

# First half 2024 FINANCIAL RESULTS

31 JULY 2024



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## 2024 first half financial results - highlights



Operating revenue was €329.3 Mn in H1 2024, a 14% decrease on H1 2023, mainly due to: (i) lower revenues from the manufacture of the COVID-19 vaccine in comparison to H1 2023, when ROVI (the "Company" or the "Group") had booked higher income related to the production of the "pandemic" COVID-19 vaccine; and, (ii) lower revenues related to the activities carried out to prepare the plant for the production of the vaccine under the agreement with Moderna.



Positive evolution of Okedi® (Risperidone ISM®), which sales multiplied H1 2023 sales by 141% in H1 2024, totalling €12.5 Mn.



Sales of the heparin franchise decreased by 2% to €120.7 Mn in H1 2024 mainly due to lower orders from enoxaparin partners. However, ROVI expects greater concentration of orders from partners in H2 2024 compared to H1 2024.



Good performance of Neparvis®, sales of which increased by 13%, in H1 2024 compared to H1 2023, rising to €25.0 Mn.



Gross margin was 59.4% in H1 2024, an increase of 2.8 pp on H1 2023. This increase was mainly due to: (i) the decrease in the contribution to the manufacturing business (CDMO) of revenue relating to activities to prepare the plant to produce medicines under the agreement with Moderna, which contributed lower margins to Group sales; (ii) the increased contribution to the CDMO business by existing customers (excluding Moderna), which contributed higher margins; and (iii) the increased contribution of sales of Okedi®, which added higher margins.



In 2024, ROVI expects its operating revenue to decrease by a mid-single-digit percentage in comparison with 2023.

# Milestones achieved – Risperidone ISM® peak sales, completion of the Buy-back programme and agreement to manufacture pre-filled syringes



**ROVI expects Risperidone ISM® to reach potential sales of between 200 and 300 million euros globally in upcoming years and will become a significant player worldwide in the field of long-acting injectables to treat schizophrenia**

- In H1 2024, Risperidone ISM® obtained approval for commercialization in Australia, Canada and the United States.



**ROVI announces completion of the Buy-Back Programme launched on 26 July 2023**

- On 11 June 2024, ROVI informed on the completion of the Buy-Back Programme launched on 26 July 2023. Under the framework of this programme, a total of 2,233,466 shares were acquired for an amount of 130.0 million euros, which represents approximately 4.3% of the share capital.



**ROVI announces an agreement to support the manufacture of pre-filled syringes**

- In April 2024, ROVI announced that its subsidiary ROVI Pharma Industrial Services, S.A.U. (“ROIS”) entered into an agreement to support the manufacture of pre-filled syringes for a global pharmaceutical company. Under the terms of the agreement, ROIS will provide a high-speed production line at the ROIS’ San Sebastián de los Reyes facility in Madrid, with an estimated annual capacity of 100 million units. Commercial production is expected to commence in 2026, and as from 2027, which is expected to be the first full recurrent manufacturing year, ROVI's CDMO division expects to have a positive revenue increase impact ranging between 20% and 45% over 2023 sales.



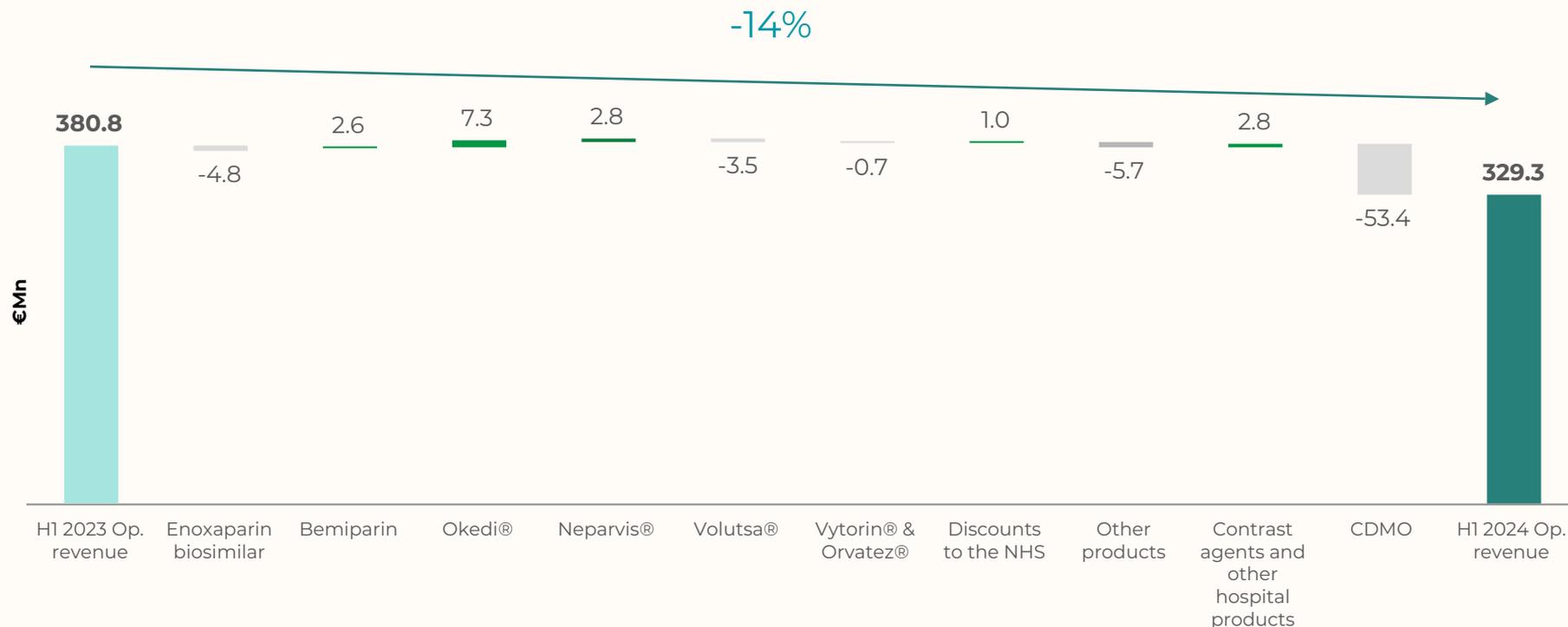
Juan López-Belmonte  
Chairman and Chief Executive Officer

