# FINANCIAL RESULTS

for the nine-month period ending 30<sup>th</sup> September of

2024

07/11/2024



# **KEY FIGURES**

# **Summary**

| IN € MILLIONS  | 9M 2024                | 9M 2023               | Growth | % Growth |
|--|------------------------|-----------------------|--------|----------|
| Operating revenue(1)   | 564.6                  | 594.9                 | (30.3) | -5%      |
| Gross profit(2)  | 359.0                  | 350.6                 | 8.4    | 2%       |
| EBITDA(3)  | 167.2                  | 171.2                 | (4.0)  | -2%      |
| EBIT(4)  | 146.6                  | 153.4                 | (6.8)  | -4%      |
| Net profit(5)  | 113.5                  | 118.8                 | (5.3)  | -4%      |
| Purchases of property, plant and equipment and intangible assets ("Capex") | 33.8                   | 26.8                  | 7.0    | 26%      |
| FCF(6)   | 31.4                   | 27.0                  | 4.5    | 17%      |
|  |                        |                       |        |          |
| Gross profit as % of operating revenue                                     | 63.6%                  | 58.9%                 |        | 4.7 pp   |
| EBITDA as % of operating revenue   | 29.6%                  | 28.8%                 |        | 0.8 pp   |
| EBIT as % of operating revenue   | 26.0%                  | 25.8%                 |        | 0.2 pp   |
| Net profit as % of operating revenue                                       | 20.1%                  | 20.0%                 |        | 0.1 pp   |
| Capex as % of operating revenue  | 6.0%                   | 4.5%                  |        | 1.5 pp   |
| FCF as % of operating revenue  | 5.6%                   | 4.5%                  |        | 1.0 pp   |
|  |                        |                       |        |          |
|  | As of Sept<br>30, 2024 | As of Dec<br>31, 2023 | Growth | % Growth |
| Net debt (€m)(7)   | 108.8                  | 38.6                  | 70.2   | 182%     |

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.

The consolidated financial statements of Grupo ROVI for the first nine months of 2024 and the comparative information for 2023 (balance sheet) and for the first nine months of 2023 (consolidated income statement and cash flow statement) are attached to this report (see Appendix 1). The figures for the first nine months of 2024 and the first nine months of 2023 are unaudited figures. Likewise, the figures as of December 31, 2023 are audited figures.

<sup>(1)</sup> Operating revenue refers to revenue.

<sup>(2)</sup> 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.

<sup>(3)</sup> EBITDA calculated as profit before interest, taxes, depreciation and amortization.

<sup>(4)</sup> EBIT calculated as profit before taxes and interest.

<sup>(5)</sup> Net profit refers to profit for the period.

<sup>(6)</sup> 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.

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

# **CONTENTS**

| HIGHLIGHTS 9M 2024                               | <u>3</u>   |
|--|------------|
| GROUP MANAGEMENT REPORT                          | 8          |
| INCOME STATEMENT                                 | 8          |
| <u>REVENUES</u>                                  | <u>8</u>   |
| SPECIALTY PHARMACEUTICAL BUSINESS                | 10         |
| LOW MOLECULAR WEIGHT HEPARINS                    | <u>11</u>  |
| OTHER PRESCRIPTION-BASED PHARMACEUTICAL PRODUCTS | 12         |
| CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS      | <u>13</u>  |
| CDMO BUSINESS                                    | 13         |
| OTHER INCOME                                     | 14         |
| <u>COSTS</u>                                     | 14         |
| GROSS PROFIT                                     | 14         |
| RESEARCH AND DEVELOPMENT EXPENSES                | 14         |
| SELLING, GENERAL AND ADMINISTRATIVE EXPENSES     | 14         |
| <u>DEPRECIATION</u>                              | <u>15</u>  |
| NET FINANCE RESULT                               | <u>15</u>  |
| EFFECTIVE TAX RATE                               | 16         |
| FINANCIAL PERFORMANCE                            | <u> 16</u> |
| <u>DIVIDEND</u>                                  | 18         |
| FINANCIAL POSITION                               | <u>19</u>  |
| <u>LIQUIDITY</u>                                 | 22         |
| <u>OUTLOOK</u>                                   | <u>25</u>  |
| R&D UPDATE                                       | <u>25</u>  |
| <u>ESG</u>                                       | <b>27</b>  |
| KEY OPERATING AND FINANCIAL EVENTS               | <u>27</u>  |
| APPENDIX 1                                       | <u>35</u>  |
| ADDENDIY 2                                       | 70         |

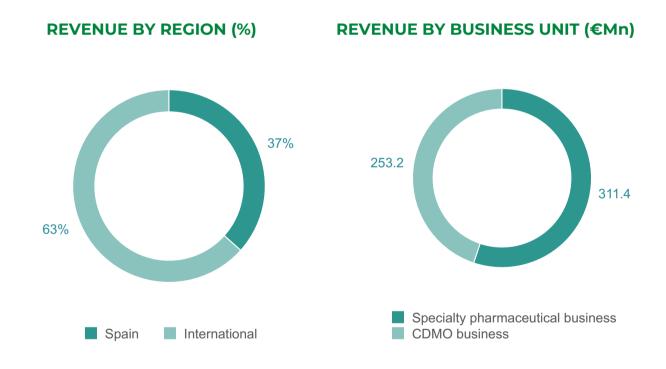
# **HIGHLIGHTS 9M 2024**

# ROVI ACHIEVED OPERATING REVENUE OF 564.6 MILLION EUROS AND INCREASED ITS GROSS MARGIN BY 4.7 PERCENTAGE POINTS

- Operating revenue in the first nine months of 2024 was 564.6 million euros, a 5% decrease on the first nine months of 2023, mainly due to the performance of the contract development and manufacturing business ("CDMO"). This division generated (i) lower revenues from the manufacture of the COVID-19 vaccine in comparison to the first nine months of 2023, when ROVI (the "Company" or the "Group") had booked higher income related to the production of the "pandemic" COVID-19 vaccine; and (ii) lower revenues related to the activities carried out to prepare the plant for production of the vaccine under the agreement with Moderna. However, CDMO sales increased by 16% to 134.4 million euros in the third quarter of 2024 compared to the third quarter of 2023, as a result of (i) higher revenue from existing customers (excluding Moderna); and (ii) higher revenue related to production of the COVID-19 vaccine due to a more concentrated seasonality in the third quarter. It should likewise be noted that the third quarter of 2024 is expected to be the strongest of the year in terms of CDMO sales performance.
- Positive evolution of Okedi® (Risperidone ISM®), sales of which increased 126% compared to the first nine months of 2023, totalling 20.3 million euros.
- ROVI announces that Risvan® (Risperidone ISM®), a product indicated for the treatment of schizophrenia in adults, will not be marketed in the United States, following an assessment of the uncertainties and opportunities associated to this launch. ROVI has, therefore, chosen to focus on the European development of Okedi® and expects this product to reach potential global sales of between 100 and 200 million euros in upcoming years.
- Sales of the heparin franchise (low-molecular-weight heparins (LMWH) and other heparins) decreased by 2% to 177.8 million euros in the first nine months of 2024, mainly due to lower orders from enoxaparin partners. Bemiparin sales, however, increased by 6% to 71.1 million euros in the first nine months of 2024. Additionally, ROVI forecasts full-year sales of bemiparin to increase by a low-single-digit percentage in 2024 compared to 2023, and the fourth quarter of 2024 to be the strongest quarter of the year in terms of enoxaparin sales, as a higher volume of orders from partners is expected.
- Good performance of Neparvis®, sales of which increased by 13% in the first nine months of 2024 compared to the same period of 2023, rising to 38.1 million euros.
- Gross margin was 63.6% in the first nine months of 2024, an increase of 4.7 percentage points on the first nine months of 2023. This increase was mainly due to: (i) the decrease in the contribution to the manufacturing business (CDMO) of revenue relating to activities to prepare the plant to produce

medicines under the agreement with Moderna, which contributed lower margins to Group sales; (ii) the increased contribution to the CDMO business by existing customers (excluding Moderna), which contributed higher margins; and (iii) the increased contribution of sales of Okedi®, which likewise added higher margins.

- EBITDA margin increased 0.8 percentage point to 29.6% in the first nine months of 2024 from 28.8% in the same period of 2023.
- Net profit was 113.5 million euros in the first nine months of 2024.
- The ROVI General Shareholders Meeting, held on 24 June 2024, approved the payment of a gross dividend of 1.1037 euros per share; which represents approximately a 35% pay-out. This dividend was paid on 10 July 2024.
- Effective 13 September 2024, ROVI delisted 2,780,395 shares from the Stock-Exchange Interconnection System (*Sistema de Interconexión Bursátil*) and the Madrid, Barcelona, Bilbao and Valencia Stock Exchanges. As a result, the share capital of ROVI is now EUR 3,074,145.72, divided into 51,235,762 ordinary shares. By redeeming these shares, the shareholders have automatically increased their percentage interest in the capital stock.



# **OUTLOOK**

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

For 2025, ROVI expects its operating revenue to **decrease by a mid-single-digit percentage** in comparison with 2024. Notwithstanding, this guidance is calculated using certain factors that could be relevant to the estimates and that are difficult to specify at the present time. They include, among others, the following:

- 1. First, the 2024 vaccination campaigns, for flu and COVID-19, are still in progress and, as of today's date, the Company is unable to forecast how the demand and production might evolve for the vaccination campaigns that will take place in 2025.
- 2. Second, it is hoped that the expansion of the compounding, aseptic filling, inspection, labelling and packaging capacities at the ROVI facilities in Madrid and the current high market demand for contract manufacturing services (CDMO) will favour obtaining new customers, with the resulting sales impact. This would have to be considered but is impossible to estimate at this time.

