

# First nine months 2023 FINANCIAL RESULTS

8 NOVEMBER 2023



# DISCLAIMER

This Presentation has been prepared by Laboratorios Farmacéuticos ROVI, S.A. (the "Company") and comprises the slides for a presentation concerning the Company and its subsidiaries (the "Group"). For the purposes of this disclaimer, "Presentation" means this document, its contents or any part of it, any oral presentation, any question or answer session and any written or oral material discussed or distributed during the Presentation meeting or otherwise in connection with it.

This Presentation does not constitute or form part of, and should not be construed as, any offer to sell or issue or invitation to purchase or subscribe for, or any solicitation of any offer to purchase or subscribe for any securities of the Company, nor shall it or any part of it nor the fact of its distribution form the basis of, or be relied on in connection with, any contract or investment decision.

The information contained in this Presentation does not purport to be comprehensive. None of the Company, its respective subsidiaries or affiliates, or its or their respective directors, officers, employees, advisers or agents accepts any responsibility or liability whatsoever for, or makes any representation or warranty, express or implied, as to the truth, fullness, accuracy or completeness of the information in this Presentation (or whether any information has been omitted from the Presentation) or any other information relating to the Group, whether written, oral or in a visual or electronic form, and howsoever transmitted or made available or for any loss howsoever arising from any use of this Presentation or its contents or otherwise arising in connection therewith. Each of such persons accordingly disclaims all and any liability whatsoever, whether arising in tort, contract or otherwise in respect of this Presentation or any such information.

The information in this Presentation may include forward-looking statements, which are based on current expectations, projections and assumptions about future events. These forward-looking statements as well as those included in any other information discussed in the Presentation are subject to known or unknown risks, uncertainties and assumptions about the Group and its investments, including, among other things, the development of its business, its growth plan, trends in its operating industry, its future capital expenditures and acquisitions. In light of these risks, uncertainties and assumptions, the events in the forward-looking statements may not occur and actual results, performance or achievements may materially differ from any future results, performance or achievements that may be expressed or implied in this Presentation.

No representation or warranty is made that any forward-looking statement will come to pass. Forward-looking statements speak as of the date of this Presentation and no one undertakes to publicly update or revise any such forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, undue reliance should not be placed on any forward-looking statement contained in this Presentation.

To the extent available, the industry, market and competitive position data contained in this Presentation come from official or third party sources. Third party industry publications, studies and surveys generally state that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data. While the Company reasonably believes that each of these publications, studies and surveys has been prepared by a reputable source, the Company has not independently verified the data contained therein. In addition, certain of the industry, market and competitive position data contained in this Presentation come from the Company's own internal research and estimates based on the knowledge and experience of the Company's management in the markets in which the Group operates. While the Company reasonably believes that such research and estimates are reasonable and reliable, they, and their underlying methodology and assumptions, have not been verified by any independent source for accuracy or completeness and are subject to change. Accordingly, undue reliance should not be placed on any of the industry, market or competitive position data contained in this Presentation.

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.

Certain financial and statistical information contained in this Presentation is subject to rounding adjustments. Accordingly, any discrepancies between the totals and the sums of the amounts listed are due to rounding. Certain financial information and operating data relating to the Company contained in this Presentation has not been audited and in some cases is based on management information and estimates, and is subject to change.

No reliance may or should be placed by any person for any purposes whatsoever on this Presentation, or on its completeness, accuracy or fairness. The information in this Presentation is in summary draft form for discussion purposes only. The information and opinions contained in this Presentation are provided as at the date of the Presentation and are subject to verification, correction, completion and change without notice. In giving this Presentation, none of the Company, its subsidiaries or affiliates, or its or their respective directors, officers, employees, advisers or agents, undertakes any obligation to amend, correct or update this Presentation or to provide the recipient with access to any additional information that may arise in connection with it.

## 9M 2023 financial results - highlights



Operating revenue increased 3% to €594.9 Mn in 9M 2023 driven by the CDMO<sup>1</sup> business which grew 7% to €287.6 Mn and the stable sales of the specialty pharmaceutical business which stood at €307.3 Mn.



Positive evolution of Okedi® (Risperidone ISM®), which reached sales of €9.0 Mn in 9M 2023.



Sales of the heparin franchise decreased by 10% to €181.7 Mn in 9M 2023 mostly due to the increase in orders from partners in 2022 related to the treatment of COVID-19, which has led to lower orders from partners in 2023, since they still hold a high level of stocks from 2022.



Good performance of Neparvis® and Orvatez®, of which sales increased by 17% and 10% respectively in 9M 2023, rising to €33.7 Mn and €19.8Mn respectively.



Gross profit increased 2% to €350.6 Mn. Gross margin showed a decrease of 0.9 p.p. This drop is mainly due to the higher contribution to the CDMO<sup>1</sup> business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to group sales.



ROVI is again upgrading its operating revenue guidance for the full year 2023 from high-single-digit negative growth on 2022 to stable sales.

# Milestones achieved – FDA approval of CDMO's injectables plants, evaluation process for Risvan® in US and first place in the Sustainalytics ESG ranking



## U.S. Food and Drug Administration (FDA) approved ROVI's CDMO's injectable plants for the manufacture of Moderna's COVID-19 mRNA vaccine

In September 2023, the U.S. Food and Drug Administration approved the company's CDMO's plants for injectables in Madrid, San Sebastián de los Reyes and Alcalá de Henares for the fill-finish syringe manufacturing of Moderna's COVID-19 mRNA vaccine. ROVI also expects to produce Moderna vaccines for supply in the United States from 2023 onwards.



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

On 27 July 2023, ROVI reported that the FDA had issued a Complete Response Letter. In this letter, the FDA informed ROVI that satisfactory resolution of the deficiencies from the last inspection was required before the approval of the application and that there were no outstanding questions related to the dossier. On 21 September 2023, ROVI received the Establishment Inspection Report from the FDA with 4 outstanding observations from the FDA inspection of the facility. ROVI provided responses on 29 September 2023 and the FDA has established a new Goal Date of 29 March 2024.



## ROVI takes first place in the Sustainalytics world ESG risk ranking for the second year running

ROVI has improved its ESG risk rating by almost one point, improving its “Low Risk” rating to 16.4 versus 17.3 in 2022 and remaining in first place among the 431 companies rated in the pharmaceutical industry category.