## OPERATING RESULTS



# Okedi®, Neparvis®, Bemiparin and the contrast agents and other hospital products division, strategic products within the specialty pharma business

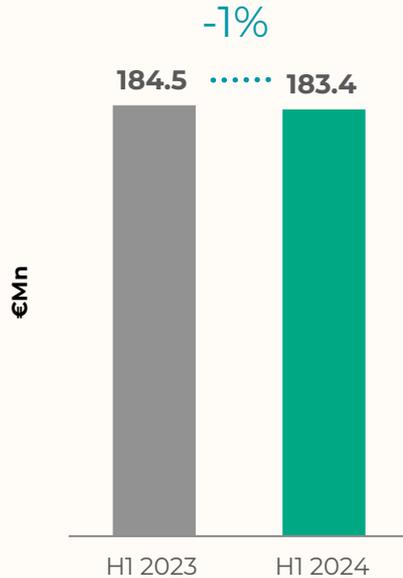
## H1 2024 operating revenue variation



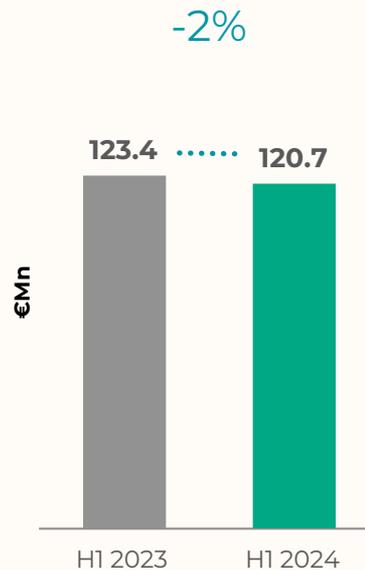


# ROVI aspires to become a benchmark player in the LMWH field worldwide

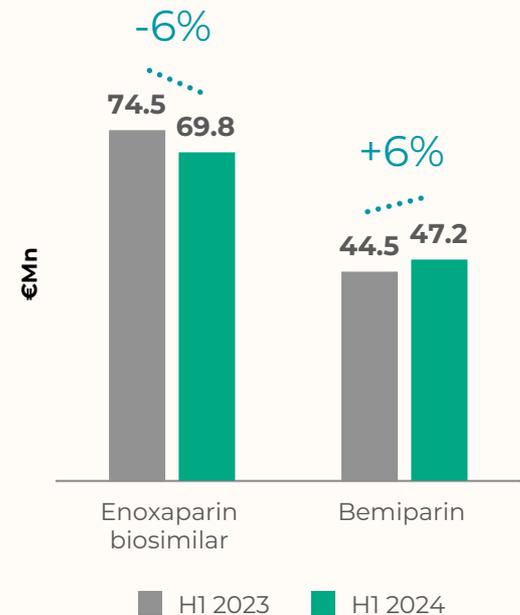
## Prescription-based sales



## Heparin franchise sales



## LMWH sales

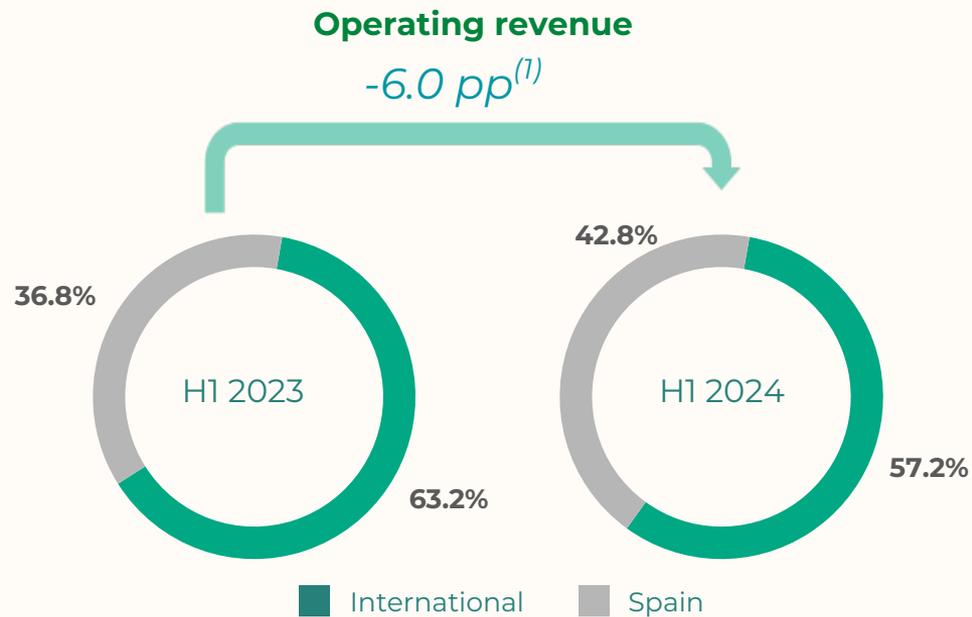


- Sales of prescription-based pharmaceutical products decreased 1% to €183.4 Mn in H1 2024.
- Sales of the heparin franchise<sup>(1)</sup> decreased by 2% to €120.7 Mn in H1 2024 mainly due to lower orders from enoxaparin partners. However, ROVI expects a greater concentration of orders from enoxaparin partners in H2 2024 compared to H1 2024. In addition, sales of the heparin franchise increased by 14% to 64.3 million euros in Q2 2024 compared to Q1 2024.
- Heparin sales represented 37% of operating revenue in H1 2024 compared to 32% in H1 2023.

(1) Heparin franchise includes low molecular weight heparins and other heparins. Other heparins are reported in the "Contrast agents and other hospital products" line.

## 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 22% in H1 2024 mainly due to the decrease in sales from the CDMO business.
- Sales outside Spain represented 57% of operating revenue in H1 2024, compared to 63% in H1 2023.



(1) Variation in international sales between H1 2023 and H1 2024 in percentage points.

# Growth evolution of Enoxaparin Biosimilar (Becat®)

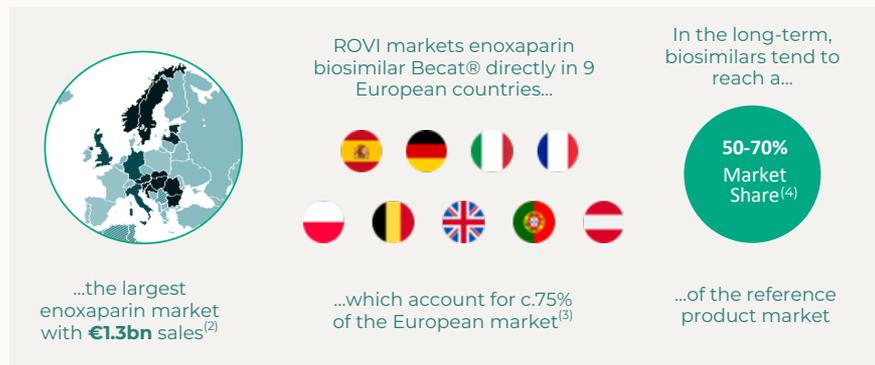
## Well-established network to minimize time-to-market



## Enoxaparin biosimilar Becat® Sales Ramp-up



## Commercial Strategy



ROVI launched its Enoxaparin biosimilar in Jordan and Sri Lanka in 2023.

