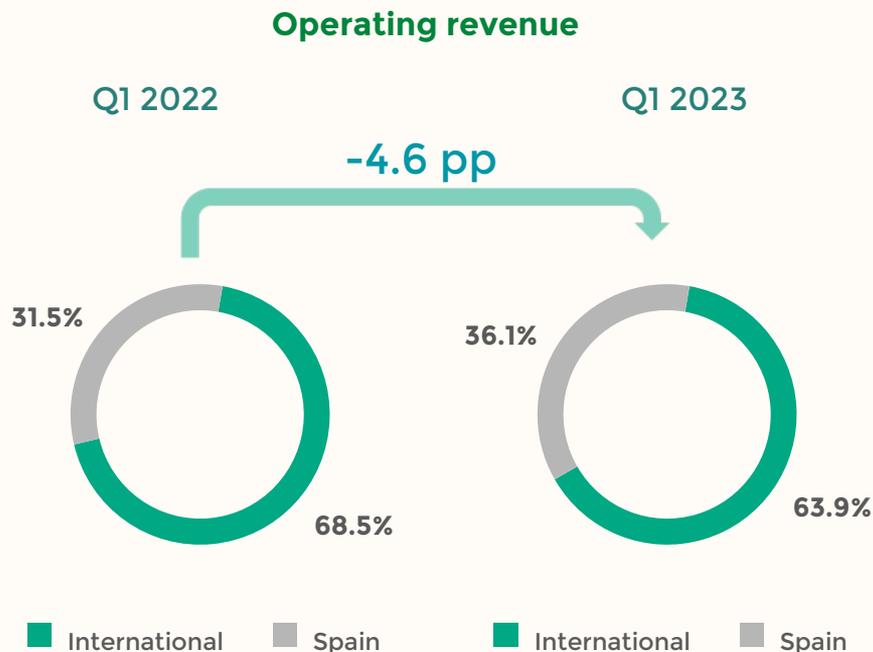
-19%



- Sales of prescription-based pharmaceutical products decreased by 8% to €92.4 Mn in Q1 2023.
- Sales of the heparin franchise decreased by 19% to €61.2 Mn, mainly due to fewer orders from partners in Q1 2023 vs Q1 2022, when enoxaparin biosimilar sales peaked.
- Heparin sales represented 30% of operating revenue in Q1 2023 compared to 37% in Q1 2022.
- ROVI expects low-molecular-weight heparin sales to decrease by a low-single-digit figure in 2023.

## ROVI's internationalisation strategy as one of its pillars of future growth

- Well positioned to drive long-term leadership in low-molecular-weight heparins (LMWH).
- Sales outside Spain decreased by 9% in Q1 2023 mainly due to the drop in LMWH international sales.
- Sales outside Spain represented 64% of operating revenue in Q1 2023.

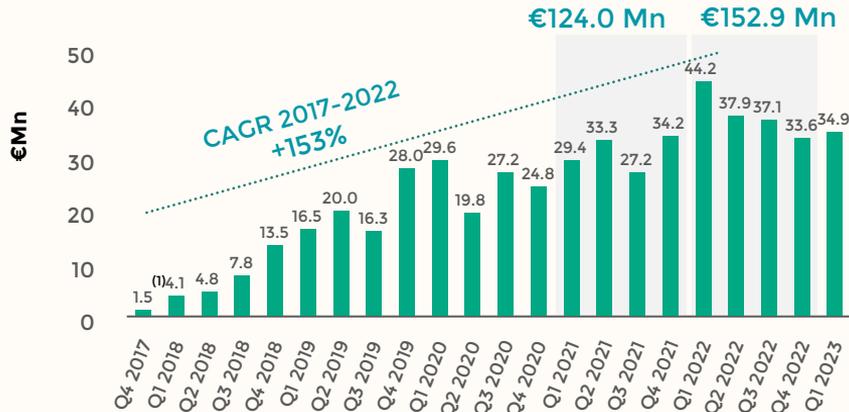


# Strong growth potential of Enoxaparin Biosimilar Becat®

## Well-established network to minimize time-to-market



## Enoxaparin biosimilar Becat® Sales Ramp-up



## Commercial Strategy

ROVI markets enoxaparin biosimilar Becat® directly in 9 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

