FINANCIAL RESULTS

for the nine-month period ending 30th September of

2023

08/11/2023



Laboratorios Farmacéuticos Rovi, S.A. and Subsidiaries - Investor Relations

KEY FIGURES

Summary

IN € MILLIONS	9M 2023	9M 2022	Growth	% Growth
Operating revenue(1)	594.9	575.5	19.4	3%
Gross profit(2)	350.6	344.4	6.2	2%
EBITDA(3)	171.2	173.9	(2.6)	-2%
EBIT(4)	153.4	156.8	(3.4)	-2%
Net profit(5)	118.8	121.5	(2.7)	-2%
Purchases of property, plant and equipment and intangible assets ("Capex")	26.8	18.5	8.3	45%
FCF(6)	27.0	151.7	(124.7)	-82%
Gross profit as % of operating revenue	58.9%	59.9%		-0.9 p.p
EBITDA as % of operating revenue	28.8%	30.2%		-1.4 p.p
EBIT as % of operating revenue	25.8%	27.3%		-1.5 p.p
Net profit as % of operating revenue	20.0%	21.1%		-1.1 p.p
Capex as % of operating revenue	4.5%	3.2%		1.3 p.p
FCF as % of operating revenue	4.5%	26.4%		-21.8 p.p

	As of Sep 30, 2023	As of Dec 31, 2022	Growth	% Growth
Net debt (€m)(7)	5.8	(54.2)	60.0	-111%

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

(1) Operating revenue refers to revenue.

(2) Cross profit calculated as revenue plus the recognition of government grants on non-financial non-current assets and other less change in inventories of finished goods and work in progress and raw materials and consumables used.

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

- (4) EBIT calculated as profit before taxes and interest.
- (5) Net profit refers to profit for the period.

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

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

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

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HIGHLIGHTS 9M 2023

ROVI REPORTS OPERATING REVENUE GROWTH OF 3% FOR THE FIRST NINE MONTHS OF THE FIRST POST-PANDEMIC YEAR

- Operating revenue increased 3% to 594.9 million euros in the first nine months of 2023 driven by the CDMO business, which grew 7% to 287.6 million euros, and the stable sales of the specialty pharmaceutical business, which stood at 307.3 million euros.
- In September 2023, the United States Food and Drug Administration (FDA) approved the company's CDMO's¹ plants for injectables in Madrid, San Sebastián de los Reyes and Alcalá de Henares for the fill-and-finish syringe manufacturing of Moderna's COVID-19 mRNA vaccine. ROVI also expects to produce Moderna vaccines for supply in the United States from 2023 onwards.
- Positive evolution of Okedi® (Risperidone ISM®), which reached sales of 9.0 million euros in the first nine months of 2023. Okedi® sales increased by 27% in the third quarter of 2023 compared to the second quarter of the year.
- Sales of the heparin franchise (low molecular weight heparins (LMWH) and other heparins) decreased by 10% to 181.7 million euros in the first nine months of 2023, mostly due to the increase in orders from partners in 2022 related to the treatment for COVID-19, which has led to a lower expected volume of orders from partners in 2023, since they still hold a high level of stocks from 2022.
- Good performance of Neparvis® and Orvatez®, of which sales increased by 17% and 10% respectively, in the first nine months of 2023 compared to the first nine months of 2022, rising to 33.7 million euros and 19.8 million euros respectively.
- Gross profit increased 2% to 350.6 million euros in the first nine months of 2023 compared to the same period of 2022. Gross margin showed a decrease of 0.9 percentage points, from 59.9% in the first nine months of 2022 to 58.9% in the same period of 2023. This drop is mainly due to the higher contribution to the CDMO business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to Group sales. Gross margin increased by 12.6 percentage points in the third quarter of 2023 compared to the second quarter of 2023 and 3.0 percentage points in the third quarter of 2023 versus the third quarter of 2022.
- Net profit decreased by 2% to 118.8 million euros in the first nine months of 2023.
- On 27 July 2023, ROVI reported that the FDA had issued a Complete Response Letter. In this letter, the FDA informed ROVI that satisfactory resolution of the

¹ Contract Development and Manufacturing Organisation

deficiencies from the last inspection was required before the approval of the application and that there were no outstanding questions related to the dossier. On 21 September 2023, ROVI received the Establishment Inspection Report from the FDA with 4 outstanding observations from the FDA inspection of the facility. ROVI provided responses on 29 September 2023 and the FDA has established a new Goal Date of 29 March 2024.

- ROVI takes first place in the Sustainalytics world ESG risk ranking for the second year running. The company has improved its ESG risk rating by almost one point, improving its "Low Risk" rating to 16.4 versus 17.3 in 2022 and remains in first place among the 431 companies rated in the pharmaceutical industry category.
- The ROVI General Shareholders Meeting, on 14 June 2023, approved the payment of a gross dividend of 1,2938 euros per share; which means an increase of 35% compared to the dividend charged to the 2021 profit (€0.9556/ share) and represents approximately a 35% pay out. This dividend was paid on 5 July 2023.



REVENUE BY REGION (%)

REVENUE BY BUSINESS UNIT (€Mn)

OUTLOOK

In November 2022 and February 2023, ROVI announced that it expected the 2023 operating revenue to decrease by a low-teen percentage in comparison with 2022. When the company published its results for the first half of 2023, this guidance was updated to a high-single-digit percentage decrease on 2022. With the visibility that the company has at present, ROVI is again raising its operating revenue guidance for 2023 from a high-single-digit percentage decrease on 2022 to **stable sales**.

It is reasonable to expect the company's results to undergo a downward adjustment in 2023.

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

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

LAUNCHING OF A SHARE BUY-BACK PROGRAMME

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

- 1. **Purpose and scope**: the Buy-back Programme's purpose is to redeem own shares of ROVI (share capital reduction) while, at the same time, boost the remuneration of the ROVI shareholder by increasing the profit per share.
- 2. Term: from 26 July 2023 for a period of 12 months.
- 3. Maximum monetary amount: up to 130,000,000 euros.
- 4. Maximum number of shares to be acquired: 2,700,000 shares of the Company, representing approximately 5% of the Company's share capital on 26 July 2023.

As of 31 October 2023, ROVI had executed approximately 27.67% of the buy-back programme, having acquired 747,049 shares.



