

**FINANCIAL RESULTS**  
for the full year  
**2023**

27/02/2024



# KEY FIGURES

## Summary

IN € MILLIONS	2023	2022	Growth	% Growth
Operating revenue(1)	829.5	817.7	11.8	1%
Gross profit(2)	489.2	518.9	(29.7)	-6%
EBITDA(3)	244.5	278.9	(34.5)	-12%
EBIT(4)	220.1	256.0	(35.9)	-14%
Net profit(5)	170.3	199.7	(29.4)	-15%
Purchases of property, plant and equipment and intangible assets ("Capex")	55.2	51.4	3.8	7%
FCF(6)	59.9	186.3	(126.4)	-68%
Gross profit as % of operating revenue	59.0%	63.5%		-4.5 p.p
EBITDA as % of operating revenue	29.5%	34.1%		-4.6 p.p
EBIT as % of operating revenue	26.5%	31.3%		-4.8 p.p
Net profit as % of operating revenue	20.5%	24.4%		-3.9 p.p
Capex as % of operating revenue	6.7%	6.3%		0.4 p.p
FCF as % of operating revenue	7.2%	22.8%		-15.6 p.p

	As of Dec 31, 2023	As of Dec 31, 2022	Growth	% Growth
Net debt (€m)(7)	38.6	(54.2)	92.8	-171%

Note: certain numerical figures included in this document have been rounded. Therefore, discrepancies in tables between totals and the sums of the amounts listed may occur due to such rounding.

(1) Operating revenue refers to revenue.

(2) 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.

(3) EBITDA calculated as profit before interest, taxes, depreciation and amortization.

(4) EBIT calculated as profit before taxes and interest.

(5) Net profit refers to profit for the year.

(6) Free Cash Flow (FCF) calculated as net cash generated from operating activities less purchases of property, plant and equipment and intangible assets ("Capex") plus proceeds from sale of property, plant and equipment plus interest received.

(7) Net debt composed of equity securities, plus deposits, plus financial derivatives, plus cash and cash equivalents, less current and non-current financial debt.

The consolidated financial statements of Grupo ROVI for 2023 and the comparative information for 2022 (balance sheet, consolidated income statement and cash flow statement) are attached to this report (see Appendix 1). The figures as of December 31, 2023 and as of December 31, 2022 are audited figures.

# CONTENTS

<b>HIGHLIGHTS FY 2023</b> .....	<b>3</b>
<b>GROUP MANAGEMENT REPORT</b> .....	<b>8</b>
<b>INCOME STATEMENT</b> .....	<b>8</b>
<b>REVENUES</b> .....	<b>8</b>
<b>SPECIALTY PHARMACEUTICAL BUSINESS</b> .....	<b>10</b>
<b>LOW MOLECULAR WEIGHT HEPARINS</b> .....	<b>11</b>
<b>OTHER PRESCRIPTION-BASED PHARMACEUTICAL PRODUCTS</b> .....	<b>12</b>
<b>CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS</b> .....	<b>13</b>
<b>CDMO BUSINESS</b> .....	<b>13</b>
<b>OTHER INCOME</b> .....	<b>13</b>
<b>COSTS</b> .....	<b>13</b>
<b>GROSS PROFIT</b> .....	<b>14</b>
<b>RESEARCH AND DEVELOPMENT EXPENSES</b> .....	<b>14</b>
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b> .....	<b>14</b>
<b>DEPRECIATION</b> .....	<b>14</b>
<b>NET FINANCE RESULT</b> .....	<b>15</b>
<b>EFFECTIVE TAX RATE</b> .....	<b>15</b>
<b>FINANCIAL PERFORMANCE</b> .....	<b>15</b>
<b>DIVIDEND</b> .....	<b>17</b>
<b>FINANCIAL POSITION</b> .....	<b>18</b>
<b>LIQUIDITY</b> .....	<b>21</b>
<b>OUTLOOK</b> .....	<b>24</b>
<b>R&amp;D UPDATE</b> .....	<b>24</b>
<b>ESG</b> .....	<b>25</b>
<b>KEY OPERATING AND FINANCIAL EVENTS</b> .....	<b>26</b>
<b>APPENDIX 1</b> .....	<b>31</b>
<b>APPENDIX 2</b> .....	<b>35</b>

# HIGHLIGHTS FY 2023

## ROVI ACHIEVED OPERATING REVENUE GROWTH OF 1% IN THE FIRST POST-PANDEMIC YEAR

- Operating revenue increased 1% to 829.5 million euros in 2023 driven by the CDMO business, which grew 1% to 409.3 million euros, and the specialty pharmaceutical business, where sales rose 1% compared to 2022.
- 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 United States.
- In September 2023, the FDA approved the company's CDMO's<sup>1</sup> plants for injectables in Madrid, San Sebastián de los Reyes and Alcalá de Henares for the fill-and-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.
- Positive evolution of Okedi® (Risperidone ISM®), which reached sales of 14.4 million euros in 2023. Okedi® sales increased by 42% in the fourth quarter of 2023 compared to the third quarter of the year.
- Sales of the heparin franchise (low molecular weight heparins (LMWH) and other heparins) decreased by 5% to 250.6 million euros in 2023, mostly due to 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.
- Good performance of Neparvis® and Orvatez®, of which sales increased by 16% and 8% respectively, in 2023 compared to 2022, rising to 45.5 million euros and 26.5 million euros respectively.
- Gross margin showed a decrease of 4.5 percentage points 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 added lower margins to Group sales; and (ii) the lower margin from the manufacture of the COVID-19 vaccine in 2023 compared to 2022.
- Net profit decreased by 15% to 170.3 million euros in 2023.
- Regarding the evaluation process to obtain marketing authorization for Risvan® in the United States, 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

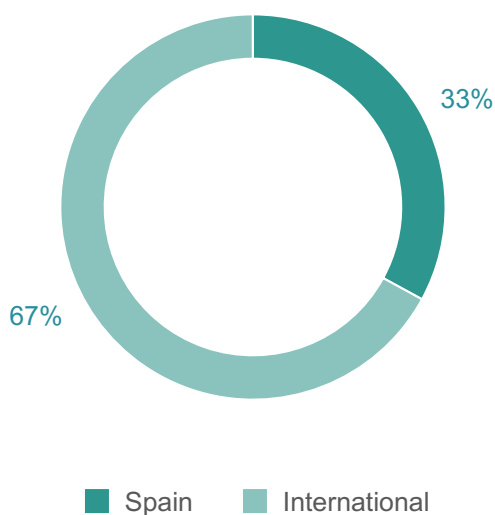
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<sup>1</sup> Contract Development and Manufacturing Organisation

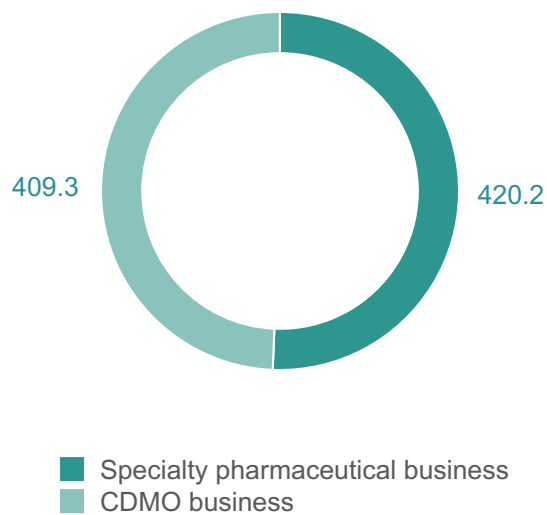
before the approval of the application and that there were no outstanding questions related to the dossier. On 21 September 2023, ROVI received the Establishment Inspection Report from the FDA with 4 outstanding observations from the FDA inspection of the facility. ROVI provided responses on 29 September 2023 and the FDA 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. The company has improved its ESG risk rating by almost one point, improving its “Low Risk” rating to 16.4 versus 17.3 in 2022 and remains in first place among the 431 companies rated in the pharmaceutical industry category.
- ROVI will propose to the General Shareholders' Meeting a dividend of 1.1037 euros per share charge to the 2023 profit and retained earnings, This proposed dividend represents 35% of the net profit for 2023 attributed to the parent company.