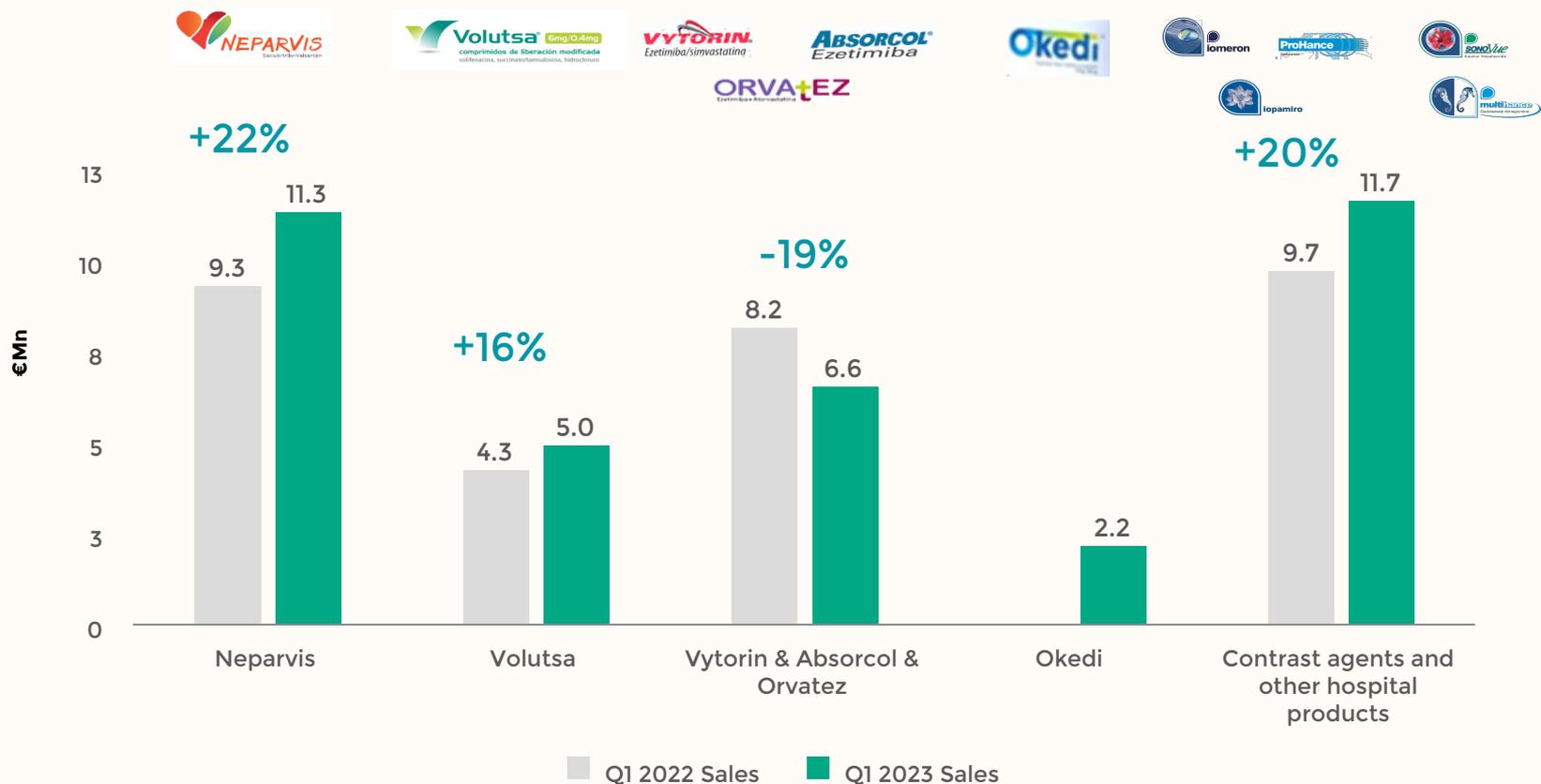
ROVI launched its Enoxaparin biosimilar in Jordan in Q1 2023.

