# Full year 2023 FINANCIAL RESULTS



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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 financial results - highlights



Operating revenue increased 1% to €829.5 Mn in 2023 driven by the CDMO<sup>(1)</sup> business which grew 1% to €409.3 Mn and the specialty pharmaceutical business, where sales rose 1% to €420.2 Mn.



Positive evolution of Okedi® (Risperidone ISM®), which reached sales of €14.4 Mn in 2023.



Sales of the heparin franchise decreased by 5% to €250.6 Mn in 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®, which sales increased by 16% and 8% respectively in 2023, rising to €45.5 Mn and €26.5 Mn respectively.



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

# Milestones achieved - FDA approved the active substance manufacturing plant and CDMO's injectable plants, evaluation process for Risvan® in U.S. and first place in the Sustainalytics ESG ranking



The FDA approved ROVI's active substance manufacturing plant in Granada for the manufacture of Moderna's mRNA COVID-19 vaccine

In January 2024, the FDA inspected the company's active substance manufacturing plant in Granada with a satisfactory result. The inspection focused on the processes of manufacture and control of the active substance to be used in the manufacture of Moderna's mRNA COVID-19 vaccine. This result authorises Moderna to market the vaccine manufactured by ROVI in the U.S.



The FDA approved ROVI's CDMO's injectable plants for the manufacture of Moderna's COVID-19 mRNA vaccine

In September 2023, the FDA 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.



In July 2023, ROVI achieved 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**

Juan López-Belmonte Chairman and Chief Executive Officer



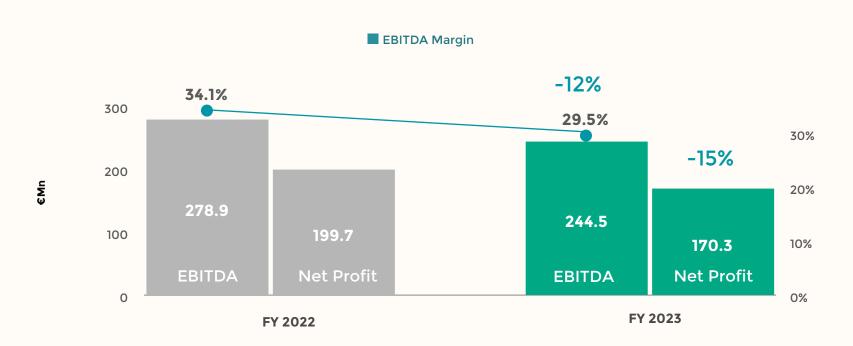
# Growth mainly driven by CDMO business, Okedi® and Neparvis®







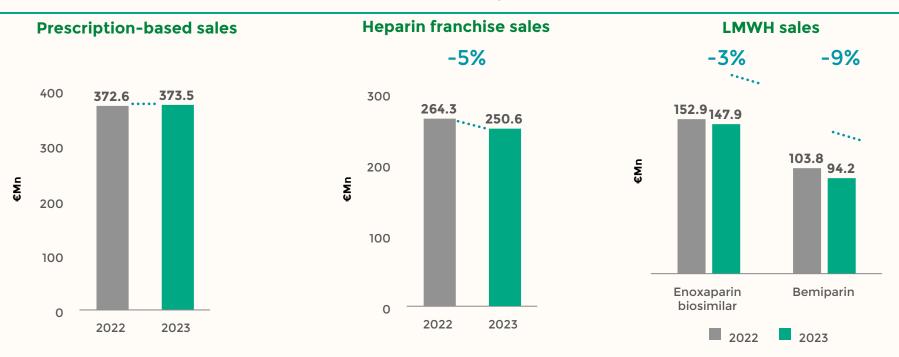
# **Evolution of EBITDA and net profit in the first post-pandemic year**



- EBITDA reached €244.5 Mn in 2023, a decrease of 12% compared to 2022.
- Net profit decreased by 15%, from €199.7 Mn in 2022 to €170.3 Mn in 2023.



