

First half 2023 FINANCIAL RESULTS

26 JULY 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 half financial results - highlights



Operating revenue remained stable, reaching €380.8 Mn in the first post-pandemic half year.



Positive evolution of Okedi® (Risperidone ISM®), which reached sales of €5.2 Mn in H1 2023.



CMO sales increased by 4% to €172.2 Mn in H1 2023.



Sales of the enoxaparin biosimilar decreased by 9% to €74.5 Mn in H1 2023. However, sales of the product increased 14% in Q2 2023 to €39.6 Mn, compared to Q1 2023, and rose 5% in Q2 2023 compared to Q2 2022.

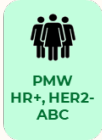


Good performance of Neparvis® and Orvatez®, whose sales increased by 17% and 12% in H1 2023, rising to €22.1 Mn and €13.6 Mn respectively.



ROVI is upgrading its operating revenue guidance for the full year 2023 from low-double-digit negative growth to high-single-digit negative growth.

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.

This first clinical trial of Letrozole LEBE is planned to start by Q3 2023.



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. The Company is awaiting an FDA notification on the user fee goal date. The content of this notification will be reported as soon as it is received.

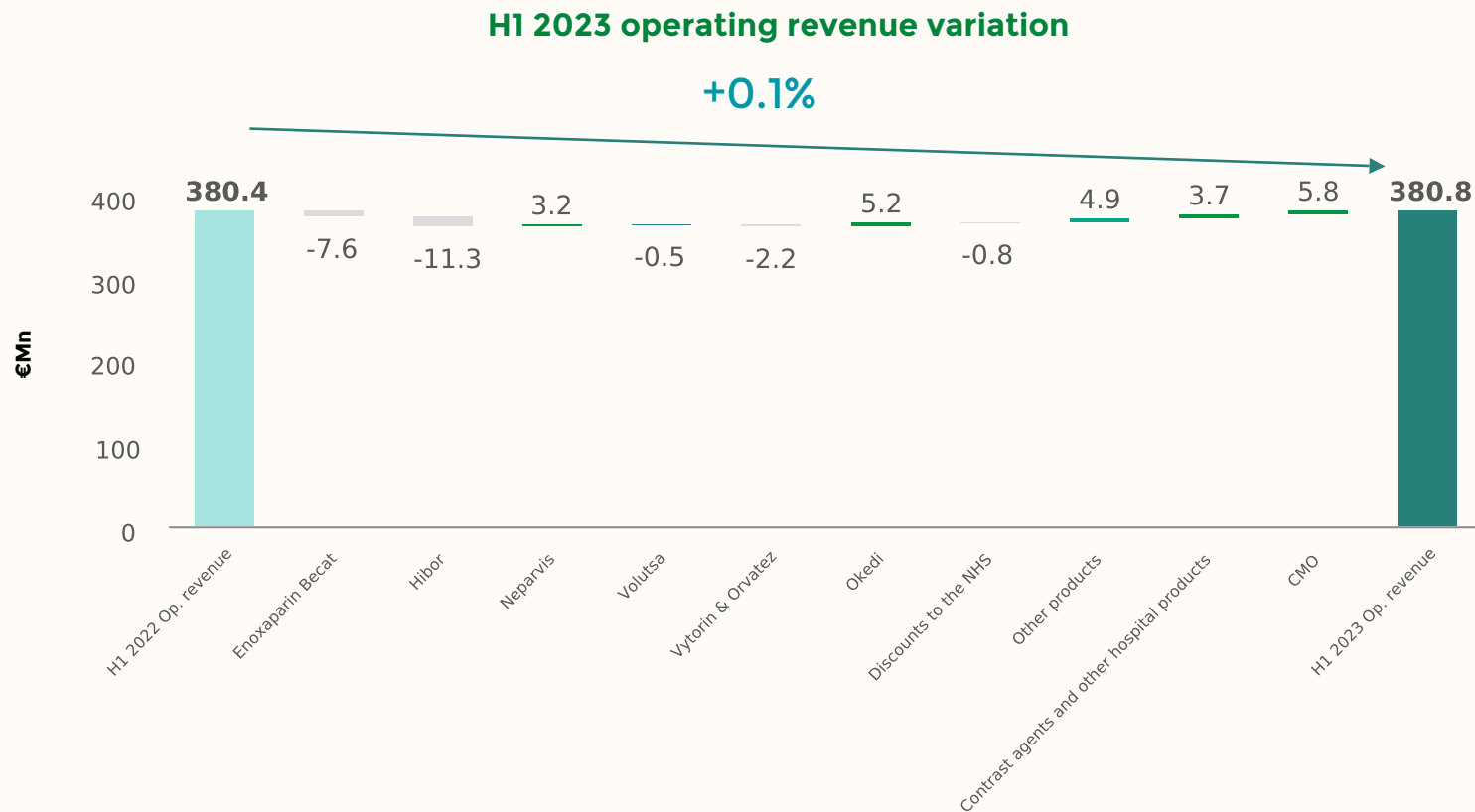


OPERATING RESULTS

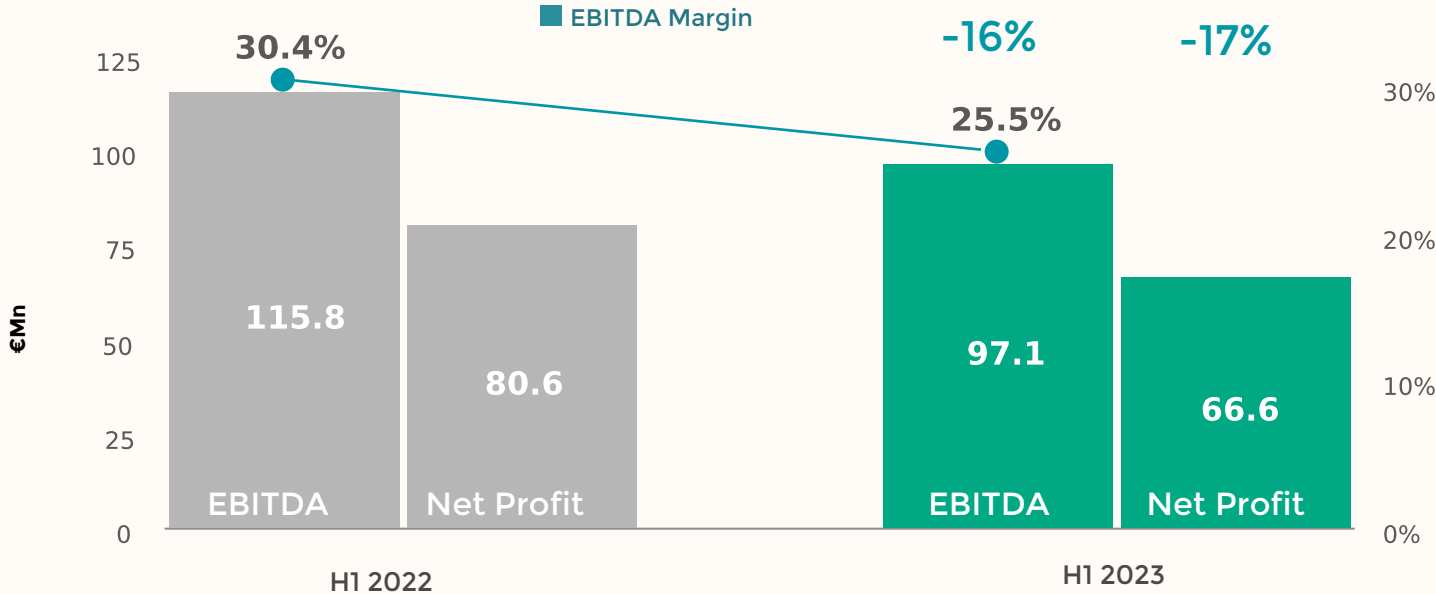
Juan López-Belmonte
Chairman and Chief Executive Officer



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



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

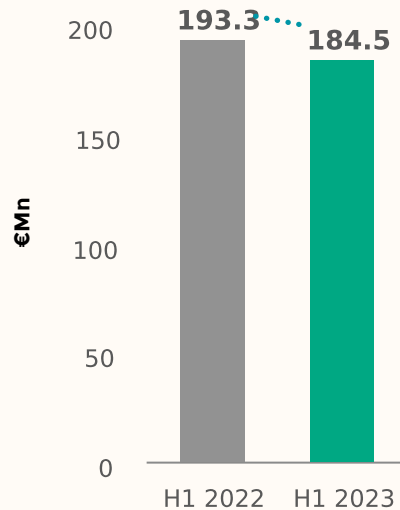


- EBITDA reached €97.1 Mn in H1 2023, a decrease of 16% compared to H1 2022.
- Net profit decreased by 17%, from €80.6 Mn in H1 2022 to €66.6 Mn in H1 2023.