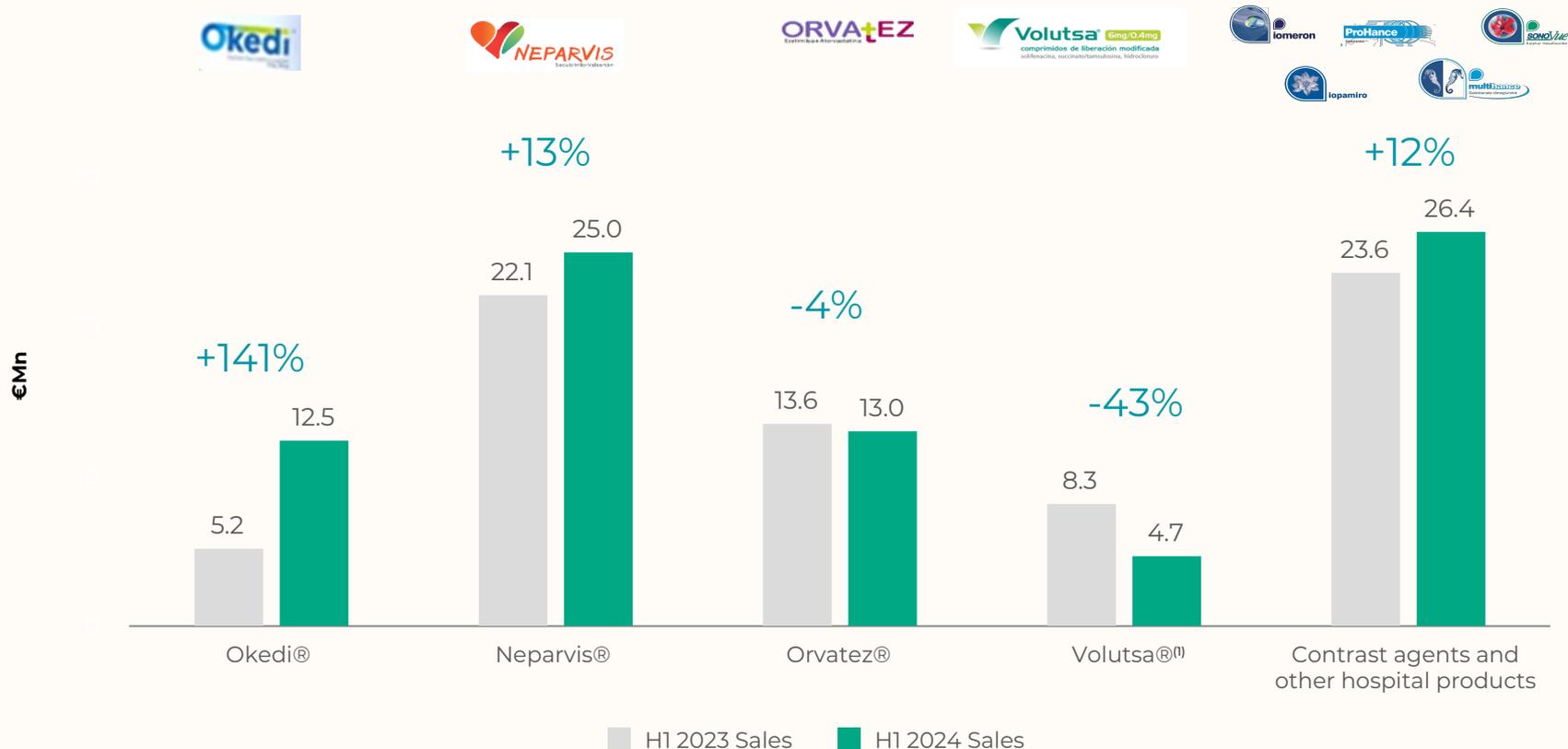


It will continue international expansion in other markets with strong growth potential through out-licensing agreements.

**€0.7 bn**  
Q1 2020 MAT  
Market Sales<sup>(2)</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.

# Okedi®, Neparvis® and contrast agents and other hospital products, key drivers of the performance of the specialty pharma business



(1) Volutsa® price decreased by 47% in Q2 2023.

# Value added CDMO services

## CDMO business

### ROVI and Moderna continue along the path of their long-term collaboration:

- Under a long-term agreement (10 years), ROVI is taking part in Moderna's pipeline program for the new generation of COVID-19 vaccines, as well as mRNA vaccines against RSV<sup>(1)</sup> and influenza.
- ROVI collaborates with Moderna in the end-to-end supply chain, including the active substance at the Granada plant and fill-and-finish at the Madrid facilities.
- All ROVI's Madrid facilities were inspected and approved by the FDA in Q3 2023, which has allowed it to support the 2023 COVID-19 Moderna vaccination campaign in the U.S.
- ROVI's Granada facility was inspected and approved by the FDA in January 2024, allowing Moderna to market the vaccine manufactured by ROVI in the U.S.
- ROVI's SSRR has been inspected and approved (No action indicated) by the FDA in July 2024 with regard to the first of the three new high-speed filling lines.

**ROVI through its subsidiary ROIS entered an agreement to support the manufacture of pre-filled syringes for a global pharmaceutical company. ROIS will provide a high-speed production line at the ROIS' San Sebastián de los Reyes facility in Madrid, with an estimated annual capacity of 100 million units.**

### New capacities for our plants

ROVI San Sebastián de los Reyes	<ul style="list-style-type: none"> <li>-The first high-speed PFS filling line (36,000 syr/h) has already been installed and qualified. The FDA has inspected and approved the line (No Action Indicated) to produce the mRNA COVID vaccine in July 2024</li> <li>-The second high-speed PFS filling line (isolator technology-36,000 syr/h) will be installed in August 2024 and will be dedicated to fulfill the demand agreed in the mentioned agreement with a global pharmaceutical company</li> <li>-The third high-speed PFS filling line will be installed in Q1 2026</li> </ul>