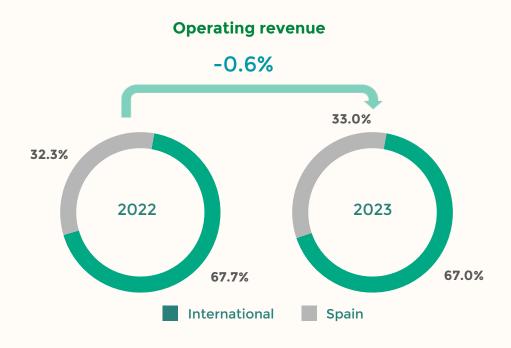
# ROVI aspires to become a benchmark player in the LMWH field worldwide



- Sales of prescription-based pharmaceutical products remained stable at €373.5 Mn in 2023.
- Sales of the heparin franchise<sup>(1)</sup> decreased by 5% to €250.6 Mn in 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 volume of orders from partners in 2023, since they still hold a high level of stocks from 2022.
- Heparin sales represented 30% of operating revenue in 2023 compared to 32% in 2022.

## 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 remained stable in 2023 mainly due to the CDMO business.
- Sales outside Spain represented 67% of operating revenue in 2023, compared to 68% in 2022.





# **Growth evolution of Enoxaparin Biosimilar (Becat®)**

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

Direct marketed in Germany, UK, Italy, France, Poland, Austria, Belgium, Portugal and Spain

Approved in 26 countries in Europe and 33 in the Rest of the World Launched in 40 countries

#### **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 and Sri Lanka in 2023.

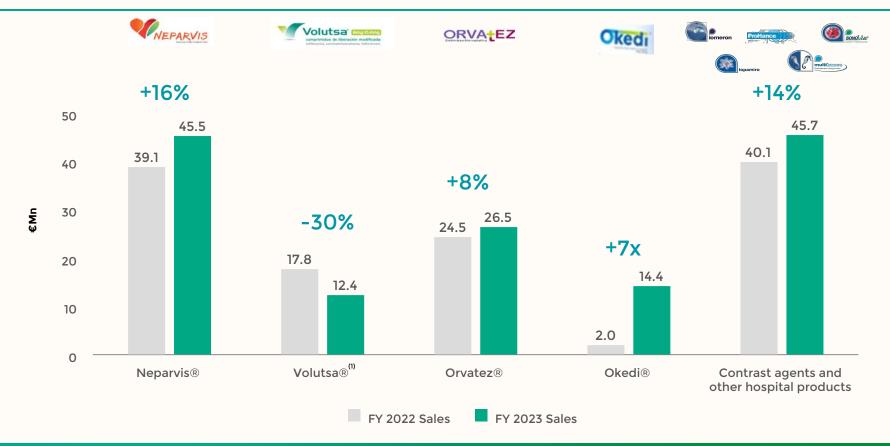




It will continue international expansion in other markets with strong growth potential through out-licensing agreements.

€0.7 bn
Q1 2020
MAT
Market
Sales

# 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**

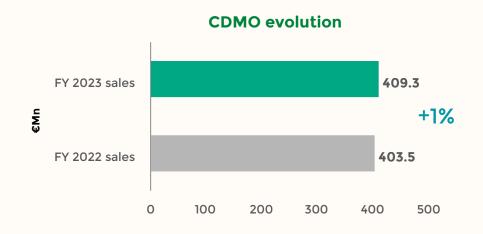
#### **CDMO** business

# 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.
- All ROVI's Madrid facilities were inspected and approved by 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 FDA in January 2024, allowing Moderna to market the vaccine manufactured by ROVI in the U.S.