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

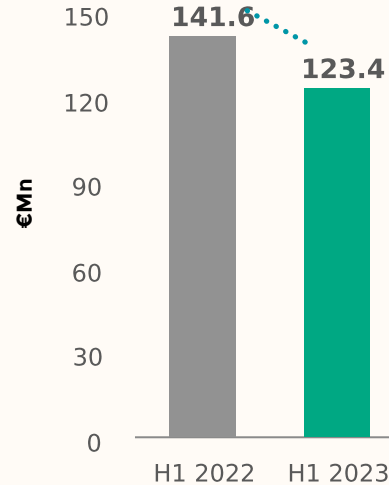
Prescription-based sales

-5%



Heparin franchise sales

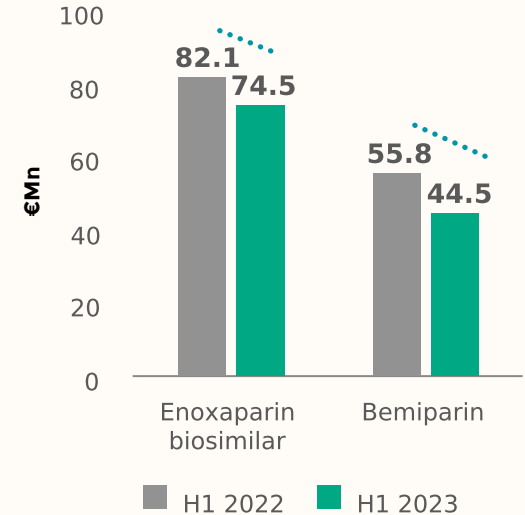
-13%



LMWH sales

-9%

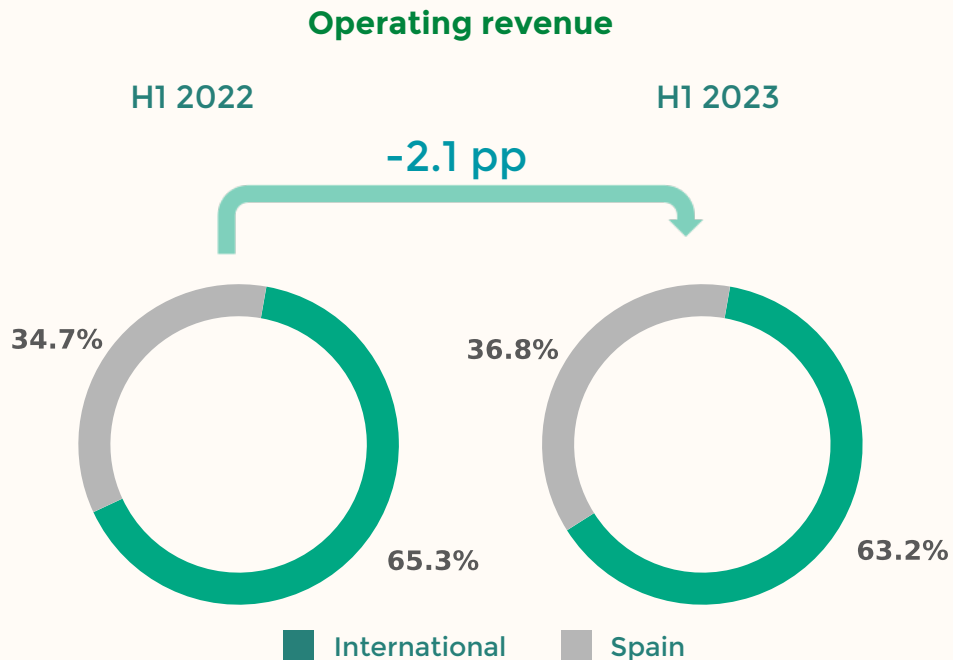
-20%



- Sales of prescription-based pharmaceutical products decreased by 5% to €184.5 Mn in H1 2023.
- Sales of the heparin franchise decreased by 13% to €123.4 Mn in H1 2023 mainly as a result of the increase in orders from partners in 2022 related to 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 32% of operating revenue in H1 2023 compared to 37% in H1 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 3% in H1 2023 mainly due to the drop in LMWH international sales.
- Sales outside Spain represented 63% of operating revenue in H1 2023.

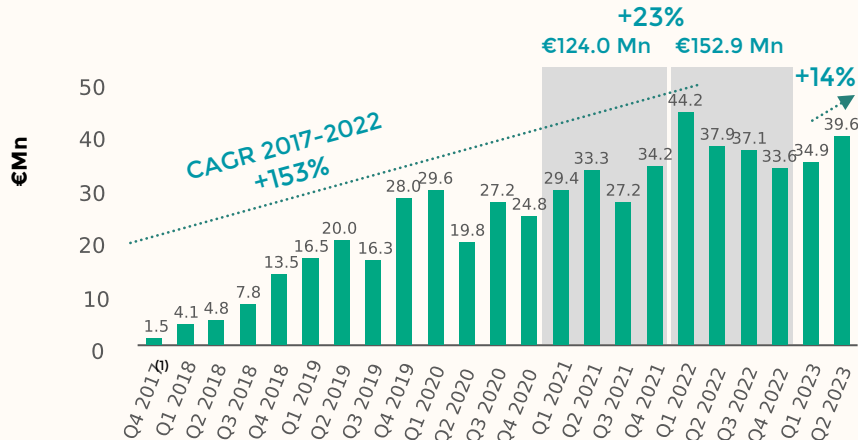


Strong growth potential of Enoxaparin Biosimilar Becat®

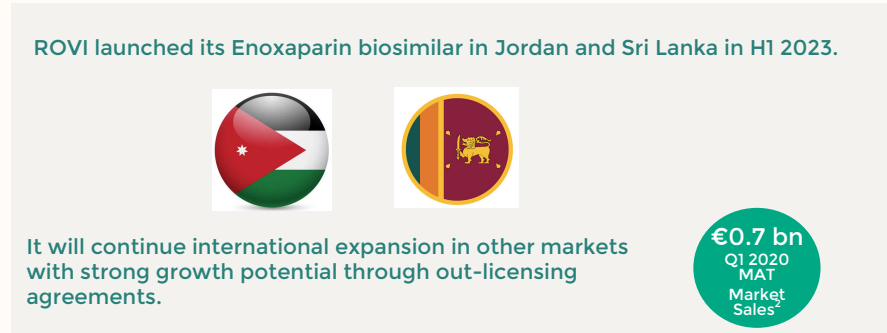
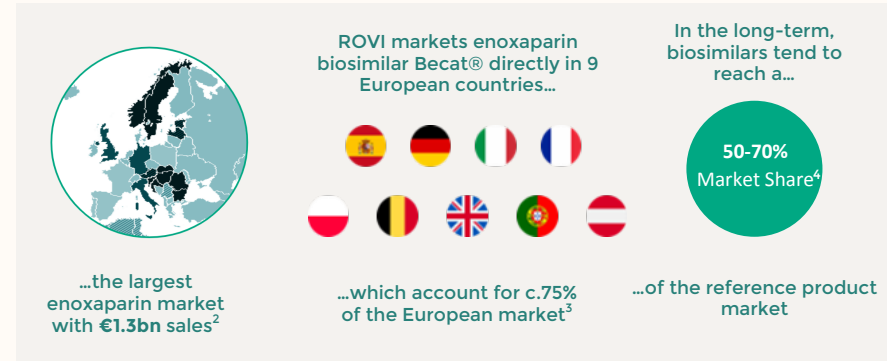
Well-established network to minimize time-to-market