It will continue international expansion in other markets with strong growth potential through out-licensing agreements

€0.7 bn 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 Okedi® leading the growth of the specialty pharma business



Note: ROVI ceased to distribute Absorcol as of 31 December of 2022 and Vytorin as of 31 January 2023.

# 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.

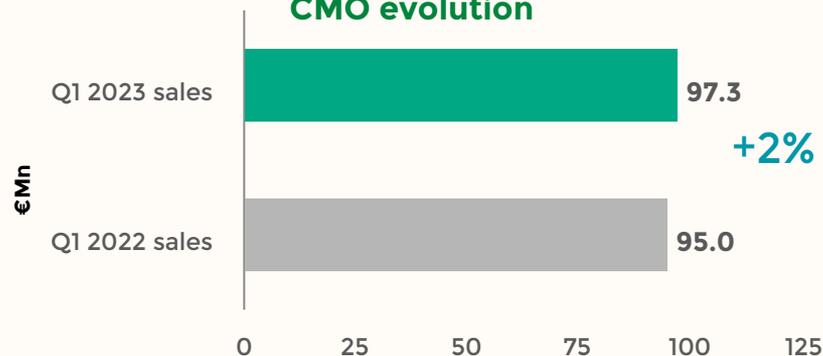
### Packaging Excellence Centre in our Alcalá de Henares plant

State-of-the-art installations	2 new high-speed blister lines. 7 packaging lines fully dedicated to injectables. Total 14 packaging lines.
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### 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 vial filling lines. Total 4 lines. 2 new automatic vial inspection machine. Total 4 lines. 1 new automatic vial packaging machine.
Granada	1 new line supporting production phases of the active substance of the mRNA vaccine.

## CMO evolution



CMO sales increased by 2% to €97.3 Mn in Q1 2023 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.

# 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 containing, respectively, (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)<sup>(2)</sup> path of approval for candidates leveraging ISM<sup>®</sup> technology

Product	Potential Indication	Current Situation	Key Milestones
Risperidone-ISM <sup>®</sup> , monthly	Schizophrenia	Approved	Marketed in Europe and in approval process in USA
Letrozole ISM <sup>®</sup> , annual	Breast Cancer	Clinical development on hold	Phase I: Superior oestrogen suppression vs Femara <sup>®</sup>
Letrozole LEBE, quarterly	Breast Cancer	Phase I	
Risperidone, quarterly	Schizophrenia	Preparing Phase I	

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 Risperidone-ISM <sup>®</sup> in Phase I & II Clinical Program	Expected high success rate in Phase III in new developments
2	Usability	Improved stability	No cold chain needed
3	Flexibility	Selecting the most convenient posology depending on clinical needs	From 1 to 12 months administration
4	Improved Clinical Management	Long-acting injection (1-12 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 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