**REVENUE BY REGION (%)**



**REVENUE BY BUSINESS UNIT (€Mn)**



## OUTLOOK

For 2024, ROVI expects its operating revenue to **decrease by a mid-single-digit percentage** in comparison with 2023. Notwithstanding, there are certain factors that have been considered when calculating this guidance that, although they could be relevant to the estimates, are difficult to specify at present, including, among others:

1. First, the saturation of the National Health Systems due to the low vaccination ratios during the 2023 COVID-19 campaign could favour a more successful vaccination campaign in 2024. However, as of today's date, the Company is not in a position to forecast how demand and production might evolve for the vaccination campaign in 2024.
2. Second, it is hoped that the expansion of the compounding, aseptic filling, inspection, labelling and packaging capacities at ROVI's facilities in Madrid and the current high demand for CDMO services in the market might favour obtaining new customers, with the resulting sales impact. This would have to be taken into consideration but cannot be estimated at present.
3. Last, ROVI expects to obtain marketing authorisation for Risvan® from the United States Food and Drug Administration (FDA) in March 2024 and to market the product on the United States market, probably through a partner. The potential sales of this product in 2024 will depend on the terms of the agreement reached with the potential partner, which could likewise affect the estimates for 2024.

## LAUNCHING OF A SHARE BUY-BACK PROGRAMME

ROVI informed that the Company launched, effective as of 26 July, 2023, a share buy-back programme (the "Buy-back Programme"), in accordance with the following terms (see further information on page 28):

1. **Purpose and scope:** the Buy-back Programme's purpose is 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.
2. **Term:** from 26 July 2023 for a period of 12 months.
3. **Maximum monetary amount:** up to 130,000,000 euros.
4. **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 buy-back programme, having acquired 1,808,392 shares for an amount of 97.3 million euros.



Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI, said: "2023 is the first year of a new post-pandemic scenario, in which COVID-19 has become a seasonal disease and the vaccine is administered once a year. In this difficult context, we have been able to continue growing. We are very excited about the launch of Okedi®, a 4-weekly Risperidone LAI based on our ISM® technology for the treatment of schizophrenia, which took place in Germany, UK and Spain in 2022, and in Portugal, Italy, Austria, Serbia and Greece in 2023. This launch consolidates our internationalization strategy as one of our pillars of future growth. Likewise, we are currently undergoing a regulatory process in the United States to obtain the marketing authorization of this product. Additionally, we are currently conducting a phase I clinical

trial of the three-monthly formulation of letrozole (Letrozole LEBE). With this clinical programme for Letrozole LEBE, we 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. Also, we made significant progress in our quarterly Risperidone formulation and we are currently carrying out a phase I clinical trial in Europe reflecting our clear commitment to our ISM® technology, which is expected to be the company's growth engine in the future. Since the first COVID-19 vaccines were launched in December 2020, ROVI as a manufacturer of the Moderna vaccine, has been a fundamental pillar in providing a swift, flexible, and effective response to take the COVID-19 vaccine to all corners of the planet. We are making a big investment effort to increase current capacities in order to produce many more pharmaceutical units in the future. One of the milestones achieved during 2023 was the approval by the U.S. Food and Drug Administration (FDA) of ROVI's CDMO injectables plants for the fill-finish syringe manufacturing of COVID-19 mRNA vaccine. This approval means that we can produce Moderna vaccines for supply in the United States from 2023 onwards. In addition, our active substance manufacturing plant in Granada was also approved by the FDA in January 2024. In 2023, we achieved total revenue of 830.3 million euros, an increase of 1% compared to 2022. Our CDMO business grew 1% to 409.3 million euros, which offsets part of the 5% decline in the heparin business. The slowdown in sales of our LMHW division in 2023 was due to the increased use of heparins in 2022 during the COVID-19 pandemic. We are very excited about the potential of our LMHW franchise and aspire to become a benchmark player in this field worldwide. The importance we place on the heparin division can be seen with the inauguration of a new production plant for the active substance of heparins in Escúzar (Granada) in the fourth quarter of 2023. Likewise, we continue investing to become self-sufficient in obtaining crude

*and sodium heparin in order to be present in all the manufacturing phases of LMWHs. We expect this investment to help us to increase the future margins of the heparin division and that the plant will be operative in 2026. In addition, heparin raw material prices are now dropping significantly and we expect this decrease to continue and have a positive impact on the division's gross margin as of 2025."*



# GROUP MANAGEMENT REPORT

for annual period ending December 31<sup>st</sup>, 2023

## INCOME STATEMENT

IN € MILLIONS	2023	2022	Growth	% Growth
Operating revenue(1)	829.5	817.7	11.8	1%
Other income(2)	0.8	2.1	(1.3)	-63%
<b>Total revenue(3)</b>	<b>830.3</b>	<b>819.8</b>	<b>10.5</b>	<b>1%</b>
Cost of goods sold(4)	(341.1)	(300.9)	(40.1)	13%
<b>Gross profit(5)</b>	<b>489.2</b>	<b>518.9</b>	<b>(29.7)</b>	<b>-6%</b>
% margin(9)	59.0%	63.5%		-4.5 pp
R&D expenses	(24.9)	(23.9)	(1.1)	4%
SG&A	(219.7)	(216.3)	(3.4)	2%
Share of profit in joint ventures	(0.1)	0.2	(0.3)	n.a.
<b>EBITDA(6)</b>	<b>244.5</b>	<b>278.9</b>	<b>(34.5)</b>	<b>-12%</b>
% margin(9)	29.5%	34.1%		-4.6 pp
<b>EBIT(7)</b>	<b>220.1</b>	<b>256.0</b>	<b>(35.9)</b>	<b>-14%</b>
% margin(9)	26.5%	31.3%		-4.8 pp
Finance Income/(Costs)	0.3	1.9	(1.6)	-85%
<b>Profit before income tax</b>	<b>220.4</b>	<b>258.0</b>	<b>(37.6)</b>	<b>-15%</b>
Income tax	(50.1)	(58.3)	8.2	-14%
Effective tax	22.7%	22.6%		0.1 pp
<b>Net profit(8)</b>	<b>170.3</b>	<b>199.7</b>	<b>(29.4)</b>	<b>-15%</b>
<b>Net profit attributable to parent company</b>	<b>170.3</b>	<b>199.7</b>	<b>(29.3)</b>	<b>-15%</b>
<b>Profit for the year attributable to non-controlling interests</b>	<b>(0.04)</b>	<b>0.00</b>	<b>(0.03)</b>	<b>n.a.</b>

(1) Operating revenue refers to revenue.

(2) Other income includes the recognition of government grants on non-financial non-current assets and other.

(3) Total revenue calculated as revenue plus the recognition of government grants on non-financial non-current assets and other.

(4) Cost of sales calculated as the amount of procurements plus that corresponding to the change in inventories of finished goods and work in progress and raw materials and consumables use.

(5) 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.

(6) EBITDA calculated as profit before interest, taxes, depreciation and amortization.

(7) EBIT calculated as profit before taxes and interest.

(8) Net profit refers to profit for the year.

(9) The gross margin and the EBITDA and EBIT margins are calculated as the result of dividing the gross profit, the EBITDA and the EBIT, respectively, by revenue, expressed as a percentage.

# REVENUES

## Total revenue by business unit

IN € MILLIONS	2023	2022	Growth	% Growth
Specialty pharmaceutical business	420.2	414.2	6.1	1%
CDMO business	409.3	403.5	5.7	1%
<b>Operating revenue(1)</b>	<b>829.5</b>	<b>817.7</b>	<b>11.8</b>	<b>1%</b>
Other income(2)	0.8	2.1	(1.3)	-63%
<b>Total revenue(3)</b>	<b>830.3</b>	<b>819.8</b>	<b>10.5</b>	<b>1%</b>

(1) Operating revenue refers to revenue excluding the recognition of government grants on non-financial non-current assets and other.

(2) Other income includes the recognition of government grants on non-financial non-current assets and other.

(3) Total revenue calculated as operating revenue plus the recognition of government grants on non-financial non-current assets and other.

**Operating revenue** increased 1% to 829.5 million euros in 2023 driven by the CDMO business which grew 1% to 409.3 million euros, and the specialty pharmaceutical business, where sales rose 1%. **Total revenue** rose 1% to 830.3 million euros in 2023.

**Sales outside Spain** remained stable at 556.2 million euros in 2023, mainly due to the CDMO business. Sales outside Spain represented 67% of operating revenue in 2023 compared to 68% in 2022.

## SPECIALTY PHARMACEUTICAL BUSINESS

### Sales of the specialty pharmaceutical business<sup>(1)</sup>

IN € MILLIONS	2023	2022	Growth	% Growth
<b>Prescription-based pharmaceutical products</b>	<b>373.5</b>	<b>372.6</b>	<b>0.9</b>	<b>0%</b>
LMWH franchise	242.1	256.6	(14.5)	-6%
Enoxaparin biosimilar	147.9	152.9	(5.0)	-3%
Bemiparin (Hibor)	94.2	103.8	(9.6)	-9%
Sales in Spain	61.6	66.9	(5.2)	-8%
International sales	32.6	36.9	(4.3)	-12%
Neparvis	45.5	39.1	6.4	16%
Volutsa	12.4	17.8	(5.4)	-30%
Vytorin & Orvatez	26.6	32.1	(5.5)	-17%
Other products	47.1	36.0	11.1	31%
Okedi	14.4	2.0	12.3	n.a.
Discounts to the National Health System	(14.5)	(11.0)	(3.5)	32%
<b>Contrast agents and other hospital products</b>	<b>45.7</b>	<b>40.1</b>	<b>5.6</b>	<b>14%</b>
<b>Other products</b>	<b>1.0</b>	<b>1.5</b>	<b>(0.4)</b>	<b>-29%</b>
<b>Total specialty pharmaceutical business</b>	<b>420.2</b>	<b>414.2</b>	<b>6.1</b>	<b>1%</b>

(1) 2022 includes sales of Absorcol.