Enoxaparin biosimilar Becat® Sales Ramp-up

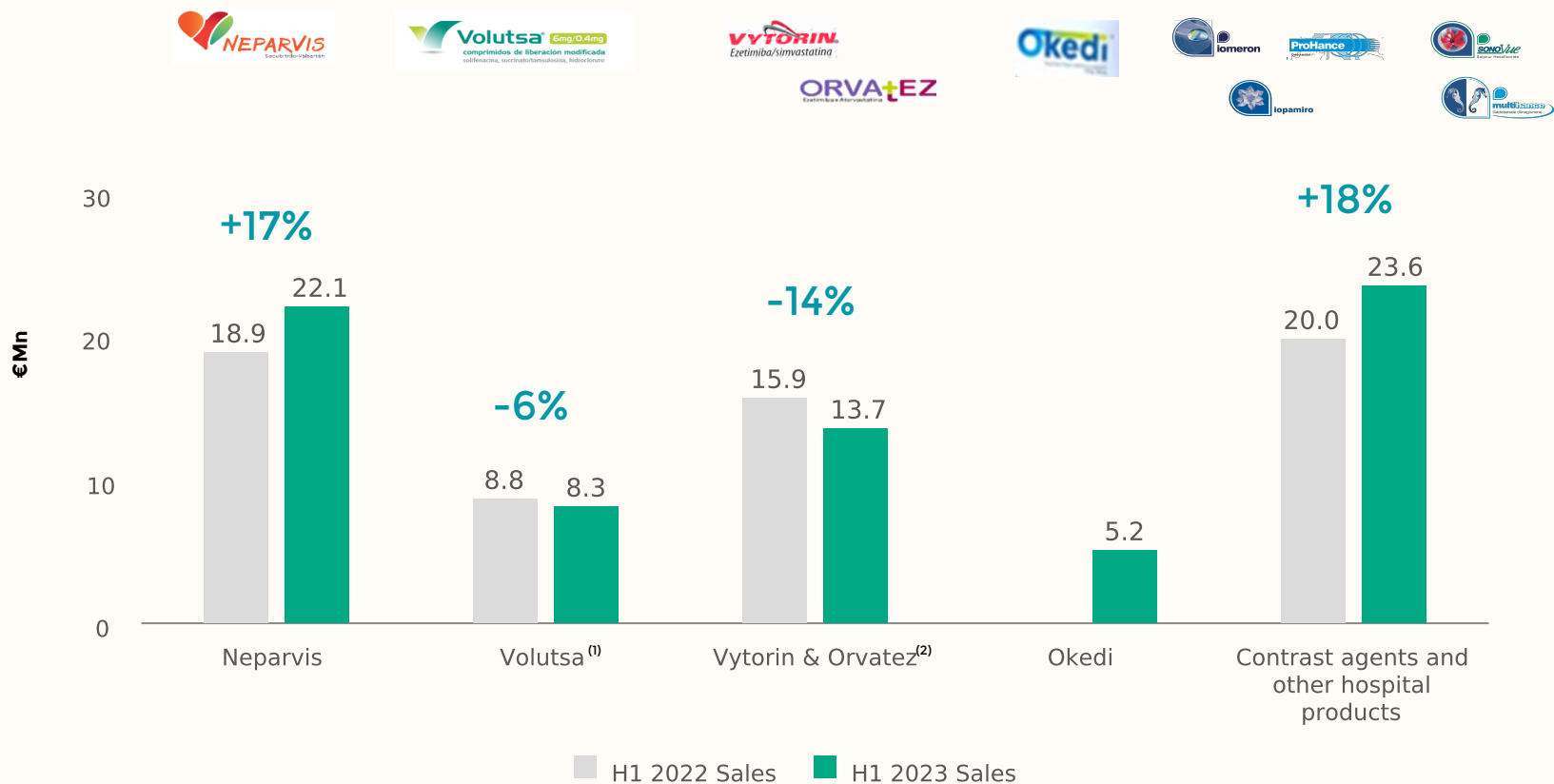


Commercial Strategy



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.

(2) 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.

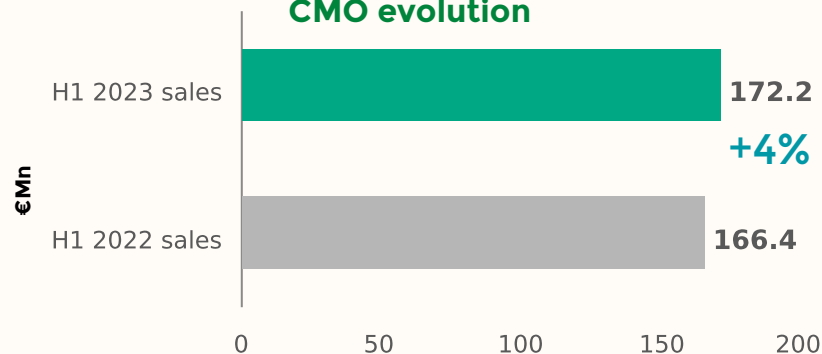
Packaging Excellence Centre in our Alcalá de Henares plant

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 4% to €172.2 Mn in H1 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[®], 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[®] technology to new chronic therapeutic areas, including psychiatry and oncology
- 505(b) path of approval for candidates leveraging ISM[®] technology

Product	Potential Indication	Current Situation	Key Milestones
Risperidone-ISM [®] , monthly	Schizophrenia	Approved	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 ² model & simulations already validated for Risperidone-ISM [®] 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



Upgrade

2023 operating revenue growth rate

High-single-digit negative growth vs 2022

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 Orvatez®)	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. 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.

