

**FINANCIAL RESULTS**  
for the first half of  
**2023**

26/07/2023



# KEY FIGURES

## Summary

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
Operating revenue(1)	380.8	380.4	0.4	0.1%
Gross profit(2)	215.7	227.2	(11.6)	-5%
EBITDA(3)	97.1	115.8	(18.7)	-16%
EBIT(4)	85.2	104.5	(19.3)	-18%
Net profit(5)	66.6	80.6	(13.9)	-17%
Purchases of property, plant and equipment and intangible assets	18.2	9.9	8.3	84%
FCF(6)	35.1	159.5	-124.4	-78%
Gross profit as % of revenue	56.6%	59.7%		-3.1 p.p
EBITDA as % of revenue	25.5%	30.4%		-5.0 p.p
EBIT as % of revenue	22.4%	27.5%		-5.1 p.p
Net profit as % of revenue	17.5%	21.2%		-3.7 p.p
Capex as % of revenue	4.8%	2.6%		2.2 p.p
FCF as % of revenue	9.2%	41.9%		-32.7 p.p

	As of June 30, 2023	As of Dec 31, 2022	Growth	% Growth
Net debt (€m)(7)	(90.4)	(54.2)	(36.2)	67%

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 period.

(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 the first half of 2023 and the comparative information for 2022 (balance sheet) and for the first half of 2022 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1). There has been a limited review of the figures for the first half of 2023 and the first half of 2022 by the auditor. Likewise, the figures as of December 31, 2022 are audited figures.

# CONTENTS

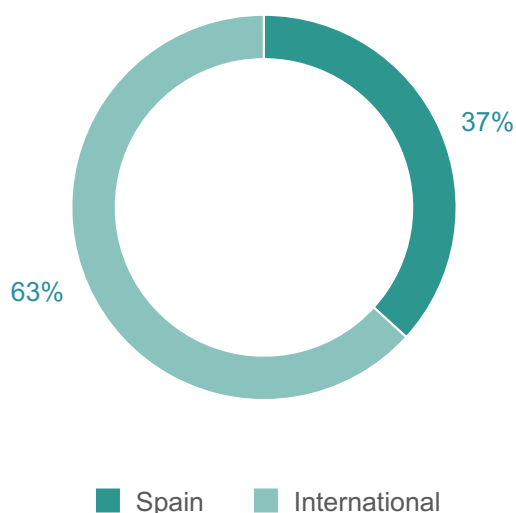
<b>HIGHLIGHTS FIRST HALF 2023</b> .....	<b>3</b>
<b>GROUP MANAGEMENT REPORT</b> .....	<b>7</b>
<b>INCOME STATEMENT</b> .....	<b>7</b>
<b>REVENUES</b> .....	<b>7</b>
<b>SPECIALTY PHARMACEUTICAL BUSINESS</b> .....	<b>9</b>
<b>LOW MOLECULAR WEIGHT HEPARINS</b> .....	<b>10</b>
<b>OTHER PRESCRIPTION-BASED PHARMACEUTICAL PRODUCTS</b> .....	<b>11</b>
<b>CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS</b> .....	<b>12</b>
<b>CONTRACT MANUFACTURING ORGANISATION (“CMO”) BUSINESS</b> .....	<b>12</b>
<b>OTHER INCOME</b> .....	<b>12</b>
<b>COSTS</b> .....	<b>12</b>
<b>GROSS PROFIT</b> .....	<b>13</b>
<b>RESEARCH AND DEVELOPMENT EXPENSES</b> .....	<b>13</b>
<b>SELLING, GENERAL AND ADMINISTRATIVE EXPENSES</b> .....	<b>13</b>
<b>DEPRECIATION</b> .....	<b>13</b>
<b>NET FINANCE RESULT</b> .....	<b>13</b>
<b>EFFECTIVE TAX RATE</b> .....	<b>14</b>
<b>FINANCIAL PERFORMANCE</b> .....	<b>14</b>
<b>DIVIDEND</b> .....	<b>16</b>
<b>FINANCIAL POSITION</b> .....	<b>17</b>
<b>LIQUIDITY</b> .....	<b>20</b>
<b>OUTLOOK</b> .....	<b>23</b>
<b>R&amp;D UPDATE</b> .....	<b>23</b>
<b>ESG</b> .....	<b>25</b>
<b>KEY OPERATING AND FINANCIAL EVENTS</b> .....	<b>26</b>
<b>APPENDIX 1</b>	

# HIGHLIGHTS FIRST HALF 2023

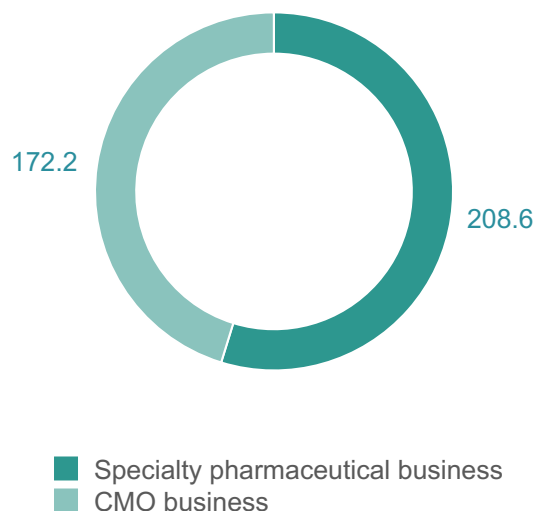
## ROVI ACHIEVED STABLE TOTAL REVENUE OF 381.0 MILLION EUROS IN THE FIRST POST-PANDEMIC HALF YEAR

- Operating revenue remained stable, reaching 380.8 million euros in the first post-pandemic half of 2023.
- Positive evolution of Okedi® (Risperidone ISM®), which reached sales of 5.2 million euros in the first half of 2023. Okedi® sales increased by 36% in the second quarter of 2023 compared to the first quarter of the year.
- CMO sales increased by 4% to 172.2 million euros in the first half of 2023.
- Sales of the enoxaparin biosimilar decreased by 9% to 74.5 million euros in the first half of 2023. However, sales of the product increased 14% in the second quarter of 2023 to 39.6 million euros, compared to the first quarter of the year, and rose 5% in the second quarter of 2023 compared to the second quarter of 2022.
- Good performance of Neparvis® and Orvatez®, whose sales increased by 17% and 12%, respectively, in the first half of 2023 compared to the first half of 2022, rising to 22.1 million euros and 13.6 million euros, respectively.
- Gross margin showed a decrease of 3.1 percentage points due to the higher contribution to the CMO business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to Group sales.
- Net profit decreased by 17% to 66.6 million euros.
- ROVI General Shareholders Meeting, on 14 June 2023, approved the payment of a gross dividend of 1,2938 euros per share; it means an increase of 35% compared to the dividend charged to the 2021 profit (€0.9556/share) and represents approximately 35% pay out. This dividend was paid on 5 July 2023.
- Regarding the evaluation process to obtain marketing authorisation for Risvan® (Risperidone ISM®) in the United States, the Food and Drug Administration (FDA) has notified ROVI that the user fee goal date is 27 July 2023. The Company is awaiting an FDA notification on that date. The content of this notification will be reported as soon as it is received.
- Considering the Group's cash generation and the market situation, ROVI has decided to launch a buy-back programme for the Company's shares effective as of today's date, 26 July, 2023, in order to cancel ROVI shares and, at the same time, boost the remuneration of the ROVI shareholder by increasing the profit per share. The programme is for a maximum amount of 130 million euros (with the maximum number of shares to be acquired representing 5% of the share capital).