Sales of **prescription-based pharmaceutical** products remained stable at 373.5 million euros in 2023.

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) decreased by 5% to 250.6 million euros in 2023. Heparin sales represented 30% of operating revenue in 2023 compared to 32% in 2022.

## Heparin franchise

IN € MILLIONS	2023	2022	Growth	% Growth
LMWH franchise	242.1	256.6	(14.5)	-6%
Enoxaparin biosimilar	147.9	152.9	(5.0)	-3%
Bemiparin (Hibor)	94.2	103.8	(9.6)	-9%
Sales in Spain	61.6	66.9	(5.2)	-8%
International sales	32.6	36.9	(4.3)	-12%
Other heparins <sup>2</sup>	8.4	7.7	0.8	10%
<b>Heparins franchise</b>	<b>250.6</b>	<b>264.3</b>	<b>(13.7)</b>	<b>-5%</b>

## LOW MOLECULAR WEIGHT HEPARINS

Sales of **Low Molecular Weight Heparins (LMWH)** (enoxaparin biosimilar and bemiparin) decreased by 6% to 242.1 million euros in 2023 mostly due to 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.

IN € MILLIONS	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023
Enoxaparin biosimilar	29.4	33.3	27.2	34.2	44.2	37.9	37.1	33.6	34.9	39.6	33.6	39.8
Bemiparin (Hibor)	32.8	32.3	21.2	24.4	30.0	25.8	20.0	27.9	24.4	20.2	22.8	26.9
Sales in Spain	18.9	17.2	15.7	17.6	17.5	17.2	15.7	16.5	17.3	14.6	14.2	15.6
International sales	13.9	15.1	5.5	6.8	12.5	8.6	4.4	11.5	7.1	5.6	8.6	11.4
<b>Total LMWH sales</b>	<b>62.2</b>	<b>65.6</b>	<b>48.3</b>	<b>58.6</b>	<b>74.2</b>	<b>63.7</b>	<b>57.2</b>	<b>61.6</b>	<b>59.3</b>	<b>59.8</b>	<b>56.3</b>	<b>66.7</b>

Sales of the **enoxaparin biosimilar** decreased by 3% to 147.9 million euros in 2023 compared to 2022. However, sales of the product increased 19% in 2023 compared to 2021, where sales increased 22% compared to 2020 due to the increased use of the product for the treatment of COVID-19. In addition, sales of enoxaparin biosimilar increased 18% in the fourth quarter of 2023 to 39.8 million euros compared to the third quarter of the year, and rose 18% in the fourth quarter of 2023 compared to the fourth quarter of 2022. The product was launched in Jordan and Sri Lanka in 2023. In Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo it was launched in 2022.

ROVI commenced the marketing of its Enoxaparin biosimilar in Germany in 2017; in UK, Italy, Spain, France, Austria, Latvia and Estonia in 2018; in Portugal, Poland, Costa Rica,

<sup>2</sup> Other heparins are reported in the "Contrast agents and other hospital products" line. These figures include Normoparin sales which were not included in the 2022 figure when it was released.

Finland, and Sweden in 2019; in South Africa, Israel, Peru, Holland, Panama, and the Dominican Republic in 2020; in Canada, Belgium, Malaysia, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia, Bahamas, Jamaica, Gabon, Democratic Republic of Congo and Trinidad and Tobago in 2021; in Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo in 2022; and in Jordan and Sri Lanka in 2023.

**Bemiparin** sales decreased 9% to 94.2 million euros in 2023. International sales of bemiparin decreased by 12% to 32.6 million euros. This decrease was mainly linked 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. Sales of bemiparin in Spain (Hibor®) showed a decrease of 8% to 61.6 million euros in 2023, mainly due to lower penetration of the product in the prophylaxis segment.

## OTHER PRESCRIPTION-BASED PHARMACEUTICAL PRODUCTS

Sales of **Neparvis®**, a specialty product from Novartis, launched in Spain in December 2016, indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction, increased 16% to 45.5 million euros in 2023, compared to 39.1 million euros in 2022.

Sales of **Volutsa®**, a specialty product from Astellas Pharma indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia, launched in Spain in February 2015, decreased by 30% to 12.4 million euros in 2023 mainly due to a product price reduction of 47% in the second quarter of 2023.

Sales of **Vytorin® and Orvatez®**, specialty products from Merck Sharp & Dohme ("MSD") indicated as adjunctive therapy to diet in patients with hypercholesterolemia, decreased 17% to 26.6 million euros in 2023. ROVI ceased to distribute Absorcol® as of 31 December of 2022 and Vytorin® as of 31 January 2023. Orvatez® sales rose 8% to 26.5 million euros in 2023, compared to 24.5 million euros in 2022. Sales of Absorcol® and Vytorin® accounted for 24% of total sales of the products indicated to treat hypercholesterolemia in 2022.

Sales of **Okedi®**, the first ROVI product based on its leading-edge drug delivery technology, ISM®, for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone, reached 14.4 million euros in 2023. Okedi® sales increased by 42% in the fourth quarter of 2023 compared to the third quarter of the year. In 2022, it was launched in Germany, UK and Spain and, in 2023, it was launched in Portugal, Italy, Austria, Greece and Serbia.

- In Germany, the product was very positively received during medical education activities carried out by ROVI. The product is already present in more than 70% of hospitals and interaction with psychiatrists is favorable, with doctors' attendance at product events having doubled compared to the previous year.

- In the United Kingdom, the product is still in the introduction phase in the "trusts" (entities that manage the health areas).
- In Spain, the product is available in 100% of the autonomous communities. In 2023, it was being marketed in 90% of hospitals and 75% of psychiatrists had been trained, 40% of whom have since acquired experience in its use.
- In Portugal, since its launch in January 2023, the product has gained prescriptions and future prospects are favourable.
- In Italy, access to doctors was positive. 92% of targeted psychiatrists were trained, 64% of whom received three or more visits. In addition, the product was being marketed in 13% of the main hospitals. We expect sales to accelerate quickly and reach all significant hospitals by the end of 2024.

ROVI ceased to promote and distribute **Xelevia®** (sitagliptin) and **Velmetia®** (sitagliptin and metformin), two antidiabetic drugs from Merck Sharp and Dohme ("MSD"), as of 31 January 2024. Sales of both products were 12.1 million euros in 2023.

## CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS

Sales of **contrast imaging agents and other hospital products** increased by 14% to 45.7 million euros in 2023. This increase shows the strong recovery of the Spanish and Portuguese hospital activity during this year after the effects of lockdowns during the pandemic.

## CDMO BUSINESS

**CDMO** sales increased by 1% to 409.3 million euros in 2023 because of (i) the booking of the income related to the production of the COVID-19 vaccine, (ii) 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 (iii) the reorientation of our contract manufacturing activities strategy towards high-value-added products.

## OTHER INCOME

**Other income** (subsidies) decreased by 1.3 million euros to 0.8 million euros in 2023 compared to 2022, mainly due lower subsidies received in the year.

## COSTS

### GROSS PROFIT

**Gross profit** decreased 6% to 489.2 million euros in 2023 compared to 2022. Gross margin showed a decrease of 4.5 percentage points, 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 the fourth quarter of 2023, low-molecular-weight heparin (LMWH) raw material prices decreased by around 35% in comparison with the fourth quarter of 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.

### RESEARCH AND DEVELOPMENT EXPENSES

**R&D expenses** increased 4% to 24.9 million euros in 2023. They were mainly related to (i) the development of the phase I of Letrozole LEBE and (ii) the development of the phase I of a new formulation of Risperidone ISM® for a 3-monthly injection.

### SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

**SG&A expenses** increased 2% to 219.7 million euros in 2023 mainly as a result of an increase in expenses due to the Okedi® launch in Europe.