ROVI Alcalá de Henares	<ul style="list-style-type: none"> <li>- The first two direct PFS cartoning packaging lines (24,000 syr/h) have already been installed and qualified and are in operation to cover US seasonal COVID vaccine</li> <li>- Two more will be installed in 2024 in a new production building within the same facility</li> </ul>

## CDMO evolution



CDMO sales decreased by 31% to €118.9 Mn in H1 2024 as a result of:

- lower revenues from the manufacture of the COVID-19 vaccine in comparison to H1 2023, when ROVI had booked higher income related to the production of the "pandemic" COVID-19 vaccine; and,
- lower revenues related to the activities carried out to prepare the plant for the production of the vaccine under the agreement with Moderna.



# 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 containing, respectively, (i) the drug and polymer (solid state) and (ii) 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	<b>Schizophrenia</b>	Approved	Marketed in Europe and approved in USA, Canada & Australia Phase I: Superior oestrogen suppression vs Femara <sup>®</sup>
Letrozole ISM <sup>®</sup> , annual	<b>Breast Cancer</b>	Clinical development on hold	
Letrozole LEBE, quarterly	<b>Breast Cancer</b>	Phase I	
Risperidone, quarterly	<b>Schizophrenia</b>	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	<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 in new developments
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 12 months administration
4	<b>Improved Clinical Management</b>	Long-acting injection (1-12 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 2024



## 2024 operating revenue growth rate

Decrease by a mid-single-digit percentage vs 2023

### The key growth levers in 2024

Specialty Pharma	CDMO
Marketing of Okedi® in Europe	New customers to be acquired
Launch of Risperidone ISM® in new countries	Agreement with Moderna
LMWH franchise	Capacity increase
License agreements (Neparvis® and Orvatez®)	
Existing portfolio of specialty pharmaceuticals	
New product distribution licenses	