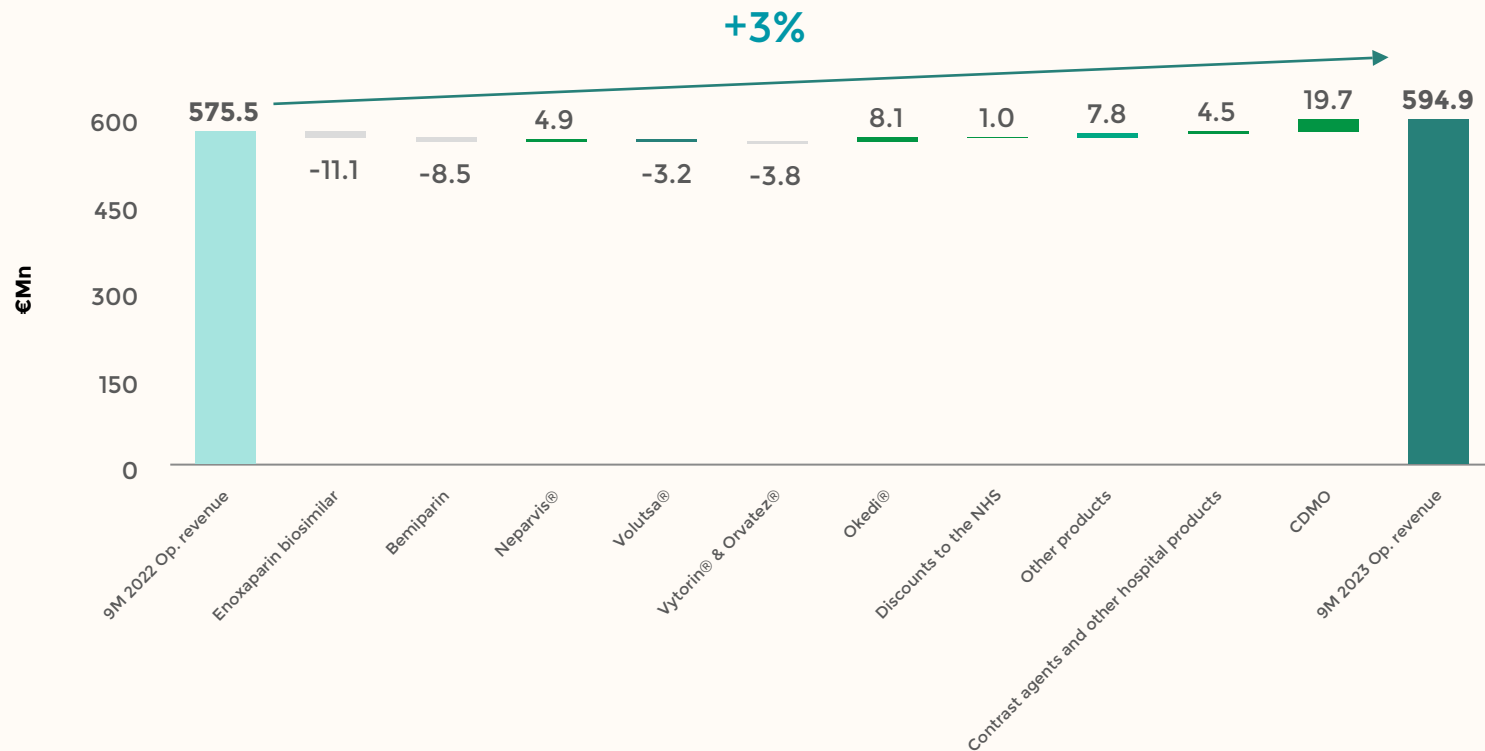
This result reinforces ROVI's position as a pharmaceutical sector leader in sustainable business management.