#### SG&A expenses

IN € MILLIONS	2023	2022	Growth	% Growth
Employee benefit expenses (exc. R&D)	113.3	97.3	16.0	16%
Other operating expenses (exc. R&D)	106.4	119.0	(12.6)	-11%
<b>Total SG&amp;A expenses</b>	<b>219.7</b>	<b>216.3</b>	<b>3.4</b>	<b>2%</b>

## SHARE OF PROFIT IN ASSOCIATES AND JOINT VENTURES

On 6 November 2023, ROVI signed a binding agreement with Enervit S.p.A. ("Enervit") to divest 50% of the share capital held by ROVI in Enervit Nutrition S.L, a Spanish company that distributes Enervit products in Spain and Portugal, in which Enervit held the other 50%. The parties agreed on a price of 1.8 million euros for the sale by ROVI of 50% of the share capital of Enervit Nutrition, S.L. to Enervit S.p.a. The transaction was signed on 15 December 2023. In 2023, **share of profit in associates and joint ventures** showed the booking of an expense of 0.1 million euros, compared to income of 0.2 million euros in the previous year.

## DEPRECIATION

**Depreciation and amortisation expenses** increased by 6% to 24.3 million euros in 2023, as a result of the new property, plant and equipment and intangible asset purchases made during the last year.

## NET FINANCIAL INCOME

**Net financial income** decreased 85% to 0.3 million euros in 2023 mainly due to the lower income related to exchange-rate derivative financial instruments.

## EFFECTIVE TAX RATE

The **effective tax rate** remained stable at 22.7% in 2023.

## FINANCIAL PERFORMANCE

Million euros



<sup>(1)</sup>Net profit refers to the profit for the year.

<sup>(2)</sup>Gross profit calculated as total revenue less change in inventories of finished goods and work in progress and raw materials and consumables used.



## EBITDA

**EBITDA** reached 244.5 million euros in 2023, a decrease of 12% compared to 2022, reflecting a 4.6 percentage point decrease in the EBITDA margin, which was down to 29.5% in 2023 from 34.1% in 2022.

## EBIT

**EBIT** decreased by 14% to 220.1 million euros in 2023, reflecting a 4.8 percentage point decline in the EBIT margin, which was down to 26.5% in 2023 from 31.3% in 2022.

## NET PROFIT

**Net profit** decreased by 15%, from 199.7 million euros in 2022 to 170.3 million euros in 2023.

Non-controlling interests refer to ROVI's partners in Glicopepton Biotech, S. L.

## PRE-R&D/FLAT R&D

**EBITDA "Pre-R&D"**, calculated excluding R&D expenses, decreased by 11%, from 302.8 million euros in 2022 to 269.4 million euros in 2023, reflecting a 4.6 percentage point decrease in the EBITDA margin to 32.5% in 2023 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2023 as in 2022, EBITDA would have decreased by 12% to 245.5 million euros, reflecting a 4.5 percentage point decrease in the EBITDA margin to 29.6% in 2023, down from 34.1% in the previous year (see "Flat R&D costs" columns of the table below).

**EBIT "Pre-R&D"**, calculated excluding R&D expenses, decreased by 12%, from 279.9 million euros in 2022 to 245.1 million euros in 2023, reflecting a 4.7 percentage point decrease in the EBIT margin to 29.5% in 2023 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2023 as in 2022, EBIT would have decreased by 14% to 221.2 million euros, reflecting a 4.6 percentage point decline in the EBIT margin to 26.7% in 2023, down from 31.3% in 2022 (see "Flat R&D costs" columns of the table below).

**Net profit "Pre-R&D"**, calculated excluding R&D expenses, decreased by 13%, from 218.1 million euros in 2022 to 189.6 million euros in 2023 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in 2023 as in 2022, net profit would have decreased by 14% to 171.1 million euros (see "Flat R&D costs" columns of the table below) in 2023.

## Pre-R&D/Flat R&D

IN € MILLIONS	Reported		Pre-R&D costs			Flat R&D costs		
	2023	2022	2023	2022	% Growth	2023	2022	% Growth
Operating revenue(1)	829.5	817.7	829.5	817.7	1%	829.5	817.7	1%
Other income(2)	0.8	2.1	0.8	2.1	-63%	0.8	2.1	-63%
<b>Total revenue(3)</b>	<b>830.3</b>	<b>819.8</b>	<b>830.3</b>	<b>819.8</b>	<b>1%</b>	<b>830.3</b>	<b>819.8</b>	<b>1%</b>
Cost of sales(4)	(341.1)	(300.9)	(341.1)	(300.9)	13%	(341.1)	(300.9)	13%
<b>Gross profit(5)</b>	<b>489.2</b>	<b>518.9</b>	<b>489.2</b>	<b>518.9</b>	<b>-6%</b>	<b>489.2</b>	<b>518.9</b>	<b>-6%</b>
% margin(9)	59.0%	63.5%	59.0%	63.5%	-4.5 pp	59.0%	63.5%	-4.5 pp
R&D expenses	(24.9)	(23.9)	0.0	0.0	n.a.	(23.9)	(23.9)	n.a.
SG&A	(219.7)	(216.3)	(219.7)	(216.3)	2%	(219.7)	(216.3)	2%
Share of profit in associates and joint ventures	(0.1)	0.2	(0.1)	0.2	n.a.	(0.1)	0.2	n.a.
<b>EBITDA(6)</b>	<b>244.5</b>	<b>278.9</b>	<b>269.4</b>	<b>302.8</b>	<b>-11%</b>	<b>245.5</b>	<b>278.9</b>	<b>-12%</b>
% margin(9)	29.5%	34.1%	32.5%	37.0%	-4.6 pp	29.6%	34.1%	-4.5 pp
<b>EBIT(7)</b>	<b>220.1</b>	<b>256.0</b>	<b>245.1</b>	<b>279.9</b>	<b>-12%</b>	<b>221.2</b>	<b>256.0</b>	<b>-14%</b>
% margin(9)	26.5%	31.3%	29.5%	34.2%	-4.7 pp	26.7%	31.3%	-4.6 pp
<b>Net profit(8)</b>	<b>170.3</b>	<b>199.7</b>	<b>189.6</b>	<b>218.1</b>	<b>-13%</b>	<b>171.1</b>	<b>199.7</b>	<b>-14%</b>
% margin(9)	20.5%	24.4%	22.9%	26.7%	-3.8 pp	20.6%	24.4%	-3.8 pp

(1) Operating revenue refers to revenue.

(2) Other income includes the recognition of government grants on non-financial non-current assets and other.

(3) Total revenue calculated as revenue plus the recognition of government grants on non-financial non-current assets and other.

(4) Cost of sales calculated as the amount of procurements plus that corresponding to the change in inventories of finished goods and work in progress and raw materials and consumables use.

(5) 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.

(6) EBITDA calculated as profit before interest, taxes, depreciation and amortization.

(7) EBIT calculated as profit before taxes and interest.

(8) Net profit refers to profit for the year.

(9) The gross margin and the EBITDA, EBIT and net profit margins are calculated as the result of dividing the gross profit, the EBITDA, the EBIT and the net profit, respectively, by revenue, expressed as a percentage.

## DIVIDEND

ROVI's General Shareholders Meeting on 14 June 2023 approved the payment of a gross dividend of 1.2938 euros per share. This represents a 35% increase on the dividend charged to the 2021 profit (€0.9556/share) and entails the distribution of a sum equivalent to approximately 35% of the 2022 consolidated net profit attributed to the parent company. This dividend was paid on 5 July 2023.

ROVI's Board of Directors will put a proposal to the Ordinary General Meeting for distribution of a dividend of 59,617,632.48 euros, equivalent to 1.1037 per share entitled to receive it. This represents approximately 35% of the 2023 consolidated net profit attributed to the parent company, broken down as follows:

- Application of profit: the entire profit of Laboratorios Farmacéuticos ROVI, S.A. for 2023, 12,071,013.68 euros, was applied to the dividend distribution; and

- Additionally, a further 47,546,618.80 euros was distributed as dividends charged to the freely-available reserves accounted for as “Retained earnings”.

## FINANCIAL POSITION

### Balance Sheet

IN € MILLIONS	Dec 31, 2023	Dec 31, 2022	Growth	% Growth
<b>Assets</b>				
Non-current assets	290.6	255.6	34.9	14%
Current assets	509.3	623.1	(113.7)	-18%
<b>Total assets</b>	<b>799.9</b>	<b>878.7</b>	<b>(78.8)</b>	<b>-9%</b>
<b>Equity</b>	<b>543.5</b>	<b>521.4</b>	<b>22.1</b>	<b>4%</b>
<b>Liabilities</b>				
Non-current liabilities	56.5	63.4	(6.9)	-11%
Financial debt	52.2	59.4	(7.2)	-12%
Current liabilities	199.8	293.9	(94.0)	-32%
Financial debt	13.2	12.7	0.5	4%
<b>Total liabilities</b>	<b>256.4</b>	<b>357.3</b>	<b>(100.9)</b>	<b>-28%</b>
<b>Total equity and liabilities</b>	<b>799.9</b>	<b>878.7</b>	<b>(78.8)</b>	<b>-9%</b>

### TOTAL ASSETS

ROVI's **total assets** decreased by 9%, from 878.7 million euros as of December 31, 2022 to 799.9 million euros as of December 31, 2023, mainly due to (i) a decrease of 99.6 million euros in "Cash and cash equivalents", mostly due to the dividend payment, the lower cash flow from provision of manufacturing services and the buy-back programme; and (ii) a decrease of 36.7 million euros in "Trade and other receivables", mainly related to the billing linked to Moderna. This drop was partially offset by the increases of 38.1 million euros in "Property, plant and equipment" due to the expansion of the capacity of the manufacturing facilities in 2023, and 26.0 million euros in "Inventories", mostly because of an increase in heparin and risperidone stocks.