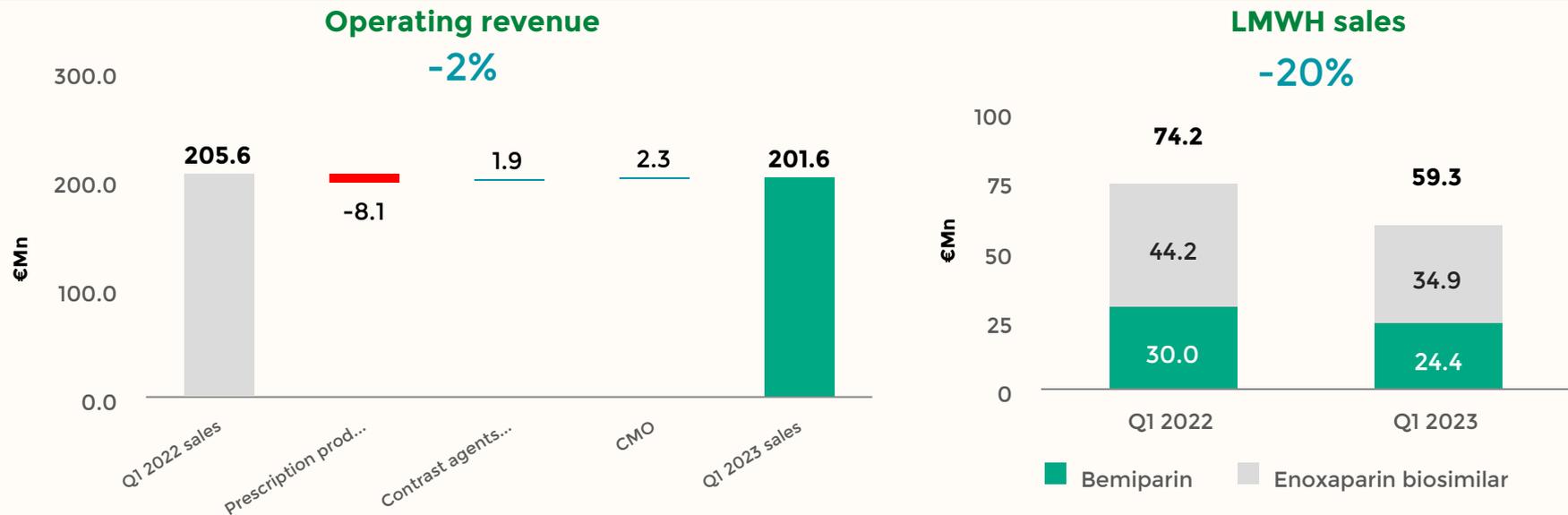
Specialty Pharma	CMO
Marketing of Okedi® in Europe	New customers to be acquired
LMWH franchise	Agreement with Moderna
License agreements (Neparvis® and Volutsa®)	Capacity increase
Existing portfolio of specialty pharmaceuticals	
New product distribution licenses	

For 2023, ROVI is assuming a new post-pandemic scenario in which COVID-19 would foreseeably be a seasonal disease and, in principle, the vaccine would be administered once a year. For this reason, ROVI expects a stronger second half of the year compared to the first half regarding the CMO business. The first quarter of 2023 includes revenues linked to the production of vaccine in the fourth quarter of 2022. ROVI expects that the second quarter of 2023 will be the lowest quarter in terms of CMO sales. Nevertheless, 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 the CMO business. Likewise, under the terms of the agreement signed with Moderna in February 2022, ROVI is still investing in increasing the compounding, aseptic filling, inspection, labelling and packaging capacities at its facilities and expects them to be fully installed by the end of 2024. Taking account of the aforementioned guidance on a decrease in operating revenue in 2023, as well as the fact that ROVI will continue with its investment policy as stated, it is reasonable to expect that the Company's profits may also see a downward adjustment in 2023.

# FINANCIAL RESULTS



## Revenue impacted by fewer heparin orders from partners



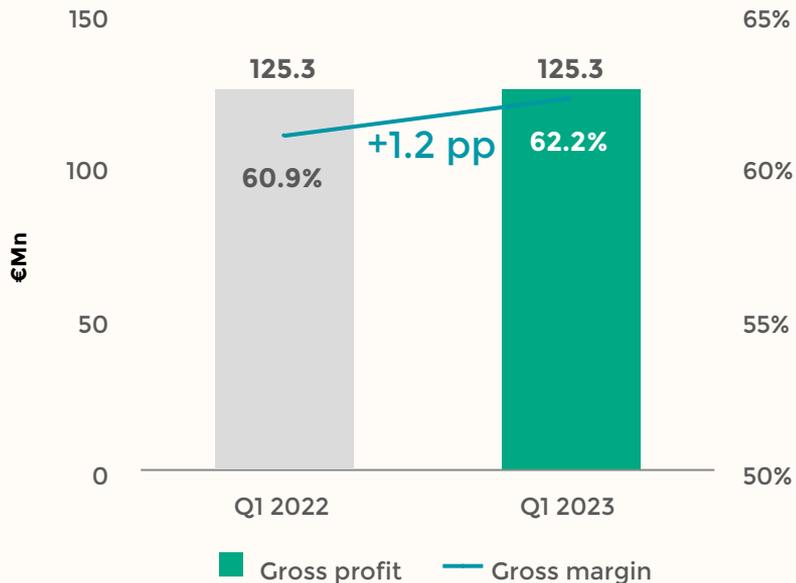
**Operating revenue** decreased by 2% to €201.6 Mn in the first post-pandemic quarter due to the 8% drop in the prescription-based pharmaceutical products that was partially offset by (i) the 2% increase in the CMO business and (ii) the 20% increase in the sales of contrast agents and other hospital products in Q1 2023.