## FINANCIAL RESULTS

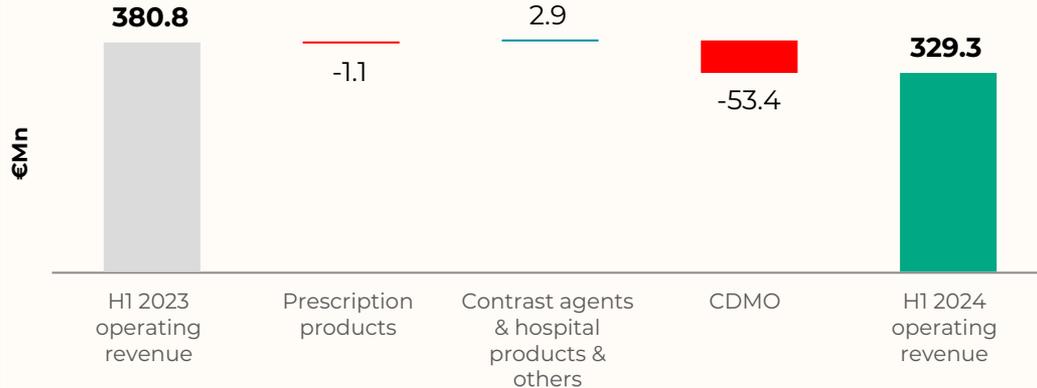
Javier López-Belmonte  
Deputy Chairman and Chief Financial Officer



# Revenue level affected by the performance of the CDMO business

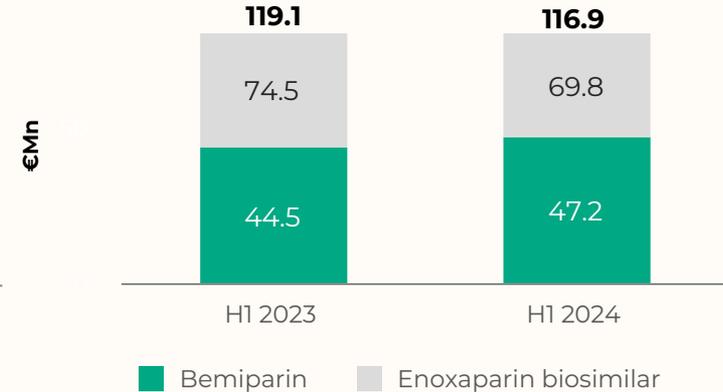
## Operating revenue

-14%



## LMWH sales

-2%



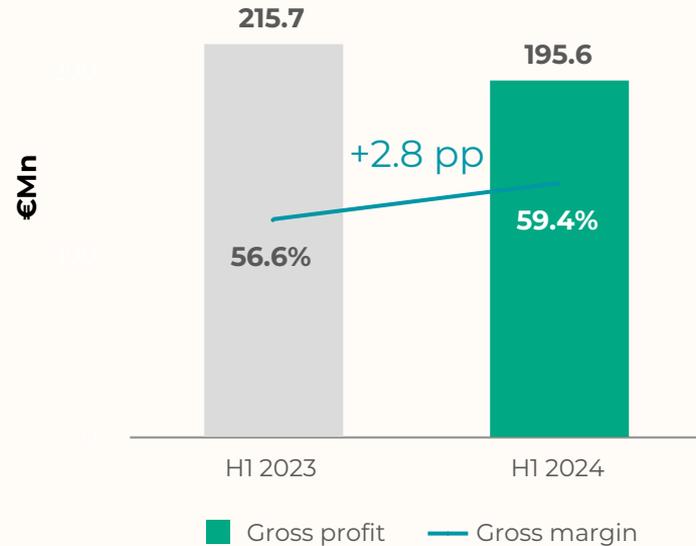
**Operating revenue** decreased 14% to €329.3 Mn in H1 2024 mainly due to the performance of the CDMO business. This division generated (i) lower revenues from the manufacture of the COVID-19 vaccine in comparison to H1 2023, when ROVI had booked higher income related to the production of the "pandemic" COVID-19 vaccine; and, (ii) lower revenues related to the activities carried out to prepare the plant for the production of the vaccine under the agreement with Moderna.

Sales of LMWH decreased by 2% to €116.9 Mn in H1 2024.

- **Enoxaparin** biosimilar sales decreased by 6% to €69.8 Mn in H1 2024.
  - This decrease was mainly due to lower orders from partners in H1 2024. However, ROVI expects a greater concentration of orders from partners in H2 2024 compared to H1 2024.
- **Bemiparin** sales increased by 6% to €47.2 Mn mainly linked to higher orders from partners in China, Turkey and Greece.
  - ROVI expects full year sales of Bemiparin to increase by a low-single-digit percentage in 2024 compared to 2023.

# Gross margin positively impacted by the CDMO division

## Gross profit and Gross margin



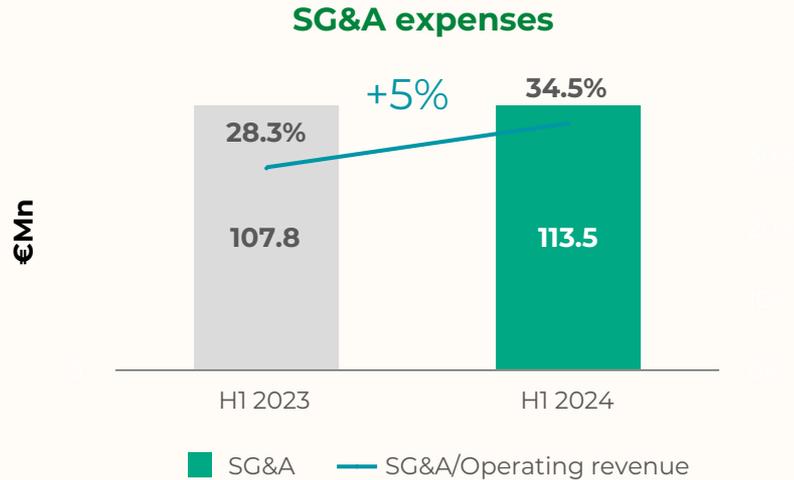
## Gross margin impacts

Gross profit decreased 9% to €195.6 Mn in H1 2024.