### EQUITY

ROVI's **equity** increased by 22.1 million euros to 543.5 million euros as of December 31, 2023. This increase mainly resulted from the “Retained earnings and voluntary reserves”.

## TOTAL LIABILITIES

ROVI's total **liabilities** decreased by 28% from 357.3 million euros as of December 31, 2022 to 256.4 million euros as of December 31, 2023, mainly due to (i) a decrease of 23.9 million euros in the "Trade and other payables" caption; and (ii) a decrease of 76.0 million euros in the "Contract liabilities" item, which mainly related to amounts billed to customers that had been taken to profit and loss as service revenue as of December 31, 2023.

As of December 31, 2023, ROVI **total debt** decreased to 65.4 million euros. Debt with public administration, which is 0% interest rate debt, represented 14% of total debt as of December 31, 2023.

### Total Debt

IN € THOUSANDS	Dec 31, 2023	Dec 31, 2022	Interest rate
Bank borrowings	37,745	44,107	0.68-4.82
Debt with public administration	8,890	10,175	0
Financial liabilities for leases	18,792	17,856	-
Derivative financial instruments	-	28	-
<b>Total</b>	<b>65,427</b>	<b>72,166</b>	

As of December 31, 2023, bank borrowings decreased by 6.4 million euros. In December 2017, ROVI announced the European Investment Bank (EIB) had granted it a loan to support its investments in Research, Development and Innovation. The loan was for 45 million euros. As of December 31, 2023, ROVI had drawn 45 million euros against this credit line; 5 million euros at a variable interest rate of Euribor at 3 months + 0.844% (the latest interest rate paid was 4.816% in January 2024) and 40 million euros at a fixed interest of 0.681%. Repayment of the variable interest loan started in October 2021 (quarterly repayments) and its current outstanding balance is 3.4 million euros. Likewise, repayment of the fixed interest loan started in February 2023 (quarterly repayments) and its current outstanding balance is 34.3 million euros. The credit at a variable interest matures in 2028 and the credit at a fixed interest matures in 2029, both includes a grace period of 3 years.

In July 2022, ROVI announced that the European Investment Bank (EIB) had granted it a new loan to support its investments in Research, Development and Innovation. The loan is for 50 million euros with a repayment period of 10 years, has a three-year grace period, and may be drawn down over a term of two years. As of 31 January 2024, ROVI had drawn 10 million euros against this new credit at a variable rate of Euribor at 3 months + 0.655% (the interest rate for the first repayment is 4.625%).

## GROSS CASH POSITION AND NET DEBT

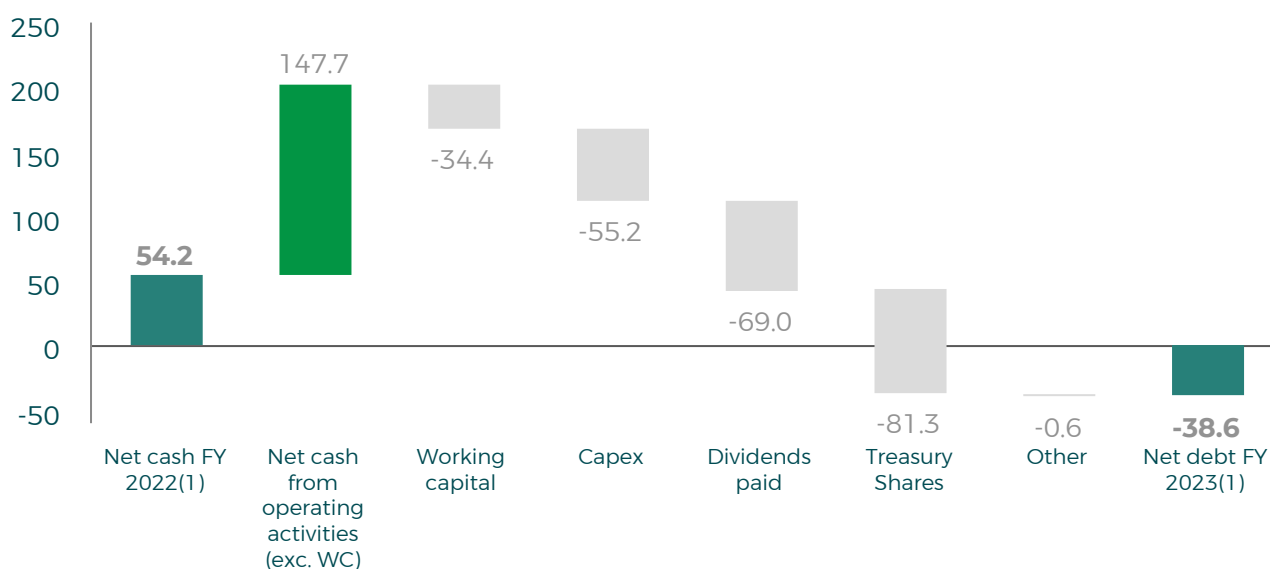
As of December 31, 2023, ROVI had a **gross cash position** of 26.8 million euros, compared to 126.4 million euros as of December 31, 2022, and **net debt** of 38.6 million euros, compared to net cash of 54.2 million euros as of December 31, 2022.

### Gross cash position and net debt

IN € MILLIONS	Dec 31, 2023	Dec 31, 2022
Equity securities	0.02	0.01
Deposits	1.4	1.4
Cash and cash equivalents	25.3	124.9
<b>Gross cash position</b>	<b>26.8</b>	<b>126.4</b>
Financial debt	(65.4)	(72.2)
<b>(Net debt)/Net cash</b>	<b>(38.6)</b>	<b>54.2</b>

**Net cash generated in operating activities** amounted to 113.2 million euros in 2023, compared to 237.6 million euros in 2022. Net cash generated from operating activities excluding changes in working capital decreased 50% to 147.7 million euros in 2023 from 294.6 million euros in the previous year.

### Million euros



(1) Net financial debt or net debt is composed of equity securities, plus deposits, plus financial derivatives, plus financial assets at amortised cost, plus cash and cash equivalents, less current and non-current financial debt.

# LIQUIDITY

## Cash Flow

IN € MILLIONS	2023	2022	Growth	% Growth
Cash flow from operating activities	113.2	237.6	(124.4)	-52%
Cash flow from investing activities	(52.0)	(57.2)	5.1	-9%
Cash flow from financing activities	(160.8)	(154.5)	(6.3)	4%
<b>Net increase/ (decrease) in cash</b>	<b>(99.6)</b>	<b>25.9</b>	<b>(125.5)</b>	<b>n.a.</b>
Cash at the beginning of the period	124.9	99.0	25.9	26%
<b>Cash at the end of the year</b>	<b>25.3</b>	<b>124.9</b>	<b>(99.6)</b>	<b>-80%</b>

## CASH FLOW FROM OPERATING ACTIVITIES

**Cash flow from operating activities** decreased to 113.2 million euros in 2023 from 237.6 million euros in 2022. This decrease was mainly due to:

- the booking of (58.4) million euros under the “Cash flow from contract 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 million euros recognized in 2022;
- the decrease of 23.9 million euros in the “Trade and other payables” item in 2023, compared to an increase of 41.7 million euros in 2022; and
- the decrease of 37.6 million euros in "Profit before income tax".

These negative impacts were partially offset by:

- the increase of 19.5 million euros in the “Trade and other receivables” caption in 2023 compared to a decrease of 26.8 million euros in 2022 mostly due to the billing linked to Moderna; and
- the decrease of 29.3 million euros in the “Inventory” item in 2023 compared to a decrease of 71.6 million euros in 2022, mostly because of an increase in heparin and risperidone stocks.

## CASH FLOW FROM INVESTING ACTIVITIES

ROVI invested 55.2 million euros in 2023, compared to 51.4 million euros in 2022.