Juan López-Belmonte Encina, Chairman and Chief Executive Officer of ROVI. said: "We are verv excited about the launch of Okedi®. a 4weekly Risperidone LAI based on our ISM® technoloav for the treatment of schizophrenia, which took place in Germany, UK and Spain in 2022, and in Portugal and Italy in the first nine months of 2023. This launch consolidates our internationalization strategy as one of our pillars of future growth. Likewise, we are currently undergoing a regulatory process in the United States to obtain the marketing authorization of this product. Additionally, we are currently conducting a phase I clinical trial of the three-monthly formulation of letrozole (Letrozole LEBE). With this clinical programme for Letrozole LEBE, we could reduce the research times in comparison to those for an annual formulation of the

product, thus making it likely that the three-monthly formulation could be marketed several years earlier and, furthermore, the investment necessary to attain the objectives of this project could also be reduced. Also, we made significant progress in our quarterly Risperidone formulation and we are currently carrying out a phase I clinical trial in Europe reflecting our clear commitment to our ISM® technology, which is expected to be the company's growth engine in the future. Since the first COVID-19 vaccines were launched in December 2020, ROVI as a manufacturer of the Moderna vaccine, has been a fundamental pillar in providing a swift, flexible, and effective response to take the COVID-19 vaccine to all corners of the planet. We are making a big investment effort, together with Moderna, to increase current capacities in order to produce many more pharmaceutical units in the future. In the first nine months of the first post-pandemic year, we achieved total revenue of 595.1 million euros, an increase of 3% compared to the same period of 2022. Our CDMO business grew 7% to 287.6 million euros, which offset the 10% decline in the heparin business. The slowdown in sales of our LMHW division in the first nine months of 2023 was due to the increased use of heparins in 2022 during the COVID-19 pandemic. We forecast continued growth in this business thanks to the internationalization of our enoxaparin biosimilar, which is already marketed in 40 countries and we expect it will enable us to be present in more than 90 countries in the long term. We are very excited about the potential of our LMHW franchise and aspire to become a benchmark player in this field worldwide. Likewise, we are investing to become selfsufficient in obtaining crude and sodium heparin in order to be present in all the manufacturing phases of LMWHs. We expect this investment to help us to increase the future margins of the heparin division."

GROUP MANAGEMENT REPORT

for the nine-month period ending September 30th, 2023

INCOME STATEMENT

9M 2023	9M 2022	Growth	% Growth
594.9	575.5	19.4	3%
0.3	1.3	(1.1)	-80%
595.1	576.8	18.3	3%
(244.5)	(232.4)	(12.1)	5%
350.6	344.4	6.2	2%
58.9%	59.9%		-0.9 pp
(16.5)	(16.2)	(0.3)	2%
(162.7)	(154.5)	(8.3)	5%
(0.1)	0.1	(0.2)	n.a.
171.2	173.9	(2.6)	-2%
28.8%	30.2%		-1.4 pp
153.4	156.8	(3.4)	-2%
25.8%	27.3%		-1.5 pp
0.8	1.1	(0.4)	-32%
154.2	158.0	(3.8)	-2%
(35.4)	(36.5)	1.1	-3%
22.9%	23.1%		-0.2 pp
118.8	121.5	(2.7)	-2%
118.8	121.5	(2.7)	-2%
(0.01)	(0.01)	0.00	-22%
	0.3 595.1 (244.5) 350.6 (358.9% (16.5) (162.7) (0.1) (594.9 575.5 0.3 1.3 595.1 576.8 (244.5) (232.4) 350.6 344.4 58.9% 59.9% (16.5) (16.2) (162.7) (154.5) (162.7) (154.5) (0.1) 0.1 171.2 173.9 28.8% 30.2% 153.4 156.8 25.8% 27.3% 0.8 1.1 154.2 158.0 (35.4) (36.5) 22.9% 23.1% 118.8 121.5	594.9 575.5 19.4 0.3 1.3 (1.1) 595.1 576.8 18.3 (244.5) (232.4) (12.1) 350.6 344.4 6.2 58.9% 59.9% (16.2) (16.5) (16.2) (0.3) (162.7) (154.5) (8.3) (162.7) (154.5) (8.3) (0.1) 0.1 (0.2) (162.7) 173.9 (2.6) 28.8% 30.2% (3.4) 28.8% 30.2% (3.4) 25.8% 27.3% (3.4) 25.8% 27.3% (3.4) 154.2 158.0 (3.8) (35.4) (36.5) 1.1 (22.9% 23.1% (2.7) 118.8 121.5 (2.7)

(1) Operating revenue refers to revenue.

(2) Other income includes the recognition of government grants on non-financial non-current assets and other.
(3) Total revenue calculated as revenue plus the recognition of government grants on non-financial non-current assets and other.
(4) Cost of sales calculated as the amount of procurements plus that corresponding to the change in inventories of finished goods and work in

progress and raw materials and consumables use. (5) Gross profit calculated as revenue plus the recognition of government grants on non-financial non-current assets and other less change in inventories of finished goods and work in progress and raw materials and consumables used.

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

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

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

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

REVENUES

Total revenue by business unit

IN € MILLIONS	9M 2023	9M 2022	Growth	% Growth
Specialty pharmaceutical business	307.3	307.6	(0.3)	0%
CDMO business	287.6	267.9	19.7	7%
Operating revenue(1)	594.9	575.5	19.4	3%
Other income(2)	0.3	1.3	(1.1)	-80%
Total revenue(3)	595.1	576.8	18.3	3%

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

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

Operating revenue increased 3% to 594.9 million euros in the first nine months of 2023 driven by the CDMO business which grew 7% to 287.6 million euros, and the stable sales of the specialty pharmaceutical business, which stood at 307.3 million euros. Total revenue rose 3% to 595.1 million euros in the first nine months of 2023.

Sales outside Spain increased by 2% compared to the first nine months of 2022 to 391.1 million euros in the first nine months of 2023, mainly due to the increase in the CDMO business. Sales outside Spain represented 66% of operating revenue in the first nine months of 2023 compared to 67% in the same period of 2022.