Gross margin was 59.4% in H1 2024, an increase of 2.8 pp on H1 2023. This increase was mainly due to: (i) the decrease in the contribution to the manufacturing business (CDMO) of revenue relating to activities to prepare the plant to produce medicines under the agreement with Moderna, which contributed lower margins to Group sales; (ii) the increased contribution to the CDMO business by existing customers (excluding Moderna), which contributed higher margins; and (iii) the increased contribution of sales of Okedi®, which added higher margins.

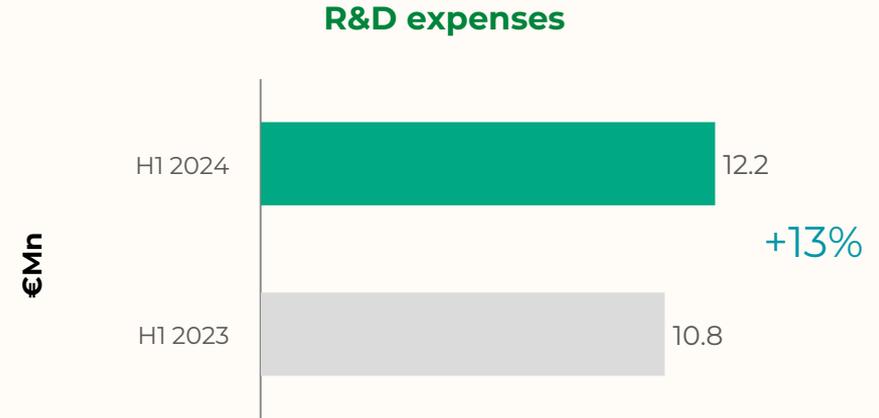
In H1 2024, low-molecular-weight heparin (LMWH) raw material prices decreased by around 55% in comparison with H1 2023. ROVI expects this decrease in LMWH raw material prices to be confirmed in 2024. Notwithstanding, in spite of the decrease in LMWH raw material prices, the impact on the gross margin was negative in H1 2024. However, a positive impact on the gross margin is expected from 2025 onwards.

## SG&A and commitment to R&D



**SG&A expenses** increased by 5% at €113.5 Mn in H1 2024:

- **Employee benefit expenses (exc. R&D)** increased 10% in H1 2024 versus H1 2023 mainly due to a 10.3% wage increase under the General Collective Agreement for the Chemical Industry.
- **Other operating expenses (exc. R&D)** increased by 1% to €54.2 Mn in H1 2024 versus H1 2023 as a result of Okedi®'s launch in Europe.

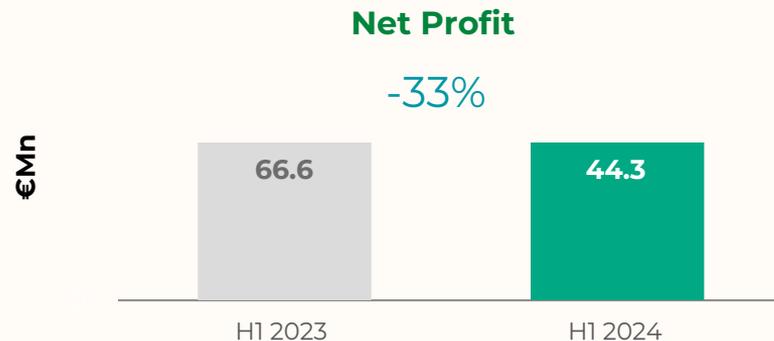
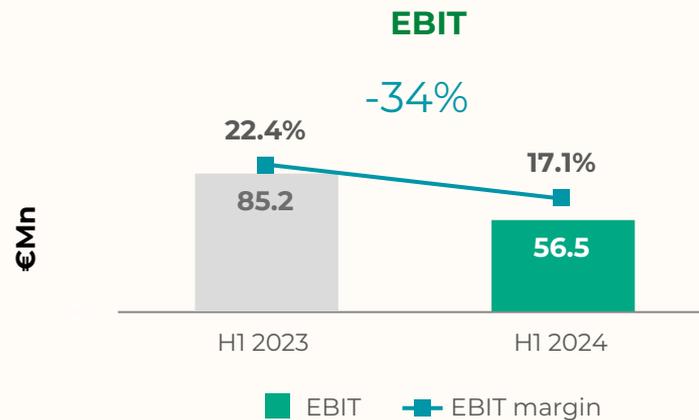
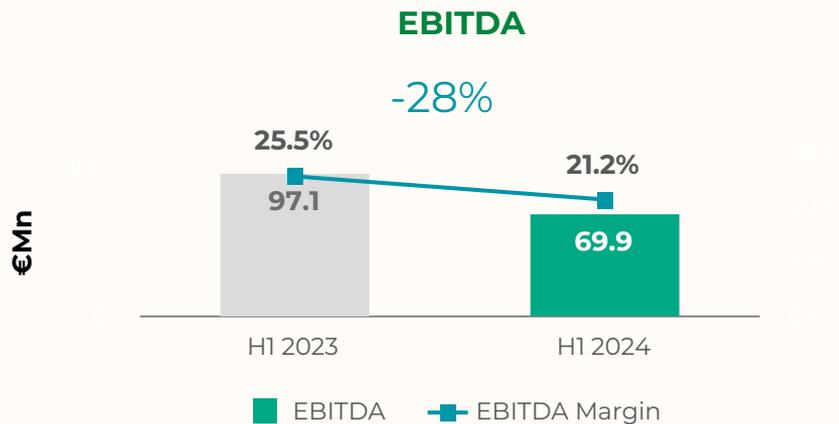