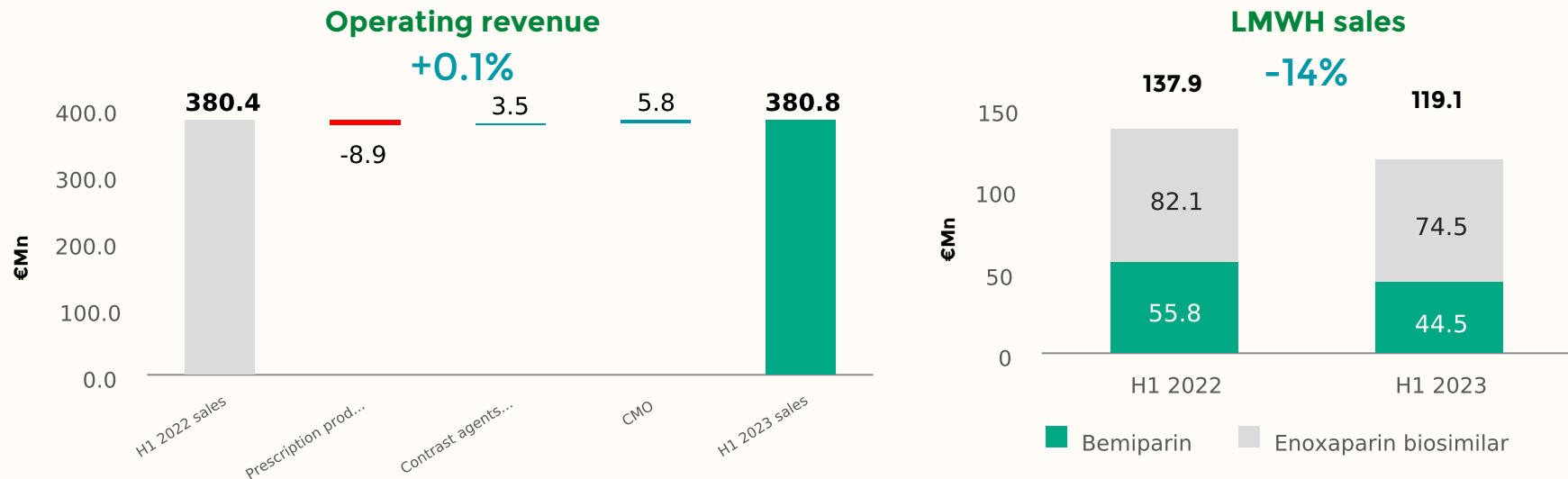


FINANCIAL RESULTS

Javier López-Belmonte
Deputy Chairman and Chief Financial Officer



Stable revenue in the first post-pandemic half year



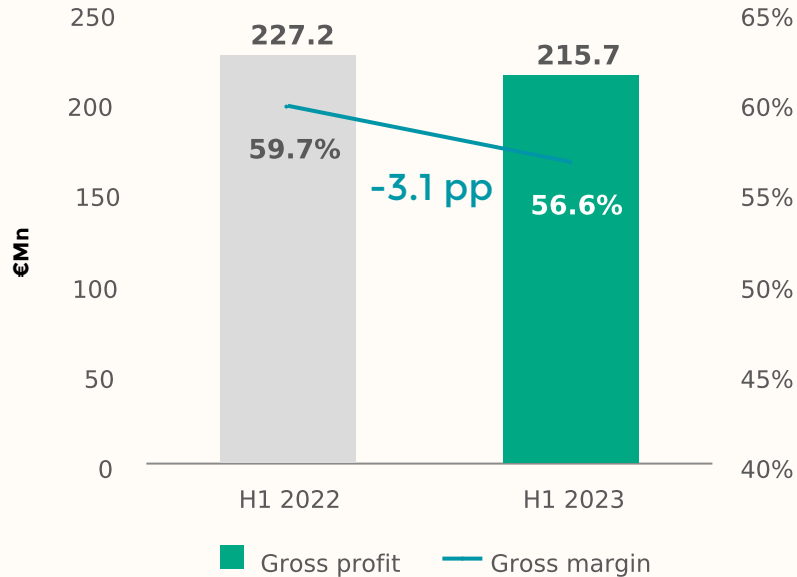
Operating revenue remained stable at €380.8 Mn in the first post-pandemic half year. The 5% drop in the prescription-based pharmaceutical product business was offset by (i) the 4% growth in the CMO business and (ii) the 18% increase in the sales of contrast agents and other hospital products in H1 2023.

Sales of **LMWH** decreased by 14% to €119.1 Mn in H1 2023.

- **Enoxaparin biosimilar** sales decreased by 9% to €74.5 Mn in H1 2023. However, sales increased 14% in Q2 2023 to €39.6 Mn, compared to Q1 2023, and rose 5% in Q2 2023 compared to Q2 2022. In Q2 2023, the product's sales were €4.5 Mn (or 13%) higher than the average quarterly sales of the product in the last ten quarters.
- **Bemiparin** sales decreased by 20% to €44.5 Mn mainly due to lower volume of orders from partners, as a result of the increase in the product use in H1 2022 because of COVID-19.