SPECIALTY PHARMACEUTICAL BUSINESS

Sales of the specialty pharmaceutical business

	9M	9M		
IN € MILLIONS	2023	2022	Growth	% Growth
Prescription-based pharmaceutical products	272.7	277.2	(4.5)	-2%
LMWH franchise	175.4	195.1	(19.6)	-10%
Enoxaparin biosimilar	108.1	119.2	(11.1)	-9%
Bemiparin (Hibor)	67.3	75.8	(8.5)	-11%
Sales in Spain	46.1	50.4	(4.3)	-9%
International sales	21.2	25.4	(4.2)	-17%
Neparvis	33.7	28.8	4.9	17%
Volutsa	10.0	13.2	(3.2)	-24%
Vytorin & Orvatez	19.9	23.7	(3.8)	-16%
Other products	35.7	27.6	8.1	29%
Okedi	9.0	0.9	8.1	n.a.
Discounts to the National Health System	(11.0)	(12.0)	1.0	-8%
Contrast agents and other hospital products	33.8	29.3	4.5	15%
Other products	0.8	1.1	(0.3)	-29%
Total specialty pharmaceutical business	307.3	307.6	(0.3)	0%

(1) H1 2022 includes sales of Absorcol.

Sales of **prescription-based pharmaceutical** products decreased 2% to 272.7 million euros in the first nine months of 2023.

Sales of the **heparin franchise** (Low Molecular Weight Heparins and other heparins) decreased by 10% to 181.7 million euros in the first nine months of 2023. Heparin sales represented 31% of operating revenue in the first nine months of 2023 compared to 35% in the same period of 2022.

IN € MILLIONS	9M 2023	9M 2022	Growth	% Growth
LMWH franchise	175.4	195.1	(19.6)	-10%
Enoxaparin biosimilar	108.1	119.2	(11.1)	-9%
Bemiparin (Hibor)	67.3	75.8	(8.5)	-11%
Sales in Spain	46.1	50.4	(4.3)	-9%
International sales	21.2	25.4	(4.2)	-17%
Other heparins ²	6.2	5.7	0.5	9%
Heparins franchise	181.7	200.8	(19.1)	-10%

LOW MOLECULAR WEIGHT HEPARINS

Sales of Low Molecular Weight Heparins (LMWH) (enoxaparin biosimilar and bemiparin) decreased by 10% to 175.4 million euros in the first nine months of 2023. ROVI expects low-molecular-weight heparin sales to decrease by a low-single-digit figure in 2023, mainly as a result of the increase in orders from partners in 2022 related to the treatment for COVID-19, which has led to a lower expected volume of orders from partners in 2023, since they still hold a high level of stocks from 2022.

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

Sales of the **enoxaparin biosimilar** decreased by 9% to 108.1 million euros in the first nine months of 2023 compared to the first nine months of 2022. However, sales of the product rose 20% in the first nine months of 2023 compared to the same period of 2021, where sales increased 17% compared to 9M 2020 due to the increased use of the product for the treatment of COVID-19. The product was launched in Jordan and Sri Lanka in the first nine months of 2023. In Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo it was launched in the same period of 2022.

ROVI commenced the marketing of its Enoxaparin biosimilar in Germany in 2017; in UK, Italy, Spain, France, Austria, Latvia and Estonia in 2018; in Portugal, Poland, Costa Rica, Finland, and Sweden in 2019; in South Africa, Israel, Peru, Holland, Panama, and the

² Other heparins are reported in the "Contrast agents and other hospital products" line. These figures include Normoparin sales which were not included in the 9M 2022 figure when it was released.

Dominican Republic in 2020; in Canada, Belgium, Malaysia, Albania, North Macedonia, Guatemala, El Salvador, Honduras, Georgia, Bahamas, Jamaica, Gabon, Democratic Republic of Congo and Trinidad and Tobago in 2021; in Brazil, Luxembourg, Colombia, Bosnia and Herzegovina and Kosovo in 2022; and in Jordan and Sri Lanka in the first nine months of 2023.

Bemiparin sales decreased 11% to 67.3 million euros in the first nine months of 2023. International sales of Bemiparin decreased by 17% to 21.2 million euros. This decrease was mainly linked to (i) the decrease in sales in the Russian market, (ii) the political-economic instability of some countries in which we are present such as Sudan, Turkey and Argentina, (iii) the fewer orders from partners and (iv) the lower sales related to COVID-19. Sales of Bemiparin in Spain (Hibor®) showed a decrease of 9% to 46.1 million euros in the first nine months of 2023, mainly due to lower penetration of the product in the prophylaxis segment.

OTHER PRESCRIPTION-BASED PHARMACEUTICAL PRODUCTS

Sales of **Neparvis®**, a specialty product from Novartis, launched in Spain in December 2016, indicated for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction, increased 17% to 33.7 million euros in the first nine months of 2023, compared to 28.8 million euros in the first nine months of 2022.

Sales of **Volutsa®**, a specialty product from Astellas Pharma indicated for the treatment of moderate to severe storage symptoms and voiding symptoms associated with benign prostatic hyperplasia, launched in Spain in February 2015, decreased by 24% to 10.0 million euros in the first nine months of 2023 mainly due to a product price reduction of 47% in the second quarter of 2023.

Sales of **Vytorin® and Orvatez®**, specialty products from Merck Sharp & Dohme ("MSD") indicated as adjunctive therapy to diet in patients with hypercholesterolemia, decreased 16% to 19.9 million euros in the first nine months of 2023. ROVI ceased to distribute Absorcol® as of 31 December of 2022 and Vytorin® as of 31 January 2023. Orvatez® sales rose 10% to 19.8 million euros in the first nine months of 2022, compared to 17.9 million euros in the first nine months of 2022. Sales of Absorcol® and Vytorin® accounted for 24% of total sales of the products indicated to treat hypercholesterolemia in the first nine months of 2022.

Sales of **Okedi®**, the first ROVI product based on its leading-edge drug delivery technology, ISM®, for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone, reached 9.0 million euros in the first nine months of 2023. Okedi® sales increased by 27% in the third quarter of 2023 compared to the second quarter of the year. In 2022, it was launched in Germany in April, UK in July and Spain in September and, in 2023, it was launched in Portugal in January and in Italy in September. ROVI expects to launch the product in Austria during the fourth quarter of the year.