## REVENUE BY REGION (%)



## REVENUE BY BUSINESS UNIT (€Mn)



## OUTLOOK

In November 2022 and February 2023, ROVI announced it expected the operating revenue for the full year 2023 to show a low-double-digit negative growth on 2022, although positive growth of between 5% and 10% is expected in comparison with the 2021 figure. With the visibility that the Company has at this moment, ROVI is upgrading its operating revenue guidance for the full year 2023 from low-double-digit negative growth to **high-single-digit negative growth**.

For 2023, ROVI is assuming a new post-pandemic scenario in which COVID-19 would foreseeably be a seasonal disease and, in principle, the vaccine would be administered once a year. The uncertainty related to the evolution of the disease is very high. It is not, therefore, possible to make a precise assessment of the impact that this new scenario could have on the CMO business. Likewise, under the terms of the agreement signed with Moderna in February 2022, ROVI is still investing in increasing the compounding, aseptic filling, inspection, labelling and packaging capacities at its facilities and expects them to be fully installed by the end of 2024.

Taking account of the aforementioned guidance on a decrease in operating revenue in 2023, as well as the fact that ROVI will continue with its investment policy as stated, it is reasonable to expect that the Company's profits may also see a downward adjustment in 2023.

## LAUNCHING OF A SHARE BUY-BACK PROGRAMME

ROVI informs the market that, effective as of today's date, 26 July, 2023, a share buy-back programme (the "Buy-back Programme") will commence under the following terms (see further information on page 26):

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 today, 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.



*Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI, said: "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 in the first half of 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 decided to commence the clinical development of a new three-monthly formulation of letrozole (Letrozole LEBE). With this new 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 expect to begin a phase I clinical trial by the third quarter of 2023, 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, together with Moderna, to increase current capacities to be able to produce*

*many more pharmaceutical units in the future. At ROVI we are confident that we will take part in the manufacturing of new mRNA candidates in the future. We achieved stable total revenue of 381.0 million euros in the first post-pandemic half year. Despite the slowdown in sales of our LMHW division in the first half of 2023 due to the increased use of heparins in the first half of 2022 because of COVID-19, sales of our enoxaparin biosimilar increased 5% in the second quarter of 2023 compared to the second quarter of 2022. We forecast continued growth thanks to the internationalization of our enoxaparin biosimilar, which is already marketed in 40 countries and we expect it will enable us to be present in more than 90 countries in the long term. We are very excited about the potential of our LMHW franchise and aspire to become a benchmark player in this field worldwide. Likewise, we are 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."*

# GROUP MANAGEMENT REPORT

for the six-month period ending June 30<sup>th</sup>, 2023

## INCOME STATEMENT

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
Operating revenue(1)	380.8	380.4	0.4	0.1%
Other income(2)	0.2	0.9	(0.7)	-81%
<b>Total revenue(3)</b>	<b>381.0</b>	<b>381.3</b>	<b>(0.3)</b>	<b>-0.1%</b>
Cost of goods sold(4)	(165.3)	(154.1)	(11.3)	7%
<b>Gross profit(5)</b>	<b>215.7</b>	<b>227.2</b>	<b>(11.6)</b>	<b>-5%</b>
% margin	56.6%	59.7%		-3.1 pp
R&D expenses	(10.8)	(10.4)	(0.4)	4%
SG&A	(107.8)	(101.1)	(6.7)	7%
Share of profit of a joint venture	0.0	0.1	(0.1)	-112%
<b>EBITDA(6)</b>	<b>97.1</b>	<b>115.8</b>	<b>(18.7)</b>	<b>-16%</b>
% margin	25.5%	30.4%		-5.0 pp
<b>EBIT(7)</b>	<b>85.2</b>	<b>104.5</b>	<b>(19.3)</b>	<b>-18%</b>
% margin	22.4%	27.5%		-5.1 pp
Finance Income/(Costs)	0.6	0.9	(0.2)	-26%
<b>Profit before income tax</b>	<b>85.8</b>	<b>105.3</b>	<b>(19.5)</b>	<b>-19%</b>
Income tax	(19.2)	(24.8)	5.6	-22%
Effective tax	22.4%	23.5%		-1.1 pp
<b>Net profit(8)</b>	<b>66.6</b>	<b>80.6</b>	<b>(13.9)</b>	<b>-17%</b>
<b>Net profit attributable to parent company</b>	<b>66.6</b>	<b>80.6</b>	<b>(13.9)</b>	<b>-17%</b>
<b>Profit attributable to minority interests</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</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 period.



# REVENUES

## Total revenue by business unit

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
Specialty pharmaceutical business	208.6	214.0	(5.4)	-3%
CMO business	172.2	166.4	5.8	4%
<b>Operating revenue(1)</b>	<b>380.8</b>	<b>380.4</b>	<b>0.4</b>	<b>0.1%</b>
Other income(2)	0.2	0.9	(0.7)	-81%
<b>Total revenue(3)</b>	<b>381.0</b>	<b>381.3</b>	<b>(0.3)</b>	<b>-0.1%</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** remained stable at 380.8 million euros in the first half of 2023 compared to the same period of 2022. The 3% drop in the specialty pharmaceutical business was offset by the 4% growth in the contract manufacturing business in the first six months of 2023. **Total revenue** remained stable at 381.0 million euros in the first post-pandemic half of 2023.

**Sales outside Spain** decreased by 3% compared to the first half of 2022 to 240.8 million euros in the first half of 2023, 43.6 million euros (or 18%) of which related to international subsidiaries, mainly due to the decrease in LMWH international sales. Sales outside Spain represented 63% of operating revenue in the first half of 2023 compared to 65% in the same period of 2022.