Gross margin negatively impacted by the CMO division

Gross profit and Gross margin

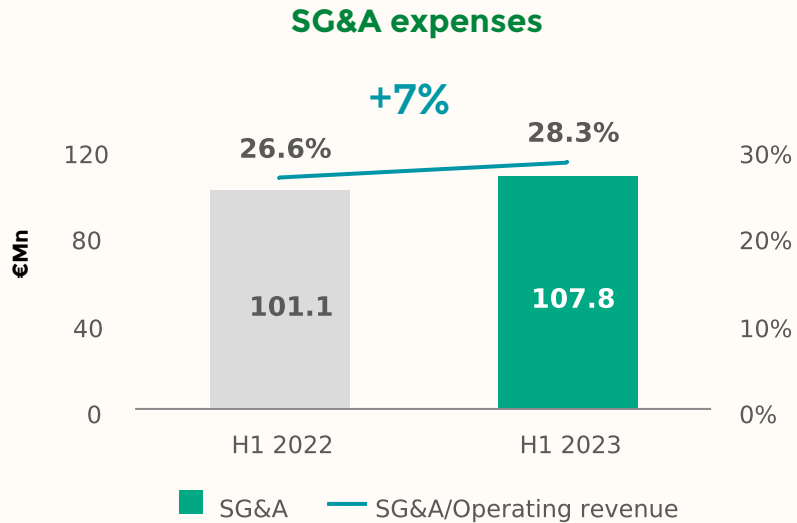


Gross margin impacts

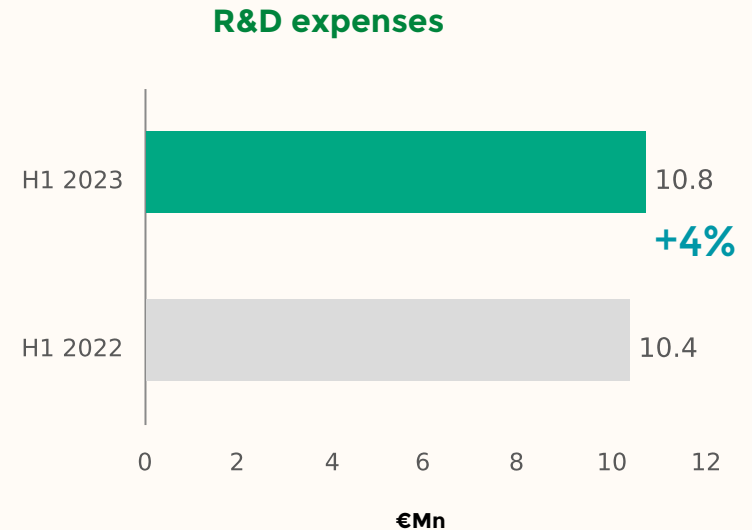
Gross profit decreased 5% to €215.7 Mn in H1 2023.

Gross margin showed a decrease of 3.1 p.p. from 59.7% in H1 2022 to 56.6% in H1 2023. This drop is mainly due to the higher contribution to the CMO 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.