- In Germany, the product was received very positively during medical education activities carried out by ROVI. In the first nine months of the year, interaction with psychiatrists continued to increase, doubling the attendance of doctors at product events compared to the last nine months of the previous year.
- In the United Kingdom, the product is still in the introduction phase in the "trusts" (entities that manage the health areas). In the first nine months of 2023, it had already been approved in 20% of the "trusts". It is expected that it will soon become available in most hospital pharmacies.
- In Spain, the product is available in 100% of the autonomous communities. In the first nine months of 2023, it was being marketed in 90% of hospitals and 35% of psychiatrists had been trained.
- In Portugal, access to doctors was positive. Since its launch in January 2023, the product has gained prescriptions and future prospects are positive. Sales are expected to accelerate by the end of 2023.
- In Italy, we expect sales to accelerate quickly and reach all significant hospitals by the end of the year.

ROVI will cease 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 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 15% to 33.8 million euros in the first nine months of 2023. This increase shows the strong recovery of the Spanish and Portuguese hospital activity during this period after the effects of lockdowns during the pandemic.

CDMO BUSINESS

CDMO sales increased by 7% to 287.6 million euros in the first nine months of 2023 because of (i) the booking of the income related to the production of the COVID-19 vaccine, (ii) the booking of the income related to the activities to prepare the plant for the COVID-19 vaccine production under the agreement with Moderna, and (iii) the reorientation of our contract manufacturing activities strategy towards high-value-added products.

OTHER INCOME

Other income (subsidies) decreased by 1.1 million euros to 0.3 million euros in the first nine months of 2023 compared to the same period of 2022, mainly due lower subsidies received in the period.

COSTS

GROSS PROFIT

Gross profit increased 2% to 350.6 million euros in the first nine months of 2023 compared to the same period of 2022. Gross margin showed a decrease of 0.9 percentage points, from 59.9% in the first nine months of 2022 to 58.9% in the same period of 2023. This drop is mainly due to the higher contribution to the CDMO³ business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to Group sales. Additionally, gross margin increased by 12.6 percentage points in the third quarter of 2023 compared to the second quarter of 2023 and 3.0 percentage points in the third quarter of 2023 versus the third quarter of 2022.

In the third quarter of 2023, low molecular weight heparin (LMWH) raw material prices decreased by a mid-teen percentage in comparison with the third quarter of 2022. ROVI expects them to continue to fall in 2023 and that this decrease will accelerate during 2024. Nevertheless, despite this potential price decrease, the impact on the gross margin will continue to be negative in 2023 because of the length of the LMWH manufacturing process, in which the raw material currently being used has been stocked for several months and was purchased at higher prices.

RESEARCH AND DEVELOPMENT EXPENSES

R&D expenses increased 2% to 16.5 million euros in the first nine months of 2023. They were mainly related to (i) the development of the phase I of Letrozole LEBE and (ii) the development of the phase I of a new formulation of Risperidone ISM® for a 3-monthly injection.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

SG&A expenses increased 5% to 162.7 million euros in the first nine months of 2023 mainly as a result of an increase in expenses due to the Okedi® launch in Europe.

³ Contract Development and Manufacturing Organisation

IN € MILLIONS	9M 2023	9M 2022	Growth	% Growth
Employee benefit expenses (exc. R&D)	83.2	70.3	13.0	18%
Other operating expenses (exc. R&D)	79.5	84.2	(4.7)	-6%
Total SG&A expenses	162.7	154.5	8.3	5%
Expenses related to international subsidiaries	18.9	13.0	5.9	45%

SHARE OF PROFIT IN ASSOCIATES AND JOINT VENTURES

On 6 November 2023, ROVI signed a binding agreement with Enervit S.p.A. ("Enervit") to divest the 50% of the share capital that ROVI holds in Enervit Nutrition S.L, a Spanish company that distributes Enervit products in Spain and Portugal, in which Enervit already holds the other 50%. The parties have agreed a price of 1.8 million euros for the sale by ROVI of 50% of the share capital of Enervit Nutrition, S.L. to Enervit S.p.a. The transaction is expected to be signed on 30 November 2023. In the first nine months of 2023, **share of profit in associates and joint ventures** showed the booking of an expense of 0.1 million euros, compared to income of 0.1 million euros in the same period of the previous year.

DEPRECIATION

Depreciation and amortisation expenses increased by 5% to 17.8 million euros in the first nine months of 2023, as a result of the new property, plant and equipment and intangible assets purchases made during the last year.

NET FINANCIAL INCOME

Net financial income decreased 32% to 0.8 million euros in the first nine months of 2023 mainly due to the lower income related to exchange-rate derivative financial instruments.

EFFECTIVE TAX RATE

The **effective tax rate** was 22.9% in the first nine months of 2023, compared to 23.1% in the same period of 2022, mainly due to the decrease of the profit before income tax.

FINANCIAL PERFORMANCE



Million euros

¹Gross profit calculated as total revenue less change in inventories of finished goods and work in progress and raw materials and consumables used.

EBITDA

EBITDA reached 171.2 million euros in the first nine months of 2023, a decrease of 2% compared to the same period of 2022, reflecting a 1.4 percentage point decrease in the EBITDA margin, which was down to 28.8% in the first nine months of 2023 from 30.2% in the same period of 2022.

EBIT

EBIT decreased by 2% to 153.4 million euros in the first nine months of 2023, reflecting a 1.5 percentage point decline in the EBIT margin, which was down to 25.8% in the first nine months of 2023 from 27.3% in the same period of 2022.

NET PROFIT

Net profit decreased by 2%, from 121.5 million euros in the first nine months of 2022 to 118.8 million euros in the same period of 2023.

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

PRE-R&D/FLAT R&D

EBITDA "Pre-R&D", calculated excluding R&D expenses, decreased by 1%, from 190.1 million euros in the first nine months of 2022 to 187.8 million euros in the same period of 2023, reflecting a 1.5 percentage point decrease in the EBITDA margin to 31.6% in the first nine months of 2023 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2023 as in the same period of 2022, EBITDA would have decreased by 1% to 171.5 million euros, reflecting a 1.4 percentage point decrease in the EBITDA margin to 28.8% in the first nine months of 2023, down from 30.2% in the previous year (see "Flat R&D costs" columns of the table below).

EBIT "pre-R&D", calculated excluding R&D expenses, decreased by 2%, from 173.1 million euros in the first nine months of 2022 to 170.0 million euros in the same period of 2023, reflecting a 1.5 percentage point decrease in the EBIT margin to 28.6% in the first nine months of 2023 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2023 as in the first nine months of 2022, EBIT would have decreased by 2% to 153.7 million euros, reflecting a 1.4 percentage point decline in the EBIT margin to 25.8% in the first nine months of 2023, down from 27.3% in the same period of 2022 (see "Flat R&D costs" columns of the table below).