# OPERATING RESULTS

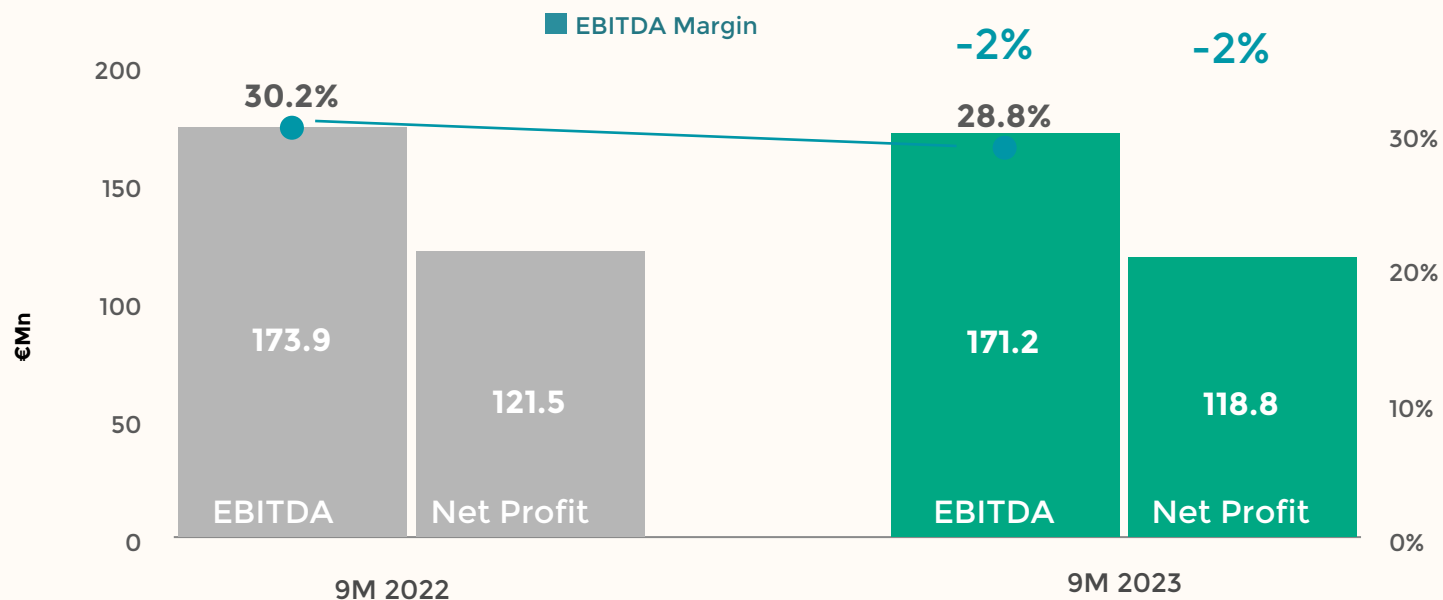


## Growth driven by CDMO business, Okedi® and Neparvis®

### 9M 2023 operating revenue variation



## Evolution of EBITDA and net profit in the first nine months of the first post-pandemic year

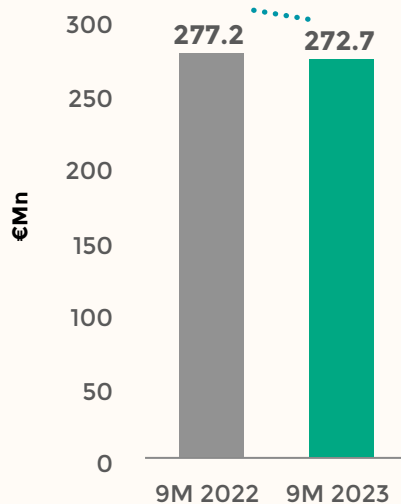


- EBITDA reached €171.2 Mn in 9M 2023, a decrease of 2% compared to 9M 2022.
- Net profit decreased by 2%, from €121.5 Mn in 9M 2022 to €118.8 Mn in 9M 2023.

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

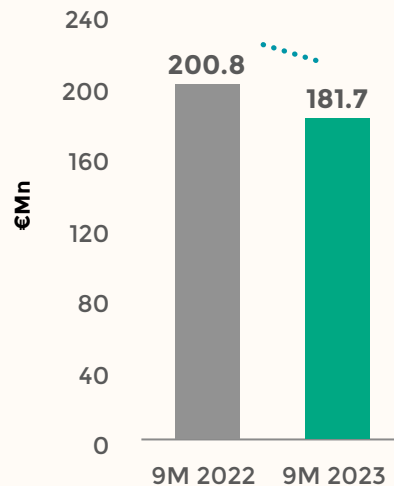
## Prescription-based sales

-2%



## Heparin franchise sales<sup>1</sup>

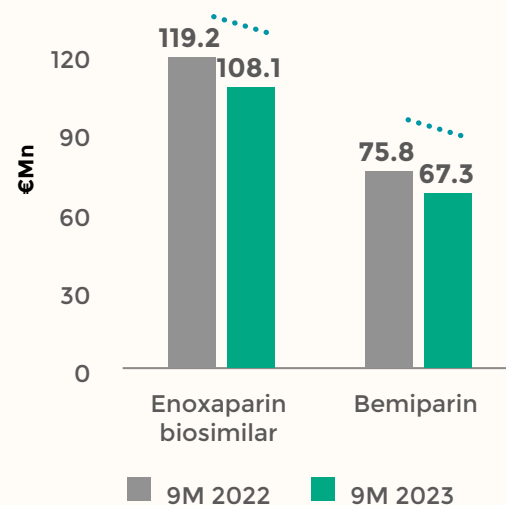
-10%



## LMWH sales

-9%

-11%



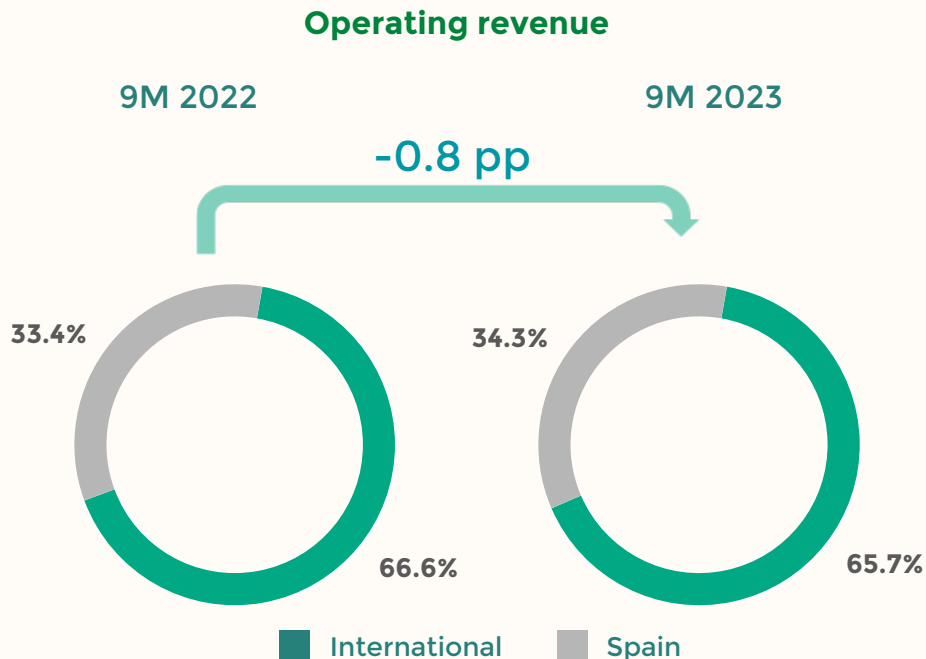
- Sales of prescription-based pharmaceutical products decreased by 2% to €272.7 Mn in 9M 2023.
- Sales of the heparin franchise<sup>1</sup> decreased by 10% to €181.7 Mn in 9M 2023 mainly as a result of the increase in orders from partners in 2022 related to the treatment for COVID-19, which has led to a lower expected volume of orders from partners in 2023, since they still hold a high level of stocks from 2022.
- Heparin sales represented 31% of operating revenue in 9M 2023 compared to 35% in 9M 2022.
- ROVI expects low-molecular-weight heparin sales to decrease by a low-single-digit figure in 2023.

<sup>1</sup> Heparin franchise includes low molecular weight heparins and other heparins. Other heparins are reported in the "Contrast agents and other hospital products" line. These figures include Normoparin sales which were not included in the 9M 2022 figure when it was released.