Sales of **LMWH** decreased by 20% to €59.3 Mn in Q1 2023 due to fewer orders from partners compared to Q1 2022.

- **Enoxaparin biosimilar** sales decreased by 21% to €34.9 Mn and **Bemiparin** sales decreased by 19% to €24.4 Mn.
- In Q1 2022, enoxaparin biosimilar sales reached their peak, climbing to €44.2 Mn, almost €10 Mn higher than the average quarterly sales of the product in the last nine quarters.

## Gross margin positively impacted by the CMO division

### Gross profit and Gross margin



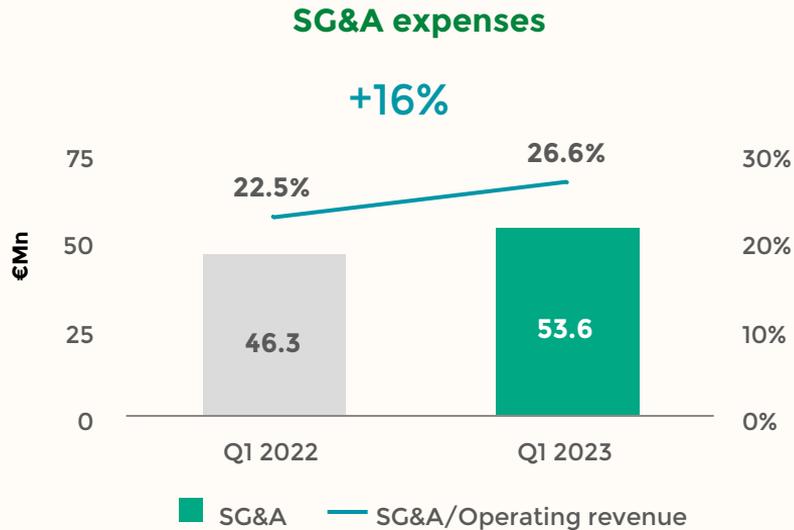
### Gross margin impacts

Gross profit remained stable at €125.3 Mn in Q1 2023.

Gross margin showed an increase of 1.2 p.p. from 60.9% in Q1 2022 to 62.2% in Q1 2023, mainly due to:

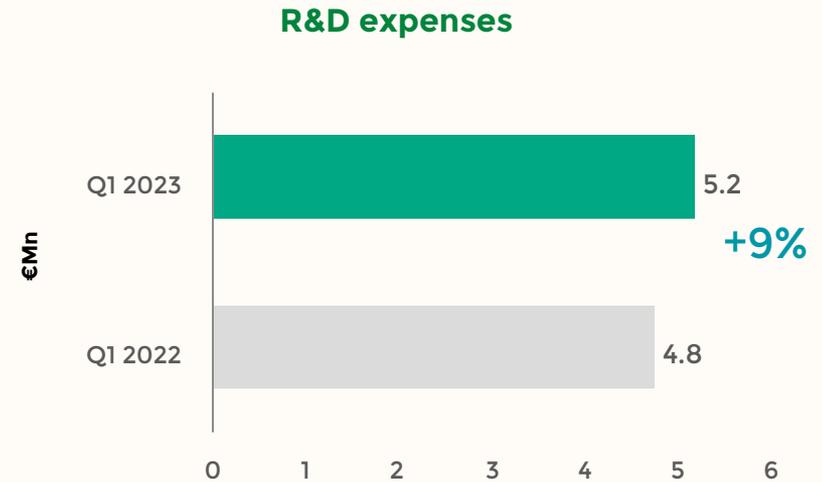
- the increase in the CMO business, which contributes higher margins to the Group sales; and
- the decrease in heparin sales through partners.