## SPECIALTY PHARMACEUTICAL BUSINESS

### Sales of the specialty pharmaceutical business

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
<b>Prescription-based pharmaceutical products</b>	<b>184.5</b>	<b>193.3</b>	<b>(8.9)</b>	<b>-5%</b>
LMWH franchise	119.1	137.9	(18.8)	-14%
Biosimilar of enoxaparin	74.5	82.1	(7.6)	-9%
Bemiparin (Hibor)	44.5	55.8	(11.3)	-20%
Sales in Spain	31.9	34.7	(2.8)	-8%
International sales	12.6	21.1	(8.4)	-40%
Neparvis	22.1	18.9	3.2	17%
Volutsa	8.3	8.8	(0.5)	-6%
Vytorin & Orvatez	13.7	15.9	(2.2)	-14%
Other products	23.9	18.8	5.1	27%
Okedi	5.2	-	5.2	n.a.
Discounts to the National Health System	(7.8)	(7.0)	(0.8)	12%
<b>Contrast agents and other hospital products</b>	<b>23.6</b>	<b>20.0</b>	<b>3.7</b>	<b>18%</b>
<b>Other products</b>	<b>0.5</b>	<b>0.8</b>	<b>(0.2)</b>	<b>-28%</b>
<b>Total specialty pharmaceutical business</b>	<b>208.6</b>	<b>214.0</b>	<b>(5.4)</b>	<b>-3%</b>

(1) H1 2022 includes sales of Absorcol.

Sales of **prescription-based pharmaceutical** products decreased 5% to 184.5 million euros in the first half of 2023.

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) decreased by 13% to 123.4 million euros in the first half of 2023. Heparin sales represented 32% of operating revenue in the first six months of 2023 compared to 37% in the same period of 2022.

## Heparin franchise

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
LMWH franchise	119.1	137.9	(18.8)	-14%
Biosimilar of enoxaparin	74.5	82.1	(7.6)	-9%
Bemiparin (Hibor)	44.5	55.8	(11.3)	-20%
Sales in Spain	31.9	34.7	(2.8)	-8%
International sales	12.6	21.1	(8.4)	-40%
Other heparins <sup>1</sup>	4.3	3.7	0.6	17%
<b>Heparins franchise</b>	<b>123.4</b>	<b>141.6</b>	<b>(18.2)</b>	<b>-13%</b>

## LOW MOLECULAR WEIGHT HEPARINS

Sales of Low Molecular Weight Heparins (LMWH) (enoxaparin biosimilar and bemiparin) decreased by 14% to 119.1 million euros in the first half of 2023. ROVI expects low-molecular-weight heparin sales to decrease by a low-single-digit figure in 2023, mainly as a result of the increase in orders from partners in 2022 related to the treatment for COVID-19, which has led to a lower expected 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	Avg.
Biosimilar of enoxaparin	29.4	33.3	27.2	34.2	44.2	37.9	37.1	33.6	34.9	39.6	35.1
Bemiparin	32.8	32.3	21.2	24.4	30.0	25.8	20.0	27.9	24.4	20.2	25.9
Sales in Spain	18.9	17.2	15.7	17.6	17.5	17.2	15.7	16.5	17.3	14.6	16.8
International sales	13.9	15.1	5.5	6.8	12.5	8.6	4.4	11.5	7.1	5.6	9.1
<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>	

Sales of the **enoxaparin biosimilar** decreased by 9% to 74.5 million euros in the first half of 2023. However, sales of the product increased 14% in the second quarter of 2023 to 39.6 million euros, compared to the first quarter of the year, and rose 5% in the second quarter of 2023 compared to the second quarter of 2022. In the second quarter of 2023, the product's sales were 4.5 million euros (or 13%) higher than the average quarterly sales of the product in the last ten quarters. The product was launched in Jordan and Sri Lanka in the first half of 2023. In Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo it was launched in the same period of 2022.

<sup>1</sup> Other heparins are reported in the "Contrast agents and other hospital products" line.

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, 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 the first half of 2023.

**Bemiparin** sales decreased 20% to 44.5 million euros in the first half of 2023. International sales of Bemiparin decreased by 40% to 12.6 million euros. This decrease was mainly linked to (i) the decrease in sales in the Russian market, (ii) fewer orders from partners and (iii) lower sales related to COVID-19. Sales of Bemiparin in Spain (Hibor®) showed a decrease of 8% to 31.9 million euros in the first half of 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 17% to 22.1 million euros in the first half of 2023, compared to 18.9 million euros in the first half of 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 6% to 8.3 million euros in the first half of 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 14% to 13.7 million euros in the first half of 2023. ROVI ceased to distribute Absorcol® as of 31 December of 2022 and Vytorin® as of 31 January 2023. Orvatez® sales rose 12% to 13.6 million euros in the first half of 2023, compared to 12.1 million euros in the first half of 2022. Sales of Absorcol® and Vytorin® accounted for 24% of total sales of the products indicated to treat hypercholesterolemia in the first half of 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 5.2 million euros in the first half of 2023. Okedi® sales increased by 36% in the second quarter of 2023 compared to the first quarter of the year. In 2022, it was launched in Germany in April, the UK in July and Spain in September and, in January 2023, in Portugal. ROVI expects to launch the product in Italy and Austria during the second half of the year.

- In Germany, the product was received very positively in the medical education activities carried out by ROVI. It is already present in 58% of hospitals. Okedi®'s average monthly sales growth in the first six months of 2023 was 20%.
- In the United Kingdom, the product is still in the introduction phase in the "trusts" (entities that manage the health areas). In the first half of 2023, it had already been approved in 20% of the "trusts". It is expected that it will soon become available in most hospital pharmacies.
- In Spain, at the end of 2022, the product was already available in the 100% of the autonomous communities. In the first half of 2023, it was being marketed in more than 80% of hospitals and 33% of psychiatrists had been trained.
- In Portugal, access to doctors was positive. In the first half of 2023, it was being marketed in 40% of hospitals and it is expected to be in most of the hospitals by the end of the year. Sales are expected to accelerate during the second half of 2023.

## **CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS**

Sales of **contrast imaging agents and other hospital products** increased by 18% to 23.6 million euros in the first half of 2023. This increase shows the strong recovery of the Spanish and Portuguese hospital activity during this period after the effects of lockdowns during the pandemic.

## **CONTRACT MANUFACTURING ORGANISATION (“CMO”) BUSINESS**

**CMO** sales increased by 4% to 172.2 million euros in the first half of 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 0.7 million euros to 0.2 million euros in the first half of 2023 compared to the same period of 2022, mainly due lower subsidies received in the period.

## COSTS

### GROSS PROFIT

**Gross profit** decreased 5% to 215.7 million euros in the first half of 2023 compared to the same period of 2022. Gross margin showed a decrease of 3.1 percentage points, from 59.7% in the first six months of 2022 to 56.6% in the same period of 2023. This drop is mainly due to the higher contribution to the CMO business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to Group sales.

### RESEARCH AND DEVELOPMENT EXPENSES

**R&D expenses** increased 4% to 10.8 million euros in the first half of 2023. They were mainly related to (i) preparing the development of the next phase of Letrozole LEBE and (ii) the development of a new formulation of Risperidone ISM® for a 3-monthly injection.

### SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

**SG&A expenses** increased 7% to 107.8 million euros in the first half of 2023 mainly as a result of an increase in expenses due to the Okedi® launch in Europe.