# **END OF THE SHARE BUY-BACK PROGRAMME**

On 11 June 2024, ROVI informed (by publication of the other relevant information number 29094) on the completion of the Buy-Back Programme launched on 26 July 2023. Under the framework of this programme, a total of 2,233,466 shares were acquired for an amount of 130 million euros, which represents approximately 4.13% of the share capital.

As announced when the Buy-Back Programme commenced, the purpose of the Programme was to cancel shares of ROVI through a reduction of capital while, at the same time, contributing to ROVI's shareholder remuneration by increasing the earnings per share. The capital was reduced by cancelling 2,780,395 shares. These shares corresponded to (i) the shares repurchased within the framework of the aforementioned Buy-Back Programme, and (ii) part of the existing treasury shares. The capital reduction was approved at the Ordinary General Shareholders' Meeting held on 24 June 2024 and executed by entering the pertinent deed of capital reduction into public record. The new amount of the share capital, after the shares mentioned had been cancelled and excluded from trading, has now been recorded at the registers of the National Securities Market Commission and Iberclear.

On 12 September 2024, ROVI informed (by publication of the other relevant information number 30484) that the cancelled shares had been delisted from the Stock-Exchange Interconnection System (*Sistema de Interconexión Bursátil*) and the Madrid, Barcelona, Bilbao and Valencia Stock Exchanges effective 13 September 2024. As a result, the share capital of the Company is now an amount of EUR 3,074,145.72, divided into 51,235,762 ordinary shares, with a nominal value of EUR 0.06 each, which grant a total of 51,235,762 voting rights (one per share). By redeeming these shares, the shareholders

automatically increase their percentage interest in the share capital (see further information on pages 28-29).



Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI, said: "2024 is of crucial importance in establishing the bases for ROVI's future. We are undergoing a growth phase focused on increasing our production capacities in the CDMO business reinforcing the company's internationalisation with Risperidone ISM®, the first innovative ROVI product based on ISM® technology. The positive reception of the product in the European countries where it has been launched, the FDA marketina authorisation for Risperidone ISM® in the United States and the approval of the product in Canada and Australia open up new growth opportunities for us all over the world in the field of long-acting injectables to treat schizophrenia. Innovation is one of ROVI's hallmarks and the ISM® platform provides new channels for growth. We

continue to progress with the phase I clinical trial of the three-monthly formulation of letrozole (Letrozole LEBE) and the phase 1 clinical trial in Europe of our three-monthly formulation of risperidone, reflecting a clear commitment to our ISM® technology. Additionally, in March 2024, we announced the incorporation of a new public-private investment vehicle, Terafront Farmatech, to develop advanced, innovative or emerging medicines, therapies and/or technologies jointly with Insud Pharma, S.L. and Innvierte Economía Sostenible SICC, SME, S.A. (investment company of Centro para el Desarrollo Tecnológico Industrial EPE - CDTI). This represents an opportunity to contribute to placing Spain in a leading position in the clinical research into new therapies, with the capacity to translate this research into manufacturing and thus improve the availability of new therapies to patients. Regarding our industrial presence, over the last five years we have invested substantial capital to build global leadership in sterile fill-and-finish capacity and technology services. In this context, we have been working on a process to assess the different strategic alternatives to maximise the value of our assets, which included a possible corporate transaction of ROVI relating to its third-party CDMO business. After due assessment of the offers received from several international investment funds and industrial companies, the Board of Directors of ROVI concluded that the third-party contract and development manufacturing business will generate higher value for all the shareholders if the current structure of the ROVI Group is maintained. This will allow the Company to continue capitalising on the significant imbalance between the available capacity and the rising demand in the sterile fill-and-finish market, building on the strong drive in commercial activity, which is providing multiple opportunities for business and alliances across strategic high-growth modalities. With the recent investments and

the expansions currently underway, we expect to significantly increase our current syringes and cartridges capacity. We will thus be able to position ourselves as one of the largest industrial pharmaceutical groups worldwide. In relation to our low-molecular-weight heparin ("LMWH") business, we aspire to become a global leader in this field. In this context, we continue to invest to become self-sufficient in obtaining crude heparin with the Glicopepton project and thus become a vertically integrated company in all the low-molecular-weight heparin manufacturing phases. We hope this investment will help us to increase the future margins of the heparin franchise."

# **GROUP MANAGEMENT REPORT**

for the nine-month period ending September 30<sup>th</sup>, 2024

# **INCOME STATEMENT**

| IN € MILLIONS   | 9M 2024 | 9M 2023 | Growth | % Growth |
|---|---------|---------|--------|----------|
| Operating revenue(1)  | 564.6   | 594.9   | (30.3) | -5%      |
| Other income(2)   | 0.3     | 0.3     | 0.1    | 25%      |
| Total revenue(3)  | 565.0   | 595.1   | (30.2) | -5%      |
| Cost of goods sold(4)   | (205.9) | (244.5) | 38.6   | -16%     |
| Gross profit(5)   | 359.0   | 350.6   | 8.4    | 2%       |
| % margin(11)  | 63.6%   | 58.9%   |        | 4.7 pp   |
| R&D expenses(6)   | (17.4)  | (16.5)  | (0.9)  | 5%       |
| SG&A(7)   | (174.3) | (162.7) | (11.6) | 7%       |
| Share of profit/(loss) of joint ventures and associated companies | (0.08)  | (0.10)  | 0.02   | -22%     |
| EBITDA(8)   | 167.2   | 171.2   | (4.0)  | -2%      |
| % margin(11)  | 29.6%   | 28.8%   |        | 0.8 pp   |
| EBIT(9)   | 146.6   | 153.4   | (6.8)  | -4%      |
| % margin(11)  | 26.0%   | 25.8%   |        | 0.2 pp   |
| Finance Income/(Costs)  | (1.1)   | 0.8     | (1.9)  | n.a.     |
| Profit before income tax  | 145.5   | 154.2   | (8.7)  | -6%      |
| Income tax  | (32.0)  | (35.4)  | 3.3    | -9%      |
| Effective tax   | 22.0%   | 22.9%   |        | -0.9 pp  |
| Net profit(10)  | 113.5   | 118.8   | (5.3)  | -4%      |
|   |         |         |        |          |
| Net profit attributable to parent company                         | 113.5   | 118.8   | (5.3)  | -4%      |
| Profit attributable to minority interests                         | (0.01)  | (0.01)  | 0.00   | 29%      |

<sup>(2)</sup> 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) R&D expenses are calculated as the sum of employee benefit expenses and other operating expenses related to scientific research and

technological development.

<sup>(7)</sup> SG&A calculated as the amount of employee benefit expenses plus other operating expenses plus work carried out by the Group on non-current assets" minus research & development expenses.

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

<sup>(9)</sup> EBIT calculated as profit before taxes and interest.

<sup>(10)</sup> Net profit refers to profit for the period.
(11) 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                     | 9M 2024 | 9M 2023 | Growth | % Growth |
|-----------------------------------|---------|---------|--------|----------|
| Specialty pharmaceutical business | 311.4   | 307.3   | 4.1    | 1%       |
| CDMO business                     | 253.2   | 287.6   | (34.4) | -12%     |
| Operating revenue(1)              | 564.6   | 594.9   | (30.3) | -5%      |
| Other income(2)                   | 0.3     | 0.3     | 0.1    | 25%      |
| Total revenue(3)                  | 565.0   | 595.1   | (30.2) | -5%      |

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

**Operating revenue** in the first nine months of 2024 was 564.6 million euros, a 5% decrease on the first nine months of 2023. This decrease was mainly caused by a drop in contribution of the CDMO business, sales of which fell to 253.2 million euros from 287.6 million euros in the first nine months of 2023, due to: (i) lower revenues from the manufacture of the COVID-19 vaccine in comparison to the first nine months of 2023. when ROVI had booked higher income related to the production of the "pandemic" COVID-19 vaccine; and, (ii) lower revenues related to the activities to prepare the plant for production of the vaccine under the agreement with Moderna. However, sales from the specialty pharmaceutical business increased 1% to 311.4 million euros, compared to 307.3 million euros in the first nine months of 2023. **Total revenue** fell 5% to 565.0 million. euros in the first nine months of 2024. It should likewise be noted that the third quarter of 2024 is expected to be the strongest of the year in terms of sales performance.

Sales outside Spain decreased 9% in the first nine months of 2024, compared to the first nine months of 2023, to 357.8 million euros, mainly due to the decrease in sales from the CDMO business. Sales outside Spain represented 63% of operating revenue in the first nine months of 2024 compared to 66% in the same period of 2023.

<sup>(2)</sup> 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.

# SPECIALTY PHARMACEUTICAL BUSINESS

# Sales of the specialty pharmaceutical business

|   | 9М     | 9M     |        |          |
|---|--------|--------|--------|----------|
| IN € MILLIONS                               | 2024   | 2023   | Growth | % Growth |
| Prescription-based pharmaceutical products  | 272.1  | 272.7  | (0.6)  | -0.2%    |
| LMWH franchise                              | 172.6  | 175.4  | (2.8)  | -2%      |
| Enoxaparin biosimilar                       | 101.6  | 108.1  | (6.6)  | -6%      |
| Bemiparin (Hibor)                           | 71.1   | 67.3   | 3.8    | 6%       |
| Sales in Spain                              | 44.0   | 46.1   | (2.1)  | -5%      |
| International sales                         | 27.1   | 21.2   | 5.8    | 28%      |
| Okedi                                       | 20.3   | 9.0    | 11.3   | 126%     |
| Neparvis                                    | 38.1   | 33.7   | 4.4    | 13%      |
| Volutsa                                     | 7.0    | 10.0   | (3.0)  | -30%     |
| Vytorin & Orvatez                           | 18.9   | 19.9   | (1.0)  | -5%      |
| Other products                              | 25.2   | 35.7   | (10.4) | -29%     |
| Discounts to the National Health System     | (10.2) | (11.0) | 0.8    | -7%      |
| Contrast agents and other hospital products | 38.4   | 33.8   | 4.6    | 14%      |
| Other products                              | 0.9    | 0.8    | 0.2    | 21%      |
| Total specialty pharmaceutical business     | 311.4  | 307.3  | 4.1    | 1%       |

Sales of **prescription-based pharmaceutical** products remained stable at 272.1 million euros in the first nine months of 2024 in comparison to the first nine months of 2023.