## Cost control and commitment to R&D



**SG&A** increased 16% to €53.6 Mn in Q1 2023 mainly as a result of:

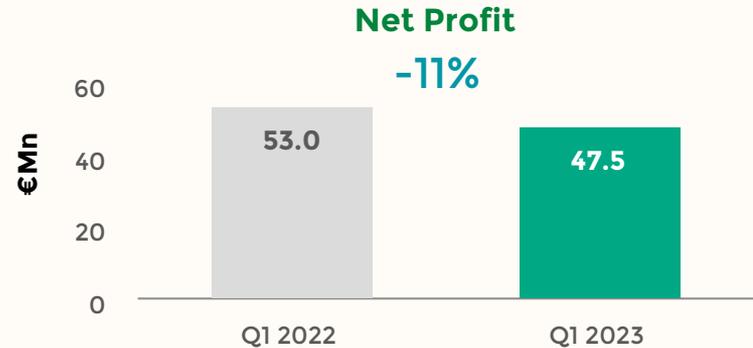
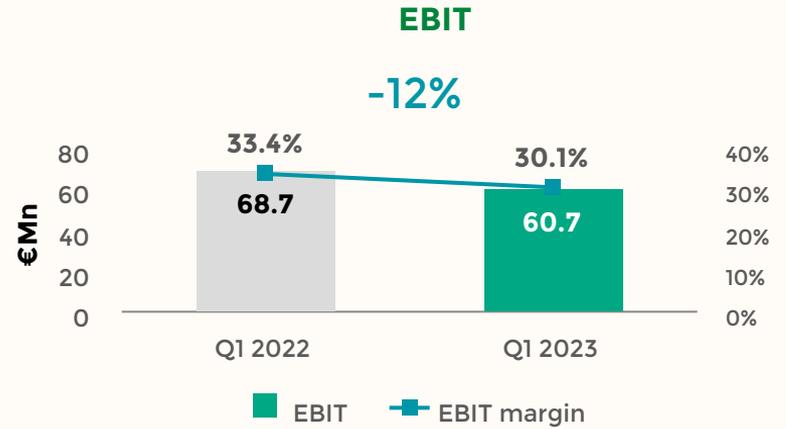
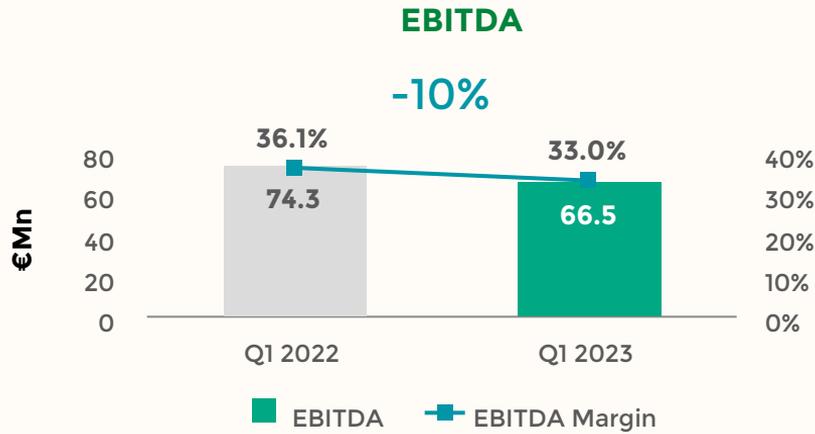
- An increase in expenses related to the CMO business; and
- An increase in expenses due to the Okedi® launch in Europe.