#### SG&A expenses

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
Employee benefit expenses (exc. R&D)	54.0	46.5	7.5	16%
Other operating expenses (exc. R&D)	53.8	54.6	(0.8)	-2%
<b>Total SG&amp;A expenses</b>	<b>107.8</b>	<b>101.1</b>	<b>6.7</b>	<b>7%</b>
Expenses related to international subsidiaries	11.8	8.3	3.5	42%

### DEPRECIATION

**Depreciation and amortisation expenses** increased by 5% to 11.9 million euros in the first half of 2023, as a result of the new property, plant and equipment and intangible assets purchases made during the last year.

### NET FINANCIAL INCOME

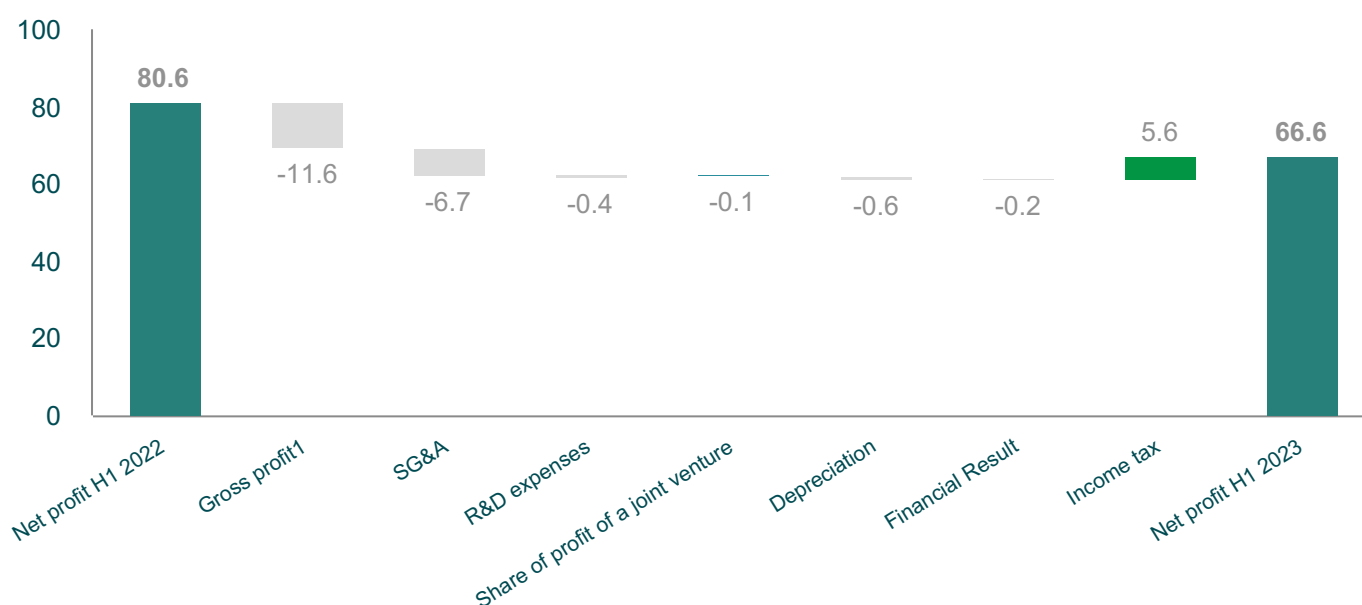
**Net financial income** decreased 26% to 0.6 million euros in the first half of 2023 mainly due to lower returns on financial investments .

## EFFECTIVE TAX RATE

The **effective tax rate** was 22% in the first half of 2023, compared to 23% in the same period of 2022, mainly due to the decrease of the profit before income tax.

## FINANCIAL PERFORMANCE

Million euros



<sup>1</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 97.1 million euros in the first half of 2023, a decrease of 16% compared to the same period of 2022, reflecting a 5.0 percentage point decrease in the EBITDA margin, which was down to 25.5% in the first half of 2023 from 30.4% in the same period of 2022.

## EBIT

**EBIT** decreased by 18% to 85.2 million euros in the first half of 2023, reflecting a 5.1 percentage point decline in the EBIT margin, which was down to 22.4% in the first six months of 2023 from 27.5% in the same period of 2022.

## NET PROFIT

**Net profit** decreased by 17%, from 80.6 million euros in the first half of 2022 to 66.6 million euros in the same period of 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 15%, from 126.2 million euros in the first half of 2022 to 107.9 million euros in the same period of 2023, reflecting a 4.9 percentage point decrease in the EBITDA margin to 28.3% in the first half of 2023 (see “Pre-R&D costs” columns of the table below). Likewise, recognising the same amount of R&D expenses in the first six months of 2023 as in the same period of 2022, EBITDA would have decreased by 16% to 97.4 million euros, reflecting a 4.9 percentage point decrease in the EBITDA margin to 25.6% in the first half of 2023, down from 30.4% 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 16%, from 114.9 million euros in the first half of 2022 to 96.0 million euros in the same period of 2023, reflecting a 5.0 percentage point decrease in the EBIT margin to 25.2% in the first six months of 2023 (see “Pre-R&D costs” columns of the table below). Likewise, recognising the same amount of R&D expenses in the first half of 2023 as in the first half of 2022, EBIT would have decreased by 18% to 85.6 million euros, reflecting a 5.0 percentage point decline in the EBIT margin to 22.5% in the first six months of 2023, down from 27.5% in the same period of 2022 (see “Flat R&D costs” columns of the table below).

**Net profit “pre-R&D”**, calculated excluding R&D expenses, decreased by 15%, from 88.6 million euros in the first half of 2022 to 75.0 million euros in the same period of 2023 (see “Pre-R&D costs” columns of the table below). Likewise, recognising the same amount of R&D expenses in the first six months of 2023 as in the same period of 2022, net profit would have decreased by 17% to 66.9 million euros (see “Flat R&D costs” columns of the table below).