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) decreased by 2% to 177.8 million euros in the first nine months of 2024. Heparin sales represented 31% of operating revenue in the first nine months of 2024, in line with the same period of 2023.

| IN € MILLIONS               | 9M 2024 | 9M 2023 | Growth | % Growth |
|-----------------------------|---------|---------|--------|----------|
| LMWH franchise              | 172.6   | 175.4   | -2.8   | -2%      |
| Enoxaparin biosimilar       | 101.6   | 108.1   | (6.6)  | -6%      |
| Bemiparin (Hibor)           | 71.1    | 67.3    | 3.8    | 6%       |
| Sales in Spain              | 44.0    | 46.1    | (2.1)  | -5%      |
| International sales         | 27.1    | 21.2    | 5.8    | 28%      |
| Other heparins <sup>1</sup> | 5.2     | 6.2     | (1.0)  | -16%     |
| Heparins franchise          | 177.8   | 181.7   | (3.8)  | -2%      |

### LOW MOLECULAR WEIGHT HEPARINS

Sales of **Low Molecular Weight Heparins (LMWH)** (enoxaparin biosimilar and bemiparin) decreased by 2% to 172.6 million euros in the first nine months of 2024 mostly due to a decrease in enoxaparin biosimilar sales.

| IN €<br>MILLIONS         | Q1<br>2022 | Q2<br>2022 | Q3<br>2022 | Q4<br>2022 | Q1<br>2023 | Q2<br>2023 | Q3<br>2023 | Q4<br>2023 | Q1<br>2024 | Q2<br>2024 | Q3<br>2024 |
|--------------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Enoxaparin<br>biosimilar | 44.2       | 37.9       | 37.1       | 33.6       | 34.9       | 39.6       | 33.6       | 39.8       | 34.6       | 35.1       | 31.8       |
| Bemiparin<br>(Hibor)     | 30.0       | 25.8       | 20.0       | 27.9       | 24.4       | 20.2       | 22.8       | 26.9       | 19.7       | 27.5       | 23.9       |
| Sales in<br>Spain        | 17.5       | 17.2       | 15.7       | 16.5       | 17.3       | 14.6       | 14.2       | 15.6       | 15.4       | 15.1       | 13.5       |
| Intl. sales              | 12.5       | 8.6        | 4.4        | 11.5       | 7.1        | 5.6        | 8.6        | 11.4       | 4.3        | 12.4       | 10.4       |
| Total LMWH<br>sales      | 74.2       | 63.7       | 57.2       | 61.6       | 59.3       | 59.8       | 56.3       | 66.7       | 54.3       | 62.6       | 55.7       |

Sales of the **enoxaparin biosimilar** decreased by 6% to 101.6 million euros in the first nine months of 2024 mainly due to lower orders from partners. However, ROVI expects the fourth quarter to be the strongest quarter of the year in terms of sales, as a higher volume of orders from partners is anticipated.

**Bemiparin** sales increased by 6% to 71.1 million euros in the first nine months of 2024. International sales of bemiparin increased by 28% to 27.1 million euros, mainly linked to higher orders from partners in China, Turkey and Greece. Sales of bemiparin in Spain (Hibor®) showed a decrease of 5% to 44.0 million euros in the first nine months of 2024 compared to the same period of 2023, mainly due to lower penetration of the product in the prophylaxis segment. Nevertheless, ROVI expects full-year sales of bemiparin to increase by a low-single-digit percentage in 2024 compared to 2023.

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

### 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 13% to 38.1 million euros in the first nine months of 2024, compared to 33.7 million euros in the same period of 2023.

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 7.0 million euros in the first nine months of 2024 mainly due to a product price reduction of 47% in the second quarter of 2023.

Sales of **Vytorin®**<sup>2</sup> and **Orvatez®**, specialty products from Organon & Co. ("Organon") indicated as adjunctive therapy to diet in patients with hypercholesterolemia, decreased 5% to 18.9 million euros in the first nine months of 2024, compared to the same period of 2023. This decrease was mostly caused by the entry of generics into the market, which resulted in a product price reduction by competitors. ROVI consequently dropped the price of Orvatez® by 40% in October 2024.

Sales of **Okedi®**, the first ROVI product based on its leading-edge drug delivery technology, ISM®, and indicated for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone, totalled 20.3 million euros in the first nine months of 2024. Okedi® sales increased by 126% in the first nine months of 2024 compared to the first nine months of 2023. In the first nine months of 2024, it was approved in the United States (under the brand name Risvan®), Canada and Australia; in 2023, it was launched in Portugal, Italy, Austria, Greece and Serbia; and in 2022, it was launched in Germany, UK and Spain.

- In Germany, the product continues to be received very favourably in the medical education and dissemination activities carried out by ROVI. At present, the product is available in 83% of the hospitals that we have targeted. In the third quarter, ROVI conducted a training event for German and Austrian doctors which had a great impact in the sector. Likewise, work continues on the training project for nurses in order to improve the administration of Okedi® in hospitals and continue to increase the product's sales.
- In Spain, the product is available in 100% of the autonomous communities and is marketed in over 90% of hospitals. Additionally, more than 60% of psychiatrists that were approached, attended educational activities carried out by ROVI. Likewise, the capture of market share in the retail and hospital markets is progressing favourably.
- In Portugal, sales of the product are performing very positively. In the first nine months of 2024, Okedi® was being marketed in 78% of the hospitals. Additionally, 70% of the psychiatrist that were approached, attended educational activities carried out by ROVI.

<sup>&</sup>lt;sup>2</sup> ROVI ceased to distribute Vytorin® as of 31 January 2023.

- In Italy, access to doctors continues to be very positive. In the first nine months of 2024, 57% of psychiatrists that were approached, attended educational activities carried out by ROVI. Likewise, Okedi® is available in 95% of the main hospitals.
- In Austria, the penetration of the product is positive. Okedi® was launched in the fourth quarter of 2023 and, in the first nine months of 2024, ROVI visited 90% of the psychiatrists who had been targeted.

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 1.2 million euros in the first nine months of 2024 compared to 9.2 million euros in the first nine months of 2023.

### CONTRAST AGENTS AND OTHER HOSPITAL PRODUCTS

Sales of **contrast imaging agents and other hospital products** increased by 14% to 38.4 million euros in the first nine months of 2024.

## **CDMO BUSINESS**

**CDMO** sales fell by 12% to 253.2 million euros in the first nine months of 2024 in comparison to the same period of 2023, mainly due to (i) lower revenues from the manufacture of the COVID-19 vaccine in comparison to the first nine months of 2023, when ROVI had booked higher income related to the production of the "pandemic" COVID-19 vaccine; and, (ii) lower revenues related to the activities carried out to prepare the plant for production of the vaccine under the agreement with Moderna. However, CDMO sales increased by 16% to 134.4 million euros in the third quarter of 2024 compared to the third quarter of 2023, as a result of (i) higher revenue from existing customers (excluding Moderna); and (ii) higher revenue related to production of the COVID-19 vaccine due to a more concentrated seasonality in the third quarter. It should likewise be noted that the third quarter of 2024 is expected to be the strongest of the year in terms of CDMO sales performance.

In October 2024, after the assessment of strategic alternatives for its assets including a potential corporate transaction of ROVI relating to its third party contract development and manufacturing business ("CDMO"), ROVI concluded that, given the strength, momentum and prospects of this business, the best way to maximize value for shareholders at this time is to continue executing the Company's standalone strategic plan, with the interest of the CDMO business best served and developed under the current ROVI group structure, with no entry of third-party investors.

Over the past five years, ROVI has invested substantial capital to build global leadership in sterile fill & finish (F&F) capacity and technology services. With these recent investments, and with current expansions underway, ROVI expects to significantly increase its current sterile capacity at its FDA and EMA / EU GMP Annex-1 compliant facilities in Spain. This will allow ROVI to continue to capitalize on the imbalance between the available capacity and the rising demand across the sterile fill & finish market, building on recent momentum with the addition of a high-volume product

from a global pharmaceutical customer and the good drive in commercial activity and alliance opportunities across strategic high-growth modalities – including innovative biologics, biosimilars, vaccines and novel modalities for pre-filled syringes and cartridges.

### **OTHER INCOME**

**Other income** (subsidies) increased by 0.07 million euros to 0.3 million euros in the first nine months of 2024 compared to the same period of 2023, mainly due to higher subsidies received in the period.

# **COSTS**

### **GROSS PROFIT**

**Gross profit** increased 2% to 359.0 million euros in the first nine months of 2024 compared to the same period of 2023. Likewise, the gross margin increased from 58.9% in the first nine months of 2023 to 63.6% in the same period of 2024, an increase of 4.7 percentage points. This increase was mainly due to: (i) the decrease in the contribution to the manufacturing business (CDMO) of revenue relating to activities to prepare the plant to produce medicines under the agreement with Moderna, which contributed lower margins to Group sales; (ii) the increased contribution to the CDMO business by existing customers (excluding Moderna), which contributed higher margins; and (iii) the increased contribution of sales of Okedi®, which added higher margins.