## 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 increased by 2% in 9M 2023 mainly due to the increase in the CDMO business.
- Sales outside Spain represented 66% of operating revenue in 9M 2023.

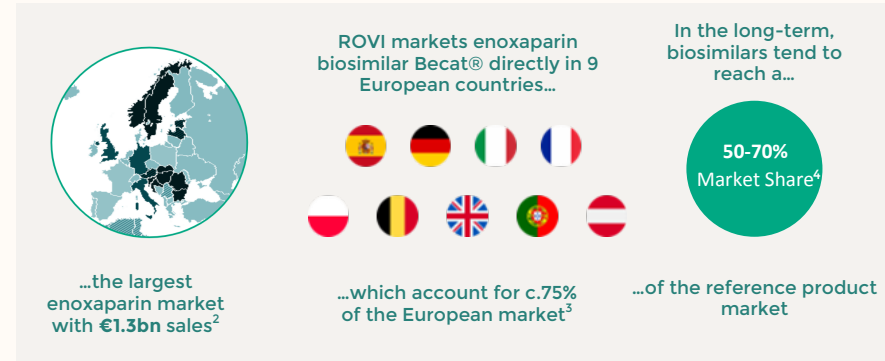


# Strong growth potential of Enoxaparin Biosimilar Becat®

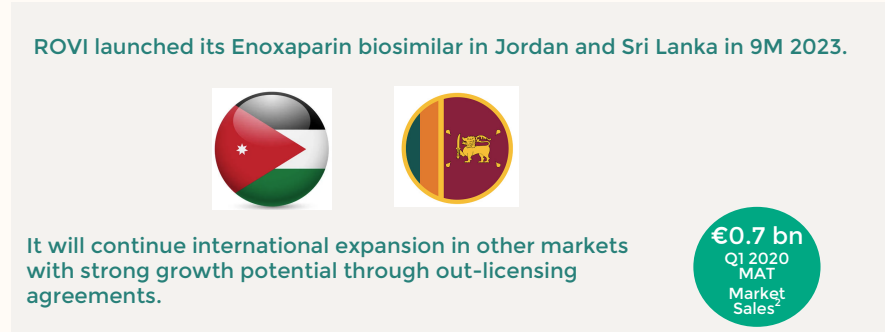
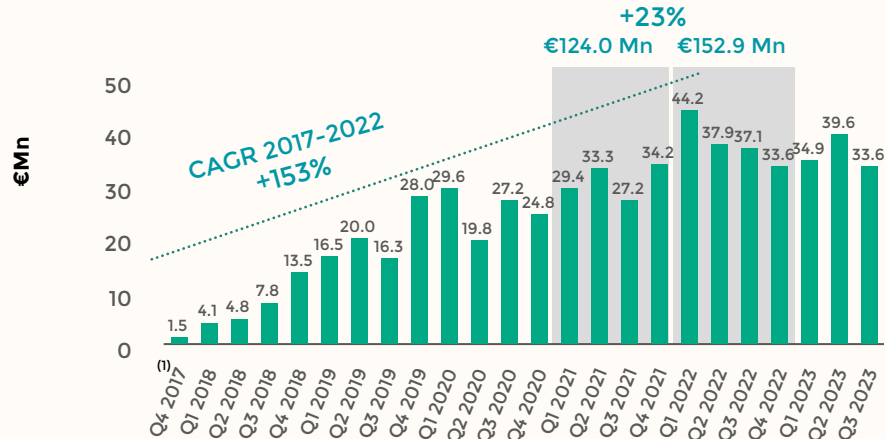
## Well-established network to minimize time-to-market



