Full year 2022 FINANCIAL RESULTS



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2022 financial results - highlights



Operating revenue growth of 26% to €817.7 Mn and EBITDA growth of 37% to €278.9 Mn in 2022.



Sales of the heparin franchise increased by 9% to €264.0 Mn in 2022.



Sales of Neparvis® and Volutsa® increased by 2% to €39.1 Mn and by 9% to €17.8 Mn respectively in 2022.



CMO sales increased by 52% to €403.5 Mn in 2022.



At the end of 2022, ROVI exceeded the higher end of its operating revenue guidance range (15% - 20%), standing at 26%.

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



Milestones achieved - Glicopepton Biotech, launch of Okedi® in Europe, agreement with Moderna and first position in the Sustainalytics ESG ranking (1/2)





Glicopepton Biotech founded to produce compounds of high technological value

ROVI announced that it presented Glycopepton Biotech, S.L., a joint venture with Càrniques Celrà, S.L. and Grupo Empresarial Costa, S.L. that involves the creation of one of the first national structures for self-sufficiency in heparins.

The project involves the construction of a facility at the Industrial Logistics Platform of Fraga (Huesca), which will produce compounds of high biological value that derive from the intestinal mucosa of pigs. It will involve a joint investment of approximately 40 million euros over the next four years and is expected to create around 30 direct skilled jobs. The project will be subject to obtaining the applicable administrative and regulatory permits and authorisations.



ROVI receives the European Commission's approval of Okedi® as a treatment for schizophrenia

The European Commission has authorised the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone.

This approval is based on the positive results of the pivotal PRISMA-3 study on the efficacy and safety of Risperidone ISM® in schizophrenia patients¹.

The product was launched in Germany in April 2022, in UK in July 2022 and in Spain in September 2022.



Milestones achieved - Glicopepton Biotech, launch of Okedi® in Europe, agreement with Moderna and first position in the Sustainalytics ESG ranking (2/2)

moderna

Moderna and ROVI expand long-term collaboration for the manufacture of mRNA medicines

ROVI announced a long-term collaboration with Moderna to increase capacities for the compounding, aseptic filling, inspection, labeling, and packaging of ROVI's facilities located in Madrid, San Sebastián de los Reyes and Alcalá de Henares.

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.



ROVI obtained an "ESG Risk Rating 2022" of 17.3, the first position in the sub-industry "pharmaceuticals"

ROVI's ESG aspects have been evaluated by Sustainalytics, having obtained an "ESG Risk Rating 2021" of 17.3, which places the company at low risk (between 10 and 20). This rating improves by 1.1 points the one achieved in the previous year (18.4).

ROVI attains the first position out of 458 companies in the sub-industry "pharmaceuticals" and 22nd out of a total of 970 companies in the "pharmaceutical industry", which includes biotech, pharmaceutical and laboratory equipment companies.

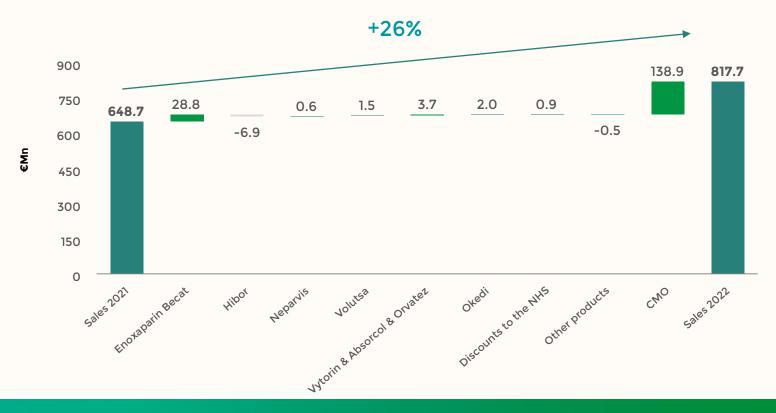


OPERATING RESULTS



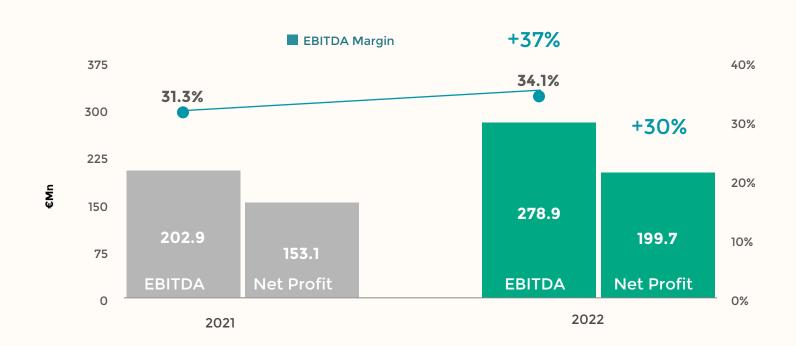
Growth driven by CMO and specialty pharma businesses...