In the first nine months of 2024, raw material prices for low-molecular-weight heparins (LMWH) fell 55% compared to the first nine months of 2023. ROVI expects this decrease in LMWH raw material prices to be confirmed in 2024. Notwithstanding, in spite of the decrease in LMWH raw material prices, the impact on the gross margin was negative in the first nine months of 2024. However, a positive impact on the gross margin is expected from 2025 onwards.

### RESEARCH AND DEVELOPMENT EXPENSES

**R&D expenses** increased 5% to 17.4 million euros in the first nine months of 2024. They were mainly related to (i) the development of the phase I of Letrozole LEBE, which began in July 2023, and (ii) the development of the phase I of a new formulation of Risperidone ISM® for a 3-monthly injection, which began in September 2023.

# **SELLING, GENERAL AND ADMINISTRATIVE EXPENSES**

**SG&A expenses** increased 7% to 174.3 million euros in the first nine months of 2024 compared to the same period of the previous year. This increase was a consequence of:

i. higher "Employee benefit expenses (excl. R&D)", which increased 8% in the first nine months of 2024 versus the first nine months of 2023 mainly due to a 10.3% wage increase under the General Collective Agreement for the Chemical Industry; and

ii. an increase of 6% in "Other operating expenses (excl. R&D)" due to Okedi®'s launch in Europe and the expenses related to the strategic assessment. Nevertheless, "Other operating expenses (excl. R&D and strategic assessment)" slightly increased by 2% to 80.7 million euros due to an efficient cost containment policy.

Additionally, in the fourth quarter of 2024, "Employee benefit expenses (excl. R&D)" are expected to increase due to the signing of the pre-agreement of the XXI Collective Agreement of the Chemical Industry<sup>3</sup>. The agreement includes annual salary increases of 3% for 2024, 2025 and 2026, all retroactive to 1 January of each year. It also includes a salary review clause for each of these years, in line with the AENC (Agreement for Employment and Collective Bargaining), at the actual CPI for each year, with a cap of 1% in 2024, 1% in 2025 and 2% in 2026, with no retroactive effect. These salary increases will take effect once the governing bodies of the signatory parties have ratified the Collective Agreement of the Chemical Industry.

# **SG&A** expenses

| IN € MILLIONS   | 9M 2024 | 9M 2023 | Growth | % Growth   |
|---|---------|---------|--------|------------|
| Employee benefit expenses (excl. R&D)                           | 90.0    | 83.2    | 6.8    | 8%         |
| Other operating expenses (excl. R&D)                            | 84.3    | 79.5    | 4.8    | 6%         |
| Total SG&A expenses   | 174.3   | 162.7   | 11.6   | <b>7</b> % |
| Strategic assessment  | 3.6     |         |        |            |
| Total SG&A expenses excluding expenses related to non-recurrent | 170.7   | 162.7   | 8.0    | 5%         |
| expenses  |         |         |        |            |

# **DEPRECIATION**

**Depreciation and amortisation expenses** increased by 16% to 20.6 million euros in the first nine months of 2024, as a result of the new property, plant and equipment and intangible asset purchases made during the last year.

# **NET FINANCIAL COST**

**Net financial cost** amounted to 1.1 million euros in the first nine months of 2024, compared to net financial income of 0.8 million euros in the first nine months of 2023. This decrease was mainly due to (i) lower financial income, and (ii) higher financial expenses due to an increase in financial debt (please see page 20 for further detail).

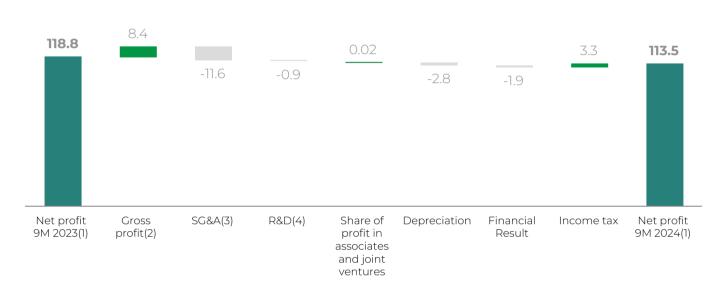
<sup>3</sup> Source: https://www.feique.org/wp-content/uploads/2024/10/Acta-Preacuerdo-XXI-CGIQ.pdf

### **EFFECTIVE TAX RATE**

The **effective tax rate** was 22.0% in the first nine months of 2024 compared to 22.9% in the same period of 2023. This decrease in the effective tax rate was due to (i) a decrease in "Profit before income tax," and (ii) an increase in tax credits derived from research and development expenses compared to the first nine months of 2023.

# FINANCIAL PERFORMANCE

#### Million euros



Net profit refers to the profit for the period.

<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.
<sup>[3]</sup>SG&A calculated as the amount of employee benefit expenses plus other operating expenses plus work carried out by the Group on non-current assets minus research. § development expenses

assets"minus research & development expenses.

(4) R&D expenses are calculated as the sum of employee benefit expenses and other operating expenses related to scientific research and technological development.

## **EBITDA**

**EBITDA** totalled 167.2 million euros in the first nine months of 2024, a decrease of 2% compared to the same period of 2023, reflecting a 0.8 percentage point increase in the EBITDA margin, which increased to 29.6% in the first nine months of 2024 from 28.8% in the same period of 2023.

### **EBIT**

**EBIT** decreased by 4% to 146.6 million euros in the first nine months of 2024, reflecting a 0.2 percentage point increase in the EBIT margin, which increased to 26.0% in the first nine months of 2024 from 25.8% in the same period of 2023.

#### **NET PROFIT**

**Net profit** decreased by 4%, from 118.8 million euros in the first nine months of 2023 to 113.5 million euros in the same period of 2024.

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 2%, from 187.8 million euros in the first nine months of 2023 to 184.6 million euros in the same period of 2024, reflecting a 1.1 percentage point increase in the EBITDA margin to 32.7% in the first nine months of 2024 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2024 as in the first nine months of 2023, EBITDA would have decreased by 2% to 168.1 million euros, reflecting a 1.0 percentage point increase in the EBITDA margin to 29.8% in the first nine months of 2024, up from 28.8% in the same period of 2023 (see "Flat R&D costs" columns of the table below).

**EBIT "Pre-R&D"**, calculated excluding R&D expenses, decreased by 3%, from 170.0 million euros in the first nine months of 2023 to 164.0 million euros in the same period of 2024, reflecting a 0.5 percentage point increase in the EBIT margin to 29.1% in the first nine months of 2024 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2024 as in the same period of 2023, EBIT would have decreased by 4% to 147.5 million euros, reflecting a 0.3 percentage point increase in the EBIT margin to 26.1% in the first nine months of 2024, up from 25.8% in the same period of 2023 (see "Flat R&D costs" columns of the table below).

**Net profit "Pre-R&D"**, calculated excluding R&D expenses, decreased by 3%, from 131.6 million euros in the first nine months of 2023 to 127.1 million euros in the same period of 2024 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2024 as in the same period of 2023, net profit would have decreased by 4% to 114.2 million euros (see "Flat R&D costs" columns of the table below) in the first nine months of 2024.

|  | Reported Pre-R&D costs |         | Pı      | osts    | Fla    | at R&D co | osts         |        |
|--|------------------------|---------|---------|---------|--------|-----------|--------------|--------|
|  | 9М                     | 9M      | 9М      | 9M      | %      | 9М        | 9M           | %      |
| IN € MILLIONS                                    | 2024                   | 2023    | 2024    | 2023    | Growth | 2024      | 2023         | Growth |
| Operating revenue(1)                             | 564.6                  | 594.9   | 564.6   | 594.9   | -5%    | 564.6     | 594.9        | -5%    |
| Other income(2)                                  | 0.3                    | 0.3     | 0.3     | 0.3     | 25%    | 0.3       | 0.3          | 25%    |
| Total revenue(3)                                 | 565.0                  | 595.1   | 565.0   | 595.1   | -5%    | 565.0     | 595.1        | -5%    |
| Cost of sales(4)                                 | (205.9)                | (244.5) | (205.9) | (244.5) | -16%   | (205.9)   | (244.5)      | -16%   |
| Gross profit(5)                                  | 359.0                  | 350.6   | 359.0   | 350.6   | 2%     | 359.0     | 350.6        | 2%     |
| % margin(11)                                     | 63.6%                  | 58.9%   | 63.6%   | 58.9%   | 4.7 pp | 63.6%     | 58.9%        | 4.7 pp |
| R&D expenses(6)                                  | (17.4)                 | (16.5)  | 0.0     | 0.0     | n.a.   | (16.5)    | (16.5)       | n.a.   |
| SG&A(7)  | (174.3)                | (162.7) | (174.3) | (162.7) | 7%     | (174.3)   | -162.74<br>9 | 7%     |
| Share of profit in associates and joint ventures | (0.08)                 | (0.10)  | (0.08)  | (0.10)  | -22%   | (0.08)    | (0.10)       | -22%   |
| EBITDA(8)  | 167.2                  | 171.2   | 184.6   | 187.8   | -2%    | 168.1     | 171.2        | -2%    |
| % margin(11)                                     | 29.6%                  | 28.8%   | 32.7%   | 31.6%   | 1.1 pp | 29.8%     | 28.8%        | 1.0 pp |
| EBIT(9)  | 146.6                  | 153.4   | 164.0   | 170.0   | -3%    | 147.5     | 153.4        | -4%    |
| % margin(11)                                     | 26.0%                  | 25.8%   | 29.1%   | 28.6%   | 0.5 pp | 26.1%     | 25.8%        | 0.3 pp |
| Net profit(10)                                   | 113.5                  | 118.8   | 127.1   | 131.6   | -3%    | 114.2     | 118.8        | -4%    |
| % margin(11)                                     | 20.1%                  | 20.0%   | 22.5%   | 22.1%   | 0.4 pp | 20.2%     | 20.0%        | 0.2 pp |

<sup>(1)</sup> Operating revenue refers to revenue.