## Commercial Strategy

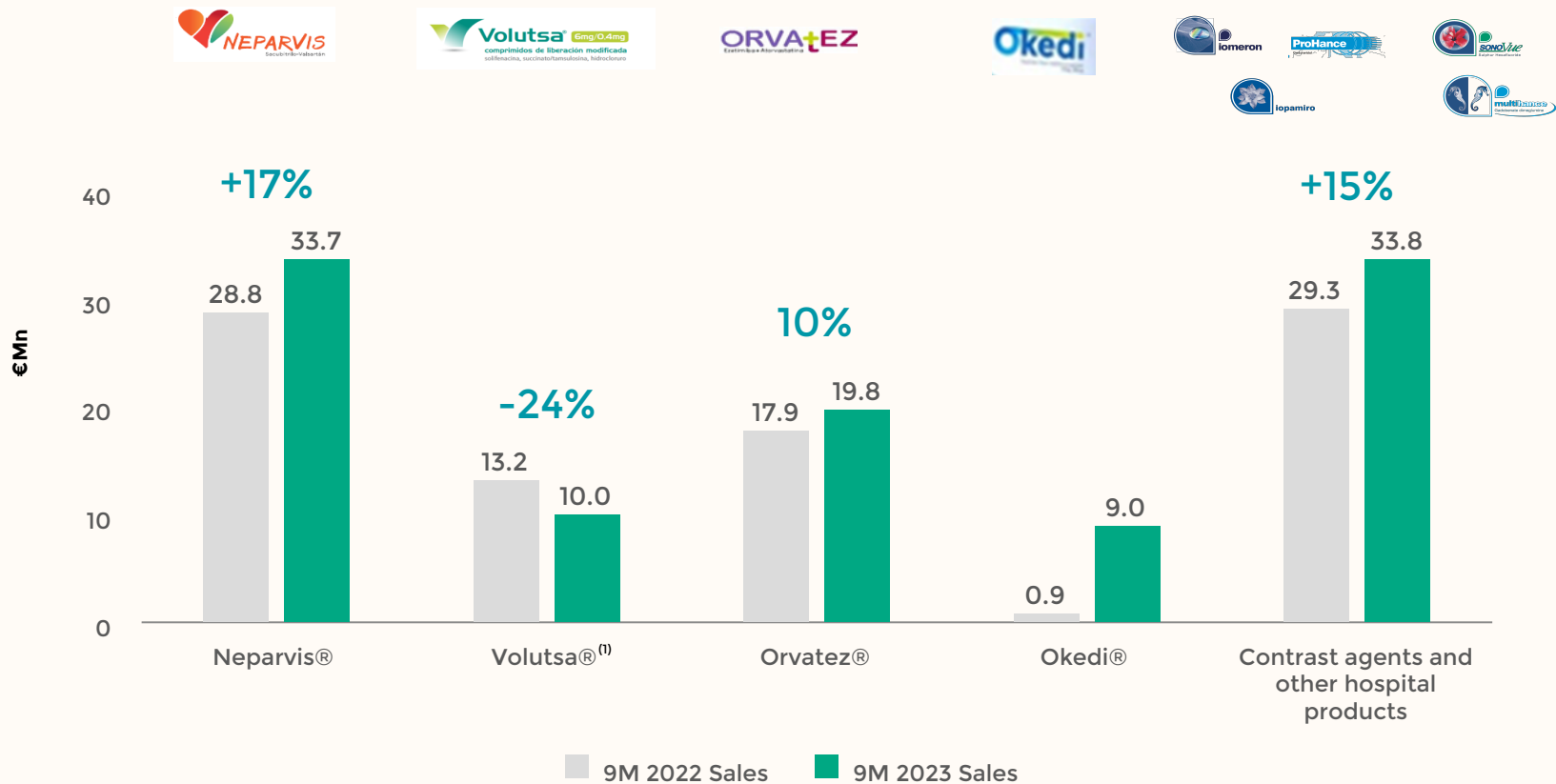


## Enoxaparin biosimilar Becat® Sales Ramp-up



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®, Orvatez® and Okedi® leading the growth 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.
- ROVI's Madrid facilities were inspected and approved by FDA in Q3 2023, allowing it to support the 2023 COVID-19 vaccination campaign in the USA.

## New capacities for our plants

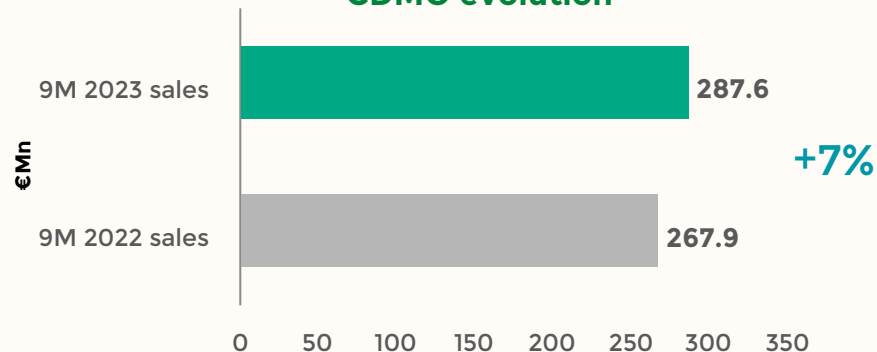
**ROVI San Sebastián de los Reyes**

The first of two high-speed PFS filling lines (36,000 syr/h) has already been installed. The second one (isolator technology-36,000 syr/h) will be installed in 2024.

**ROVI Alcalá de Henares**

The first two direct PFS cartoning packaging lines (24,000 syr/h) have already been installed. Two more will be installed in 2024 in a new facility within the same campus.

## CDMO evolution



CDMO sales increased by 7% to €287.6 Mn in 9M 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)(2) 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	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 2024



## 2024 operating revenue growth rate

Decrease by a mid-single-digit percentage vs 2023

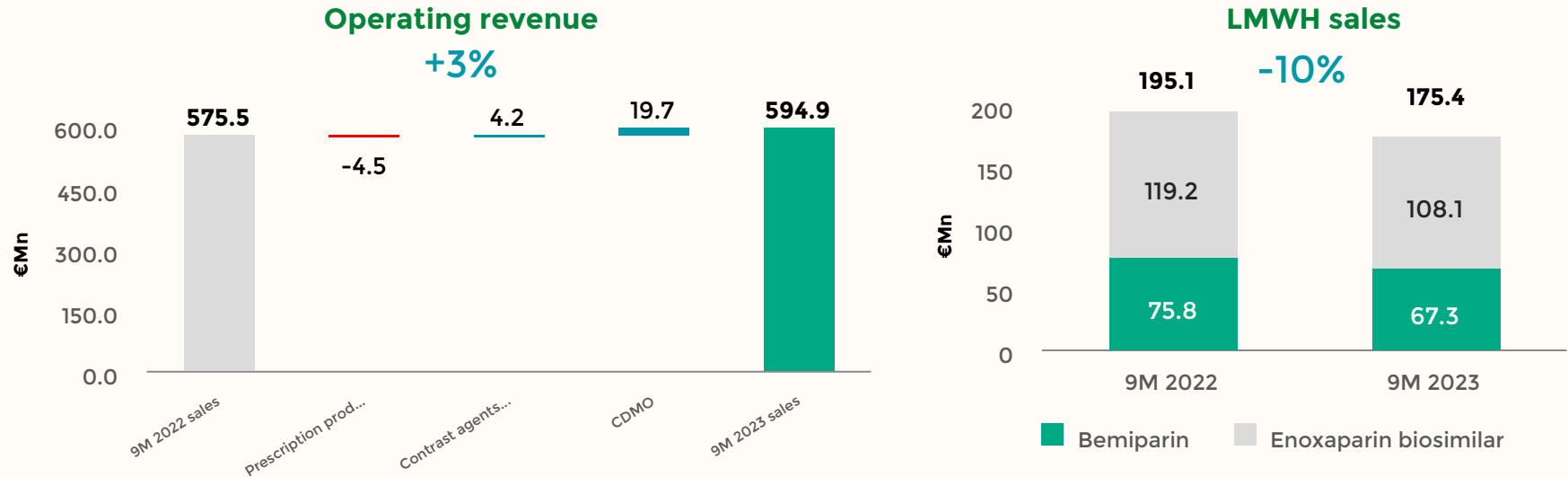
### The key growth levers in 2024

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

# FINANCIAL RESULTS



## Revenue level improves thanks to resilient sales growth



**Operating revenue** increased 3% to €594.9 Mn in 9M 2023 driven by (i) the CDMO business which grew 7% to €287.6 Mn, and (ii) the 15% increase in the sales of contrast agents and other hospital products in 9M 2023. The prescription-based pharmaceutical product business decreased by 2% in 9M 2023.