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

IN € MILLIONS	Reported		Pre-R&D costs			Flat R&D costs		
	H1 2023	H1 2022	H1 2023	H1 2022	% Growth	H1 2023	H1 2022	% Growth
Operating revenue(1)	380.8	380.4	380.8	380.4	0.1%	380.8	380.4	0.1%
Other income(2)	0.2	0.9	0.2	0.9	-81%	0.2	0.9	-81%
<b>Total revenue(3)</b>	<b>381.0</b>	<b>381.3</b>	<b>381.0</b>	<b>381.3</b>	<b>-0.1%</b>	<b>381.0</b>	<b>381.3</b>	<b>-0.1%</b>
Cost of sales(4)	(165.3)	(154.1)	(165.3)	(154.1)	7%	(165.3)	(154.1)	7%
<b>Gross profit(5)</b>	<b>215.7</b>	<b>227.2</b>	<b>215.7</b>	<b>227.2</b>	<b>-5%</b>	<b>215.7</b>	<b>227.2</b>	<b>-5%</b>
% margin	56.6%	59.7%	56.6%	59.7%	-3.1 pp	56.6%	59.7%	-3.1 pp
R&D expenses	(10.8)	(10.4)	0.0	0.0	n.a.	(10.4)	(10.4)	n.a.
SG&A	(107.8)	(101.1)	(107.8)	(101.1)	7%	(107.8)	(101.1)	7%
Share of profit of a joint venture	0.0	0.1	0.0	0.1	-112%	0.0	0.1	-112%
<b>EBITDA(6)</b>	<b>97.1</b>	<b>115.8</b>	<b>107.9</b>	<b>126.2</b>	<b>-15%</b>	<b>97.4</b>	<b>115.8</b>	<b>-16%</b>
% margin	25.5%	30.4%	28.3%	33.2%	-4.9 pp	25.6%	30.4%	-4.9 pp
<b>EBIT(7)</b>	<b>85.2</b>	<b>104.5</b>	<b>96.0</b>	<b>114.9</b>	<b>-16%</b>	<b>85.6</b>	<b>104.5</b>	<b>-18%</b>
% margin	22.4%	27.5%	25.2%	30.2%	-5.0 pp	22.5%	27.5%	-5.0 pp
<b>Net profit(8)</b>	<b>66.6</b>	<b>80.6</b>	<b>75.0</b>	<b>88.6</b>	<b>-15%</b>	<b>66.9</b>	<b>80.6</b>	<b>-17%</b>
% margin	17.5%	21.2%	19.7%	23.3%	-3.6 pp	17.6%	21.2%	-3.6 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 period.

## 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, broken down as follows:

- Application of profit: the entire profit of Laboratorios Farmacéuticos ROVI, S.A. for 2022, 39,116,103.39 euros, was applied to the dividend distribution; and
- Additionally, a further 30,770,000.54 euros was distributed as dividends charged to the freely-available reserves accounted for as "Retained earnings".

This dividend was paid on 5 July 2023.

# FINANCIAL POSITION

## Balance Sheet

IN € MILLIONS	Jun 30, 2023	Dec 31, 2022	Growth	% Growth
<b>Assets</b>				
Non-current assets	261.9	255.6	6.2	2%
Current assets	638.0	623.1	14.9	2%
<b>Total assets</b>	<b>899.8</b>	<b>878.7</b>	<b>21.1</b>	<b>2%</b>
<b>Equity</b>	<b>519.8</b>	<b>521.4</b>	<b>(1.6)</b>	<b>-0.3%</b>
<b>Liabilities</b>				
Non-current liabilities	58.5	63.4	(5.0)	-8%
Financial debt	54.5	59.4	(4.9)	-8%
Current liabilities	321.6	293.9	27.7	9%
Financial debt	12.0	12.7	(0.8)	-6%
<b>Total liabilities</b>	<b>380.0</b>	<b>357.3</b>	<b>22.7</b>	<b>6%</b>
<b>Total equity and liabilities</b>	<b>899.8</b>	<b>878.7</b>	<b>21.1</b>	<b>2%</b>

## TOTAL ASSETS

ROVI's **total assets** increased by 2%, from 878.7 million euros as of December 31, 2022 to 899.8 million euros as of June 30, 2023, mainly due to (i) an increase in "inventories" of 39.5 million euros, mostly because of an increase in heparin stock and in stock related to production of the COVID-19 vaccine, and (ii) an increase in "cash and cash equivalents" of 28.9 million euros.

## EQUITY

ROVI's **equity** decreased by 1.6 million euros to 519.8 million euros as of June 30, 2023. This decrease resulted from the "profit for the period".

## TOTAL LIABILITIES

ROVI's total **liabilities** increased by 6% from 357.3 million euros as of December 31, 2022 to 380.0 million euros as of June 30, 2023, mainly due to an increase of 48.2 million euros in the "trade and other payables" caption. This offset the decrease of 22.6 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 June 30, 2023.

As of June 30, 2023, ROVI **total debt** decreased to 66.5 million euros. Debt with public administration, which is 0% interest rate debt, represented 14% of total debt as of June 30, 2023.

## Total Debt

IN € THOUSANDS	Jun 30, 2023	Dec 31, 2022	Interest rate
Bank borrowings	40,893	44,107	0.68-3.90
Debt with public administration	9,598	10,175	0
Financial liabilities for leases	16,009	17,856	-
Derivative financial instruments	-	28	-
<b>Total</b>	<b>66,500</b>	<b>72,166</b>	

As of June 30, 2023, bank borrowings decreased by 3.2 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 June 30, 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 3.899% in July 2023) 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 3.7 million euros. Likewise, repayment of the fixed interest loan started in February 2023 (quarterly repayments) and its current outstanding balance is 37.1 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.

## GROSS CASH POSITION AND NET DEBT

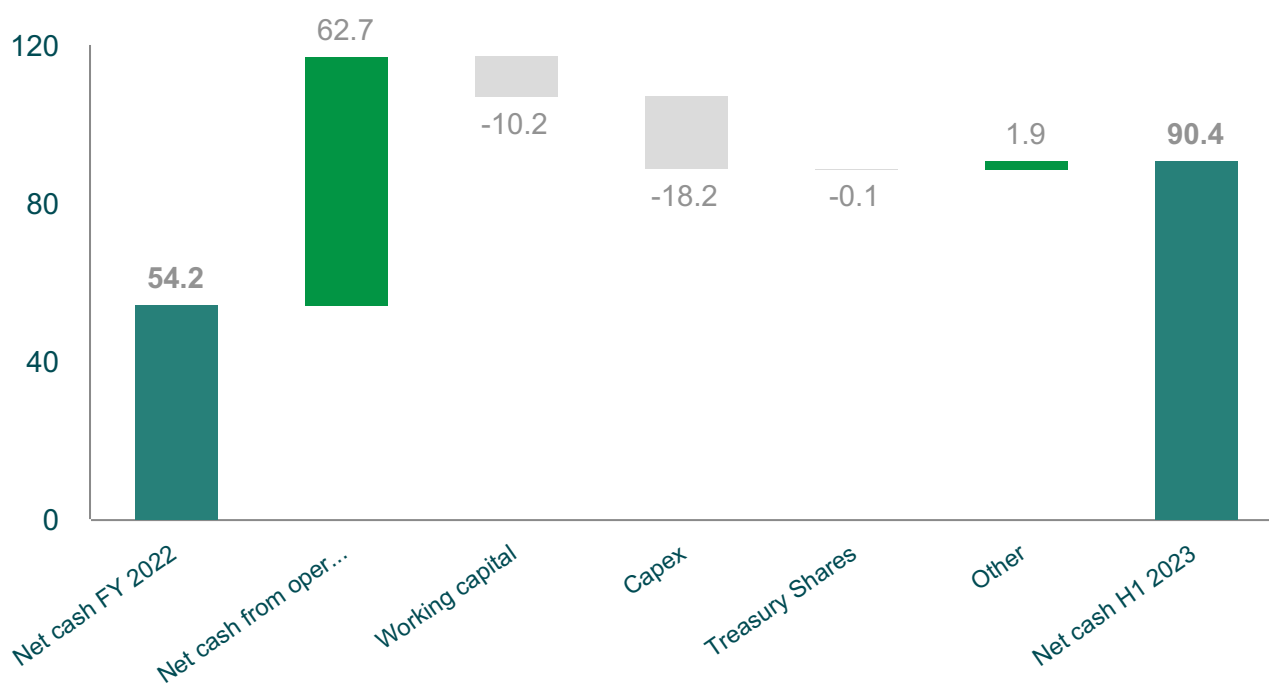
As of June 30, 2023, ROVI had a gross cash position of 156.9 million euros, compared to 126.4 million euros as of December 31, 2022, and net cash of 90.4 million euros, compared to 54.2 million euros as of December 31, 2022.