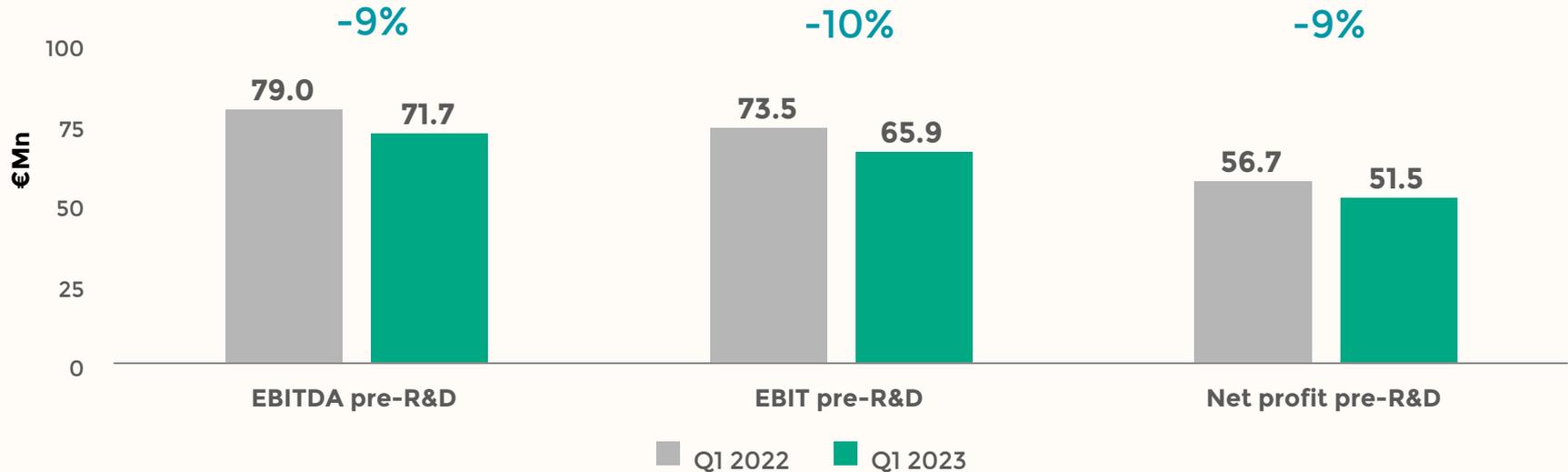
**R&D expenses** increased 9% to €5.2 Mn in Q1 2023. These expenses are related to:

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

# EBITDA, EBIT & Net Profit analysis



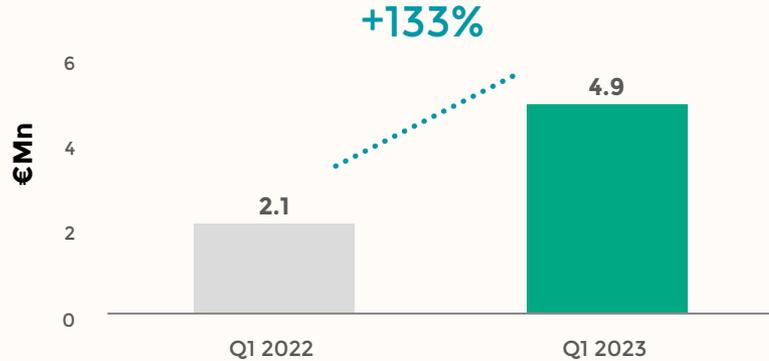
## PRE-R&D analysis



- **EBITDA “pre-R&D”** decreased by 9%, from €79.0 Mn in Q1 2022 to €71.7 Mn in Q1 2023.
- **EBIT “pre-R&D”** decreased by 10%, from €73.5 Mn in Q1 2022 to €65.9 Mn in Q1 2023.
- **Net profit “pre R&D”** decreased by 9%, from €56.7 Mn in Q1 2022 to €51.5 Mn in Q1 2023.