### Purchases of property, plant and equipment and intangible assets ("Capex")

IN € MILLIONS	2023	2022	Growth	% Growth
Madrid Injectable plant	2.6	2.1	0.5	24%
San Sebastián de los Reyes plant	2.6	3.0	(0.4)	-14%
Granada plant	1.2	0.7	0.6	84%
Alcalá de Henares plant	4.3	3.4	0.9	28%
Expenditure on maintenance and other capex	2.2	2.6	(0.4)	-15%
<b>Maintenance Capex</b>	<b>13.0</b>	<b>11.8</b>	<b>1.2</b>	<b>10%</b>
ISM industrialisation	9.1	6.7	2.4	35%
Escúzar plant	6.3	13.8	(7.5)	-54%
Glicopepton	2.8	1.9	0.9	47%
New filling lines and operations expansion	24.0	17.2	6.9	40%
<b>Investment Capex</b>	<b>42.2</b>	<b>39.6</b>	<b>2.6</b>	<b>7%</b>
<b>Total Capex</b>	<b>55.2</b>	<b>51.4</b>	<b>3.8</b>	<b>7%</b>

## FREE CASH FLOW

Free cash flow decreased to 59.9 million euros in 2023 from 186.3 million euros in 2022.

### Free cash flow

IN € MILLIONS	2023	2022
Net cash generated from (used in) operating activities	113.2	237.6
Purchases of intangible assets	(1.4)	(0.7)
Purchases of property, plant and equipment	(53.8)	(50.7)
Proceeds from sale of property, plant and equipment	0.4	0.1
Interest received	1.5	0.0
<b>Free cash flow</b>	<b>59.9</b>	<b>186.3</b>

## CASH FLOW FROM FINANCING ACTIVITIES

**Cash flow from financing activities** was (160.8) million euros in 2023 from (154.5) million euros in 2022. This decrease was mainly attributable to (i) the dividend paid in July 2023, which was 69.0 million euros compared to 51.0 million euros dividend paid in July 2022; and (ii) the reissue of treasury shares, which was 52.6 million euros in 2023, compared to 77.8 million euros in 2022.



Javier López-Belmote Encina, Deputy Chairman and Chief Financial Officer of ROVI, said “We are very happy with the company's evolution. 2023 was a year of transition, the first year of a new post-pandemic scenario, where COVID-19 became a seasonal disease with annual vaccination. In this context, we achieved a 1% increase in total revenue, which rose to 830.3 million euros, and were able to reduce our operating expenses (excluding R&D and employee benefit expenses) by 11% thanks to an efficient cost containment policy. In addition, despite the decrease of 4.5 percentage points in gross margin in 2023 due to the lower contribution to the margin by the CDMO business, we expect lower raw material prices for low-molecular-weight heparins to have a positive effect on gross margin as of 2025. Likewise, we are very satisfied with the execution of the buy-back programme and

the efficient use of the company resources, which has allowed us to achieve a return on capital employed (ROCE) of 37%. ROVI's commitment to innovation is reflected in the figures for 2023. We are in a new phase of growth and we expect our robust balance sheet to allow us to take advantage of other opportunities to expand our sales base and improve the utilisation of our asset base”.



## OUTLOOK

For 2024, ROVI expects its operating revenue to **decrease by a mid-single-digit percentage** in comparison with 2023. Notwithstanding, there are certain factors that have been considered when calculating this guidance that, although they could be relevant to the estimates, are difficult to specify at present, including, among others:

1. First, the saturation of the National Health Systems due to the low vaccination ratios during the 2023 COVID-19 campaign could favour a more successful vaccination campaign in 2024. However, as of today's date, the Company is not in a position to forecast how demand and production might evolve for the vaccination campaign in 2024.
2. Second, it is hoped that the expansion of the compounding, aseptic filling, inspection, labelling and packaging capacities at ROVI's facilities in Madrid and the current high demand for CDMO services in the market might favour obtaining new customers, with the resulting sales impact. This would have to be taken into consideration but cannot be estimated at present.
3. Last, ROVI expects to obtain marketing authorisation for Risvan® from the United States Food and Drug Administration (FDA) in March 2024 and to market the product on the United States market, probably through a partner. The potential sales of this product in 2024 will depend on the terms of the agreement reached with the potential partner, which could likewise affect the estimates for 2024.

## R&D UPDATE

### ISM® technology platform

Okedi® (Risperidone ISM®) is the first ROVI product based in its leading-edge drug delivery technology, ISM®. It is a novel investigational antipsychotic for the treatment of schizophrenia with once-monthly (every 28 days) injections which has been developed and patented by Laboratorios Farmacéuticos ROVI S.A. and which, as of the first injection, provides immediate and sustained plasmatic drug levels and does not require loading doses or supplementation with oral risperidone.

On 15 February 2022, the European Commission 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, and it was launched in 2022 in Germany, UK and Spain and in 2023 in Portugal, Italy, Austria, Greece and Serbia.

On 27 July 2023, ROVI reported that the United States Food and Drug Administration (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 established a new Goal Date of 29 March 2024.

Furthermore, there were no observations that have not yet been resolved by ROVI's suppliers.

Therefore, ROVI will continue to report on the milestones deemed significant in the process to obtain authorisation of Risvan® from the FDA.

Likewise, ROVI's R&D team is progressing in the development of a new formulation of Risperidone for a 3-monthly injection, which would complement the current 4-weekly formulation of Risperidone ISM® for the maintenance treatment of adult patients with clinically stable schizophrenia. The company is currently conducting a phase I clinical trial to evaluate the safety, tolerability, and pharmacokinetics of various candidate formulations at different dose strengths and injection sites; patient's recruitment for this study began in September of 2023.

Lastly, the company 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.

Accordingly, ROVI is currently carrying out a phase I clinical trial in Europe to evaluate the pharmacokinetics, safety and tolerability of single ascending doses of Letrozole LEBE, at different strengths, in voluntary healthy post-menopausal women (LEILA-1 study). This first clinical trial of Letrozole LEBE began in July 2023.

## ESG

For the second year running, ROVI has obtained the best ranking in the pharmaceutical industry category in the world rating of environmental, social and corporate governance (ESG) risks drawn up by Sustainalytics, a leading independent ESG research, rating and analytics firm that supports investors around the world with the development and implementation of responsible investment strategies. ROVI has revalidated its first place among 431 companies rated in the pharmaceutical industry group and remains in 22nd place among a total of 895 companies rated in the entire sector, which includes "biotechnology companies, pharmaceutical laboratories and laboratory equipment companies."

In the rating process carried out in July 2023, Sustainalytics has analysed the company's performance in sustainability aspects considered material in the pharmaceutical sector, highlighting ROVI's sound management of ESG risks related to product quality and safety, corporate governance, business ethics, human capital, the fight against climate

change and anti-corruption and anti-bribery practices. ROVI has obtained a higher than-average score in areas such as the board's involvement in the company's environmental and social aspects, implementation of the environmental policy and a sound quality and safety programme for products and services, as well as the integration of ethical practices into all tiers of the organisation.

## **Commitment to sustainability**

In 2022, ROVI approved its ESG Master Plan 2023-2025, a document that sets out 19 strategic ESG goals. With a three-year horizon, the Group has established a roadmap for attaining the Sustainable Development Goals (SDGs) of the United Nations Agenda 2030, with which ROVI, as a member of the Global Compact, is aligned.

The Group focuses its action on five priority areas:

- Becoming a leader in governance committed to sustainability.
- Commitment to sustainable management to combat the global environmental challenges: fight against climate change, promotion of the circular economy and efficient water management.
- Positioning itself as a key player in caring for persons and integrating specialised and diverse talent.
- Promoting responsible management of the supply chain, ensuring ethical and environmental standards in each one of its links.
- Promoting R&D&I activities by establishing partnerships with key players.

In addition, ROVI, as a member of the United Nations Global Compact, upholds, by adopting and disseminating it, the inclusion of the principles of this Compact, as well as other international instruments, especially in the spheres of human rights, workplace practices, the environment and the fight against corruption.

Likewise, ROVI monitors the ESG aspects evaluated by MSCI, a rating agency highly valued among the investment community, obtaining an "A" rating since 2021(\*). MSCI ESG Research provides ESG ratings on companies on a scale from AAA ("Leader") to CCC ("Laggard"), based on their exposure to and ability to manage industry-specific ESG risks relative to their comparable companies.

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# KEY OPERATING AND FINANCIAL EVENTS

## ROVI Share Buy-back Programme

ROVI informed (by publication of the inside information number 1926 dated 26<sup>th</sup> of July 2023) that the Company launched, effective as of 26 July, 2023, a share buy-back programme (the “Buy-back Programme”), in accordance with the following terms:

1. **Purpose and scope:** the Buyback Program’s purpose is to redeem own shares of ROVI (share capital reduction) and, at the same time, boost the remuneration of the ROVI shareholder by increasing the profit per share.
2. **Term:** from 26 July 2023, and for a period of 12 months.
3. **Maximum monetary amount:** up to 130,000,000 euros, provided that the maximum price per share may not exceed that provided for by article 3.2 of Delegated Regulation 2016/1052.