## Gross cash position and net debt

IN € MILLIONS	Jun 30, 2023	Dec 31, 2022
Equity securities	0.0	0.0
Deposits	1.4	1.4
Financial assets at amortised cost	1.6	–
Cash and cash equivalents	153.8	124.9
<b>Gross cash position</b>	<b>156.9</b>	<b>126.4</b>
Financial debt	(66.5)	(72.2)
<b>Net cash</b>	<b>90.4</b>	<b>54.2</b>

**Net cash generated in operating activities** amounted to 52.5 million euros in the first half of 2023, compared to 169.4 million euros in the same period of 2022. Net cash generated from operating activities excluding changes in working capital decreased 64% to 62.7 million euros in the first half of 2023 from 176.6 million euros in the same period of the previous year.

### Million euros



# LIQUIDITY

## Cash Flow

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
Cash flow from operating activities	52.5	169.4	(116.9)	-69%
Cash flow from investing activities	(17.4)	(9.9)	(7.5)	76%
Cash flow from financing activities	(6.3)	(101.0)	94.7	-94%
<b>Net increase/ (decrease) in cash</b>	<b>28.9</b>	<b>58.6</b>	<b>(29.7)</b>	<b>-51%</b>
Cash at the beginning of the period	124.9	99.0	25.9	26%
<b>Cash at the end of the period</b>	<b>153.8</b>	<b>157.6</b>	<b>(3.8)</b>	<b>-2%</b>

## CASH FLOW FROM OPERATING ACTIVITIES

**Cash flow from operating activities** decreased to 52.5 million euros in the first half of 2023 from 169.4 million euros in the same period of 2022. This decrease was mainly due to:

- the decrease of 19.5 million euros in profit before income tax;
- the booking of (23.3) million euros under the “cash flow from provision of manufacturing services” caption in the first half of 2023 mainly due to the allocation of more revenue to the income statement than payments received, compared to the 74.1 million euros recognized in the first half of 2022;
- the decrease of 40.1 million euros in the “inventory” item in the first half of 2023 compared to a decrease of 21.2 million euros in the first half of 2022 mostly due to an increase in heparin stock and in stock related to production of the COVID-19 vaccine; and
- the decrease of 21.6 million euros in the “trade and other payables” item in the first half of 2023, compared to an increase of 2.9 million euros in the same period of 2022, mainly due to recognition of a 69.9 million euros dividend in the first half of 2023, which had not yet been paid at the end of the period, compared to a 53.6 million euros dividend figure in the first half of 2022.

These negative impacts were partially offset by:

- the increase of 54.2 million euros in the “trade and other receivables” caption in the first half of 2023 compared to a decrease of 11.8 million euros in the same period of 2022.

## CASH FLOW FROM INVESTING ACTIVITIES

ROVI invested 18.2 million euros in the first half of 2023, compared to 9.9 million euros in the same period of 2022.

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

IN € MILLIONS	H1 2023	H1 2022	Growth	% Growth
Madrid Injectable plant	0.4	0.3	0.2	64%
San Sebastián de los Reyes plant	0.5	0.4	0.1	26%
Granada plant	0.3	0.2	0.1	78%
Alcalá de Henares plant	0.5	1.2	(0.7)	-59%
Expenditure on maintenance and other capex	0.8	0.7	0.1	20%
<b>Maintenance Capex</b>	<b>2.5</b>	<b>2.7</b>	<b>(0.2)</b>	<b>-7%</b>
ISM industrialisation	2.9	2.2	0.7	34%
Escúzar plant	3.3	3.4	(0.2)	-5%
Glicopepton	0.3	-	0.3	n.a.
New filling lines and operations expansion	9.2	1.7	7.5	n.a.
<b>Investment Capex</b>	<b>15.7</b>	<b>7.2</b>	<b>8.4</b>	<b>117%</b>
<b>Total Capex</b>	<b>18.2</b>	<b>9.9</b>	<b>8.3</b>	<b>84%</b>

## FREE CASH FLOW

**Free cash flow** decreased to 35.1 million euros in the first half of 2023 from 159.5 million euros in the first half of 2022.

### Free cash flow

IN € MILLIONS	H1 2023	H1 2022
Net cash generated from (used in) operating activities	52.5	169.4
Purchases of intangible assets	(0.2)	(0.1)
Purchases of property, plant and equipment	(18.0)	(9.8)
Proceeds from sale of property, plant and equipment	0.0	-
Interest received	0.8	0.0
<b>Free cash flow</b>	<b>35.1</b>	<b>159.5</b>

## CASH FLOW FROM FINANCING ACTIVITIES

**Cash flow from financing activities** increased to (6.3) million euros in the first half of 2023 from (101.0) million euros in the first half of 2022. This increase was mainly attributable to ROVI's share buy-back programs executed in the first half of 2022, amounting to 135.0 million euros.



Javier López-Belmote Encina, Deputy Chairman and Chief Financial Officer of ROVI, said “We are very happy with the evolution of the Company. 2023 is the first year of a new post-pandemic scenario, a year of transition where COVID-19 would foreseeably be a seasonal disease. In this difficult context, we have been able to deliver stable total revenue of 381.0 million euros. Profitability was negatively impacted by (i) the higher contribution to the CMO business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna and (ii) our commercial effort to launch Okedi® in Europe. ROVI's commitment to innovation is reflected in the figures of the first six months of 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 utilization of our asset base”.

## OUTLOOK

In November 2022 and February 2023, ROVI announced it expected the operating revenue for the full year 2023 to show a low-double-digit negative growth on 2022, although positive growth of between 5% and 10% is expected in comparison with the 2021 figure. With the visibility that the Company has at this moment, ROVI is upgrading its operating revenue guidance for the full year 2023 from low-double-digit negative growth to **high-single-digit negative growth**.