**R&D expenses** increased 13% to €12.2 Mn in H1 2024. These expenses are related to:

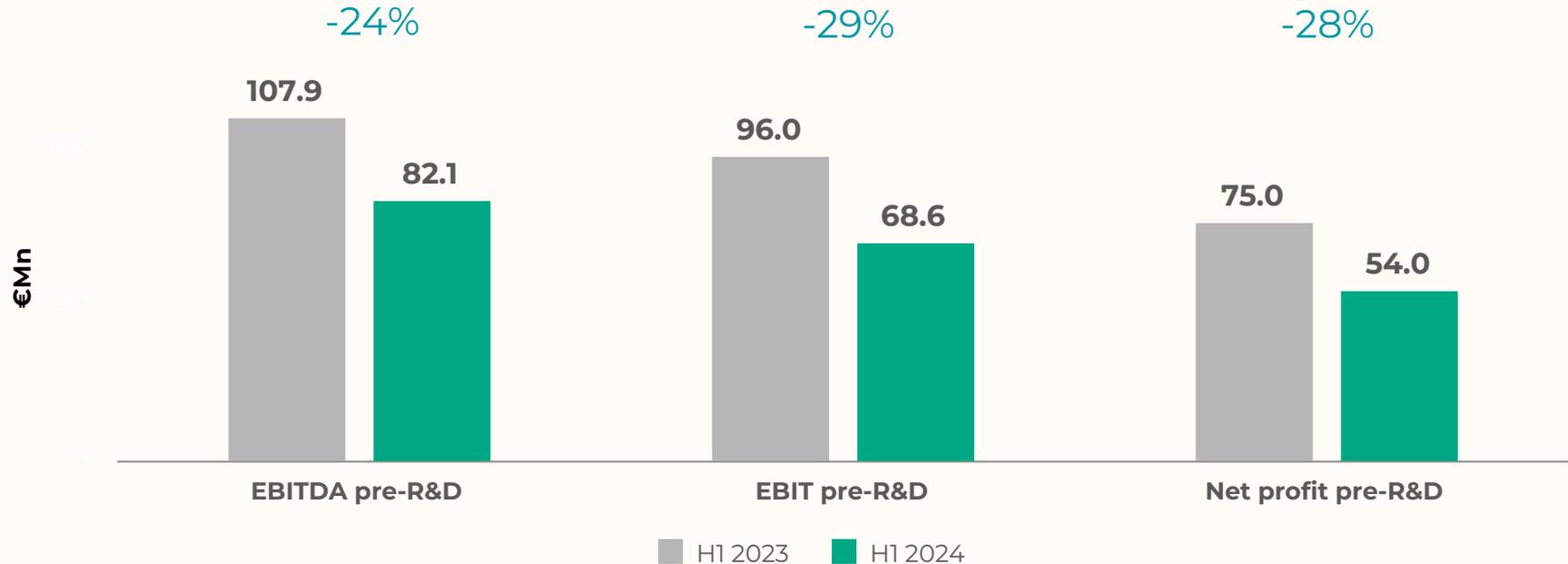
- the development of the phase I of Letrozole LEBE; and
- the development of the phase I of a new formulation of Risperidone ISM® for a 3-monthly injection.

Both projects were in the preparation phase in H1 2023.

## EBITDA, EBIT & Net Profit analysis



## PRE-R&D analysis<sup>(1)</sup>



- **EBITDA “pre-R&D”** decreased by 24%, from €107.9 Mn in H1 2023 to €82.1 Mn in H1 2024.
- **EBIT “pre-R&D”** decreased by 29%, from €96.0 Mn in H1 2023 to €68.6 Mn in H1 2024.
- **Net profit “pre R&D”** decreased by 28%, from €75.0 Mn in H1 2023 to €54.0 Mn in H1 2024.

(1) EBITDA, EBIT and Net profit “pre-R&D” calculated excluding R&D expenses in H1 2024 and H1 2023.

To obtain further information on the alternative performance measures (APMs) and non-IFRS financial indicators used, including the definition thereof and a reconciliation between the applicable management indicators and the financial information set out in the consolidated financial statements prepared under IFRSs, please consult the information included on this subject on page 16 and Appendix 2 (pages 35-39) of the press release on the financial results for the first half of 2024. Said document is available on ROVI’s website and may be accessed on the following link: <https://www.rovi.es/en/shareholders-investors/financial-business-information>.