(10) Net profit refers to profit for the period.

# **DIVIDEND**

ROVI's General Shareholders Meeting, held on 24 June 2024, approved the payment of a gross dividend of 1.1037 per share. 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".

This dividend was paid on 10 July 2024.

<sup>(2)</sup> 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.

<sup>(5)</sup> 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.

<sup>(6)</sup> R&D expenses are calculated as the sum of employee benefit expenses and other operating expenses related to scientific research and technological

<sup>(7)</sup> SG&A calculated as the amount of employee benefit expenses plus other operating expenses plus work carried out by the Group on non-current assets minus research & development expenses.
(8) EBITDA calculated as profit before interest, taxes, depreciation and amortization.
(9) EBIT calculated as profit before taxes and interest.

<sup>(11)</sup> 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.

# **FINANCIAL POSITION**

### **Balance Sheet**

| IN € MILLIONS                | September<br>30, 2024 | December<br>31, 2023 | Growth                   | % Growth |
|------------------------------|-----------------------|----------------------|--------------------------|----------|
| Assets                       |                       |                      |                          |          |
| Non-current assets           | 324.0                 | 290.6                | 33.5                     | 12%      |
| Current assets               | 553.8                 | 509.3                | 44.5                     | 9%       |
| Total assets                 | 877.8                 | 799.9                | 78.0                     | 10%      |
| Equity                       | 558.2                 | 543.5                | 14.7                     | 3%       |
| Liabilities                  | 330.2                 | 3-3.3                | 1-7.7                    |          |
| Non-current liabilities      | 98.2                  | 56.5                 | 41.6                     | 74%      |
| Financial debt               | 94.3                  | 52.2                 | 42.0                     | 80%      |
| Current liabilities          | 221.5                 | 199.8                | 21.646                   | 11%      |
| Financial debt               | 34.0                  | 13.2                 | 20.8                     | 158%     |
| Total liabilities            | 319.7                 | 256.39               | 63.27                    | 25%      |
| Total equity and liabilities | 877.8                 | 799.884              | 77.9639<br>999999<br>999 | 10%      |

## **TOTAL ASSETS**

ROVI's **total assets** increased by 10%, from 799.9 million euros as of December 31, 2023 to 877.8 million euros as of September 30, 2024, mainly because of (i) an increase of 42.2 million euros in "Trade and other receivables", as a result of higher invoices pending to be paid by Moderna; (ii) an increase of 19.0 million euros in "Investments in joint ventures and associates", mainly related to the cash contribution of 18.8 million euros that ROVI will be making to Terafront Farmatech, which has not yet been charged to profit and loss, and (iii) an increase of 15.9 million euros in "Property, Plant and Equipment" mainly due to the investments made in the CDMO business.

# **EQUITY**

ROVI's **equity** increased by 14.7 million euros to 558.2 million euros as of September 30, 2024. This increase resulted from the "Profit for the period".

### **TOTAL LIABILITIES**

ROVI's total **liabilities** increased by 25% from 256.4 million euros as of December 31, 2023 to 319.7 million euros as of September 30, 2024, mainly due to an increase of 62.8 million euros in the "Financial debt" item. This increase was partially offset by a decrease of 17.6 million euros in the "Trade and other payables" item.

As of September 30, 2024, ROVI **total debt** increased to 128.3 million euros. Debt with public administration, which is 0% interest rate debt, represented 8% of total debt as of September 30, 2024.

### **Total Debt**

| N. 0.T. 10.110.110.0             | September 30, |        |               |
|----------------------------------|---------------|--------|---------------|
| IN € THOUSANDS                   | 2024          | 2023   | Interest rate |
| Bank borrowings                  | 101,711       | 37,745 | 0.68-4.56     |
| Debt with public administration  | 10,483        | 8,890  | 0             |
| Financial liabilities for leases | 16,081        | 18,792 | -             |
| Total                            | 128,275       | 65,427 |               |

As of September 30, 2024, bank borrowings increased by 64.0 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 September 30, 2024, 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 4.556% in October 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 2.9 million euros. Likewise, repayment of the fixed interest loan started in February 2023 (quarterly repayments) and its current outstanding balance is 30 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 had granted it a new credit line –in addition to the previous one– to support its investments in research, development and innovation. This credit line was for 50 million euros with a ten-year repayment period and included a three-year grace period, with a drawdown period of two years. At 30 September 2024, ROVI had drawn down 10 million euros of this credit at a variable rate of Euribor 3 months + 0.655% (the latest interest rate paid being 4.343% in October 2024). No further sums will be drawn against this credit line since the two-year period for drawing additional amounts ended in July this year.

Additionally, ROVI has signed three credit policies: one in September 2023 for 20 million euros and another in March 2024 for 20 million euros, both with conditions of Euribor 3 months + 0.50%. In June 2024, a third policy was signed, also for 20 million euros, at Euribor 3 months + 0.65%, as well as two loans of 25 million euros each at fixed rates of 3% and 3.49%, respectively. As of 30 September 2024, ROVI had drawn down 11 million euros against the total of all the credit lines.

### **GROSS CASH POSITION AND NET DEBT**

As of September 30, 2024, ROVI had a **gross cash position** of 19.5 million euros, compared to 26.8 million euros as of December 31, 2023, and **net debt** of 108.8 million euros, compared to 38.6 million euros as of December 31, 2023.

# Gross cash position and net debt

| IN € MILLIONS             | Sept 30, 2024 | Dec 31, 2023 |
|---------------------------|---------------|--------------|
| Equity securities         | _             | 0.02         |
| Deposits                  | 1.9           | 1.4          |
| Cash and cash equivalents | 17.6          | 25.3         |
| Gross cash position       | 19.5          | 26.8         |
| Financial debt            | (128.3)       | (65.4)       |
| (Net debt)/Net cash       | (108.8)       | (38.6)       |

**Net cash generated in operating activities** amounted to 65.2 million euros in the first nine months of 2024, compared to 52.2 million euros in the same period of 2023. Net cash generated from operating activities excluding changes in working capital increased 8% to 129.3 million euros in the first nine months of 2024 from 119.7 million euros in the same period of 2023.

### Million euros



(1) Net cash/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                       | 9M 2024 | 9M 2023 | Growth | % Growth |
|-------------------------------------|---------|---------|--------|----------|
| Cash flow from operating activities | 65.2    | 52.2    | 12.9   | 25%      |
| Cash flow from investing activities | (33.9)  | (25.7)  | (8.1)  | 32%      |
| Cash flow from financing activities | (39.0)  | (95.0)  | 56.0   | -59%     |
| Net increase/ (decrease) in cash    | (7.8)   | (68.6)  | 60.8   | -89%     |
| Cash at the beginning of the period | 25.3    | 124.9   | (99.6) | -80%     |
| Cash at the end of the period       | 17.6    | 56.4    | (38.8) | -69%     |

### **CASH FLOW FROM OPERATING ACTIVITIES**

**Cash flow from operating activities** increased to 65.2 million euros in the first nine months 2024 from 52.2 million euros in the same period of 2023. This increase was mainly due to:

- the decrease of 4.3 million euros in the "Inventory" item in the first nine months of 2024 compared to a decrease of 53.3 million euros in the same period of 2023;
- the decrease of 36.4 million euros in the "Trade and other payables" item in the first nine months of 2024, compared to a decrease of 52.1 million euros in the same period of 2023; and
- the booking of (24.4) million euros under the "Cash flow from contract manufacturing services" caption in the first nine months of 2024 mainly due to the allocation of more revenue to the income statement than payments received, compared to the (39.4) million euros recognized in the same period of 2023.

These positive impacts were partially offset by:

- the decrease of 8.7 million euros in "Profit before income tax"; and
- the decrease of 22.1 million euros in the "Trade and other receivables" item in the first nine months of 2024, compared to an increase of 41.7 million euros in the same period of 2023.

# **CASH FLOW FROM INVESTING ACTIVITIES**

ROVI invested 33.8 million euros in the first nine months of 2024, compared to 26.8 million euros in the same period of 2023.

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

| IN € MILLIONS                              | 9M 2024 | 9M 2023 | Growth | % Growth    |
|--|---------|---------|--------|-------------|
| Madrid Injectable plant                    | 0.7     | 1.0     | (0.2)  | -26%        |
| San Sebastián de los Reyes plant           | 1.9     | 0.7     | 1.3    | 189%        |
| Granada plant                              | 0.5     | 0.6     | (O.1)  | -21%        |
| Alcalá de Henares plant                    | 1.2     | 1.4     | (O.1)  | -10%        |
| Escúzar plant <sup>(1)</sup>               | 0.6     | 5.0     | (4.3)  | -87%        |
| Expenditure on maintenance and other capex | 1.4     | 1.2     | 0.2    | 13%         |
| Maintenance Capex                          | 6.4     | 9.8     | (3.4)  | -35%        |
| ISM industrialisation                      | 2.2     | 4.0     | (1.8)  | -44%        |
| Glicopepton                                | 4.7     | 0.6     | 4.1    | n.a         |
| New filling lines and operations expansion | 20.5    | 12.4    | 8.1    | 65%         |
| Investment Capex                           | 27.4    | 17.0    | 10.5   | <b>62</b> % |
| Total Capex                                | 33.8    | 26.8    | 7.0    | 26%         |

<sup>(1)</sup> In the press release of the first nine months of 2023, this figure was reported as Investment Capex.