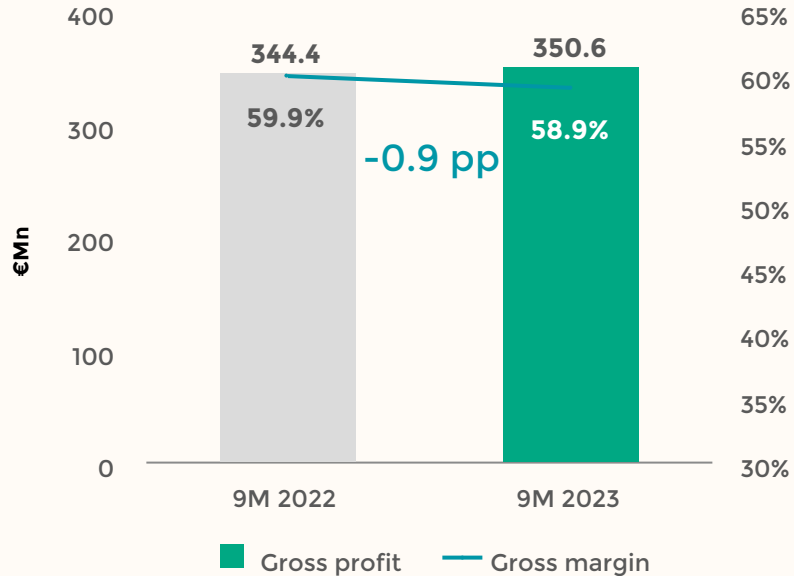
Sales of **LMWH** decreased by 10% to €175.4 Mn in 9M 2023.

- **Enoxaparin biosimilar** sales decreased by 9% to €108.1 Mn in 9M 2023. However, sales rose 20% in 9M 2023 compared to 9M 2021, where sales increased 18% compared to 9M 2020 due to the increased use of the product for the treatment of COVID-19.
- **Bemiparin** sales decreased by 11% to €67.3 Mn mainly due to (i) the decrease in sales in the Russian market, (ii) the political-economic instability of some countries in which we are present such as Sudan, Turkey and Argentina; (iii) the fewer orders from partners, and (iv) the lower sales related to COVID-19.



# Gross margin negatively impacted by the CDMO division

## Gross profit and Gross margin



## Gross margin impacts

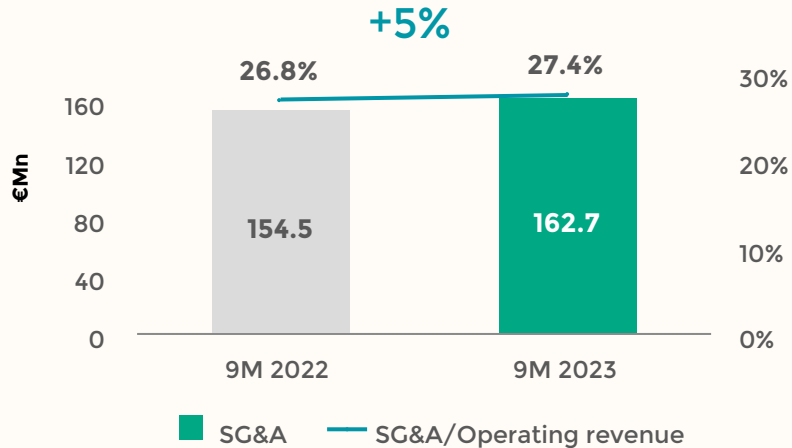
Gross profit increased 2% to €350.6 Mn in 9M 2023.

Gross margin showed a decrease of 0.9 p.p. from 59.9% in 9M 2022 to 58.9% in the same period of 2023. This drop is mainly due to the higher contribution to the CDMO business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to Group sales. Additionally, gross margin increased by 12.6 p.p. in Q3 2023 compared to Q2 2023 and 3.0 p.p. in Q3 2023 versus Q3 2022.

In Q3 2023, low molecular weight heparin (LMWH) raw material prices decreased by a mid-teen percentage in comparison with the Q3 2022. ROVI expects them to continue to fall in 2023 and that this decrease will accelerate during 2024. Nevertheless, despite this potential price decrease, the impact on the gross margin will continue to be negative in 2023 because of the length of the LMWH manufacturing process, in which the raw material currently being used has been stocked for several months and was purchased at higher prices.

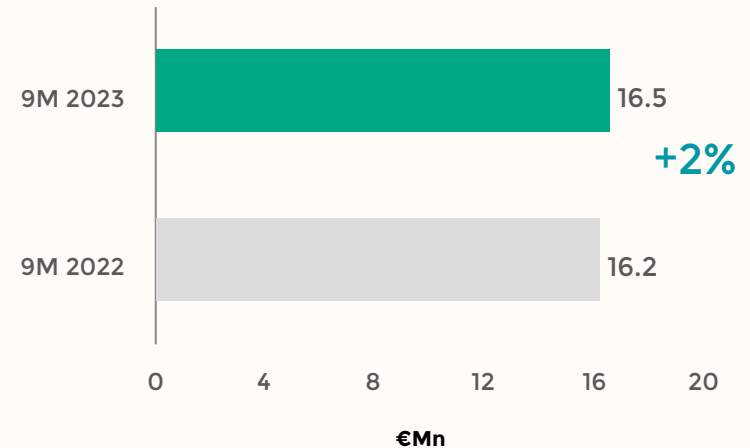
## Cost control and commitment to R&D

### SG&A expenses



**SG&A** increased 5% to €162.7 Mn in 9M 2023 mainly as a result of an increase in expenses due to the Okedi® launch in Europe.