...with high profitability

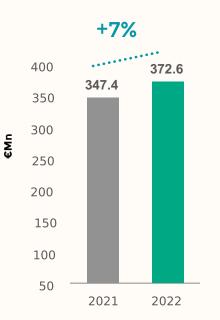


- EBITDA increased to €278.9 Mn in 2022, a rise of 37% compared to 2021.
- Net profit increased by 30%, from €153.1 Mn in 2021 to €199.7 Mn in 2022.

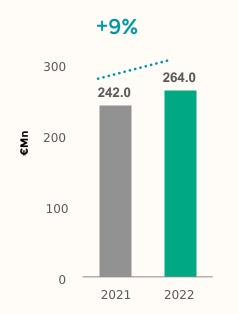


Heparins, leading the specialty pharmaceutical business

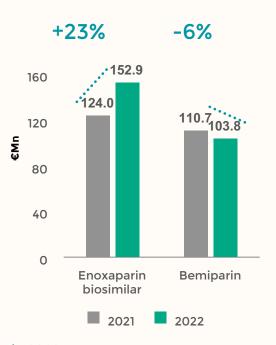
Prescription-based sales



Heparin franchise sales



LMWH sales



- Sales of prescription-based pharmaceutical products increased by 7% to €372.6 Mn in 2022.
- Sales of the heparin franchise increased by 9% to €264.0 Mn in 2022.
- Heparin sales represented 32% of operating revenue in 2022 compared to 37% in 2021.



Successful internationalization plan

- Well positioned to drive long-term leadership in Low Molecular Weight Heparins (LMWH)
- Sales of LMWH (Enoxaparin biosimilar and Bemiparin) increased by 9% to €256.6 Mn in 2022

Total group sales





Strong growth potential of Enoxaparin Biosimilar Becat®

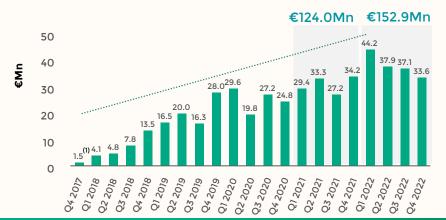
Well-Established Network to Minimize Time-to-Market

Direct marketed in Germany, UK, Italy, Spain, Portugal and Poland

Approved in 26 countries in Europe and 31 in the Rest of the World Launched in 38 countries

Enoxaparin Biosimilar Becat® Sales Ramp-up

+23%



Commercial Strategy



ROVI will directly market enoxaparin biosimilar Becat® in 7 European countries...



In the long-term, biosimilars tend to reach a...



...the largest enoxaparin market with €1.3bn sales²

...which account for c.75% of the European market³

...of the reference product market

ROVI launched its enoxaparin biosimilar in 5 countries in 2022: Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo.











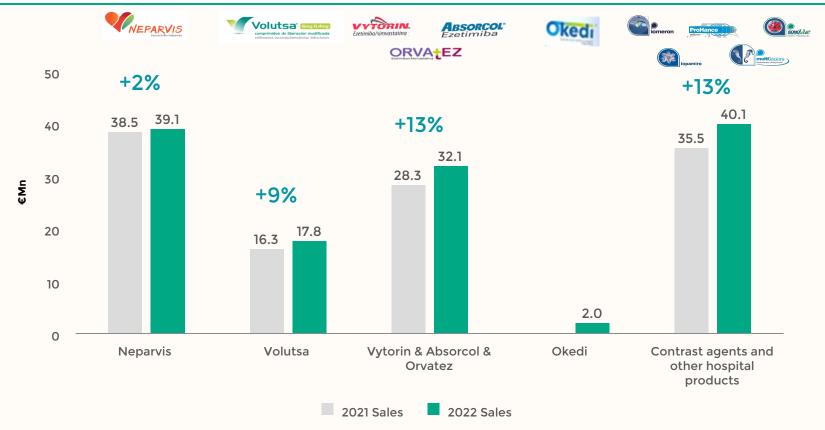
Continue international expansion in other markets with strong growth potential through out-licensing agreements





Becat® 4Q 2017 sales include sales throughout September. As the product was launched that month, sales were negligible. IQVIA MIDAS QI 2020 QuintilesIMS, 2015.
Technavio 2016 biosimilars report.