#### 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 sales increased by 1% to €409.3 Mn in 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® 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® technology to new chronic therapeutic areas, including psychiatry and oncology
- 505(b)(2) path of approval for candidates leveraging ISM® technology

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

# Sustainable management at ROVI

#### **ESG Strategy**

#### **Sustainability Policy**

#### ESG Master Plan 2023-2025

- 19 strategic goals
- 44 KPIs



#### **ESG Commitments**



#### **ESG Valuations**

**Sustainalytics:** 16.4 (low risk) 1° ranking in the global pharmaceutical industry



MSCI

MSCI: rating "A"



#### **Environmental management**

#### **Net Zero Strategy**

· Climate neutrality in scope 1 and 2

# TCFD (Task Force on Climate related Financial Disclosures)

 Alignment with TCFD recommensations for the identification and financial quantification of climate risks

#### **Energy efficiency**

- 100% of electric energy consumed by production plants comes from renewable energy sources
- Energy efficiency program implemented across all production plants

#### **ISO Certification**

· ISO 14001 & ISO 50001 (energy certifications)

#### **Social Management**

#### **Diversity, Equity & Inclusion**

- 1,135 women vs 976 men
- · 32% women in leadership positions
- 21 different nationalities
- · There is no gender pay gap

#### Commitment to safety and health

- Low accident incident (1,847)
- Absenteeism rate (3.67%) below the industry's average (4.24%)
- · ISO 45001

#### **Commitment with employees**

- · Job creation (456 hirings in 2023)
- · 89% of permanent contracts
- · 32.27 hours of training per employee

#### Sustainable chain value

 Progressive increase in evaluated suppliers through Ecovadis (19% in 2023)

#### **Corporate Governance**

#### **Diversity in the Board of Directors**

- · 42.85% women
- · 42.85% independent members

#### Sustainability oversight

 The Audit and Nomination/Remuneration Committees oversee ESG aspects

#### **Sustainability Committee**

Reports to the Board Committees

# Incentives for Executive Directors linked to ESG aspects

#### **Ethical code for employees and suppliers**

· Independent whistleblowing channel

Implementation of the internal control system for non-financial information (ICSNFI)



#### Outlook 2024



#### 2024 operating revenue growth rate

Decrease by a mid-single-digit percentage vs 2023

#### The key growth levers in 2024

# Marketing of Okedi® in Europe LMWH franchise License agreements (Neparvis® and Orvatez®) Existing portfolio of specialty pharmaceuticals New product distribution licenses



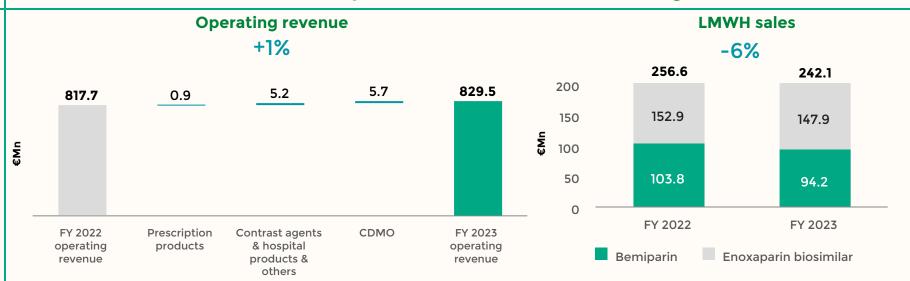


# **FINANCIAL RESULTS**

Javier López-Belmonte Deputy Chairman and Chief Financial Officer



# Revenue level improves thanks to resilient sales growth



Operating revenue increased 1% to €829.5 Mn in 2023 driven by (i) the CDMO business which grew 1% to €409.3 Mn, and (ii) the 14% increase in the sales of contrast agents and other hospital products. The prescription-based pharmaceutical product business remained stable at €373.5 Mn in 2023.

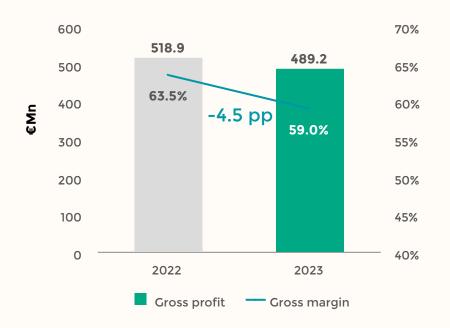
Sales of LMWH decreased by 6% to €242.1 Mn in 2023.