# **FREE CASH FLOW**

**Free cash flow** increased to 31.4 million euros in the first nine months of 2024 from 27.0 million euros in the same period of 2023.

# Free cash flow

| IN € MILLIONS  | 9M 2024 | 9M 2023 |
|--|---------|---------|
| Net cash generated from (used in) operating activities | 65.2    | 52.2    |
| Purchases of intangible assets                         | (1.1)   | (0.5)   |
| Purchases of property, plant and equipment             | (32.8)  | (26.2)  |
| Proceeds from sale of property, plant and equipment    | 0.02    | 0.2     |
| Interest received                                      | 0.1     | 1.3     |
| Free cash flow   | 31.4    | 27.0    |

#### **CASH FLOW FROM FINANCING ACTIVITIES**

Cash flow from financing activities was (39.0) million euros in the first nine months of 2024 versus (95.0) million euros in the same period of 2023. This increase was mainly attributable to (i) an increase in "Proceeds from financial debt" of 84.7 million euros in the first nine months of 2024 in comparison to 0.7 million euros in the same period of 2023, and a (ii) a decrease in "Dividends paid" of (56.5) million euros in the first nine months of 2024 in comparison to (69.0) million euros in the same period of 2023. This increase was partially offset by (i) an increase in "Reissue of treasury shares" of 22.9 million euros in the first nine months of 2024 in comparison to 52.6 million euros in the same period of 2023, and (ii) a decrease in "Repayments of financial debt" of (23.8) million euros in the first nine months of 2024 in comparison to (9.9) million euros in the same period of 2023.



López-Belmote Javier Encina. Deputy Chairman and Chief Financial Officer of ROVI, said: "since the pandemic, we have been in a transition period, in which value is being created for the future. In this context, in the first nine months of the year, operating revenue was 564.6 million euros, we increased the gross margin by 4.7 percentage points to 63.6%, due to the performance of the CDMO business and the higher contribution to sales of Risperidone ISM®. Likewise, we expect an additional improvement in said margin from 2025 onwards as a result of the drop in the raw material prices for lowmolecular-weight heparins. In relation to "Other operating expenses (excl. R&D)", they increased due to the launch of Okedi® in Europe and the expenses related to the strategic assessment. However, if we exclude these expenses,

"Other operating expenses (excl. R&D and strategic assessment)" slightly increased to 80.7 million euros as the result of an efficient cost-containment policy, allowing the Company to maintain the EBITDA at the same level as in the first nine months of 2023. We remain committed to our shareholders. In September this year, after completion of the Share Buy-Back Programme in June in the terms set out therein, we reduced the company's share capital in order to contribute to the remuneration of ROVI's shareholders by increasing the earnings per share. Likewise, the company's commitment to innovation was reflected in the figures for the first nine months of 2024. We are in a new growth phase and hope that the strength of our balance sheet will allow us to take further opportunities to expand our sales and increase the return on our asset".

# **OUTLOOK**

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

For 2025, ROVI expects its operating revenue to **decrease by a mid-single-digit percentage** in comparison with 2024. Notwithstanding, this guidance is calculated using certain factors that could be relevant to the estimates and that are difficult to specify at the present time. They include, among others, the following:

- 1. First, the 2024 vaccination campaigns, for flu and COVID-19, are still in progress and, as of today's date, the Company is unable to forecast how the demand and production might evolve for the vaccination campaigns that will take place in 2025.
- 2. Second, it is hoped that the expansion of the compounding, aseptic filling, inspection, labelling and packaging capacities at the ROVI facilities in Madrid and the current high market demand for contract manufacturing services (CDMO) will favour obtaining new customers, with the resulting sales impact. This would have to be considered but is impossible to estimate at this time.

# **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 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 21 March 2024, ROVI received authorisation from Health Canada for the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults throughout Canada. ROVI has likewise obtained approval in Australia.

On 29 March 2024, ROVI reported that the United States Food and Drug Administration (FDA) had authorised the marketing of Risvan® (Risperidone ISM® for the treatment of schizophrenia in adults in the United States. Additionally, as a postmarketing requirement, the FDA required that a pharmacokinetic study be conducted to evaluate exposure to Risvan® similar to the daily administration of 6mg of oral risperidone. It was planned to review and agree the protocol for the clinical study previously with the FDA and that the final report on the study would be submitted by July 2026, although this additional study would not affect the approval or marketing of the product.

However, ROVI has decided not to market Risvan® (Risperidone ISM®) in the United States after assessing the uncertainties and opportunities associated to this launch. The main factors that have contributed to this decision are:

- The prioritisation of the Company's investments in the CDMO business and the clinical development of a new quarterly formulation of Letrozole (hereinafter, Letrozole LEBE).
- The absence of a partner that furnishes the Company with the capacities and structure necessary to ensure adequate continuous distribution of Risvan® in the United States market, in order to thus maximise the benefits of this innovative prolonged-release, long-acting injectable drug therapy for the patients and take advantage of all the potential for expansion and commercial development that the schizophrenia field offers.
- The delay in the launch, which coincides with a forecast price reduction in the area of long-acting injectables (LAIs) for the treatment of schizophrenia in the United States and potential amendments to United States legislation or policy regarding the pharmaceutical industry, jeopardising the expected profitability of Risvan®.
- The United States market lacks regulatory differentiation or specification on the technical data sheet of prolonged-release, long-acting injectables that share the indication "Treatment of schizophrenia in adult patients", which does not favour the positioning of Risvan® in a market with strong competitors. To this, it would be necessary to add the time and cost of the pharmacokinetic studies required to evaluate exposure to Risvan® similar to the daily administration of 6mg of oral risperidone.

ROVI has, therefore, chosen to focus on the European development of Okedi®, where there are less uncertainties, and expects this product to reach potential global sales of between 100 and 200 million euros in upcoming years.

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 decided to commence the clinical development of a new three-monthly formulation of Letrozole (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**

# **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 it is aligned as a member of the Global Compact.

The Group focuses its action on five priority areas:

- · Reinforcing its governance committed to sustainability.
- Committing to sustainable development in the face of the global environmental challenges: combatting climate change, promoting a circular economy and efficient water management.
- Advancing and promoting care of people and the integration of diverse and specialised talent.
- Driving responsible management of the supply chain by promoting ethical and environmental standards in its different 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.

# **KEY OPERATING AND FINANCIAL EVENTS**

# **ROVI completes the strategic review of its CDMO business**

ROVI informed the market (by publication of the inside information number 2415 dated 24 October 2024) on the assessment it had made in the last few months of strategic alternatives for its assets, including a potential corporate transaction of ROVI relating to its third party contract development and manufacturing business ("CDMO") that after

the assessment and analysis of the non-binding offers received by investment funds and industrial companies, ROVI's Board of Directors concluded that, given the strength, momentum and prospects of this business, the best way to maximize value for shareholders at this time is to continue executing on the Company's standalone strategic plan, with the interest of the CDMO business best served and developed under the current ROVI group structure, with no entry of third party investors.

Over the past five years, ROVI has invested substantial capital to build global leadership in sterile fill & finish (F&F) capacity and technology services. With these recent investments, and with current expansions underway, ROVI expects to significantly increase its current sterile capacity at its FDA and EMA / EU GMP Annex-1 compliant facilities in Spain. This will allow ROVI to continue to capitalize on the imbalance between the available capacity and the rising demand across the sterile fill & finish market, building on recent momentum with the addition of a high-volume product from a global pharmaceutical customer and the good drive in commercial activity and alliance opportunities across strategic high-growth modalities – including innovative biologics, biosimilars, vaccines and novel modalities for pre-filled syringes and cartridges.

"The Board of Directors appreciates all of the hard work put into the strategic review process by the Company and its advisors. I am pleased with the process that was undertaken, which has ultimately made us conclude that the CDMO business will drive the highest shareholder value within the current ROVI Group structure" said Mr. Juan López-Belmonte Encina, Chairman and CEO of ROVI. "We remain excited about the near- and long-term potential of our globally leading CDMO business to became a world leader, given the attractive market dynamics and the pride we take in supporting the manufacture of medicines that are able to prolong the life of millions of people" added Mr. Javier López-Belmonte Encina, Vice President and CFO of ROVI.

# **ROVI's 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 Buy-back 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 was 25% of the average daily volume of ROVI's shares on the trading venue on which the purchase carried out during the twenty trading days prior to the date of the purchase.

On 11 June 2024, ROVI concluded the Buy-Back programme, having acquired 2,233,466 shares for an amount of 130 million euros, representing approximately 4.13% of the share capital.

As announced when the Buy-Back Programme commenced, the purpose of the Programme was to cancel shares of ROVI through a reduction of capital while, at the same time, contributing to ROVI's shareholder remuneration by increasing the earnings per share. The capital was reduced by cancelling 2,780,395 shares. These shares corresponded to (i) the shares repurchased within the framework of the aforementioned Buy-Back Programme, and (ii) part of the existing treasury shares, which totalled 546,929. The capital reduction was approved at the Ordinary General Shareholders' Meeting held on 24 June 2024 and executed by entering the pertinent deed of capital reduction into public record. The new amount of the share capital, after the shares mentioned had been cancelled and excluded from trading, has now been recorded at the registers of the National Securities Market Commission and Iberclear.