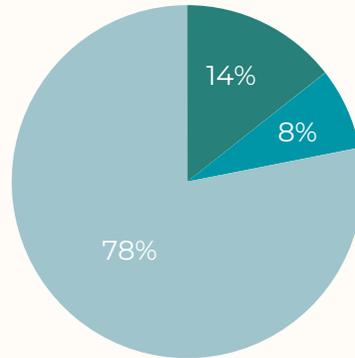


# Debt analysis

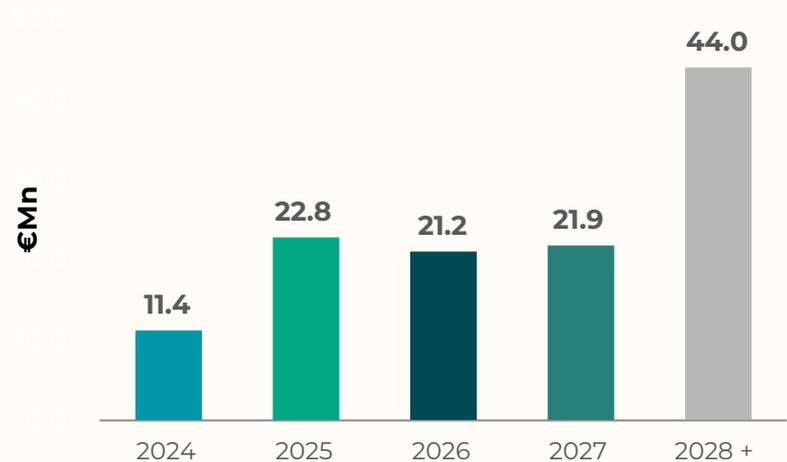
## Debt breakdown by source (%)

Total debt  
€121.2 Mn

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



## Debt maturities



- **Debt with public administration represented 8% of total debt, with 0% interest rate.**
- **Net debt of €74.7 Mn** as of 30 June 2024 vs net debt of €38.6 Mn as of 31 December 2023.
- As of 30 June 2024, ROVI had drawn €10 Mn against the new credit granted by the EIB in July 2022 at a variable rate of Euribor at 3 months + 0.655% (the interest rate for the first repayment is 4.552%).
- Additionally, ROVI has signed three credit policies: one in September 2023 for €20 Mn and another in March 2024 for €20 Mn, both with conditions of Euribor 3 months + 0.50%. In June 2024, a third policy was signed, also for €20 Mn, at Euribor 3 months + 0.65%, as well as two loans of €25 Mn each at fixed rates of 3% and 3.49%, respectively. As of 30 June 2024, ROVI had not drawn down on any of the policies.
- ROVI's General Shareholders' Meeting, held on June 24<sup>th</sup> 2024, approved the payment of a gross dividend of 1,1037 euros per share charged to the 2023 profit and retained earnings. This dividend represents 35% of the net profit for 2023 attributed to the parent company. This dividend was paid on 10 July 2024.

# Completion of the Share Buyback Program

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## Purpose and scope

To redeem own shares of ROVI (share capital reduction) while, at the same time, boost the remuneration of the ROVI shareholder by increasing the profit per share

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## Duration

26 July 2023 for a **twelve-month period**

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## Maximum monetary amount

Up to **130,000,000** euros

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## Maximum number of shares to be acquired

**2,700,000** shares of the Company, representing approximately **5%** of the Company's share capital on 26 July 2023

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**On 11 June 2024, ROVI had executed the buy-back program, having acquired 2,233,466 shares for an amount of €130.0 Mn.**

**Together with the shares acquired under the Buy-Back Programme, 546,929 of the existing treasury shares will be cancelled.**

# News flow 2024



## Specialty pharma

Sales of biosimilar of enoxaparin

Additional new products to be launched

Granting by the competent local authorities of the marketing authorisation of an enoxaparin biosimilar outside Europe

## CDMO

Evolution of Moderna's products manufacturing  
Announcement of new contracts

## ISM<sup>®</sup> technology platform

Marketing of Okedi<sup>®</sup> in Europe, Canada, Australia and other countries  
Marketing of Risvan<sup>®</sup> in USA

Phase I clinical development of a new three-monthly formulation of letrozole (Letrozole LEBE)

Phase I clinical development of Risperidone for a 3-monthly injection

## Alternative performance measures

In addition to the financial information prepared in accordance with International Financial Reporting Standards (“IFRSs”) taken from our financial statements, this document includes certain alternative performance measures (“APMs”) as defined in the ESMA (European Securities and Markets Authority) Guidelines on Alternative Performance Measures of 5 October, 2015 (ESMA/2015/1415), as well as some non-IFRS financial indicators. The financial measures contained in this document that are considered APMs or non-IFRS financial indicators have been prepared on the basis of the ROVI Group’s financial information but are not defined or set out in detail within the framework of the applicable financial information and have not been audited or reviewed by ROVI's auditors.

These APMs are considered figures that have been adjusted in respect of those that are presented in accordance with the International Financial Reporting Standards endorsed by the European Union (IFRS-EU), which form the applicable accounting framework for the consolidated financial statements of the ROVI Group. Therefore, the reader should consider them to complement the latter but not to replace them.

We use these APMs and non-IFRS financial indicators to plan, oversee and assess our performance. We consider the APMs and non-IFRS financial indicators to be useful to allow the management team and investors to compare the past or future financial performance, the financial situation and the cash flows. Notwithstanding, these APMs and non-IFRS financial indicators are considered complementary and are not intended to replace IFRS measures. Furthermore, other companies, including some in ROVI's sector, may calculate such measures differently, which reduces their usefulness for comparative purposes.

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