- Enoxaparin biosimilar sales decreased by 3% to €147.9 Mn in 2023 compared to 2022. However, sales of enoxaparin biosimilar increased 18% in Q4 2023 to €39.8 Mn compared to Q3 2023, and rose 18% in Q4 2023 compared to Q4 2022.
- Bemiparin sales decreased by 9% to €94.2 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 Turkey; (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**



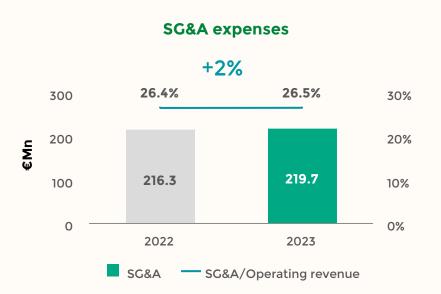
#### **Gross margin impacts**

Gross profit decreased 6% to €489.2 Mn in 2023.

Gross margin showed a decrease of 4.5 p.p. from 63.5% in 2022 to 59.0% in 2023. This drop is mainly due to (i) 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; and (ii) the lower margin from the manufacture of the COVID-19 vaccine in 2023 compared to 2022.

In Q4 2023, low-molecular-weight heparin (LMWH) raw material prices decreased by around 35% in comparison with Q4 2022. ROVI expects this decline to accelerate in 2024. Nevertheless, despite this price decrease, the impact on gross margin remained negative in 2023 due to the length of the LMWH manufacturing process, where the raw material currently being used has been stocked for several months and was purchased at higher prices. However, a positive impact on gross margin is expected to be seen from 2025.

#### Cost control and commitment to R&D



**R&D** expenses

SG&A increased 2% to €219.7 Mn in 2023 mainly as a result of an increase in expenses due to the Okedi<sup>®</sup> launch in Europe.

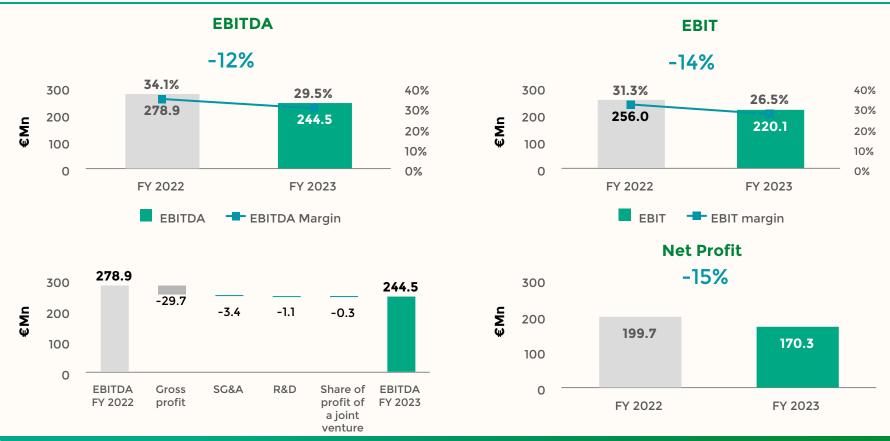
Other operating expenses (excluding R&D and employee benefit expenses) decreased by 11% to €106.4 Mn in 2023.