For 2023, ROVI is assuming a new post-pandemic scenario in which COVID-19 would foreseeably be a seasonal disease and, in principle, the vaccine would be administered once a year. The uncertainty related to the evolution of the disease is very high. It is not, therefore, possible to make a precise assessment of the impact that this new scenario could have on the CMO business. Likewise, under the terms of the agreement signed with Moderna in February 2022, ROVI is still investing in increasing the compounding, aseptic filling, inspection, labelling and packaging capacities at its facilities and expects them to be fully installed by the end of 2024.

Taking account of the aforementioned guidance on a decrease in operating revenue in 2023, as well as the fact that ROVI will continue with its investment policy as stated, it is reasonable to expect that the Company's profits may also see a downward adjustment in 2023.

## 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.

In January 2020, ROVI announced the commencement of the centralised procedure for registration of Okedi® with the European Medicines Agency (EMA). On 16 December 2021, the CHMP adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Okedi®. Finally, 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 Germany in April 2022, in the UK in July 2022, in Spain in September 2022 and in Portugal in January 2023.

Likewise, at its Capital Markets Day held on 24 November 2020, ROVI announced the filing of an NDA (New Drug Application), i.e. a registration dossier to obtain marketing authorisation in the USA, with the FDA (Food and Drug Administration). ROVI was informed of the delay in a decision on granting marketing authorisation for Risvan® (Risperidone ISM®) by the U.S. Food and Drug Administration ("FDA"). Furthermore, on 24 September 2021, ROVI received a Complete Response Letter from the FDA with



outstanding questions on the Risvan® dossier, which were answered in January 2022. In the third quarter of 2022, the FDA issued a second Complete Response Letter, with some outstanding questions for ROVI and also with questions for one of its manufacturers. Both ROVI and the manufacturer provided answers to the FDA. The FDA has notified ROVI that the user fee goal date is 27 July 2023.

The grant of the marketing authorisation for Risvan® by the FDA is also subject to the closure of the observations issued by the FDA after the pre-approval inspection (PAI) of the plant where the product is manufactured (located in Madrid, Spain) that was conducted in the second half of June 2022. Responses to these observations were provided to the FDA. ROVI's plant has now been reinspected by the FDA. The Company is awaiting an FDA notification on the user fee goal date (27 July 2023). The content of this notification will be reported as soon as it is received.

In addition, in January 2023 the FDA conducted the pending inspection of a supplier to close deficiencies found by the FDA in a process not related to Risperidone ISM®. As a result of this inspection, the FDA has issued new observations and the manufacturer is currently estimating a time frame to provide the responses.

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 patients with clinically stable schizophrenia. The regulatory toxicity studies needed to start the clinical development in humans have already been completed. The company is currently initiating all arrangements to conduct 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 is planned to begin by the third quarter 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 has recently applied in Europe for authorisation of a phase I clinical trial 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 is planned to start by the third quarter of 2023.

# ESG

In July 2022, ROVI's ESG aspects were evaluated by Sustainalytics, a Global Leader in ESG & Corporate Governance, having obtained an "ESG Risk Rating 2022" 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 22th out of a total of 970 companies in the "pharmaceutical industry", which includes biotech, pharmaceutical and laboratory equipment companies.

Among ROVI's basic action principles included in the Policy against Climate Change are the following:

- Reduction in greenhouse gas emissions.
- Reduction in non-greenhouse gas emissions, improving the air quality.
- Carbon neutrality, reducing emissions and offsetting those that cannot be avoided.
- Use of renewable energies, increasing the consumption thereof until the total energy consumed comes from renewable sources. The origin of 100% of the electrical energy used in our facilities is renewable.

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.

(\*THE USE BY ROVI OF ANY MSCI ESG RESEARCH LLC OR ITS AFFILIATES ("MSCI") DATA, AND THE USE OF MSCI LOGOS, TRADEMARKS, SERVICE MARKS OR INDEX NAMES HEREIN, DO NOT CONSTITUTE A SPONSORSHIP, ENDORSEMENT, RECOMMENDATION, OR PROMOTION OF ROVI BY MSCI. MSCI SERVICES AND DATA ARE THE PROPERTY OF MSCI OR ITS INFORMATION PROVIDERS, AND ARE PROVIDED 'AS-IS' AND WITHOUT WARRANTY. MSCI NAMES AND LOGOS ARE TRADEMARKS OR SERVICE MARKS OF MSCI.

# KEY OPERATING AND FINANCIAL EVENTS

## ROVI Share Buy-back Programme

ROVI informs the market that, effective as of 26 July 2023, a share buyback program (the “Buyback Program”) will commence, 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 today, 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.
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 Buyback 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.

## 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 of 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®. Currently, this candidate has completed all the preclinical evaluation phases and is available to commence its clinical development.

Consequently, ROVI has recently applied in Europe for authorisation of a 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 would 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®.

After completing this first clinical trial, ROVI plans to conduct a pivotal clinical trial on the bioequivalence/bioavailability of Letrozole LEBE in accordance with the requirements of the FDA's 505 (b)(2) regulatory pathway and Directive 2001/83/CE of the European Parliament. ROVI intends this clinical trial to evaluate the steady-state bioequivalence of Letrozole LEBE vs Femara®. The trial would have an estimated duration of around two years.

In accordance with the results that can be expected from the LEILA-1 study, ROVI anticipates two possible clinical paths to support to the product's marketing authorisation:

- If the results of the LEILA-1 pharmacokinetic characterisation trial make it foreseeable that Letrozole LEBE meets bioequivalence criteria; in this case, ROVI will file a dossier applying for marketing authorisation for the product after completion of the bioequivalence/bioavailability study.
- If the results of the LEILA-1 pharmacokinetic characterisation trial make it foreseeable that Letrozole LEBE does not meet all the bioequivalence criteria but demonstrates bioequivalence in minimum steady-state concentrations of letrozole; in this case, ROVI might need to also conduct a single clinical efficacy trial to support the product's marketing authorisation.

## **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 20446 dated 16<sup>th</sup> of February 2023) on the evaluation process to obtain marketing authorisation for Risvan® (Risperidone ISM®) in the United States and reported that it had filed the final responses to the Complete Response Letter received from the United States Food and Drug Administration (FDA) in the third quarter of 2022. These responses likewise included the answers of one of ROVI's suppliers to outstanding questions. The FDA has notified ROVI that the user fee goal date is 27 July 2023.

Likewise, ROVI filed the final report on correction of the deficiencies noted when the FDA inspected its facilities in June 2022. The evaluation of these corrections were provided to the FDA. ROVI's plant has now been reinspected by the FDA. The

Company is awaiting an FDA notification on the user fee goal date (27 July 2023). The content of this notification will be reported as soon as it is received.

Furthermore, in January 2023, the FDA carried out a pending inspection of a ROVI supplier. As a result of the inspection, the FDA issued a series of observations to said supplier, which the latter is working to answer. The time frame for the supplier's response will depend on how the FDA evaluates the observations issued.

Thus, ROVI is continuing with the roadmap that it notified in the presentation of the update of its strategy at its 2022 Capital Markets Day and will continue to report on the milestones deemed relevant in the process to obtain authorisation of Risvan® from the FDA as the timeline for registration in the United States advances.