Net profit "pre-R&D", calculated excluding R&D expenses, decreased by 2%, from 134.0 million euros in the first nine months of 2022 to 131.6 million euros in the same period of 2023 (see "Pre-R&D costs" columns of the table below). Likewise, recognising the same amount of R&D expenses in the first nine months of 2023 as in the same period of 2022, net profit would have decreased by 2% to 119.1 million euros (see "Flat R&D costs" columns of the table below).

	Repo	orted	Pr	e-R&D c	osts	Flat R&D costs		osts
	9М	9M	9M	9M	%	9M	9M	%
IN € MILLIONS	2023	2022	2023	2022	Growth	2023	2022	Growth
Operating revenue(1)	594.9	575.5	594.9	575.5	3%	594.9	575.5	3%
Other income(2)	0.3	1.3	0.3	1.3	-80%	0.3	1.3	-80%
Total revenue(3)	595.1	576.8	595.1	576.8	3%	595.1	576.8	3%
Cost of sales(4)	(244.5)	(232.4)	(244.5)	(232.4)	5%	(244.5)	(232.4)	5%
Gross profit(5)	350.6	344.4	350.6	344.4	2%	350.6	344.4	2%
% margin(9)	58.9%	59.9%	58.9%	59.9%	-0.9 pp	58.9%	59.9%	-0.9 pp
R&D expenses	(16.5)	(16.2)	0.0	0.0	n.a.	(16.2)	(16.2)	n.a.
SG&A	(162.7)	(154.5)	(162.7)	(154.5)	5%	(162.7)	(154.5)	5%
Share of profit in associates and joint ventures	(0.1)	0.1	(0.1)	0.1	n.a.	(0.1)	0.1	n.a.
EBITDA(6)	171.2	173.9	187.8	190.1	-1%	171.5	173.9	-1%
% margin(9)	28.8%	30.2%	31.6%	33.0%	-1.5 pp	28.8%	30.2%	-1.4 pp
EBIT(7)	153.4	156.8	170.0	173.1	-2%	153.7	156.8	-2%
% margin(9)	25.8%	27.3%	28.6%	30.1%	-1.5 pp	25.8%	27.3%	-1.4 pp
Net profit(8)	118.8	121.5	131.6	134.0	-2%	119.1	121.5	-2%
% margin(9)	20.0%	21.1%	22.1%	23.3%	-1.2 pp	20.0%	21.1%	-1.1 pp

(1) Operating revenue refers to revenue.

(2) Other income includes the recognition of government grants on non-financial non-current assets and other.
(3) Total revenue calculated as revenue plus the recognition of government grants on non-financial non-current assets and other.
(4) Cost of sales calculated as the amount of procurements plus that corresponding to the change in inventories of finished goods and work in

(5) Gross profit calculated as revenue plus the recognition of government grants on non-financial non-current assets and other less change in

inventories of finished goods and work in progress and raw materials and consumables used.

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

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

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

DIVIDEND

ROVI's General Shareholders Meeting on 14 June 2023 approved the payment of a gross dividend of 1,2938 euros per share. This represents a 35% increase on the dividend charged to the 2021 profit (€0.9556/share) and entails the distribution of a sum equivalent to approximately 35% of the 2022 consolidated net profit attributed to the parent company, broken down as follows:

- Application of profit: the entire profit of Laboratorios Farmacéuticos ROVI, S.A. for 2022, 39,116,103.39 euros, was applied to the dividend distribution; and
- Additionally, a further 30,770,000,54 euros was distributed as dividends charged to the freely-available reserves accounted for as "Retained earnings".

This dividend was paid on 5 July 2023.

FINANCIAL POSITION

Balance Sheet

IN € MILLIONS	Sep 30, 2023	Dec 31, 2022	Growth	% Growth
Assets				
Non-current assets	263.7	255.6	8.0	3%
Current assets	567.1	623.1	(56.0)	-9%
Total assets	830.7	878.7	(48.0)	-5%
Equity	554.6	521.4	33.3	6%
Liabilities				
Non-current liabilities	55.3	63.4	(8.1)	-13%
Financial debt	52.1	59.4	(7.4)	-12%
Current liabilities	220.8	293.9	(73.1)	-25%
Financial debt	11.6	12.7	(1.1)	-9%
Total liabilities	276.1	357.3	(81.2)	-23%
Total equity and liabilities	830.7	878.7	(48.0)	-5%

TOTAL ASSETS

ROVI's **total assets** decreased by 5%, from 878.7 million euros as of December 31, 2022 to 830.7 million euros as of September 30, 2023, mainly due to (i) a decrease in "cash and cash equivalents" of 68.6 million euros, mostly due to the dividend payment, the lower cash flow from provision of manufacturing services and the buy-back programme; and (ii) a decrease in "Trade and other receivables" of 41.7 million euros mainly related to the billing linked to Moderna. This drop was partially offset by the increase in "inventories" of 53.7 million euros, mostly because of an increase in heparin stock and in stock related to production of the COVID-19 vaccine.

EQUITY

ROVI's **equity** increased by 33.3 million euros to 554.6 million euros as of September 30, 2023. This increase mainly resulted from the "profit for the period" and the "treasury shares".

TOTAL LIABILITIES

ROVI's total **liabilities** decreased by 23% from 357.3 million euros as of December 31, 2022 to 276.1 million euros as of September 30, 2023, mainly due to (i) a decrease of 52.1 million euros in the "trade and other payables" caption; and (ii) a decrease of 39.1

million euros in the "contract liabilities" item, which mainly related to amounts billed to customers that had been taken to profit and loss as service revenue as of September 30, 2023.

As of September 30, 2023, ROVI **total debt** decreased to 63.7 million euros. Debt with public administration, which is 0% interest rate debt, represented 15% of total debt as of September 30, 2023.