# Capital expenditure and Cash Flow

## CAPEX evolution



## CF evolution



CF from operating activities decreased to €24.5 Mn in Q1 2023 mainly due to:

- Decrease of €7.8 Mn in profit before income tax;
- Booking of €-22.5 Mn under the “Cash flow from provision of manufacturing services” caption in Q1 2023 due to the allocation of more revenue to the income statement than payments received, compared to the €44.1 Mn in Q1 2022;
- Decrease of €12.3 Mn in the “inventory” item in Q1 2023 compared to a decrease of €1.7 Mn in Q1 2022; and
- Decrease of €29.8 Mn in the “trade and other payables” item in Q1 2023, compared to an increase of €8.3 Mn in Q1 2022.

ROVI invested €4.9 Mn in Q1 2023 and the main investments projects are:

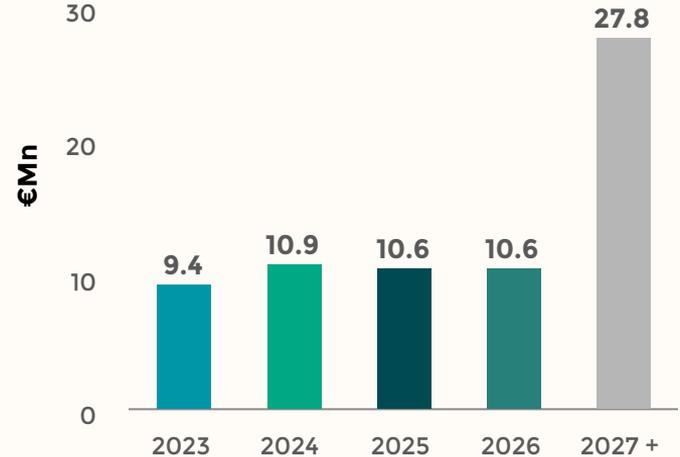
- ISM® Industrialization
- Escúzar plant
- New filling lines and operations expansion
- Glicopepton

# Debt analysis

## Debt breakdown by source (%)



## Debt maturities



- **Debt with public administration represented 14% of total debt, with 0% interest rate.**
- **Net cash of €73.6 Mn** as of 31 March 2023 vs €54.2 Mn as of 31 December 2022.
- ROVI will put a proposal to the Ordinary General Meeting for distribution of a dividend of 1.2938 euros per share charged to the 2022 profit and retained earnings. This proposed dividend would mean an increase of 35% on the dividend charged to the 2021 profit (€0.9556/share) and represents 35% of the net profit for 2022 attributed to the parent company.

# News flow 2023



Specialty pharma	Sales of biosimilar of Enoxaparin
	Additional new products to be launched in 2023
	Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar outside Europe
CMO	New contracts in the contract manufacturing area Evolution of Moderna's vaccine manufacturing
ISM <sup>®</sup> technology platform	Marketing of Okedi <sup>®</sup> in Europe Marketing authorization for Risperidone ISM <sup>®</sup> in USA
	Clinical development of a new three-monthly formulation of letrozole (Letrozole LEBE)
	Starting a Phase I clinical trial of Risperidone for a 3-monthly injection

## Alternative performance measures

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In accordance with the Guide issued by the European Securities and Markets Authority (ESMA), which has been in force since 3 July, 2016 and concerns the transparency of APM, ROVI sets out below information on the APMs that it considers significant:

- **Operating revenue** refers to revenue.
- **Gross profit** calculated as revenue plus the recognition of government grants on non-financial non-current assets and other less change in inventories of finished goods and work in progress and raw materials and consumables used.
- **Gross margin** calculated as gross profit divided by operating revenue.
- **EBITDA** calculated as profit before interest, taxes, impairment, depreciation and amortization.
- **EBIT** calculated as profit before taxes and interest.
- **Net profit** refers to profit for the period.
- **Capex** refers to purchases of intangible assets and purchases of property, plant and equipment.
- **Gross cash position** composed of equity securities, plus deposits, plus financial derivatives plus cash and cash equivalents.
- **Net debt/cash** composed of equity securities, plus deposits, plus financial derivatives, plus cash and cash equivalents, less current and non-current financial debt.
- **EBITDA, EBIT and Net profit "pre-R&D"** calculated excluding R&D expenses in Q1 2023 and Q1 2022.

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