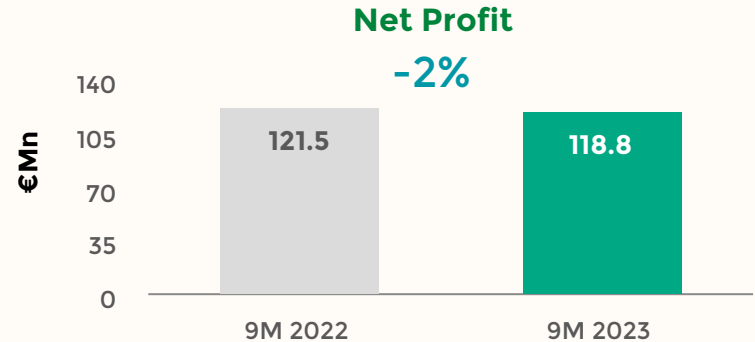
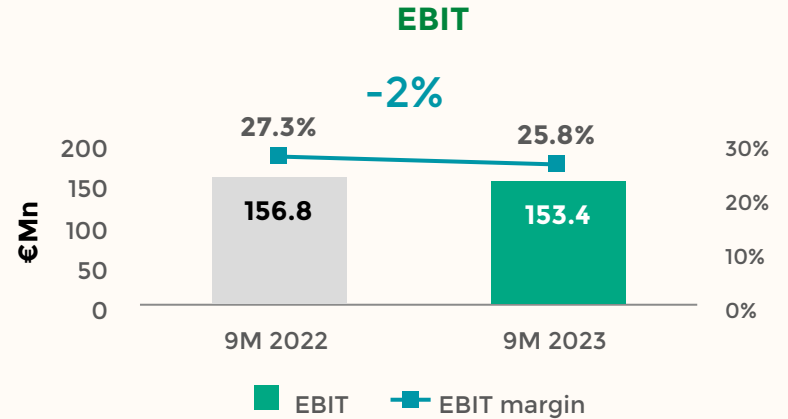
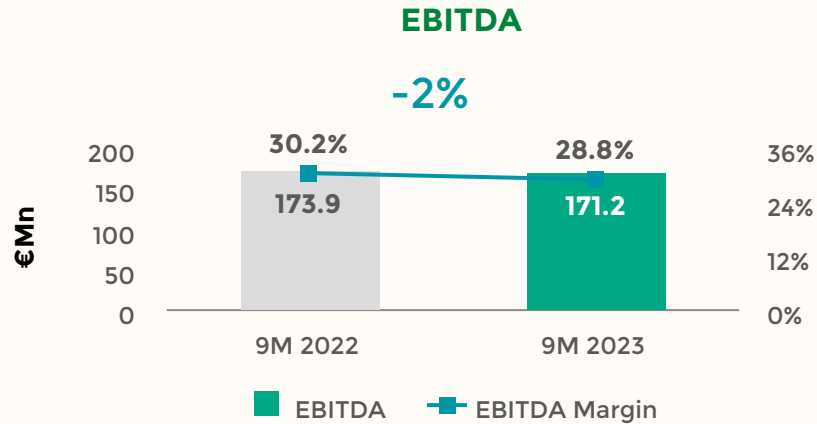
### R&D expenses



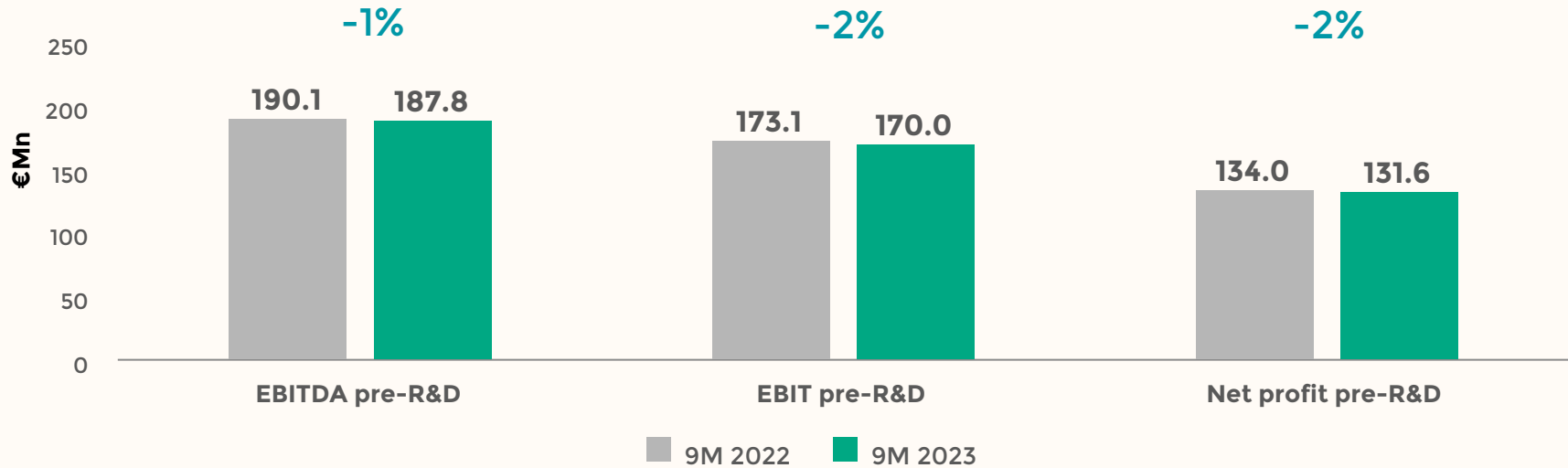
**R&D expenses** increased 2% to €16.5 Mn in 9M 2023. These expenses are related to:

- 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.

# EBITDA, EBIT & Net Profit analysis



## PRE-R&D analysis



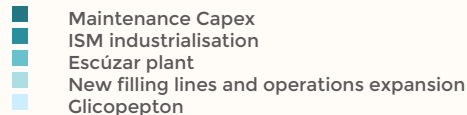
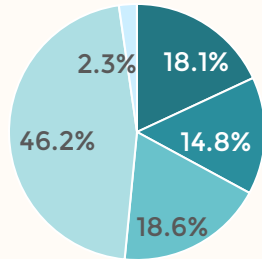
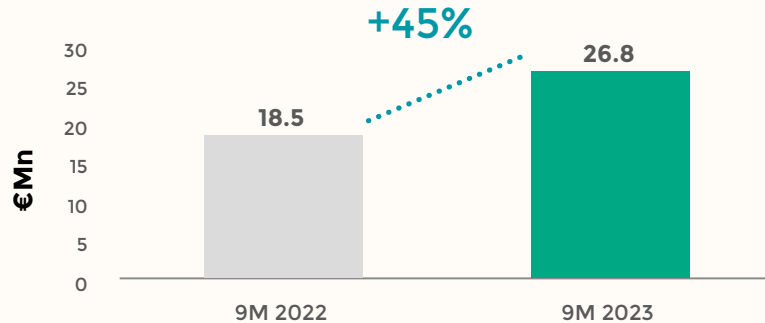
- EBITDA “pre-R&D” decreased by 1%, from €190.1 Mn in 9M 2022 to €187.8 Mn in 9M 2023.
- EBIT “pre-R&D” decreased by 2%, from €173.1 Mn in 9M 2022 to €170.0 Mn in 9M 2023.
- Net profit “pre R&D” decreased by 2%, from €134.0 Mn in 9M 2022 to €131.6 Mn in 9M 2023.