In addition, after completion of the Buy-back Programme, ROVI informed of the resumption, as of 12 June 2024, of transactions under the liquidity contract signed between the Company and Bestinver, S.V., S.A. for management of the Company's treasury shares, of which the market was informed on 5 April 2022 in the pertinent announcement of other relevant information (register number 15427). When the Buy-Back Programme commenced, the liquidity contract was suspended for the duration of the Programme, in accordance with CNMV Circular 1/2017 of 26 April, Provision Five, 2.c). Likewise, the Company and Bestinver, S.V., S.A. decided to modify the balances of securities and cash associated to the Liquidity Contract in the terms reported to the market as other relevant information on 31 July 2024 (with number 30064).

On 12 September 2024, ROVI informed (by publication of the other relevant information number 30484) that the 2,780,395 cancelled shares had been delisted from the Stock-Exchange Interconnection System (*Sistema de Interconexión Bursátil*) and the Madrid, Barcelona, Bilbao and Valencia Stock Exchanges effective 13 September 2024. As a result, the share capital of the Company is now EUR 3,074,145.72, divided into 51,235,762 ordinary shares, with a nominal value of EUR 0.06 each, which grant a total of 51,235,762 voting rights (one per share). By redeeming these shares, the shareholders automatically increased their percentage interest in the share capital.

# ROVI announces agreement to manufacture pre-filled syringes

ROVI informed (by publication of the inside information number 2207 dated 25<sup>th</sup> April 2024) that its subsidiary, ROVI's wholly owned CDMO platform, ROVI Pharma Industrial Services, S.A.U. (hereinafter "ROIS") had entered into an agreement to support the manufacture of pre-filled syringes for a global pharmaceutical company.

Under the terms of the agreement, ROIS will provide a high-speed production line at the ROIS' San Sebastián de los Reyes facility in Madrid, with an estimated annual capacity of 100 million units. The agreement includes the technology transfer for aseptic filling and has a commercial production term of five years subject to the terms of the agreement, beginning on the date of manufacture of the first commercial lot. After the technology transfer and regulatory approval, commercial production is expected to commence in 2026. As from 2027, which is expected to be the first full recurrent manufacturing year, the ROVI's Group CDMO division expects to have a positive revenues increase impact ranging between 20% and 45% over 2023 sales.

ROIS is well-equipped to support the production of pre-filled syringes given its deep expertise in the current good manufacturing practice (cGMP) production of sterile injectable products across both vials and pre-filled syringes.

Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI, said: "We are delighted to be able to support in the manufacture of medicine that is able to prolong the life of millions of people. Our proven experience in the manufacture of high-valued-added injectables and the expansion of our production capacities have positioned us to help meet the rapidly growing demand, which requires a high degree of technological capability."

# ROVI receives the FDA's approval of Risvan® as a treatment for schizophrenia

ROVI informed (by publication of the other relevant information number 27772 dated 2<sup>nd</sup> April 2024) that the U.S. Food and Drug Administration (FDA) had authorised the marketing of Risvan® (Risperidone ISM®) for the treatment of schizophrenia in adults.

Risperidone ISM® is a prolonged-release injectable antipsychotic developed and patented by ROVI for the treatment of schizophrenia in adults, which, as of the first injection, provides immediate and sustained plasmatic drug levels and does not require loading doses or supplementation with oral risperidone.

This approval is based on the positive results of the pivotal PRISMA-3 study on the efficacy and safety of Risperidone ISM® in schizophrenia patients<sup>(4)</sup>. The results obtained in this study show that the two different doses (75 mg and 100 mg once a month) have achieved the prespecified primary and secondary efficacy endpoints for treatment of patients with moderate to severe symptoms of schizophrenia. The primary efficacy

<sup>4</sup> Correll, C.U., Litman, R.E., Filts, Y. et al. Efficacy and safety of once-monthly Risperidone ISM® in schizophrenic patients with an acute exacerbation. npj Schizophr 6, 37 (2020). https://doi.org/10.1038/s41537-020-00127-y

endpoint, the PANSS<sup>(5)</sup> total score (mean difference, CI: 95%), improved significantly with Risperidone ISM® 75 mg and 100 mg from the beginning until day 85, with adjusted differences of -13.0 (17.3 to -8-8; p <0.0001) and -13.3 (-17.6 to -8.9; p<0.0001), respectively. in comparison with the placebo. Significantly improved mean changes for the secondary endpoint, the CGI-S<sup>(6)</sup> score, were also obtained for Risperidone ISM® in comparison with the placebo, -0.7 (-1.0 to -0.5; p<0.0001), for both doses, from the beginning until day 85. The significant statistical improvement for both efficacy results was observed as early as 8 days after the first injection. The most frequently reported treatment-emergent adverse events were increased blood prolactin (7.8%), headaches (7.3%), hyperprolactinemia (5%) and weight increase (4.8%). No important new or unexpected safety information was reported. Likewise, patients who successfully completed the double-blind period were offered the opportunity to continue in a longterm, open-label 12-month extension phase with once every four weeks injections of Risperidone ISM® (75 mg or 100 mg). New, clinically stable patients ("de novo" patients) were also able to enter this open phase of the study. Long-term treatment was observed to be effective, safe and well tolerated in adult patients with schizophrenia. regardless the initial severity of the disease or whether they had been treated previously with Risperidone ISM® during an acute exacerbation or switched from stable doses of oral risperidone<sup>(7)</sup>. Likewise, Risperidone ISM® provided a swift and sustained improvement in functioning (both social and personal) and health-related quality of life. These findings, together with a quick onset of effectiveness, could help strengthen the therapeutic alliance and possibly lead to an earlier hospital discharge. Furthermore, the patient's functioning either continued to improve or remained stable with long-term treatment<sup>(8)</sup>.

Notwithstanding, as mentioned above, ROVI has decided not to market Risvan® (Risperidone ISM®) in the United States after assessing the uncertainties and opportunities associated to this launch. The main factors that contributed to this decision were:

- The prioritisation of the Company's investments in the CDMO business and the clinical development of a new quarterly formulation of Letrozole (Letrozole LEBE).
- The absence of a partner that furnishes the Company with the capacities and structure necessary to ensure adequate continuous distribution of Risvan® in the United States market, in order to thus maximise the benefits of this innovative prolonged-release, long-acting injectable drug therapy for the patients and take advantage of all the potential for expansion and commercial development that the schizophrenia field offers.

<sup>5</sup> Positive and Negative Syndrome Scale: the Positive and Negative Syndrome Scale is a medical scale based on a semi-structured interview that rates the severity of the symptoms of schizophrenia patients in three domains: positive symptoms, negative symptoms and general psychopathology symptoms.

<sup>6</sup> Clinical Global Impression-Severity scale: la escala de Impresión Clínica Global–Gravedad rates the severity of schizophrenia through a question put to the doctor: "Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?".

<sup>7</sup> Filts Y, Litman RE, Martínez J, Anta L, Naber D, Correll CU. Long-term efficacy and safety of once-monthly Risperidone ISM® in the treatment of schizophrenia: Results from a 12-month open-label extension study. Schizophr Res. 2021 Nov 27;239:83-91.

<sup>8</sup> Litman R, Naber D, Anta L, Martínez J, Filts Y, Correll CU. Personal and Social Functioning and Health-Related Quality of Life in patients with Schizophrenia Treated with the Long-Acting Injectable Antipsychotic Risperidone ISM. Neuropsychiatr Dis Treat. 2023 Jan 25;19:219-232.

- The delay in the launch, which coincides with a forecast price reduction in the area of long-acting injectables (LAIs) for the treatment of schizophrenia in the United States and potential amendments to United States legislation or policy regarding the pharmaceutical industry, jeopardising the expected profitability of Risvan®.
- The United States market lacks regulatory differentiation or specification on the technical data sheet of prolonged-release, long-acting injectables that share the indication "Treatment of schizophrenia in adult patients", which does not favour the positioning of Risvan® in a market with strong competitors. To this, it would be necessary to add the time and cost of the pharmacokinetic studies required to evaluate exposure to Risvan® similar to the daily administration of 6mg of oral risperidone.

ROVI has, therefore, chosen to focus on the European development of Okedi®, where there are less uncertainties, and expects this product to reach potential global sales of between 100 and 200 million euros in upcoming years.

# ROVI, Insud Pharma and Innvierte (CDTI) create a company for the research and development of advanced therapies

ROVI informed (by publication of the other relevant information number 27397 dated 12<sup>th</sup> March 2024) of the agreement that has been concluded with Insud Pharma S.L. and Innvierte Economía Sostenible SICC, SME, S.A. (investment company of Centro para el Desarrollo Tecnológico Industrial EPE – CDTI) to incorporate, together with these two entities, a limited company (Sociedad de responsabilidad limitada) engaged in the research and development of advanced therapies.

This agreement, which was approved at the meeting of the Council of Ministers held on 12 March 2024, falls within the framework of the Vanguard Health Strategic Project for Economic Recovery and Transformation (PERTE), promoted by the Spanish Government. This PERTE concerns the creation of a public-private investment vehicle to develop advanced, innovative and/or emerging medicines, therapies and/or technologies. The goal is to favour the deployment of the technical and industrial capacities necessary to generate a high performance healthcare system intended to protect health by providing an immediate and flexible response to healthcare challenges and favouring sustainability.

The share capital of this new entity will be 49% held by the Ministry of Science, Innovation and Universities through the company Innvierte, while Insud Pharma and ROVI will hold 25.5% each. The shareholders undertake to make an initial combined contribution of 74,867,346.94 euros. The investment will be made in accordance with the needs of the projects defined in the future and will be subject to the shareholders' approval of the relevant business plan. Such investment could reach 220 million euros, which would be contributed by the public and private investors that are participating.

It is planned that Innvierte's contributions could be made with European "Next Generation EU" funds, which include the EU Recovery and Resilience Facility established in Regulation (EU) 2921/241 of the European Parliament and of the Council of 12 February 2021.