Cost control and commitment to R&D



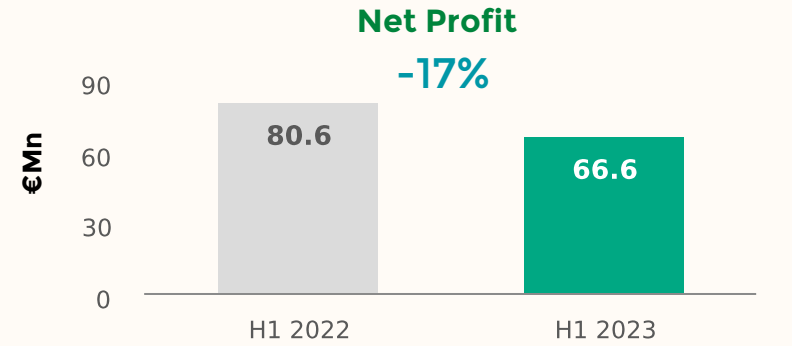
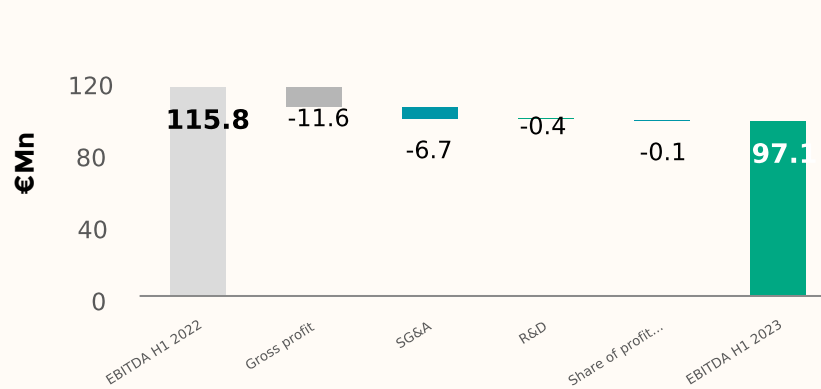
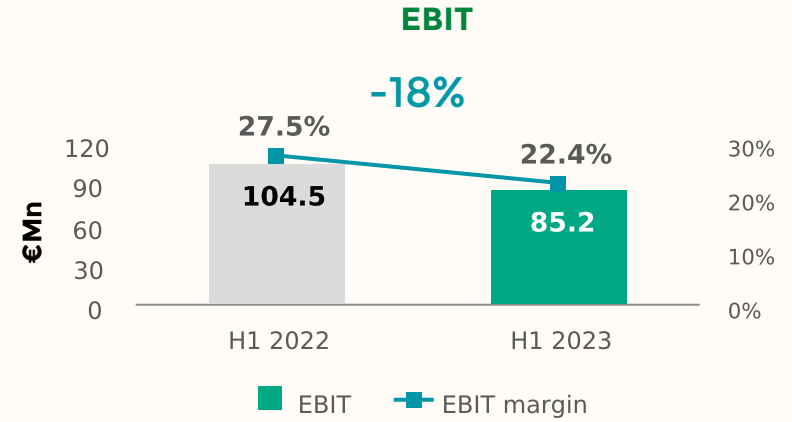
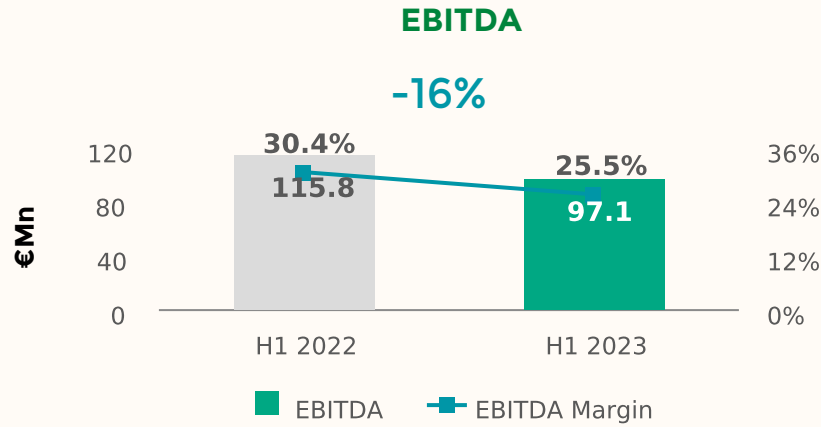
SG&A increased 7% to €107.8 Mn in H1 2023 mainly as a result of an increase in expenses due to the Okedi® launch in Europe.



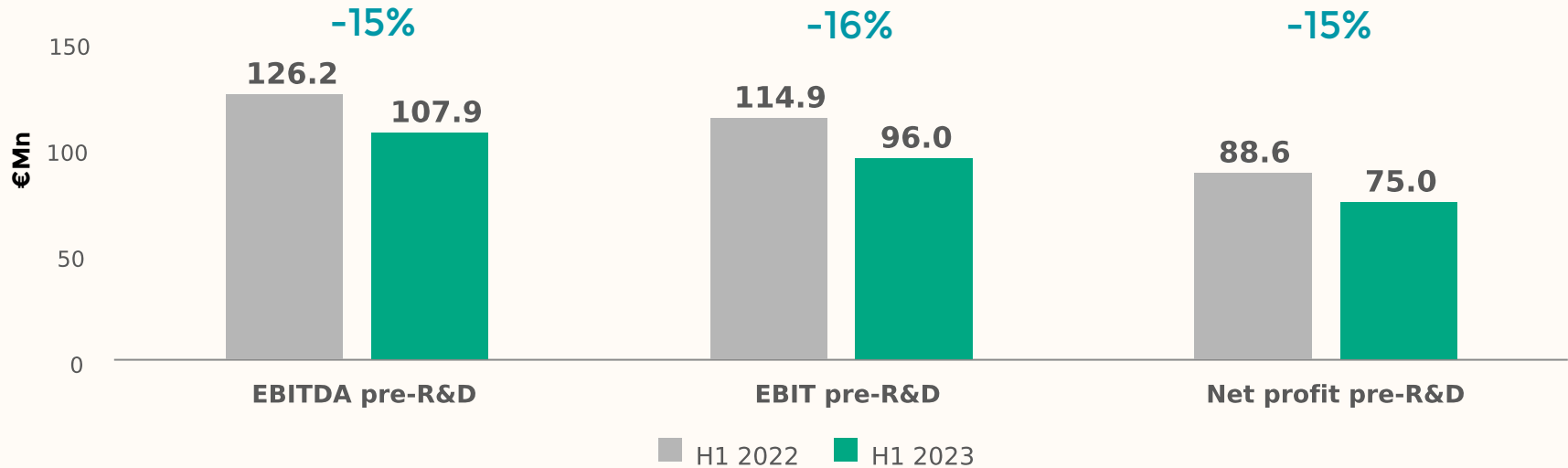
R&D expenses increased 4% to €10.8 Mn in H1 2023. These expenses are related to:

- 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



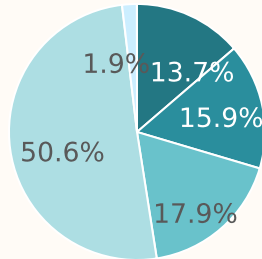
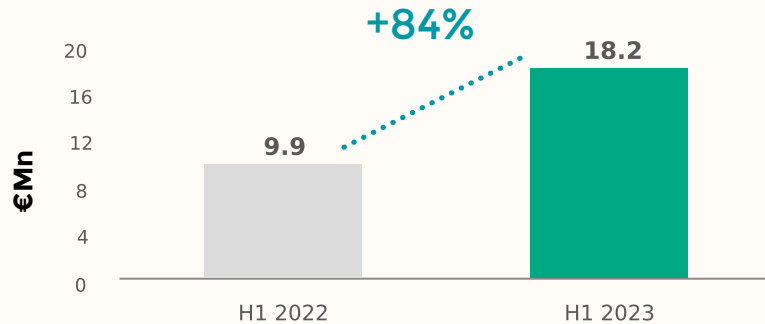
PRE-R&D analysis