IN € THOUSANDS	Sep 30, 2023	Dec 31, 2022	Interest rate
Bank borrowings	39,286	44,107	0.68-4.46
Debt with public administration	9,513	10,175	0
Financial liabilities for leases	14,857	17,856	-
Derivative financial instruments	-	28	-
Total	63,656	72,166	

Total Debt

As of September 30, 2023, bank borrowings decreased by 4.8 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, 2023, ROVI had drawn 45 million euros against this credit line; 5 million euros at a variable interest rate of Euribor at 3 months + 0.844% (the latest interest rate paid was 4.456% in October 2023) and 40 million euros at a fixed interest of 0.681%. Repayment of the variable interest loan started in October 2021 (quarterly repayments) and its current outstanding balance is 3.6 million euros. Likewise, repayment of the fixed interest loan started in February 2023 (quarterly repayments) and its current outstanding balance is 35.7 million euros. The credit at a variable interest matures in 2028 and the credit at a fixed interest matures in 2029, both includes a grace period of 3 years.

In July 2022, ROVI announced that the European Investment Bank (EIB) had granted it a new loan to support its investments in Research, Development and Innovation. The loan is for 50 million euros with a repayment period of 10 years, has a three-year grace period, and may be drawn down over a term of two years.

GROSS CASH POSITION AND NET DEBT

As of September 30, 2023, ROVI had a **gross cash position** of 57.8 million euros, compared to 126.4 million euros as of December 31, 2022, and **net debt** of 5.8 million euros, compared to net cash of 54.2 million euros as of December 31, 2022.

IN € MILLIONS	Sep 30, 2023	Dec 31, 2022
Equity securities	0.02	0.01
Deposits	1.4	1.4
Cash and cash equivalents	56.4	124.9
Gross cash position	57.8	126.4
Financial debt	(63.7)	(72.2)
(Net debt)/Net cash	(5.8)	54.2

Net cash generated in operating activities amounted to 52.2 million euros in the first nine months of 2023, compared to 170.0 million euros in the same period of 2022. Net cash generated from operating activities excluding changes in working capital decreased 44% to 119.7 million euros in the first nine months of 2023 from 214.7 million euros in the same period of the previous year.



Million euros

Cash Flow

IN € MILLIONS	9M 2023	9M 2022	Growth	% Growth
Cash flow from operating activities	52.2	170.0	(117.8)	-69%
Cash flow from investing activities	(25.7)	(18.4)	(7.4)	40%
Cash flow from financing activities	(95.0)	(153.1)	58.0	-38%
Net increase/ (decrease) in cash	(68.6)	(1.4)	(67.2)	n.a.
Cash at the beginning of the period	124.9	99.0	25.9	26%
Cash at the end of the period	56.4	97.6	(41.3)	-42%

CASH FLOW FROM OPERATING ACTIVITIES

Cash flow from operating activities decreased to 52.2 million euros in the first nine months of 2023 from 170.0 million euros in the same period of 2022. This decrease was mainly due to:

- the booking of (39.4) million euros under the "cash flow from provision of manufacturing services" caption in the first nine months of 2023 mainly due to the allocation of more revenue to the income statement than payments received, compared to the 55.3 million euros recognized in the first nine months of 2022;
- the decrease of 52.1 million euros in the "trade and other payables" item in the first nine months of 2023, compared to an increase of 2.4 million euros in the same period of 2022;
- the decrease of 53.3 million euros in the "inventory" item in the first nine months of 2023 compared to a decrease of 48.4 million euros in the first nine months of 2022 mostly due to an increase in heparin stock and in stock related to production of the COVID-19 vaccine; and
- the decrease of 3.8 million euros in profit before income tax.

These negative impacts were partially offset by the increase of 41.7 million euros in the "trade and other receivables" caption in the first nine months of 2023 compared to an increase of 2.6 million euros in the same period of 2022 mostly due to the billing linked to Moderna.

CASH FLOW FROM INVESTING ACTIVITIES

ROVI invested 26.8 million euros in the first nine months of 2023, compared to 18.5 million euros in the same period of 2022.

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

IN € MILLIONS	9M 2023	9M 2022	Growth	% Growth
Madrid Injectable plant	1.0	0.6	0.4	57%
San Sebastián de los Reyes plant	0.7	0.9	(0.3)	-28%
Granada plant	0.6	0.4	0.2	46%
Alcalá de Henares plant	1.4	1.0	0.4	35%
Expenditure on maintenance and other capex	1.2	1.0	0.2	15%
Maintenance Capex	4.8	4.0	0.8	20%
ISM industrialisation	4.0	2.8	1.1	39%
Escúzar plant	5.0	5.3	(0.3)	-6%
Glicopepton	0.6	1.9	(1.3)	-68%
New filling lines and operations expansion	12.4	4.3	8.0	185%
Investment Capex	21.9	14.4	7.5	52%
Total Capex	26.8	18.5	8.3	45%

FREE CASH FLOW

Free cash flow decreased to 27.0 million euros in the first nine months of 2023 from 151.7 million euros in the first nine months of 2022.

Free cash flow

IN € MILLIONS	9M 2023	9M 2022
Net cash generated from (used in) operating activities	52.2	170.0
Purchases of intangible assets	(0.5)	(0.3)
Purchases of property, plant and equipment	(26.2)	(18.1)
Proceeds from sale of property, plant and equipment	0.2	0.1
Interest received	1.3	0.0
Free cash flow	27.0	151.7

CASH FLOW FROM FINANCING ACTIVITIES

Cash flow from financing activities amounted to (95.0) million euros in the first nine months of 2023 from (153.1) million euros in the first nine months of 2022. This increase was mainly attributable to ROVI's share buy-back programmes executed in the first nine months of 2022, amounting to 135.0 million euros. In the first nine months of 2023, ROVI paid 18.1 million euros for the shares repurchased under the ongoing buy-back programme, effective as of 26 July, 2023.



Javier López-Belmote Encina. Deputv Chairman and Chief Financial Officer of ROVI, said "We are very happy with the company's evolution. 2023 is the first year of a new post-pandemic scenario, a vear of transition where COVID-19 has become a seasonal disease for which a vaccine is administered once a year. In this context, we have been able to deliver a 3% increase in total revenue reaching 595.1 million euros. Gross margin showed a decrease of 0.9 percentage points mainly due to the higher contribution to the CDMO business of the income related to the activities to prepare the plant for drug production under the agreement with Moderna, which adds lower margins to Group sales. ROVI's commitment to innovation is reflected in the figures of the first nine months of 2023. We are in a new phase of growth and we expect our robust balance sheet to allow us to take advantage of other opportunities to expand our sales base and improve the utilisation of our asset base".