**R&D** expenses increased 4% to €24.9 Mn in 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.

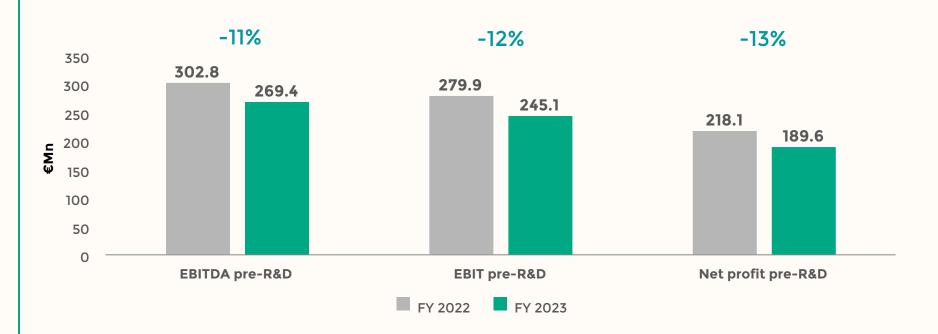


# **EBITDA, EBIT & Net Profit analysis**





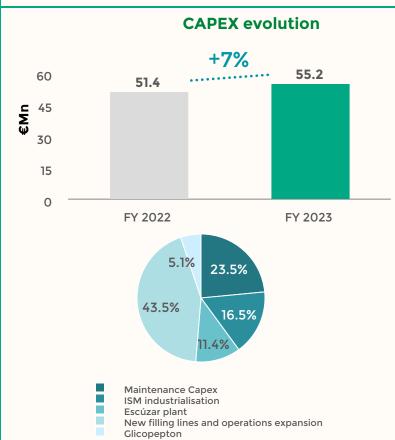
# PRE-R&D analysis<sup>(1)</sup>

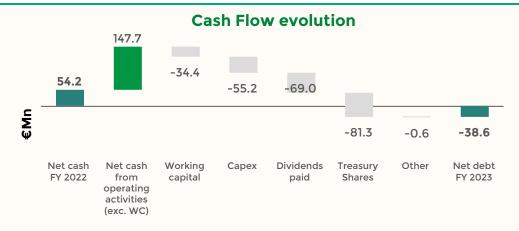


- **EBITDA** "pre-R&D" decreased by 11%, from €302.8 Mn in 2022 to €269.4 Mn in 2023.
- **EBIT "pre-R&D"** decreased by 12%, from €279.9 Mn in 2022 to €245.1 Mn in 2023.
- Net profit "pre R&D" decreased by 13%, from €218.1 Mn in 2022 to €189.6 Mn in 2023.



# **Capital expenditure and Cash Flow**





#### CF from operating activities decreased to €113.2 Mn in 2023 mainly due to:

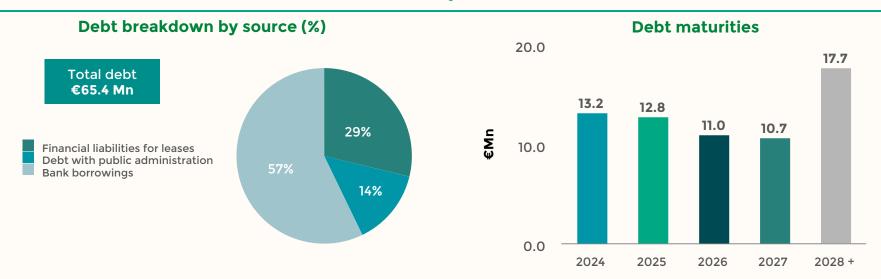
- the booking of €(58.4) Mn under the "Cash flow from provision of manufacturing services" caption in 2023 mainly due to the allocation of more revenue to the income statement than payments received, compared to the €57.1 Mn recognized in 2022;
- the decrease of €23.9 Mn in the "Trade and other payables" item in 2023, compared to an increase of €41.7 Mn in 2022; and,
- the decrease of €37.6 Mn in "Profit before income tax".

#### ROVI invested €55.2 Mn in 2023 and the main investments projects are:

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



# **Debt analysis**



- Debt with public administration represented 14% of total debt, with 0% interest rate.
- Net debt of €38.6 Mn as of 31 December 2023 vs net cash of €54.2 Mn as of 31 December 2022.
- As of 31 January 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 4.625%).
- ROVI will propose to the General Shareholders' Meeting a dividend of 1,1037 euros per share charged to the 2023 profit and retained earnings. This proposed dividend represents 35% of the net profit for 2023 attributed to the parent company.



# **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 January 2024, ROVI had executed approximately 74.85% of the buyback program, having acquired 1,808,392 shares for an amount of €97.3 Mn.



# News flow 2024

		Sales of biosimilar of Enoxaparin	
	Specialty pharma	Additional new products to be launched	
		Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar outside Europe	
	СДМО	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 35-39) of the press release on the financial results for the full year 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).



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