The authorization granted by the general shareholders’ meeting of the Company on 17 June 2021 established (a) a minimum price for the acquisition corresponding to the nominal value of the acquired shares and (b) a maximum price for the acquisition corresponding to a price not above the highest between (i) the last transaction carried out on the market by independent parties and (ii) the highest price of a purchase order amongst those contained in the orders book.

4. **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.
5. **Trading volume to be considered as reference:** the trading volume to be taken as a reference for the purposes of the provisions of article 3.3 of Delegated Regulation 2016/1052 for the entire duration of the buy-back program shall be 25% of the average daily volume of ROVI’s shares on the trading venue on which the purchase is carried out during the twenty trading days prior to the date of the purchase.

As of 31 January 2024, ROVI had executed approximately 74.85% of the buy-back programme, having acquired 1,808,392 shares for an amount of 97.3 million euros.

## ROVI commences clinical development of a new three-monthly formulation of Letrozole (Letrozole LEBE)

ROVI informed (by publication of the inside information number 1835 dated 25<sup>th</sup> of April 2023) that it 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.

The positive results of the LISA-1 trial, of which ROVI has already informed the market, showed that the first development of letrozole (annual Letrozole ISM®) allows an oestrogen suppression higher than that of Femara® to be predicted (with an initial dose of 100 mg plus a further 100 mg after 8 weeks, and annual maintenance doses of 100 mg, compared with daily oral doses of 2.5 mg), maintaining plasma levels of letrozole significantly lower than those reached with daily oral doses of 2.5 mg of Femara®, taking account the fact that the inhibition of the enzyme aromatase and, therefore, a reduction in oestrogen synthesis is the only known pharmacological mechanism of letrozole.

ROVI sought the advice of the United States Food and Drug Administration (FDA) with a view to using the suppression of the plasma oestrogen levels (oestradiol and estrone) as a surrogate efficacy endpoint in a clinical trial on the superiority of Letrozole ISM® over Femara® in oestrogen inhibition in parallel groups of post-menopausal women with early hormone-dependent breast cancer. The proposal is based on the fact that oestrogen inhibition is letrozole's only pharmacological mechanism. However, the FDA rejected the use of this variable as a surrogate efficacy endpoint.

ROVI contacted the FDA again on 26 October, 2022 to reach an agreement on the clinical development of the product. As reported at the Capital Markets Day of November 2022, the FDA required ROVI to perform a clinical efficacy trial in women with advanced breast cancer using Progression Free Survival (PFS) or the Objective Response Rate (ORR) as the key variable. Likewise, the FDA suggested that further advice should be requested ("End of Phase 2 meeting") after completion of said clinical trial to evaluate a new study that supported registration of the product.

In the light of the advice received from the FDA, the clinical development that would foreseeably be required to obtain marketing authorisation (at least in the United States) for the annual formulation of Letrozole ISM® would entail, first, a Phase 2 clinical trial on Letrozole ISM® vs Femara®, both medicines being combined with CDK 4/6 inhibitors, in post-menopausal women with advanced breast cancer and, subsequently, a Phase 3 trial in women with early breast cancer. This clinical path would probably last more than ten years and would require an investment much higher than initially planned before the dossier to apply for marketing authorisation for the product could be filed. As a result, the company has decided to place the clinical development of annual Letrozole ISM® on hold for the time being.

However, the knowledge acquired with the results of the LISA-1 trial have enabled ROVI to use the time to progress with the preclinical development of a new three-monthly formulation of letrozole (Letrozole LEBE), which aspires to obtain plasma levels equivalent to those obtained with daily oral doses of 2.5 mg of Femara®. This candidate

completed all the preclinical evaluation phases and has commenced its clinical development.

Consequently, ROVI is carrying out in Europe a phase I clinical trial to evaluate the safety and pharmacokinetic characterisation of single increasing doses of Letrozole LEBE in healthy post-menopausal women. This new clinical trial (LEILA-1 study) is designed in several cohorts. In each one of them, the volunteers will take 2.5 mg of Femara® daily for 14 days and, after a washout period of at least 28 days, will receive a single dose of Letrozole LEBE. This trial has started subjects' recruitment in July 2023 and will last approximately two years and cost around 5 million euros.

The objective of this trial is (i) to validate the conclusions reached in the preclinical development of the product regarding its capacity to be bioequivalent to the oral formulation and (ii) to identify the dosage of Letrozole LEBE necessary for humans to obtain steady-state plasma levels equivalent to Femara®.

## **ROVI informs on the evaluation process to obtain marketing authorisation for Risvan® in the United States**

ROVI informed (by publication of the relevant information number 23963 dated 28<sup>th</sup> July 2023) on the evaluation process to obtain marketing authorisation for Risvan® (Risperidone ISM®) in the United States and reported that the United States Food and Drug Administration (FDA) had issued a Complete Response Letter. In this letter, the FDA informed ROVI that it considered the responses to the evaluation of the Risvan® dossier to be complete and made no additional observations.

Likewise, the letter stated that ROVI might close the observations made by the FDA during its inspection in May 2023.

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.

Furthermore, there are no observations that have not yet been resolved by ROVI's suppliers.

Therefore, ROVI will continue to report on the milestones deemed significant in the process to obtain authorisation of Risvan® from the FDA.

## **About ROVI**

ROVI is a pan-European pharmaceutical company specializing and engaging in the research, development, contract manufacturing and marketing of small molecules and biological specialties. The company, in a continuous international expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy, France and Poland and has a diversified marketing portfolio of more than 40 products, among which its flagship product, Bemiparin, already present in more than 60 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its Enoxaparin biosimilar, developed in-house, in Europe and it is already marketed in 40 countries.

ROVI continues to develop the ISM® Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit [www.rovi.es](http://www.rovi.es).

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### **Forward-looking statements**

This news release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date after the date of this press release.

# APPENDIX 1

## LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2023 AND DECEMBER 31, 2022

IN € THOUSANDS	Dec 31, 2023	Dec 31, 2022
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property Plant and Equipment	253,652	215,541
Intangible assets	33,902	35,744
Investments in joint ventures and associates	567	2,193
Deferred tax assets	2,343	2,078
Equity securities	24	9
Financial receivables	65	65
	<b>290,553</b>	<b>255,630</b>
<b>Current assets</b>		
Inventories	337,968	311,944
Trade and other receivables	143,314	180,011
Current income tax assets	–	4,148
Prepaid expenses	2,727	2,025
Cash and cash equivalents	25,322	124,945
	<b>509,331</b>	<b>623,073</b>
<b>Total assets</b>	<b>799,884</b>	<b>878,703</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF DECEMBER 31, 2023 AND DECEMBER 31,**  
**2022**

IN € THOUSANDS	Dec 31, 2023	Dec 31, 2022
<b>EQUITY</b>		
<b>Equity attributed to the parent company</b>	<b>539,387</b>	<b>520,012</b>
Share capital	3,241	3,241
Share premium	87,636	87,636
Legal reserve	673	673
Treasury shares	(107,676)	(27,561)
Retained earnings and voluntary reserves	385,199	256,362
Profit for the year	170,335	199,669
Accumulated other comprehensive income	(21)	(8)
<b>Non-controlling interests</b>	<b>4,107</b>	<b>1,367</b>
<b>Total equity</b>	<b>543,494</b>	<b>521,379</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	52,242	59,441
Deferred tax liabilities	1,515	677
Contract liabilities	1,431	1,545
Deferred income	1,359	1,774
	<b>56,547</b>	<b>63,437</b>
<b>Current liabilities</b>		
Financial debt	13,185	12,725
Trade and other payables	141,895	165,776
Current tax liabilities	5,255	–
Contract liabilities	39,044	114,901
Deferred income	464	485
	<b>199,843</b>	<b>293,887</b>
<b>Total liabilities</b>	<b>256,390</b>	<b>357,324</b>
<b>Total equity and liabilities</b>	<b>799,884</b>	<b>878,703</b>