OUTLOOK

In November 2022 and February 2023, ROVI announced that it expected the 2023 operating revenue to decrease by a low-teen percentage in comparison with 2022. When the company published its results for the first half of 2023, this guidance was updated to a high-single-digit percentage decrease on 2022. With the visibility that the company has at present, ROVI is again raising its operating revenue guidance for 2023 from a high-single-digit percentage decrease on 2022 to **stable sales**.

It is reasonable to expect the company's results to undergo a downward adjustment in 2023.

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

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

R&D UPDATE

ISM® technology platform

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

On 15 February 2022, the European Commission authorised the marketing of Okedi® (Risperidone ISM®) for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone, and it was launched in Germany in April 2022, in the UK in July 2022, in Spain in September 2022, in Portugal in January 2023 and in Italy in September 2023.

On 27 July 2023, ROVI reported that the United States Food and Drug Administration (FDA) had issued a Complete Response Letter. In this letter, the FDA informed ROVI that satisfactory resolution of the deficiencies from the last inspection was required before the approval of the application, and that there were no outstanding questions related to the dossier. On 21 September 2023, ROVI received the Establishment Inspection Report from the FDA with 4 outstanding observations from the FDA inspection of the facility. ROVI provided responses on 29 September 2023 and the FDA has established a new Goal Date of 29 March 2024.

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

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

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

Lastly, the company has decided to commence the clinical development of a new threemonthly formulation of Letrozole (hereinafter, Letrozole LEBE), rather than the initially planned annual formulation of Letrozole ISM®. The objective of this new development is to reach bioequivalence in the plasma levels of letrozole in comparison with the daily administration of oral doses of Femara® 2.5 mg.

With this new clinical programme for Letrozole LEBE, ROVI estimates it could reduce the research times in comparison to those for an annual formulation of the product, thus making it likely that the three-monthly formulation could be marketed several years earlier and, furthermore, the investment necessary to attain the objectives of this project could also be reduced.

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

ESG

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

"biotechnology companies, pharmaceutical laboratories and laboratory equipment companies."

In the rating process, Sustainalytics has analysed the company's performance in sustainability aspects considered material in the pharmaceutical sector, highlighting ROVI's sound management of ESG risks related to product quality and safety, corporate governance, business ethics, human capital, the fight against climate change and anti-corruption and anti-bribery practices. ROVI has obtained a higher than-average score in areas such as the board's involvement in the company's environmental and social aspects, implementation of the environmental policy and a sound quality and safety programme for products and services, as well as the integration of ethical practices into all tiers of the organisation.

Commitment to sustainability

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

The Group focuses its action on five priority areas:

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

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

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

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

KEY OPERATING AND FINANCIAL EVENTS

ROVI Share Buy-back Programme

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

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

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

- 4. **Maximum number of shares to be acquired**: 2,700,000 shares of the Company, representing approximately 5% of the Company's share capital on 26 July 2023.
- 5. Trading volume to be considered as reference: the trading volume to be taken as a reference for the purposes of the provisions of article 3.3 of Delegated Regulation 2016/1052 for the entire duration of the Buyback Program shall be 25% of the average daily volume of ROVI's shares on the trading venue on which the purchase is carried out during the twenty trading days prior to the date of the purchase.

As of 31 October 2023, ROVI had executed approximately 27.67% of the buy-back programme, having acquired 747,049 shares.

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

ROVI informed (by publication of the inside information number 1835 dated 25th of April 2023) that it has decided to commence the clinical development of a new three-monthly formulation of Letrozole (hereinafter, Letrozole LEBE), rather than the initially planned annual formulation of Letrozole ISM®. The objective of this new development

is to reach bioequivalence in the plasma levels of letrozole in comparison with the daily administration of oral doses of Femara® 2.5 mg.

With this new clinical programme for Letrozole LEBE, ROVI estimates it could reduce the research times in comparison to those for an annual formulation of the product, thus making it likely that the three-monthly formulation could be marketed several years earlier and, furthermore, the investment necessary to attain the objectives of this project could also be reduced.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On 21 September 2023, ROVI received the Establishment Inspection Report from the FDA with 4 outstanding observations from the FDA inspection of the facility. ROVI provided responses on 29 September 2023 and the FDA has established a new Goal Date of 29 March 2024.

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

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

About ROVI

ROVI is a pan-European pharmaceutical company specializing and engaging in the research, development, contract manufacturing and marketing of small molecules and biological specialties. The company, in a continuous international expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy, France and Poland and has a diversified marketing portfolio of more than 40 products, among which its flagship product, Bemiparin, already present in more than 60 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its Enoxaparin biosimilar, developed in-house, in Europe and it is already marketed in 40 countries. ROVI continues to develop the ISM® Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit <u>www.rovi.es.</u>

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Forward-looking statements

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

APPENDIX 1

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

IN € THOUSANDS	Sep 30, 2023	Dec 31, 2022
ASSETS		
Non-current assets		
Property Plant and Equipment	226,655	215,541
Intangible assets	33,807	35,744
Share of profit in associates and joint venture	2,692	2,193
Deferred income tax assets	419	2,078
Equity securities	24	9
Financial receivables	65	65
	263,662	255,630
Current assets		
Inventories	365,679	311,944
Trade and other receivables	138,267	180,011
Current income tax assets	866	4,148
Prepaid expenses	5,874	2,025
Cash and cash equivalents	56,377	124,945
	567,063	623,073
Total assets	830,725	878,703

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

2022

IN € THOUSANDS	Sep 30, 2023	Dec 31, 2022
EQUITY		
Equity attributed to the company	551,501	520,012
Share capital	3,241	3,241
Share premium	87,636	87,636
Legal reserve	673	673
Treasury shares	(44,712)	(27,561)
Retained earnings and voluntary reserves	385,840	256,362
Profit for the period	118,827	199,669
Accumulated other comprehensive income	(4)	(8)
Non-controlling interests	3,137	1,367
Total equity	554,638	521,379
LIABILITIES		
Non-current liabilities		
Financial debt	52,076	59,441
Deferred income tax liabilities	280	677
Contract liabilities	1,501	1,545
Deferred income	1,456	1,774
	55,313	63,437
Current liabilities		
Financial debt	11,580	12,725
Trade and other payables	113,637	165,776
Current tax liabilities	19,263	_
Contract liabilities	75,824	114,901
Deferred income	470	485
	220,774	293,887
Total liabilities	276,087	357,324
Total equity and liabilities	830,725	878,703