Neparvis®, Volutsa® and the hypercholesterolemia franchise leading the growth of the specialty pharma business





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.

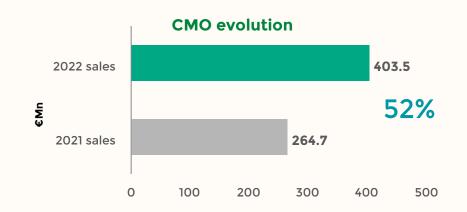
Packaging Excellence Centre in our Alcalá de Henares plant

State-of-the art installations

2 new blister high speed lines.7 packaging lines fully dedicated to injectables.Total 14 packaging lines.

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 vials filling lines. Total 4 lines. 2 new automatic vials inspection machine. Total 4 lines. 1 new automatic vials packaging machine.
Granada	1 new line supporting production phases of the active substance of the MRNA vaccine.



CMO sales increased by 52% to €403.5 Mn in 2022 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.

The growth achieved in 2022 surpassed by 12 percentage points the higher end of the range of between 30% and 40% published when the company released its 2021 results.



ISM® Platform opens up new avenues of growth for ROVI

Overview

- Internally-developed and patented innovative drug-release technology, ISM®¹, which allows for the sustained release of compounds administered by injection
- Based on two separate syringes respectively containing (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)⁽²⁾ path of approval for candidates leveraging ISM® technology

Product	Potential Indication	Current Situation	Key Milestones		
Risperidone-ISM®, monthly	Schizophrenia	Aproved	Marketed in Europe and iln approval process in USA		
Letrozole ISM [®] Long acting Letrozole	Breast Cancer	Efficacy study in advanced breast cancer	Starting efficacy clinical trial		
Risperidone, quarterly	Schizophrenia	Preparing Phase I			
Concentrated on improving posology for already approved compounds, which benefits risk / reward profile					
Multiple FDA / GMP approved facilities to support the platform					

Key Company Highlights of ISM® 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



2023 operating revenue growth rate

Low-double-digit negative growth vs 2022 Positive growth of between 5% and 10% vs 2021

The key Growth levers in 2023

Specialty Pharma CMO Marketing of Okedi® in Europe LMWH franchise License agreements (Neparvis® and Volutsa®) Existing portfolio of specialty pharmaceuticals New products distribution licenses

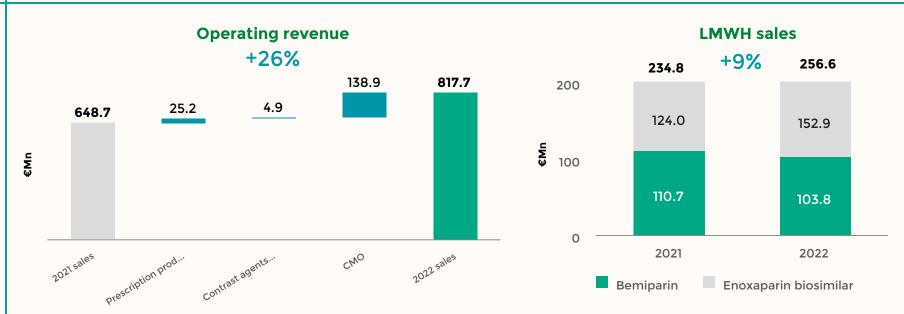
For 2023, ROVI is assuming a new post-pandemic scenario in which COVID-19 would foreseeable be a seasonal disease and, in principle, the vaccine would be administered once a year. For this reason, ROVI expects a stronger second half of the year compared to the first half regarding the CMO business. The first quarter of 2023 is expected to include revenues linked to the production of vaccine in the fourth quarter of 2022 but the second quarter of 2023 is expected to be the lowest quarter in terms of CMO sales. Nevertheless, the uncertainty related to the evolution of the disease is very high. It is not, therefore, possible to make a precise assessment of the impact that this new scenario could have on its 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 at 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



Good revenue level with resilient sales growth



Operating revenue increased by 26% to €817.7 Mn, achieved on:

- 52% increase in CMO: and
- 7% growth in prescription-based products.
- Contrast agents and other hospital products increased by 13%.