Note: EBITDA, EBIT and Net profit “pre-R&D” calculated excluding R&D expenses in 9M 2023 and 9M 2022.

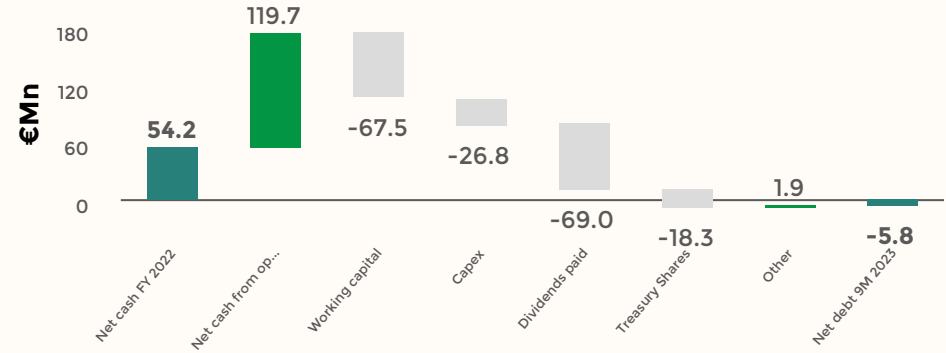
To obtain further information on the alternative performance measures (APMs) and non-IFRS financial indicators used, including the definition thereof and a reconciliation between the applicable management indicators and the financial information set out in the consolidated financial statements prepared under IFRSs, please consult the information included on this subject on pages 16 and 17 and Appendix 2 (pages 35-39) of the press release on the financial results for the first nine months of 2023. 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>.

# Capital expenditure and Cash Flow

## CAPEX evolution



## CF evolution



CF from operating activities decreased to €52.2 Mn in 9M 2023 mainly due to:

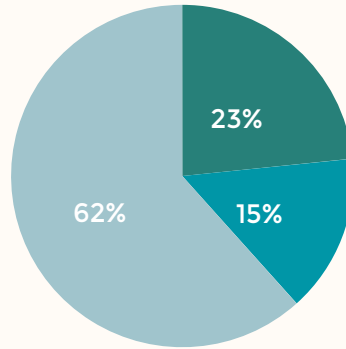
- the booking of €(39.4) Mn under the “cash flow from provision of manufacturing services” caption in 9M 2023 mainly due to the allocation of more revenue to the income statement than payments received, compared to the €55.3 Mn recognized in 9M 2022; and
- the decrease of 52.1 million euros in the “trade and other payables” item in 9M 2023, compared to an increase of 2.4 million euros in the same period of 2022.

ROVI invested €26.8 Mn in 9M 2023 and the main investments projects are:

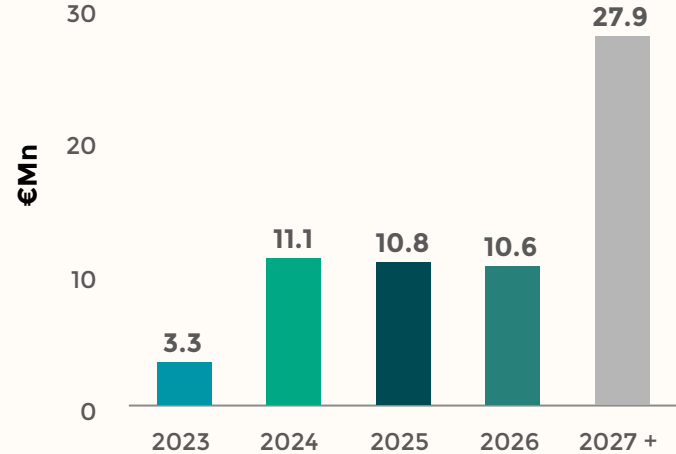
- ISM® Industrialization
- Escúzar plant
- New filling lines and operations expansion
- Glicopepton

# Debt analysis

## Debt breakdown by source (%)



## Debt maturities



- **Debt with public administration represented 15% of total debt, with 0% interest rate.**
- **Net debt of €5.8 Mn** as of 30 September 2023 vs net cash of €54.2 Mn as of 31 December 2022.
- ROVI General Shareholders Meeting, on 14 June 2023, approved the payment of a gross dividend of 1,2938 euros per share; it means an increase of 35% compared to the dividend charged to the 2021 profit (€0.9556/share) and represents approximately 35% pay out. This dividend was paid on 5 July 2023.

# ROVI Share Buyback Program

---

## 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

---

## Duration

26 July 2023 for a twelve-month period

---

## Maximum monetary amount

Up to 130,000,000 euros

---

## 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

---

**As of 31 October 2023, ROVI had executed approximately 27.67% of the buy-back programme, having acquired 747,049 shares**

## News flow 2023-2024



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
ISM <sup>®</sup> technology platform	Marketing of Okedi <sup>®</sup> in Europe Marketing authorization for Risperidone ISM <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 our 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 our sector, may calculate such measures differently, which reduces their usefulness for comparative purposes.

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 Appendix 2 (pages 35-38) of the press release on the financial results for the first nine months of 2023. 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>).

# For further information, please contact:

Juan López-Belmonte  
Chairman and Chief Executive Officer  
[www.rovi.es](http://www.rovi.es)

Javier López-Belmonte  
Deputy Chairman and Chief Financial Officer  
[www.rovi.es](http://www.rovi.es)

Marta Campos  
Head of Investor Relations  
+34 91 2444422  
[mcampos@rovi.es](mailto:mcampos@rovi.es)  
[www.rovi.es](http://www.rovi.es)

Beatriz de Zavala  
Investor Relations Analyst  
[bdezavala@rovi.es](mailto:bdezavala@rovi.es)  
[www.rovi.es](http://www.rovi.es)