**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR 2023 AND 2022**

IN € THOUSANDS	2023	2022
Revenue	829,509	817,698
Changes in inventories of finished products and work in progress	18,552	38,883
Raw materials and consumables used	(359,641)	(339,824)
Employee benefit expenses	(122,807)	(106,522)
Other operating expenses	(125,674)	(136,482)
Work carried out by the Group on non-current assets	3,865	2,856
Amortisation and depreciation	(24,331)	(22,871)
Impairment of non-current assets	–	(2)
Recognition of government grants on non-financial, non-current assets and other	781	2,112
Share of profit in joint ventures and associates	(125)	199
<b>OPERATING PROFIT (EBIT)</b>	<b>220,129</b>	<b>256,047</b>
Finance income	1,504	1,770
Finance costs	(948)	(849)
Impairment and gain or loss on measurement of financial instruments	(191)	1,820
Exchange differences	(86)	(821)
<b>FINANCE INCOME/(COSTS) - NET</b>	<b>279</b>	<b>1,920</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>220,408</b>	<b>257,967</b>
Income tax	(50,109)	(58,302)
<b>PROFIT FOR THE YEAR</b>	<b>170,299</b>	<b>199,665</b>
Profit for the year attributable to parent company	170,335	199,669
Profit for the year attributable to non-controlling interests	(36)	(4)

**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR 2023 AND 2022**

IN € THOUSANDS	2023	2022
<b>Cash flows from operating activities</b>		
Profit before income tax	220,408	257,967
<b>Adjustments for non-monetary transactions:</b>		
Amortisation and depreciation	24,331	22,871
Finance income	(1,504)	(1,770)
Valuation allowance	3,232	5,160
Adjustments for changes in value of derivatives	(28)	11
Gain or loss on derecognitions of financial assets and liabilities	219	(1,831)
Finance expenses	948	849
Exchange differences	86	821
Grants, distribution licenses and other deferred income	(1,119)	(2,904)
Share of profit in joint ventures	125	(199)
<b>Changes in working capital:</b>		
Trade and other receivables	19,471	(26,820)
Inventories	(29,294)	(71,591)
Other current assets (prepaid expenses)	(702)	(234)
Trade and other payables	(23,923)	41,672
<b>Other collections and payments:</b>		
Cash flow from contract manufacturing services	(58,402)	57,104
Proceeds from distribution licenses	255	385
Income tax cash flow	(40,856)	(43,889)
<b>Net cash flows generated (used) in operating activities</b>	<b>113,247</b>	<b>237,602</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(1,393)	(669)
Purchases of property, plant and equipment	(53,794)	(50,719)
Proceeds from sale of property, plant and equipment	382	78
Purchases of other financial assets	–	(5,870)
Proceeds from sale of financial investments	88	20
Investments in associates and joint ventures	(600)	–
Proceeds from sale of interests in associates and joint ventures	1,800	–
Interest received	1,489	6
<b>Net cash flows generated (used) in investing activities</b>	<b>(52,028)</b>	<b>(57,154)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(13,654)	(6,768)
Proceeds from financial debt	734	1,399
Interest paid	(388)	(291)
Purchase of treasury shares	(133,900)	(177,008)
Reissue of treasury shares	52,639	77,766
Dividends paid	(69,049)	(51,007)
Capital contribution to subsidiaries	2,776	1,371
<b>Net cash flows generated (used) in financing activities</b>	<b>(160,842)</b>	<b>(154,538)</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>(99,623)</b>	<b>25,910</b>
<b>Cash and cash equivalents at beginning of the year</b>	<b>124,945</b>	<b>99,035</b>
<b>Cash and cash equivalents at end of the year</b>	<b>25,322</b>	<b>124,945</b>

# APPENDIX 2

## 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.

This document contains information on the alternative performance measures (APMs) and non-IFRS financial indicators used, including their definitions and a reconciliation between the applicable management indicators and the financial information set out in the consolidated financial statements prepared under IFRSs. The 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>).

In this respect, in accordance with the Guidelines issued by the European Securities and Markets Authority (ESMA), in force since 3 July, 2016, in relation to the transparency of Alternative Performance Measures, ROVI provides below information concerning the APMs it considers significant that are included in this press release:

- **Operating revenue**

This APM shows the revenue that the group generates from its main business activities.

Operating revenue refers to revenue.

- **Other revenue**

Other revenue shows the grants obtained by the Group to develop its R&D&I and other projects.

Other revenue refers to the recognition of government grants on non-financial non-current assets and other.

- **Total revenue**

This APM shows all the group's revenues.

We calculate total revenue as revenue plus the recognition of government grants on non-financial non-current assets and other.

- **Cost of sales**

The cost of sales reflects the cost involved in producing or acquiring the products or services that ROVI sells.

The cost of sales is calculated as the amount of raw materials and consumables used plus that corresponding to the changes in inventories of finished goods and work in progress.

- **Gross profit**

Gross profit is an indicator that measures the direct profit that ROVI obtains from carrying out its income-generating activities.

We calculate gross profit as total revenue less cost of sales.

- **Gross margin or gross profit as % of operating revenue**

This APM is a percentage indicator that measures the direct profit that ROVI obtains from its operating revenue.

We calculate gross margin or gross profit as % of operating revenue as the percentage that the gross profit represents in the revenue (operating revenue).

- **EBITDA**

EBITDA (Earnings Before Interest, Tax, Depreciation and Amortization) is an indicator that measures the group's operating profit before interest, taxes, impairment, depreciation and amortization have been deducted. Management uses it to assess the results over time, allowing a comparison with other companies in the sector.

We calculate EBITDA as profit before: taxes, interest, depreciation and amortization.

- **EBITDA margin or EBITDA as % of operating revenue**

This APM is a percentage indicator that measures the operating profit that ROVI obtains from its operating revenue before interest, taxes, impairment, depreciation and amortization are deducted.

We calculate EBITDA margin or EBITDA as % of operating revenue as the percentage that the EBITDA represents in the revenue (operating revenue).

- **EBITDA “Pre-R&D”**

This APM is used by ROVI to show EBITDA from the on-going business.

We calculate EBITDA “Pre-R&D” as EBITDA excluding: Research and Development expenses (“R&D”) and non-recurring income and expenses.

- **EBIT**

EBIT (Earnings Before Interest and Taxes) is an indicator that measures the group’s operating profit before interest and tax are deducted. Like EBITDA, Management uses it to assess the results over time, allowing a comparison with other companies in the sector.

We calculate EBIT as profit before: taxes and interest.

- **EBIT margin or EBIT as % of operating revenue**

This APM is a percentage indicator that measures the operating profit that ROVI obtains from its operating revenue before interest and tax are deducted.

We calculate EBIT margin or EBIT as % of operating revenue as the percentage that the EBIT represents in the revenue (operating revenue).

- **EBIT “Pre-R&D”**

This APM is used by ROVI to show EBIT from the on-going business.

We calculate EBIT “Pre-R&D” as operating profit for the period excluding: Research and Development expenses (“R&D”) and non-recurring income and expenses.

- **Net profit**

Net profit is an indicator that measures the group’s profit for the period.

We calculate Net profit as EBIT plus finance costs-net and income tax.

- **Net profit as % of operating revenue**

This APM is a percentage indicator that measures the profit for the period that ROVI obtains from its operating revenue.

We calculate net profit as % of operating revenue as the percentage that the net profit represents in the revenue (operating revenue).

- **Net profit “Pre-R&D”**

This APM is used by ROVI to show the profit for the period related to the on-going business.

We calculate net profit “Pre-R&D” as EBIT “Pre-R&D” plus:

- Finance costs-net; and

- Income tax. Net profit “Pre-R&D” income tax is calculated by applying the same effective tax rate as reported in the income statement of the period.

- **Gross cash position**

Gross cash position is an indicator that measures the amount of cash the group has at a specific point in time.

We calculate gross cash position as equity securities plus deposits plus financial derivatives plus financial assets at amortised cost plus cash and cash equivalents.

- **Net debt/cash**

Net financial debt or net debt is the main indicator used by Management to measure the group’s indebtedness.

It is composed of equity securities, plus deposits, plus financial derivatives, plus financial assets at amortised cost, plus cash and cash equivalents, less current and non-current financial debt.

- **Capex**

Capex is an indicator used to better understand the investments made by the group in its operations.

We calculate Capex as purchases of property, plant and equipment and intangible assets.

- **Capex as % of operating revenue**

This APM is a percentage indicator that measures the group's investments in property, plant and equipment, and intangible assets to its operating revenues.

We calculate Capex as % of operating revenue as the percentage that the purchases of property, plant and equipment and intangible assets represents in the revenue (operating revenue).

- **Free Cash Flow (FCF)**

Free cash flow is an indicator that measures cash flow generation from operating and investment activities and is useful for evaluating the funds available for paying shareholder dividends and servicing debt.

We calculate free cash flow as net cash generated from or used in operating activities less purchases of property, plant and equipment and intangible assets ("Capex") plus proceeds from sale of property, plant and equipment and intangible assets plus interest received.

- **FCF as % of operating revenue**

This APM is a percentage indicator that measures the group's cash flow generation from operating and investment activities relative to its operating revenues.

We calculate FCF as % of operating revenue as the percentage that the free cash flow represents in the revenue (operating revenue).