Juan López-Belmonte, Chairman and CEO of ROVI, highlights the fact that this agreement "represents an opportunity to help place Spain in a leading position in the clinical research of new therapies, with the capacity to translate this research into manufacturing and thus improve the availability of new therapies to patients. At ROVI, we are delighted to place our knowledge and experience at the service of this great public-private alliance that reinforces our commitment to innovation".

# **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 <a href="https://www.rovi.es.">www.rovi.es.</a>

# For further enquiries, please contact:

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

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

Marta Campos Martínez Head of Finance +34 912444422 mcampos@rovi.es

www.rovi.es

Beatriz de Zavala Mazarredo Investor Relations Analyst +34 610 737 703 bdezavala@rovi.es

www.rovi.es

Victoria López-Belmonte Investor Relations Analyst +34 680 669 485 <u>vlopez-belmonte@rovi.es</u> 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.

# **APPENDIX 1**

# LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF SEPTEMBER 30, 2024 AND DECEMBER 31, 2023

| IN € THOUSANDS*                                       | September 30, 2024 | Dec 31, 2023 |
|---|--------------------|--------------|
| ASSETS  |                    |              |
| Non-current assets                                    |                    |              |
| Property Plant and Equipment                          | 269,597            | 253,652      |
| Intangible assets                                     | 32,663             | 33,902       |
| Investment in joint ventures and associated companies | 19,579             | 567          |
| Deferred income tax assets                            | 2,115              | 2,343        |
| Equity securities                                     | _                  | 24           |
| Financial receivables                                 | 65                 | 65           |
|   | 324,019            | 290,553      |
|   |                    |              |
| Current assets  |                    |              |
| Inventories   | 346,662            | 337,968      |
| Trade and other receivables                           | 185,509            | 143,314      |
| Prepaid expenses                                      | 4,104              | 2,727        |
| Cash and cash equivalents                             | 17,554             | 25,322       |
|   | 553,829            | 509,331      |
| Total assets  | 877,848            | 799,884      |

<sup>\*</sup> The figures as of September 30, 2024 have not been audited. However, figures as of December 31, 2023 are audited figures.

# LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS AS OF SEPTEMBER 30, 2024 AND DECEMBER 31, 2023

| IN € THOUSANDS*  | September 30, 2024 | Dec 31, 2023 |
|--|--------------------|--------------|
| EQUITY   |                    |              |
| Capital and reserves attributed to shareholders of the company | 548,680            | 539,387      |
| Share capital  | 3,074              | 3,241        |
| Share premium  | 87,636             | 87,636       |
| Legal reserve  | 673                | 673          |
| Treasury shares  | (6,477)            | (107,676)    |
| Retained earnings and voluntary reserves                       | 350,307            | 385,199      |
| Profit for the period  | 113,492            | 170,335      |
| Other reserves   | (25)               | (21)         |
| Non-controlling interests                                      | 9,508              | 4,107        |
| Total equity   | 558,188            | 543,494      |
|  |                    |              |
| LIABILITIES  |                    |              |
| Non-current liabilities  |                    |              |
| Financial debt   | 94,278             | 52,242       |
| Deferred income tax liabilities                                | 860                | 1,515        |
| Contract liabilities   | 2,000              | 1,431        |
| Deferred income  | 1,033              | 1,359        |
|  | 98,171             | 56,547       |
| Current liabilities  |                    |              |
| Financial debt   | 33,997             | 13,185       |
| Trade and other payables                                       | 124,270            | 141,895      |
| Current tax liabilities  | 27,779             | 5,255        |
| Contract liabilities   | 34,997             | 39,044       |
| Deferred income  | 446                | 464          |
|  | 221,489            | 199,843      |
| Total liabilities  | 319,660            | 256,390      |
| Total equity and liabilities                                   | 877,848            | 799,884      |

<sup>\*</sup> The figures as of September 30, 2024 have not been audited. However, figures as of December 31, 2023 are audited figures.

# LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING SEPTEMBER 30, 2024 AND SEPTEMBER 30, 2023

| IN € THOUSANDS*  | 9M 2024     | 9M 2023   |
|--|-------------|-----------|
| Revenue  | 564,612     | 594,873   |
| Changes in inventories of finished goods and work in progress                  | 75,499      | 79,449    |
| Raw materials and consumables used   | (281,410)   | (323,974) |
| Employee benefit expenses  | (98,087)    | (90,525)  |
| Other operating expenses   | (94,287)    | (92,140)  |
| Work carried out by the Group on non-current assets                            | 597         | 3,372     |
| Amortisation and depreciation  | (20,588)    | (17,818)  |
| Recognition of government grants on non-financial non-current assets and other | 341         | 272       |
| Share of profit in joint ventures and associated companies                     | (79)        | (101)     |
| OPERATING PROFIT (EBIT)  | 146,598     | 153,408   |
| Finance income   | 227         | 1,322     |
| Finance costs  | (1,620)     | (607)     |
| Impairment and gain or loss on measurement of financial instruments            | 54          | 128       |
| Exchange difference  | 238         | (74)      |
| FINANCE INCOME/(COSTS) - NET   | (1,101)     | 769       |
| PROFIT BEFORE INCOME TAX   | 145,497     | 154,177   |
| Income tax   | (32,014)    | (35,357)  |
| PROFIT FOR THE PERIOD  | 113,483     | 118,820   |
|  |             |           |
| Profit for the period attributable to parent                                   | 113,492     | 118,827   |
| company  | , , , , , , |           |

<sup>\*</sup> The figures as of September 30, 2024 and September 30, 2023 have not been audited.

# LABORATORIOS FARMACÉUTICOS ROVI, S.A. AND SUBSIDIARIES CONSOLIDATED CASH FLOW STATEMENTS FOR THE NINE-MONTH PERIODS ENDING SEPTEMBER 30, 2024 AND SEPTEMBER 30, 2023

| IN € THOUSANDS*  | 9M 2024  | 9M 2023   |
|--|----------|-----------|
| Cash flows from operating activities                               |          |           |
| Profit before income tax   | 145,497  | 154,177   |
| Adjustments for non-monetary transactions:                         |          |           |
| Amortisation and depreciation                                      | 20,588   | 17,818    |
| Finance income   | (227)    | (1,322)   |
| Loss allowance   | (4,510)  | (285)     |
| Adjustments for changes in value of derivatives                    | —        | (25)      |
| Gain or loss on derecognition of financial assets and liabilities  | (54)     | (103)     |
| Finance expenses   | 1,620    | 607       |
| Exchange rate differences  | (238)    | 74        |
| Grants, distribution licenses and other deferred income            | (617)    | (503)     |
| Share of profit/(loss) of joint ventures and associated companies  | 79       | 101       |
| Changes in working capital:  |          |           |
| Trade and other receivables  | (22,085) | 41,715    |
| Inventories  | (4,289)  | (53,252)  |
| Other current assets (prepaid expenses)                            | (1,377)  | (3,849)   |
| Trade and other payables   | (36,432) | (52,135)  |
| Other collections and payments:                                    |          |           |
| Cash flow from contract manufacturing services                     | (24,375) | (39,357)  |
| Proceeds from distribution licenses                                | 793      | 195       |
| Income tax cash flow   | (9,217)  | (11,635)  |
| Net cash generated from (used in) operating activities             | 65,156   | 52,221    |
| Cash flows from investing activities                               |          |           |
| Acquisition of intangible assets                                   | (1,050)  | (543)     |
| Acquisition of property, plant and equipment (not including rights | /70 PPP\ | (20.27.0) |
| of use)  | (32,777) | (26,248)  |
| Proceeds from sale of property, plant and equipment                | 16       | 249       |
| Purchases of other financial assets                                | _        | 78        |
| Proceeds from sale of financial assets                             | 80       | 10        |
| Investments in joint ventures and associated companies             | (255)    | (600)     |
| Interest received  | 102      | 1,307     |
| Net cash generated from (used in) investing activities             | (33,884) | (25,747)  |
| Cash flows from financing activities                               |          |           |
| Repayments of financial debt                                       | (23,812) | (9,854)   |
| Proceeds from financial debt                                       | 84,687   | 663       |
| Interest paid  | (1,130)  | (286)     |
| Purchase of treasury shares  | (70,672) | (70,936)  |
| Reissue of treasury shares   | 22,928   | 52,643    |
| Dividends paid   | (56,451) | (69,049)  |
| Capital contribution in subsidiaries                               | 5,410    | 1,777     |
| Net cash generated from (used in) financing activities             | (39,040) | (95,042)  |
| Net (decrease) increase in cash and cash equivalents               | (7,768)  | (68,568)  |
| Cash & cash equivalents at beginning of the period                 | 25,322   | 124,945   |
| Cash and cash equivalents at end of the period                     | 17,554   | 56,377    |

 $<sup>{\</sup>it *The figures as of September 30, 2024 and September 30, 2023 have not been audited.}$ 

# **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 ROVI's 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.

ROVI uses these APMs and non-IFRS financial indicators to plan, oversee and assess its performance. ROVI considers 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 ROVI's 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 by ROVI, 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).

### Research & Development ("R&D") Expenses

R&D expenses reflect expenses related to scientific research and technological development carried out by ROVI.

R&D expenses are calculated as the sum of employee benefits expenses and other operating expenses related to scientific research and technological development.

# SG&A Expenses

Selling, General & Administrative (SG&A) Expenses is an indicator that measures expenses related to the general internal operations and management of the company.

SG&A calculated as the amount of employee benefit expenses plus other operating expenses plus work carried out by the Group on non-current assets" minus research & development expenses.

#### 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: R&D expenses 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 cash

Net cash, also measured as 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).