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

IN € THOUSANDS	9M 2023	9M 2022
Revenue	594,873	575,497
Changes in inventories of finished goods and work in progress	79,449	20,280
Raw materials and consumables used	(323,974)	(252,675)
Employee benefit expenses	(90,525)	(77,372)
Other operating expenses	(92,140)	(93,318)
Work carried out by the Group on non-current assets	3,372	
Amortisation and depreciation	(17,818)	(17,039)
Recognition of government grants on non- financial non-current assets and other	272	1,340
Share of profit in associates and joint venture	(101)	117
OPERATING PROFIT (EBIT)	153,408	156,830
Finance income	1,322	4
Finance costs	(607)	(641)
Impairment and gain or loss on measurement of financial instruments	128	2,695
Exchange difference	(74)	(925)
FINANCE INCOME/(COSTS) - NET	769	1,133
PROFIT BEFORE INCOME TAX	154,177	157,963
Income tax	(35,357)	(36,468)
PROFIT FOR THE PERIOD	118,820	121,495
Net profit attributable to parent company	118,827	121,504
Profit attributable to minority interests	(7)	(9)

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

IN € THOUSANDS	9M 2023	9M 2022
Cash flows from operating activities		
Profit before tax	154,177	157,963
Adjustments for non-monetary transactions:		
Amortisation and depreciation	17,818	17,039
Finance income	(1,322)	(4)
Valuation allowance	(285)	2,009
Adjustments for changes in value of derivatives	(25)	(496)
Gain or loss on derecognition of financial assets and liabilities	(103)	(2,199)
Finance expenses	607	641
Exchange differences	74	925
Grants, distribution licenses and other deferred income	(503)	(2,060)
Share of profit in associates and joint ventures	101	(117)
Changes in working capital:		
Trade and other receivables	41,715	2,619
Inventories	(53,252)	(48,424)
Other current assets (prepaid expenses)	(3,849)	(1,181)
Trade and other payables	(52,135)	2,357
Other collections and payments:		,
Cash flow from provision of manufacturing services	(39,357)	55,325
Proceeds from distribution licenses	195	355
Income tax cash flow	(11,635)	(14,721)
Net cash generated from (used in) operating activities	52,221	170,031
Cash flows from investing activities		
Purchases of intangible assets	(543)	(343)
Purchases of property, plant and equipment (usage rights not		
included)	(26,248)	(18,110)
Proceeds from sale of property, plant and equipment	249	78
Purchases of other financial assets	78	_
Sales of financial assets	10	20
Investments in associates and joint ventures	(600)	_
Interest received	1,307	4
Net cash generated from (used in) investing activities	(25,747)	(18,351)
Cash flows from financing activities		
Repayments of financial debt	(9,854)	(4,963)
Proceeds from financial debt	663	1,266
Interest paid	(286)	(215)
Purchase of treasury shares	(70,936)	(149,433)
Reissue of treasury shares	52,643	49,904
Dividends paid	(69,049)	(51,007)
Capital contribution to subsidiaries	1,777	1,372
Net cash generated from (used in) financing activities	(95,042)	(153,076)
Net (decrease) increase in cash and cash equivalents	(68,568)	(1,396)
Cash & cash equivalents at the beginning of the period	124,945	99,035
Cash and cash equivalents at the end of the period	56,377	97,639

APPENDIX 2

ALTERNATIVE PERFORMANCE MEASURES

In addition to the financial information prepared in accordance with International Financial Reporting Standards ("IFRSs") taken from our financial statements, this document includes certain alternative performance measures ("APMs") as defined in the ESMA (European Securities and Markets Authority) Guidelines on Alternative Performance Measures of 5 October, 2015 (ESMA/2015/1415), as well as some non-IFRS financial indicators. The financial measures contained in this document that are considered APMs or non-IFRS financial indicators have been prepared on the basis of the ROVI Group's financial information but are not defined or set out in detail within the framework of the applicable financial information and have not been audited or reviewed by our auditors.

These APMs are considered figures that have been adjusted in respect of those that are presented in accordance with the International Financial Reporting Standards endorsed by the European Union (IFRS-EU), which form the applicable accounting framework for the consolidated financial statements of the ROVI Group. Therefore, the reader should consider them to complement the latter but not to replace them.

We use these APMs and non-IFRS financial indicators to plan, oversee and assess our performance. We consider the APMs and non-IFRS financial indicators to be useful to allow the management team and investors to compare the past or future financial performance, the financial situation and the cash flows. Notwithstanding, these APMs and non-IFRS financial indicators are considered complementary and are not intended to replace IFRS measures. Furthermore, other companies, including some in our sector, may calculate such measures differently, which reduces their usefulness for comparative purposes.

This document contains information on the alternative performance measures (APMs) and non-IFRS financial indicators used, including their definitions and a reconciliation between the applicable management indicators and the financial information set out in the consolidated financial statements prepared under IFRSs. The document is available on ROVI's website and may be accessed on the following link: (https://www.rovi.es/en/shareholders-investors/financial-business-information).

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

Operating revenue

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

Operating revenue refers to revenue.

• Other revenue

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

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

Total revenue

This APM shows all the group's revenues.

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

Cost of sales

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

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

• Gross profit

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

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

• Gross margin or gross profit as % of operating revenue

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

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

• EBITDA

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

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

• EBITDA margin or EBITDA as % of operating revenue

This APM is a percentage indicator that measures the operating profit that ROVI obtains from its operating revenue before interest, taxes, impairment, depreciation and amortization are deducted. We calculate EBITDA margin or EBITDA as % of operating revenue as the percentage that the EBITDA represents in the revenue (operating revenue).

• EBITDA "Pre-R&D"

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

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

• EBIT

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

We calculate EBIT as profit before: taxes and interest.

• EBIT margin or EBIT as % of operating revenue

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

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

• EBIT "Pre-R&D"

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

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

• Net profit

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

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

• Net profit as % of operating revenue

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

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

• Net profit "Pre-R&D"

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

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

• Finance costs-net; and

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

Gross cash position

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

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

• Net debt/cash

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

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

• Capex

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

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

• Capex as % of operating revenue

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

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

• Free Cash Flow (FCF)

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

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

• FCF as % of operating revenue

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

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