- **EBITDA “pre-R&D”** decreased by 15%, from €126.2 Mn in H1 2022 to €107.9 Mn in H1 2023.
- **EBIT “pre-R&D”** decreased by 16%, from €114.9 Mn in H1 2022 to €96.0 Mn in H1 2023.
- **Net profit “pre R&D”** decreased by 15%, from €88.6 Mn in H1 2022 to €75.0 Mn in H1 2023.

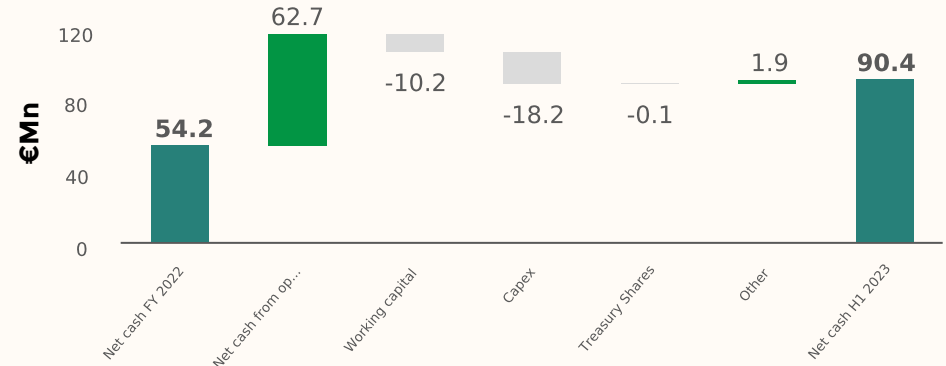
Capital expenditure and Cash Flow

CAPEX evolution



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

CF evolution



CF from operating activities decreased to €52.5 Mn in H1 2023 mainly due to:

- Decrease of €19.5 Mn in profit before income tax;
- Booking of €(23.3) Mn under the “Cash flow from provision of manufacturing services” caption in H1 2023 due to the allocation of more revenue to the income statement than payments received, compared to the €74.1 Mn in H1 2022;
- Decrease of €40.1 Mn in the “inventory” item in H1 2023 compared to a decrease of €21.2 Mn in H1 2022; and
- Decrease of €21.6 Mn in the “trade and other payables” item in H1 2023, compared to an increase of €2.9 Mn in H1 2022.

ROVI invested €18.2 Mn in H1 2023 and the main investments projects are:

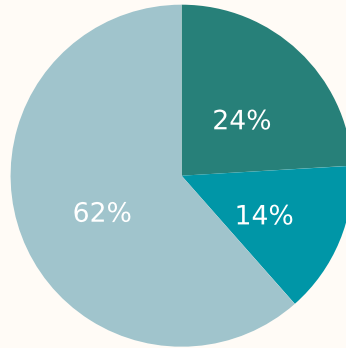
- ISM® Industrialization
- Escúzar plant
- New filling lines and operations expansion
- Glicopepton

Debt analysis

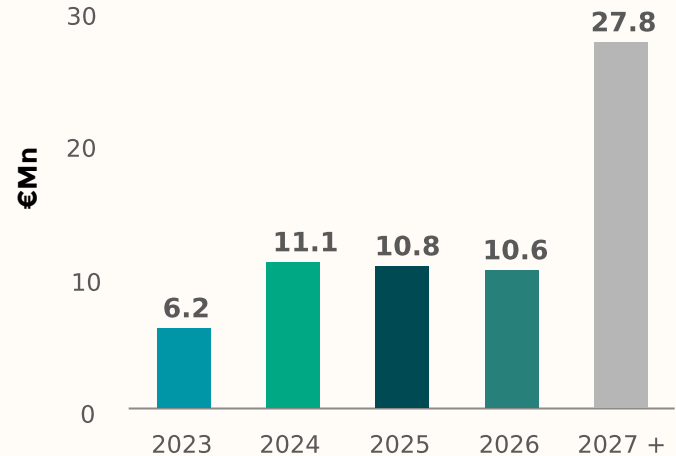
Debt breakdown by source (%)

Total debt
€66.5 Mn

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



Debt maturities



- **Debt with public administration represented 14% of total debt, with 0% interest rate.**
- **Net cash of €90.4 Mn** as of 30 June 2023 vs €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

From today, 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

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	Evolution of Moderna's products manufacturing
ISM [®] technology platform	Marketing of Okedi [®] in Europe Marketing authorization for Risperidone ISM [®] in USA
	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

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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 H1 2023 and H1 2022.

For further information, please contact:

Juan López-Belmonte
Chairman and Chief Executive Officer
www.rovi.es

Javier López-Belmonte
Deputy Chairman and Chief Financial Officer
www.rovi.es

Marta Campos
Head of Investor Relations
+34 91 2444422
mcampos@rovi.es
www.rovi.es

Beatriz de Zavala
Investor Relations Analyst
bdezavala@rovi.es
www.rovi.es