## **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).

## **For further enquiries, please contact:**

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

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

Marta Campos Martínez  
Head of Investor Relations  
+34 912444422  
[mcampos@rovi.es](mailto:mcampos@rovi.es)  
[www.rovi.es](http://www.rovi.es)

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

## **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.

## **Alternative performance measures**

This press release may include certain Alternative Performance Measures (“APMs”) not prepared under IFRS-EU and not reviewed or audited by either the Company's auditors or an independent expert. Furthermore, the way in which the Group defines and calculates these measures may differ from the way in which other companies calculate similar measures. Consequently, they may not be comparable.

# APPENDIX 1

## LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF JUNE 30, 2023 AND DECEMBER 31, 2022

IN € THOUSANDS	June 30, 2023	December 31, 2022
<b>ASSETS</b>		
<b>Non-current assets</b>		
Property Plant and Equipment	223,785	215,541
Intangible assets	34,249	35,744
Investment in a joint venture	2,180	2,193
Deferred income tax assets	1,564	2,078
Equity securities	24	9
Financial receivables	65	65
	<b>261,867</b>	<b>255,630</b>
<b>Current assets</b>		
Inventories	351,400	311,944
Trade and other receivables	126,379	180,011
Current income tax assets	–	4,148
Prepaid expenses	4,768	2,025
Financial assets at amortised cost	1,606	-
Cash and cash equivalents	153,812	124,945
	<b>637,965</b>	<b>623,073</b>
<b>Total assets</b>	<b>899,832</b>	<b>878,703</b>



**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS AS OF JUNE 30, 2023 AND DECEMBER 31, 2022**

IN € THOUSANDS	June 30, 2023	December 31, 2022
<b>EQUITY</b>		
<b>Equity attributed to the company</b>	<b>516,643</b>	<b>520,012</b>
Share capital	3,241	3,241
Share premium	87,636	87,636
Legal reserve	673	673
Treasury shares	(26,602)	(27,561)
Retained earnings and voluntary reserves	385,073	256,362
Profit for the period	66,646	199,669
Accumulated other comprehensive income	(24)	(8)
<b>Non-controlling interests</b>	<b>3,142</b>	<b>1,367</b>
<b>Total equity</b>	<b>519,785</b>	<b>521,379</b>
<b>LIABILITIES</b>		
<b>Non-current liabilities</b>		
Financial debt	54,540	59,441
Deferred income tax liabilities	784	677
Contract liabilities	1,567	1,545
Deferred income	1,562	1,774
	<b>58,453</b>	<b>63,437</b>
<b>Current liabilities</b>		
Financial debt	11,960	12,725
Trade and other payables	213,927	165,776
Current tax liabilities	2,911	–
Contract liabilities	92,320	114,901
Deferred income	476	485
	<b>321,594</b>	<b>293,887</b>
<b>Total liabilities</b>	<b>380,047</b>	<b>357,324</b>
<b>Total equity and liabilities</b>	<b>899,832</b>	<b>878,703</b>

**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED INCOME STATEMENTS FOR THE SIX-MONTH PERIODS ENDING 30**  
**JUNE 2023 AND 30 JUNE 2022**

IN € THOUSANDS	H1 2023	H1 2022
Revenue	380,845	380,399
Changes in inventories of finished goods and work in progress	19,171	32,765
Raw materials and consumables used	(184,514)	(186,851)
Work carried out by the Group on non-current assets	1,960	-
Employee benefit expenses	(59,096)	(51,464)
Other operating expenses	(61,466)	(60,100)
Amortisation and depreciation	(11,865)	(11,310)
Recognition of government grants on non-financial non-current assets and other	172	921
Share of profits of joint venture	(13)	107
<b>OPERATING PROFIT (EBIT)</b>	<b>85,194</b>	<b>104,467</b>
Finance income	766	4
Finance costs	(366)	(429)
Impairment and gain or loss on measurement of financial instruments	72	1,249
Exchange difference	166	37
<b>FINANCE INCOME/(COSTS) - NET</b>	<b>638</b>	<b>861</b>
<b>PROFIT BEFORE INCOME TAX</b>	<b>85,832</b>	<b>105,328</b>
Income tax	(19,188)	(24,752)
<b>PROFIT FOR THE PERIOD</b>	<b>66,644</b>	<b>80,576</b>
Net profit attributable to parent company	66,646	80,620
Profit attributable to minority interests	(2)	(44)

**LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES**  
**CONSOLIDATED CASH FLOW STATEMENTS FOR THE SIX-MONTH PERIODS ENDING**  
**30 JUNE 2023 AND 30 JUNE 2022**

IN € THOUSANDS	H1 2023	H1 2022
<b>Cash flows from operating activities</b>		
Profit before tax	85,832	105,328
<b>Adjustments for non-monetary transactions:</b>		
Amortisation and depreciation	11,865	11,310
Finance income	(766)	(41)
Valuation allowance	579	1,524
Adjustments for changes in value of derivatives	(24)	(217)
Gain or loss on derecognition of financial assets and liabilities	(48)	(1,032)
Exchange differences	(166)	–
Finance expenses	366	429
Grants, distribution licenses and other deferred income	(323)	(1,570)
Share of profit of joint venture	13	(107)
<b>Changes in working capital:</b>		
Trade and other receivables	54,176	11,787
Inventories	(40,063)	(21,198)
Trade and other payables	(21,567)	2,901
Other current assets (prepaid expenses)	(2,743)	(678)
<b>Other collections and payments:</b>		
Cash flow from provision of manufacturing services	(23,270)	74,149
Proceeds from distribution licenses	185	315
Income tax cash flow	(11,507)	(13,462)
<b>Net cash generated from (used in) operating activities</b>	<b>52,539</b>	<b>169,438</b>
<b>Cash flows from investing activities</b>		
Purchases of intangible assets	(173)	(105)
Purchases of property, plant and equipment (usage rights not included)	(17,998)	(9,791)
Proceeds from sale of property, plant and equipment	10	–
Sale of financial assets	10	20
Interest received	766	4
<b>Net cash generated from (used in) investing activities</b>	<b>(17,385)</b>	<b>(9,872)</b>
<b>Cash flows from financing activities</b>		
Repayments of financial debt	(6,822)	(3,260)
Proceeds from financial debt	663	1,263
Interest paid	(186)	(143)
Purchase of treasury shares	(48,739)	(127,070)
Reissue of treasury shares	48,626	28,089
Capital contribution to subsidiaries	171	147
<b>Net cash generated from (used in) financing activities</b>	<b>(6,287)</b>	<b>(100,974)</b>
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>28,867</b>	<b>58,592</b>
<b>Cash &amp; cash equivalents at the beginning of the period</b>	<b>124,945</b>	<b>99,035</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>153,812</b>	<b>157,627</b>