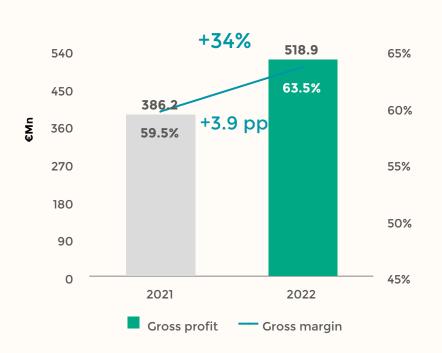
Sales of LMWH increased by 9% to €256.6 Mn in 2022.

• Enoxaparin biosimilar sales increased by 23% to €152.9 Mn and Bemiparin sales decreased by 6% to €103.8 Mn.



Gross margin positively impacted by the CMO division

Gross profit and Gross margin



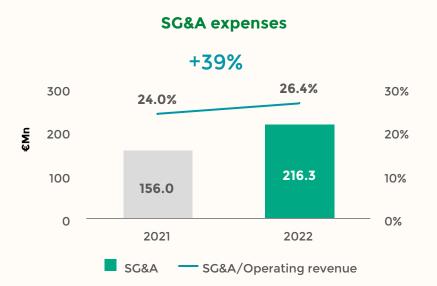
Gross margin impacts

Gross profit increased by 34% to €518.9 Mn in 2022, the gross margin showing an increase of 3.9 p.p. from 59.5% in 2021 to 63.5% in 2022, mainly because the increase in the CMO business contributed higher margins to Group sales.

This positive impact on the gross margin offset the increase in the LMWH cost of goods sold in 2022 compared to 2021.

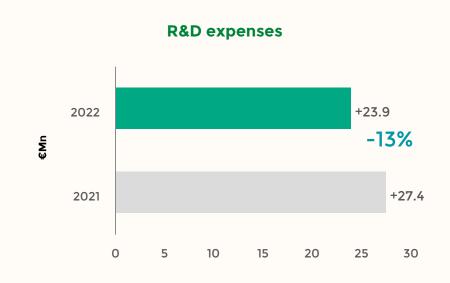


Cost control along with commitment to R&D





- An increase in expenses related to the manufacture of the Moderna vaccine:
- An increase of €5.4 Mn in the energy cost; and
- An increase in expenses due to the Okedi[®] launch in Europe.

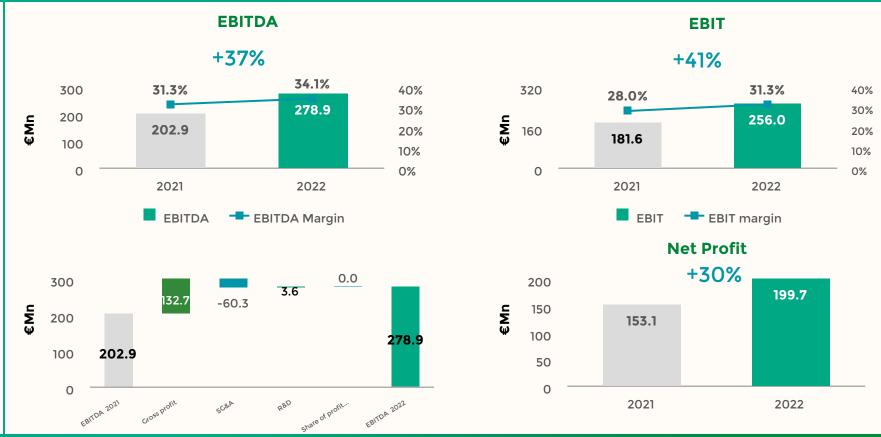


R&D expenses decreased 13% to €23.9 Mn in 2022. These expenses are related to:

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

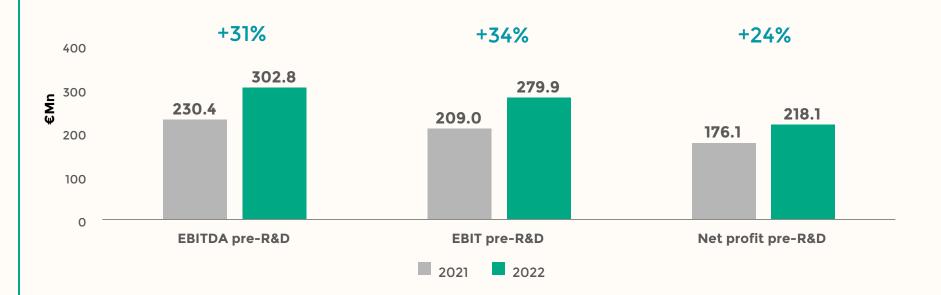


EBITDA, EBIT & Net Profit analysis





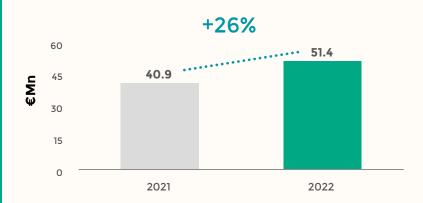
PRE-R&D analysis



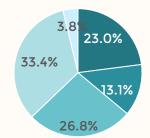
- EBITDA "pre-R&D" increased by 31%, from €230.4 Mn in 2021 to €302.8 Mn in 2022.
- EBIT "pre-R&D" increased by 34%, from €209.0 Mn in 2021 to €279.9 Mn in 2022.
- **Net profit "pre R&D"** increased by 24%, from €176.1 Mn in 2021 to €218.1 Mn in 2022.

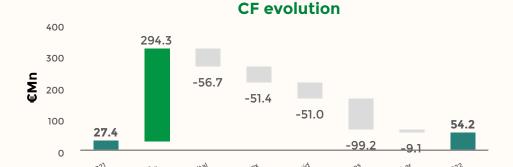
Capital expenditure and Cash Flow

CAPEX evolution









CF from operating activities increased to €237.6 Mn in 2022 mainly due to:

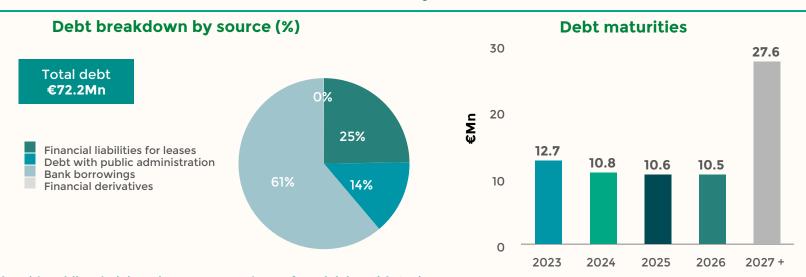
- Increase of €75.3 Mn in profit before income tax;
- Booking of €57.1 Mn under the "Proceeds from toll manufacturing services" caption in 2022 compared to the €34.4 Mn recognized in 2021;
- Decrease of €26.8 Mn in the "trade and other receivables" item in 2022 compared to a decrease of €74.2 Mn in 2021; and
- Increase of 41.7 million euros in the "trade and other payables" item in 2022, compared to an increase of 35.4 million euros in 2021.

ROVI invested €51.4 Mn in 2022 and the 4 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 cash of €54.2Mn as of 31 December 2022 vs €27.4Mn as of 31 December 2021.
- In July 2022, ROVI announced that the EIB had granted it a loan to support its investments in R&D&I. The loan is for €50 Mn with a repayment period of 10 years, has a three-year grace period, and may be drawn down over a term of two years.
- ROVI General Shareholders Meeting, on 14 June 2022, approved the payment of a gross dividend of €0.9556 per share on 2021 earnings; it means an increase of 151% and represents a 35% pay out. This dividend was paid on 7 July 2022.
- ROVI will propose to the General Shareholders' Meeting a dividend of 1.2938 euros per share charged to the 2022 profit and retained earnings. This proposed dividend would mean an increase of 35% on the dividend charged to the 2021 profit (€0.9556/share) and represents 35% of the net profit for 2022 attributed to the parent company.



News-flow 2023

		Sales of biosimilar of Enoxaparin
2)	Specialty pharma	Additional new products to be launched in 2023
		Granting by the competent local authorities of the marketing authorisation of an Enoxaparin biosimilar outside Europe
	СМО	New contracts in the toll manufacturing area Evolution of Moderna's vaccine manufacturing
t	ISM [®] technology platform	Marketing of Okedi [®] in Europe Marketing authorization for Risperidone ISM [®] in USA
		Starting a Phase I clinical trial of Risperidone for a 3-monthly injection



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